Attachment 2

Technical Studies/ References

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7. William Mitchell Law Review (2008) *Benefits of Smokefree Regulations in Outdoor Settings: Beaches, Golf Courses, Parks, Patios, and in Motor Vehicles*
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The Health Consequences of Involuntary Exposure to Tobacco Smoke

A Report of the Surgeon General

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The Health Consequences of Involuntary Exposure to Tobacco Smoke

A Report of the Surgeon General

2006

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Office of the Surgeon General
Rockville, MD

Message from Michael O. Leavitt

Secretary of Health and Human Services

This Surgeon General's report returns to the topic of the health effects of involuntary exposure to tobacco smoke. The last comprehensive review of this evidence by the Department of Health and Human Services (DHHS) was in the 1986 Surgeon General's report, *The Health Consequences of Involuntary Smoking*, published 20 years ago this year. This new report updates the evidence of the harmful effects of involuntary exposure to tobacco smoke. This large body of research findings is captured in an accompanying dynamic database that profiles key epidemiologic findings, and allows the evidence on health effects of exposure to tobacco smoke to be synthesized and updated (following the format of the 2004 report, *The Health Consequences of Smoking*). The database enables users to explore the data and studies supporting the conclusions in the report. The database is available on the Web site of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/tobacco. I am grateful to the leadership of the Surgeon General, CDC's Office on Smoking and Health, and all of the contributors for preparing this important report and bringing this topic to the forefront once again.

Secondhand smoke, also known as environmental tobacco smoke, is a mixture of the smoke given off by the burning end of tobacco products (sidestream smoke) and the mainstream smoke exhaled by smokers. People are exposed to secondhand smoke at home, in the workplace, and in other public places such as bars, restaurants, and recreation venues. It is harmful and hazardous to the health of the general public and particularly dangerous to children. It increases the risk of serious respiratory problems in children, such as a greater number and severity of asthma attacks and lower respiratory tract infections, and increases the risk for middle ear infections. It is also a known human carcinogen (cancer-causing agent). Inhaling secondhand smoke causes lung cancer and coronary heart disease in nonsmoking adults.

We have made great progress since the late 1980s in reducing the involuntary exposure of nonsmokers in this country to secondhand smoke. The proportion of nonsmokers aged 4 and older with a blood cotinine level (a metabolite of nicotine) indicating exposure has declined from 88 percent in 1988–1991 down to 43 percent in 2001–2002, a decline that exceeds the *Healthy People 2010* objective for this measure. Despite the great progress that has been made, involuntary exposure to secondhand smoke remains a serious public health hazard that can be prevented by making homes, workplaces, and public places completely smoke-free. As of the year 2000, more than 126 million residents of the United States aged 3 or older still are estimated to be exposed to secondhand smoke. Smoke-free environments are the most effective method for reducing exposures. *Healthy People 2010* objectives address this issue and seek optimal protection of nonsmokers through policies, regulations, and laws requiring smoke-free environments in all schools, workplaces, and public places.

Foreword

This twenty-ninth report of the Surgeon General documents the serious and deadly health effects of involuntary exposure to tobacco smoke. Secondhand smoke is a major cause of disease, including lung cancer and coronary heart disease, in healthy nonsmokers.

In 2005, it was estimated that exposure to secondhand smoke kills more than 3,000 adult nonsmokers from lung cancer, approximately 46,000 from coronary heart disease, and an estimated 430 newborns from sudden infant death syndrome. In addition, secondhand smoke causes other respiratory problems in nonsmokers such as coughing, phlegm, and reduced lung function. According to the CDC's National Health Interview Survey in 2000, more than 80 percent of the respondents aged 18 years or older believe that secondhand smoke is harmful and nonsmokers should be protected in their workplaces.

Components of chemical compounds in secondhand smoke, including nicotine, carbon monoxide, and tobacco-specific carcinogens, can be detected in body fluids of exposed nonsmokers. These exposures can be controlled. In 2005, CDC released the *Third National Report on Human Exposure to Environmental Chemicals,* which found that the median cotinine level (a metabolite of nicotine) in nonsmokers had decreased across the life stages: by 68 percent in children, 69 percent in adolescents, and 75 percent in adults, when samples collected between 1999 and 2002 were compared with samples collected a decade earlier. These dramatic declines are further evidence that smoking restrictions in public places and workplaces are helping to ensure a healthier life for all people in the United States.

However, too many people continue to be exposed, especially children. The recent data indicate that median cotinine levels in children are more than twice those of adults, and non-Hispanic blacks have levels that are more than twice as high as those of Mexican Americans and non-Hispanic whites. These disparities need to be better understood and addressed.

Research reviewed in this report indicates that smoke-free policies are the most economic and effective approach for providing protection from exposure to secondhand smoke. But do they provide the greatest health impact. Separating smokers and nonsmokers in the same airspace is not effective, nor is air cleaning or a greater exchange of indoor with outdoor air. Additionally, having separately ventilated areas for smoking may not offer a satisfactory solution to reducing workplace exposures. Policies prohibiting smoking in the workplace have multiple benefits. Besides reducing exposure of nonsmokers to secondhand smoke, these policies reduce tobacco use by smokers and change public attitudes about tobacco use from acceptable to unacceptable.

Research indicates that the progressive restriction of smoking in the United States to protect nonsmokers has had the additional health impact of reducing active smoking. In November 2005, CDC's Tobacco-Free Campus policy took full effect in all facilities owned by CDC in the Atlanta area. As the Director of the nation's leading health promotion and disease prevention agency, I am proud to support this effort. With this commitment, CDC continues to protect the health and safety of all of its employees and serves as a role model for workplaces everywhere.

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Preface

from the Surgeon General,
U.S. Department of Health and Human Services

Twenty years ago when Dr. C. Everett Koop released the Surgeon General's report, *The Health Consequences of Involuntary Smoking,* it was the first Surgeon General's report to conclude that involuntary exposure of nonsmokers to tobacco smoke causes disease. The topic of involuntary exposure of nonsmokers to secondhand smoke was first considered in Surgeon General Jesse Steinfeld's 1972 report, and by 1986, the causal linkage between inhaling secondhand smoke and the risk for lung cancer was clear. By then, there was also abundant evidence of adverse effects of smoking by parents on their children.

Today, massive and conclusive scientific evidence documents adverse effects of involuntary smoking on children and adults, including cancer and cardiovascular diseases in adults, and adverse respiratory effects in both children and adults. This 2006 report of the Surgeon General updates the 1986 report, *The Health Consequences of Involuntary Smoking,* and provides a detailed review of the epidemiologic evidence on the health effects of involuntary exposure to tobacco smoke. This new report also uses the revised standard language of causality that was applied in the 2004 Surgeon General's report, *The Health Consequences of Smoking*.

Secondhand smoke is similar to the mainstream smoke inhaled by the smoker in that it is a complex mixture containing many chemicals (including formaldehyde, cyanide, carbon monoxide, ammonia, and nicotine), many of which are known carcinogens. Exposure to secondhand smoke causes excess deaths in the U.S. population from lung cancer and cardiac related illnesses. Fortunately, exposures of adults are declining as smoking becomes increasingly restricted in workplaces and public places. Unfortunately, children continue to be exposed in their homes by the smoking of their parents and other adults. This exposure leads to unnecessary cases of bronchitis, pneumonia and worsened asthma. Among children younger than 18 years of age, an estimated 22 percent are exposed to secondhand smoke in their homes, with estimates ranging from 11.7 percent in Utah to 34.2 percent in Kentucky.

As this report documents, exposure to secondhand smoke remains an alarming public health hazard. Approximately 60 percent of nonsmokers in the United States have biologic evidence of exposure to secondhand smoke. Yet compared with data reviewed in the 1986 report, I am encouraged by the progress that has been made in reducing involuntary exposure in many workplaces, restaurants, and other public places. These changes are most likely the major contributing factors to the more than 75 percent reduction in serum cotinine levels that researchers have observed from 1988 to 1991. However, more than 126 million nonsmokers are still exposed. We now have substantial evidence on the efficacy of different approaches to control exposure to secondhand smoke. Restrictions on smoking can control exposures effectively, but technical approaches involving air cleaning or a greater exchange of indoor with outdoor air cannot. Consequently, nonsmokers need protection through the restriction of smoking in public places and workplaces and by a voluntary adherence to policies at home, particularly to eliminate exposures of children. Since the release of the 1986 Surgeon General's report, the public's attitude and social norms toward secondhand smoke exposure have changed significantly—a direct result of the growing body of scientific evidence on the health effects of exposure to secondhand smoke that is summarized in this report.

Finally, clinicians should routinely ask about secondhand smoke exposure, particularly in susceptible groups or when a child has had an illness caused by secondhand smoke, such as pneumonia. Because of the high levels of exposure among young children, their exposure should be considered a significant pediatric issue. Additionally, exposure to secondhand smoke poses significant risks for people with lung and heart disease. The large body of evidence documenting that secondhand smoke exposures produce substantial and immediate effects on the cardiovascular system indicates that even brief exposures could pose significant acute risks to older adults or to others at high risk for cardiovascular disease. Those caring for relatives with heart disease should be advised not to smoke in the presence of the sick relative.

An environment free of involuntary exposure to secondhand smoke should remain an important national priority in order to reach the *Healthy People 2010* objectives.

Richard Carmona, M.D., M.P.H., F.A.C.S.
Surgeon General

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The Health Consequences of Involuntary Exposure to Tobacco Smoke

Chapter 1
Introduction, Summary, and Conclusions

Introduction

The topic of passive or involuntary smoking was first addressed in the 1972 U.S. Surgeon General's report (*The Health Consequences of Smoking*, U.S. Department of Health, Education, and Welfare [USDHEW] 1972), only eight years after the first Surgeon General's report on the health consequences of active smoking (USDHEW 1964). Surgeon General Dr. Jesse Steinfeld had raised concerns about this topic, leading to its inclusion in that report. According to the 1972 report, nonsmokers inhale the mixture of sidestream smoke given off by a smoldering cigarette and mainstream smoke exhaled by a smoker, a mixture now referred to as "secondhand smoke" or "environmental tobacco smoke." Cited experimental studies showed that smoking in enclosed spaces could lead to high levels of cigarette smoke components in the air. For carbon monoxide (CO) specifically, levels in enclosed spaces could exceed levels then permitted in outdoor air. The studies supported a conclusion that "an atmosphere contaminated with tobacco smoke can contribute to the discomfort of many individuals" (USDHEW 1972, p. 7). The possibility that CO emitted from cigarettes could harm persons with chronic heart or lung disease was also mentioned.

Secondhand tobacco smoke was then addressed in greater depth in Chapter 4 (Involuntary Smoking) of the 1975 Surgeon General's report, *The Health Consequences of Smoking* (USDHEW 1975). The chapter noted that involuntary smoking takes place when nonsmokers inhale both sidestream and exhaled mainstream smoke and that this "smoking" is "involuntary" when "the exposure occurs as an unavoidable consequence of breathing in a smoke-filled environment" (p. 87). The report covered exposures and potential health consequences of involuntary smoking, and the researchers concluded that smoking on buses and airplanes was annoying to nonsmokers and that involuntary smoking had potentially adverse consequences for persons with heart and lung diseases. Two studies on nicotine concentrations in nonsmokers raised concerns about nicotine as a contributing factor to atherosclerotic cardiovascular disease in nonsmokers.

The 1979 Surgeon General's report, *Smoking and Health: A Report of the Surgeon General* (USDHEW 1979), also contained a chapter entitled "Involuntary Smoking." The chapter stressed that "attention to involuntary smoking is of recent vintage, and only limited information regarding the health effects of such exposure upon the nonsmoker is available" (p. 11–35). The chapter concluded with recommendations for research including epidemiologic and clinical studies. The 1982 Surgeon General's report specifically addressed smoking and cancer (U.S. Department of Health and Human Services [USDHHS] 1982). By 1982, there were three published epidemiologic studies on involuntary smoking and lung cancer, and the 1982 Surgeon General's report included a brief chapter on this topic. That chapter commented on the methodologic difficulties inherent in such studies, including exposure assessment, the lengthy interval during which exposures are likely to be relevant, and accounting for exposures to other carcinogens. Nonetheless, the report concluded that "Although the currently available evidence is not sufficient to conclude that passive or involuntary smoking causes lung cancer in nonsmokers, the evidence does raise concern about a possible serious public health problem" (p. 251).

Involuntary smoking was also reviewed in the 1984 report, which focused on chronic obstructive pulmonary disease and smoking (USDHHS 1984). Chapter 7 (Passive Smoking) of that report included a comprehensive review of the mounting information on smoking by parents and the effects on respiratory health of their children, data on irritation of the eye, and the more limited evidence on pulmonary effects of involuntary smoking on adults. The chapter began with a compilation of measurements of tobacco smoke components in various indoor environments. The extent of the data had increased substantially since 1972. By 1984, the data included measurements of more specific indicators such as acrolein and nicotine, and less specific indicators such as particulate matter (PM), nitrogen oxides, and CO. The report reviewed new evidence on exposures of nonsmokers using biomarkers, with substantial information on levels of cotinine, a major nicotine metabolite. The report anticipated future conclusions with regard to respiratory effects of parental smoking on child respiratory health (Table 1.1).

Involuntary smoking was the topic for the entire 1986 Surgeon General's report, *The Health Consequences of Involuntary Smoking* (USDHHS 1986). In its 359 pages, the report covered the full breadth of the

Table 1.1 Conclusions from previous Surgeon General's reports on the health effects of secondhand smoke exposure

Disease and statement	Surgeon General's report
Coronary heart disease: "The presence of such levels" as found in cigarettes "indicates that the effect of exposure to carbon monoxide may on occasion, depending upon the length of exposure, be sufficient to be harmful to the health of an exposed person. This would be particularly significant for people who are already suffering from. . .coronary heart disease." (p. 7)	1972
Chronic respiratory symptoms (adults): "The presence of such levels" as found in cigarettes "indicates that the effect of exposure to carbon monoxide may on occasion, depending upon the length of exposure, be sufficient to be harmful to the health of an exposed person. This would be particularly significant for people who are already suffering from chronic bronchopulmonary disease. . . ." (p. 7)	1972
Pulmonary function: "Other components of tobacco smoke, such as particulate matter and the oxides of nitrogen, have been shown in various concentrations to affect adversely animal pulmonary. . .function. The extent of the contributions of these substances to illness in humans exposed to the concentrations present in an atmosphere contaminated with tobacco smoke is not presently known." (pp. 7–8)	1972
Asthma: "The limited existing data yield conflicting results concerning the relationship between passive smoke exposure and pulmonary function changes in patients with asthma." (p. 13)	1984
Bronchitis and pneumonia: "The children of smoking parents have an increased prevalence of reported respiratory symptoms, and have an increased frequency of bronchitis and pneumonia early in life." (p. 13)	1984
Pulmonary function (children): "The children of smoking parents appear to have measurable but small differences in tests of pulmonary function when compared with children of nonsmoking parents. The significance of this finding to the future development of lung disease is unknown." (p. 13)	1984
Pulmonary function (adults): ". . .some studies suggest that high levels of involuntary [tobacco] smoke exposure might produce small changes in pulmonary function in normal subjects. . . . Two studies have reported differences in measures of lung function in older populations between subjects chronically exposed to involuntary smoking and those who were not. This difference was not found in a younger and possibly less exposed population." (p. 13)	1984
Acute respiratory infections: "The children of parents who smoke have an increased frequency of a variety of acute respiratory illnesses and infections, including chest illnesses before 2 years of age and physician-diagnosed bronchitis, tracheitis, and laryngitis, when compared with the children of nonsmokers." (p. 13)	1986
Bronchitis and pneumonia: "The children of parents who smoke have an increased frequency of hospitalization for bronchitis and pneumonia during the first year of life when compared with the children of nonsmokers." (p. 13)	1986
Cancers other than lung: "The associations between cancers, other than cancer of the lung, and involuntary smoking require further investigation before a determination can be made about the relationship of involuntary smoking to these cancers." (p. 14)	1986
Cardiovascular disease: "Further studies on the relationship between involuntary smoking and cardiovascular disease are needed in order to determine whether involuntary smoking increases the risk of cardiovascular disease." (p. 14)	1986

Table 1.1 Continued

Disease and statement	Surgeon General's report
Chronic cough and phlegm (children): "Chronic cough and phlegm are more frequent in children whose parents smoke compared with children of nonsmokers." (p. 13)	1986
Chronic obstructive pulmonary disease (COPD): "Healthy adults exposed to environmental tobacco smoke may have small changes on pulmonary function testing, but are unlikely to experience clinically significant deficits in pulmonary function as a result of exposure to environmental tobacco smoke alone." (pp. 13–14) "The implications of chronic respiratory symptoms for respiratory health as an adult are unknown and deserve further study." (p. 13)	1986
Lung cancer: "Involuntary smoking can cause lung cancer in nonsmokers." (p. 13)	1986
Middle ear effusions: "A number of studies report that chronic middle ear effusions are more common in young children whose parents smoke than in children of nonsmoking parents." (p. 14)	1986
Pulmonary function (children): "The children of parents who smoke have small differences in tests of pulmonary function when compared with the children of nonsmokers. Although this decrement is insufficient to cause symptoms, the possibility that it may increase susceptibility to chronic obstructive pulmonary disease with exposure to other agents in adult life, e.g., [*sic*] active smoking or occupational exposures, needs investigation." (p. 13)	1986
Other:	
"An atmosphere contaminated with tobacco smoke can contribute to the discomfort of many individuals." (p. 7)	1972
"Cigarette smoke can make a significant, measurable contribution to the level of indoor air pollution at levels of smoking and ventilation that are common in the indoor environment." (p. 13)	1984
"Cigarette smoke in the air can produce an increase in both subjective and objective measures of eye irritation." (p. 13)	1984
"Nonsmokers who report exposure to environmental tobacco smoke have higher levels of urinary cotinine, a metabolite of nicotine, than those who do not report such exposure." (p. 13)	1984
"The simple separation of smokers and nonsmokers within the same air space may reduce, but does not eliminate, the exposure of nonsmokers to environmental tobacco smoke." (p. 13)	1986
"Validated questionnaires are needed for the assessment of recent and remote exposure to environmental tobacco smoke in the home, workplace, and other environments." (p. 14)	1986

Sources: U.S. Department of Health, Education, and Welfare 1972; U.S. Department of Health and Human Services 1984, 1986.

topic, addressing toxicology and dosimetry of tobacco smoke; the relevant evidence on active smoking; patterns of exposure of nonsmokers to tobacco smoke; the epidemiologic evidence on involuntary smoking and disease risks for infants, children, and adults; and policies to control involuntary exposure to tobacco smoke. That report concluded that involuntary smoking caused lung cancer in lifetime nonsmoking adults and was associated with adverse effects on respiratory health in children. The report also stated that simply separating smokers and nonsmokers within the same airspace reduced but did not eliminate exposure to secondhand smoke. All of these findings are relevant to public health and public policy (Table 1.1). The lung cancer conclusion was based on extensive information already available on the carcinogenicity of active smoking, the qualitative similarities between secondhand and mainstream smoke, the uptake of tobacco smoke components by nonsmokers, and the epidemiologic data on involuntary smoking. The three major conclusions of the report (Table 1.2), led Dr. C. Everett Koop, Surgeon General at the time, to comment in his preface that "the right of smokers to smoke ends where their behavior affects the health and well-being of others; furthermore, it is the smokers' responsibility to ensure that they do not expose nonsmokers to the potential [*sic*] harmful effects of tobacco smoke" (USDHHS 1986, p. xii).

Two other reports published in 1986 also reached the conclusion that involuntary smoking increased the risk for lung cancer. The International Agency for Research on Cancer (IARC) of the World Health Organization concluded that "passive smoking gives rise to some risk of cancer" (IARC 1986, p. 314). In its monograph on tobacco smoking, the agency supported this conclusion on the basis of the characteristics of sidestream and mainstream smoke, the absorption of tobacco smoke materials during an involuntary exposure, and the nature of dose-response relationships for carcinogenesis. In the same year, the National Research Council (NRC) also concluded that involuntary smoking increases the incidence of lung cancer in nonsmokers (NRC 1986). In reaching this conclusion, the NRC report cited the biologic plausibility of the association between exposure to secondhand smoke and lung cancer and the supporting epidemiologic evidence. On the basis of a pooled analysis of the epidemiologic data adjusted for bias, the report concluded that the best estimate for the excess risk of lung cancer in nonsmokers married to smokers was 25 percent, compared with nonsmokers married to nonsmokers. With regard to the effects of involuntary smoking on children, the NRC report commented on the literature linking secondhand smoke exposures from parental smoking to increased risks for respiratory symptoms and infections and to a slightly diminished rate of lung growth.

Since 1986, the conclusions with regard to both the carcinogenicity of secondhand smoke and the adverse effects of parental smoking on the health of children have been echoed and expanded (Table 1.3). In 1992, the U.S. Environmental Protection Agency (EPA) published its risk assessment of secondhand smoke as a carcinogen (USEPA 1992). The agency's evaluation drew on toxicologic information on secondhand smoke and the extensive literature on active smoking. A comprehensive meta-analysis of the 31 epidemiologic studies of secondhand smoke and lung cancer published up to that time was central to the decision to classify secondhand smoke as a group A carcinogen—namely, a known human carcinogen. Estimates of approximately 3,000 U.S. lung cancer deaths per year in nonsmokers were attributed to secondhand smoke. The report also covered other respiratory health effects in

Table 1.2 Major conclusions of the 1986 Surgeon General's report, *The Health Consequences of Involuntary Smoking*

1. Involuntary smoking is a cause of disease, including lung cancer, in healthy nonsmokers.
2. The children of parents who smoke compared with the children of nonsmoking parents have an increased frequency of respiratory infections, increased respiratory symptoms, and slightly smaller rates of increase in lung function as the lung matures.
3. The simple separation of smokers and nonsmokers within the same air space may reduce, but does not eliminate, the exposure of nonsmokers to environmental tobacco smoke.

Source: U.S. Department of Health and Human Services 1986, p. 7.

Table 1.3 Selected major reports, other than those of the U.S. Surgeon General, addressing adverse effects from exposure to tobacco smoke

Agency	Publication	Place and date of publication
National Research Council	*Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects*	Washington, D.C. United States 1986
International Agency for Research on Cancer (IARC)	*Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking* (IARC Monograph 38)	Lyon, France 1986
U.S. Environmental Protection Agency (EPA)	*Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*	Washington, D.C. United States 1992
National Health and Medical Research Council	*The Health Effects of Passive Smoking*	Canberra, Australia 1997
California EPA (Cal/EPA), Office of Environmental Health Hazard Assessment	*Health Effects of Exposure to Environmental Tobacco Smoke*	Sacramento, California United States 1997
Scientific Committee on Tobacco and Health	*Report of the Scientific Committee on Tobacco and Health*	London, United Kingdom 1998
World Health Organization	*International Consultation on Environmental Tobacco Smoke (ETS) and Child Health. Consultation Report*	Geneva, Switzerland 1999
IARC	*Tobacco Smoke and Involuntary Smoking* (IARC Monograph 83)	Lyon, France 2004
Cal/EPA, Office of Environmental Health Hazard Assessment	*Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*	Sacramento, California United States 2005

children and adults and concluded that involuntary smoking is causally associated with several adverse respiratory effects in children. There was also a quantitative risk assessment for the impact of involuntary smoking on childhood asthma and lower respiratory tract infections in young children.

In the decade since the 1992 EPA report, scientific panels continued to evaluate the mounting evidence linking involuntary smoking to adverse health effects (Table 1.3). The most recent was the 2005 report of the California EPA (Cal/EPA 2005). Over time, research has repeatedly affirmed the conclusions of the 1986 Surgeon General's reports and studies have further identified causal associations of involuntary smoking with diseases and other health disorders. The epidemiologic evidence on involuntary smoking has markedly expanded since 1986, as have the data on exposure to tobacco smoke in the many environments where people spend time. An understanding of the mechanisms by which involuntary smoking causes disease has also deepened.

As part of the environmental health hazard assessment, Cal/EPA identified specific health effects causally associated with exposure to secondhand smoke. The agency estimated the annual excess deaths in the United States that are attributable to secondhand smoke exposure for specific disorders: sudden infant death syndrome (SIDS), cardiac-related illnesses (ischemic heart disease), and lung cancer (Cal/EPA 2005). For the excess incidence of other health outcomes, either new estimates were provided or estimates from the 1997 health hazard assessment were

used without any revisions (Cal/EPA 1997). Overall, Cal/EPA estimated that about 50,000 excess deaths result annually from exposure to secondhand smoke (Cal/EPA 2005). Estimated annual excess deaths for the total U.S. population are about 3,400 (a range of 3,423 to 8,866) from lung cancer, 46,000 (a range of 22,700 to 69,600) from cardiac-related illnesses, and 430 from SIDS. The agency also estimated that between 24,300 and 71,900 low birth weight or preterm deliveries, about 202,300 episodes of childhood asthma (new cases and exacerbations), between 150,000 and 300,000 cases of lower respiratory illness in children, and about 789,700 cases of middle ear infections in children occur each year in the United States as a result of exposure to secondhand smoke.

This new 2006 Surgeon General's report returns to the topic of involuntary smoking. The health effects of involuntary smoking have not received comprehensive coverage in this series of reports since 1986. Reports since then have touched on selected aspects of the topic: the 1994 report on tobacco use among young people (USDHHS 1994), the 1998 report on tobacco use among U.S. racial and ethnic minorities (USDHHS 1998), and the 2001 report on women and smoking (USDHHS 2001). As involuntary smoking remains widespread in the United States and elsewhere, the preparation of this report was motivated by the persistence of involuntary smoking as a public health problem and the need to evaluate the substantial new evidence reported since 1986. This report substantially expands the list of topics that were included in the 1986 report. Additional topics include SIDS, developmental effects, and other reproductive effects; heart disease in adults; and cancer sites beyond the lung. For some associations of involuntary smoking with adverse health effects, only a few studies were reviewed in 1986 (e.g., ear disease in children); now, the relevant literature is substantial. Consequently, this report uses meta-analysis to quantitatively summarize evidence as appropriate. Following the approach used in the 2004 report (*The Health Consequences of Smoking*, USDHHS 2004), this 2006 report also systematically evaluates the evidence for causality, judging the extent of the evidence available and then making an inference as to the nature of the association.

Organization of the Report

This twenty-ninth report of the Surgeon General examines the topics of toxicology of secondhand smoke, assessment and prevalence of exposure to secondhand smoke, reproductive and developmental health effects, respiratory effects of exposure to secondhand smoke in children and adults, cancer among adults, cardiovascular diseases, and the control of secondhand smoke exposure.

This introductory chapter (Chapter 1) includes a discussion of the concept of causation and introduces concepts of causality that are used throughout this report; this chapter also summarizes the major conclusions of the report. Chapter 2 (Toxicology of Secondhand Smoke) sets out a foundation for interpreting the observational evidence that is the focus of most of the following chapters. The discussion details the mechanisms that enable tobacco smoke components to injure the respiratory tract and cause nonmalignant and malignant diseases and other adverse effects. Chapter 3 (Assessment of Exposure to Secondhand Smoke) provides a perspective on key factors that determine exposures of people to secondhand smoke in indoor environments, including building designs and operations, atmospheric markers of secondhand smoke, exposure models, and biomarkers of exposure to secondhand smoke. Chapter 4 (Prevalence of Exposure to Secondhand Smoke) summarizes findings that focus on nicotine measurements in the air and cotinine measurements in biologic materials. The chapter includes exposures in the home, workplace, public places, and special populations. Chapter 5 (Reproductive and Developmental Effects from Exposure to Secondhand Smoke) reviews the health effects on reproduction, on infants, and on child development. Chapter 6 (Respiratory Effects in Children from Exposure to Secondhand Smoke) examines the effects of parental smoking on the respiratory health of children. Chapter 7 (Cancer Among Adults from Exposure to Secondhand Smoke) summarizes the evidence on cancer of the lung, breast, nasal sinuses, and the cervix. Chapter 8 (Cardiovascular Diseases from Exposure to Secondhand Smoke) discusses coronary heart disease (CHD), stroke, and subclinical vascular disease. Chapter 9 (Respiratory Effects in Adults from Exposure to Secondhand Smoke) examines odor and irritation, respiratory symptoms, lung function, and respiratory diseases such as asthma and chronic obstructive pulmonary disease. Chapter 10 (Control of Secondhand Smoke Exposure) considers measures used to control exposure to secondhand smoke in public places, including legislation, education, and approaches based on building designs and operations. The report concludes with "A Vision for the Future." Major conclusions of the report were distilled from the chapter conclusions and appear later in this chapter.

Preparation of the Report

This report of the Surgeon General was prepared by the Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Centers for Disease Control and Prevention (CDC), and U.S. DHHS. Initial chapters were written by 22 experts who were selected because of their knowledge of a particular topic. The contributions of the initial experts were consolidated into 10 major chapters that were then reviewed by more than 40 peer reviewers. The entire manuscript was then sent to more than 30 scientists and experts who reviewed it for its scientific integrity. After each review cycle, the drafts were revised by the scientific editors on the basis of the experts' comments. Subsequently, the report was reviewed by various institutes and agencies within U.S. DHHS. Publication lags, even short ones, prevent an up-to-the-minute inclusion of all recently published articles and data. Therefore, by the time the public reads this report, there may be additional published studies or data. To provide published information as current as possible, this report includes an Appendix of more recent studies that represent major additions to the literature.

This report is also accompanied by a companion database of key evidence that is accessible through the Internet (http://www.cdc.gov/tobacco). The database includes a uniform description of the studies and results on the health effects of exposure to secondhand smoke that were presented in a format compatible with abstraction into standardized tables. Readers of the report may access these data for additional analyses, tables, or figures.

Definitions and Terminology

The inhalation of tobacco smoke by nonsmokers has been variably referred to as "passive smoking" or "involuntary smoking." Smokers, of course, also inhale secondhand smoke. Cigarette smoke contains both particles and gases generated by the combustion at high temperatures of tobacco, paper, and additives. The smoke inhaled by nonsmokers that contaminates indoor spaces and outdoor environments has often been referred to as "secondhand smoke" or "environmental tobacco smoke." This inhaled smoke is the mixture of sidestream smoke released by the smoldering cigarette and the mainstream smoke that is exhaled by a smoker. Sidestream smoke, generated at lower temperatures and under somewhat different combustion conditions than mainstream smoke, tends to have higher concentrations of many of the toxins found in cigarette smoke (USDHHS 1986). However, it is rapidly diluted as it travels away from the burning cigarette.

Secondhand smoke is an inherently dynamic mixture that changes in characteristics and concentration with the time since it was formed and the distance it has traveled. The smoke particles change in size and composition as gaseous components are volatilized and moisture content changes; gaseous elements of secondhand smoke may be adsorbed onto materials, and particle concentrations drop with both dilution in the air or environment and impaction on surfaces, including the lungs or on the body. Because of its dynamic nature, a specific quantitative definition of secondhand smoke cannot be offered.

This report uses the term secondhand smoke in preference to environmental tobacco smoke, even though the latter may have been used more frequently in previous reports. The descriptor "secondhand" captures the involuntary nature of the exposure, while "environmental" does not. This report also refers to the inhalation of secondhand smoke as involuntary smoking, acknowledging that most nonsmokers do not want to inhale tobacco smoke. The exposure of the fetus to tobacco smoke, whether from active smoking by the mother or from her exposure to secondhand smoke, also constitutes involuntary smoking.

Evidence Evaluation

Following the model of the 1964 report, the Surgeon General's reports on smoking have included comprehensive compilations of the evidence on the health effects of smoking. The evidence is analyzed to identify causal associations between smoking and disease according to enunciated principles, sometimes referred to as the "Surgeon General's criteria" or the "Hill" criteria (after Sir Austin Bradford Hill) for causality (USDHEW 1964; USDHHS 2004). Application of these criteria involves covering all relevant observational and experimental evidence. The criteria, offered in a brief chapter of the 1964 report entitled "Criteria for Judgment," included (1) the consistency of the association, (2) the strength of the association, (3) the specificity of the association, (4) the temporal relationship of the association, and (5) the coherence of the association. Although these criteria have been criticized (e.g., Rothman and Greenland 1998), they have proved useful as a framework for interpreting evidence on smoking and other postulated causes of disease, and for judging whether causality can be inferred.

In the 2004 report of the Surgeon General, *The Health Consequences of Smoking*, the framework for interpreting evidence on smoking and health was revisited in depth for the first time since the 1964 report (USDHHS 2004). The 2004 report provided a four-level hierarchy for interpreting evidence (Table 1.4). The categories acknowledge that evidence can be "suggestive" but not adequate to infer a causal relationship, and also allows for evidence that is "suggestive of no causal relationship." Since the 2004 report, the individual chapter conclusions have consistently used this four-level hierarchy (Table 1.4), but evidence syntheses and other summary statements may use either the term "increased risk" or "cause" to describe instances in which there is sufficient evidence to conclude that active or involuntary smoking causes a disease or condition. This four-level framework also sharply and completely separates conclusions regarding causality from the implications of such conclusions.

That same framework was used in this report on involuntary smoking and health. The criteria dating back to the 1964 Surgeon General's report remain useful as guidelines for evaluating evidence (USDHEW 1964), but they were not intended to be applied strictly or as a "checklist" that needed to be met before the designation of "causal" could be applied to an association. In fact, for involuntary smoking and health, several of the criteria will not be met for some associations. Specificity, referring to a unique exposure-disease relationship (e.g., the association between thalidomide use during pregnancy and unusual birth defects), can be set aside as not relevant, as all of the health effects considered in this report have causes other than involuntary smoking. Associations are considered more likely to be causal as the strength of an association increases because competing explanations become less plausible alternatives. However, based on knowledge of dosimetry and mechanisms of injury and disease causation, the risk is anticipated to be only slightly or modestly increased for some associations of involuntary smoking with disease, such as lung cancer, particularly when the very strong relative risks found for active smokers are compared with those for lifetime nonsmokers. The finding of only a small elevation in risk, as in the

Table 1.4 Four-level hierarchy for classifying the strength of causal inferences based on available evidence

Level 1	Evidence is **sufficient** to infer a causal relationship.
Level 2	Evidence is **suggestive but not sufficient** to infer a causal relationship.
Level 3	Evidence is **inadequate** to infer the presence or absence of a causal relationship (which encompasses evidence that is sparse, of poor quality, or conflicting).
Level 4	Evidence is **suggestive of no causal relationship**.

Source: U.S. Department of Health and Human Services 2004.

example of spousal smoking and lung cancer risk in lifetime nonsmokers, does not weigh against a causal association; however, alternative explanations for a risk of a small magnitude need full exploration and cannot be so easily set aside as alternative explanations for a stronger association. Consistency, coherence, and the temporal relationship of involuntary smoking with disease are central to the interpretations in this report. To address coherence, the report draws not only on the evidence for involuntary smoking, but on the even more extensive literature on active smoking and disease.

Although the evidence reviewed in this report comes largely from investigations of secondhand smoke specifically, the larger body of evidence on active smoking is also relevant to many of the associations that were evaluated. The 1986 report found secondhand smoke to be qualitatively similar to mainstream smoke inhaled by the smoker and concluded that secondhand smoke would be expected to have "a toxic and carcinogenic potential that would not be expected to be qualitatively different from that of MS [mainstream smoke]" (USDHHS 1986, p. 23). The 2004 report of the Surgeon General revisited the health consequences of active smoking (USDHHS 2004), and the conclusions substantially expanded the list of diseases and conditions caused by smoking. Chapters in the present report consider the evidence on active smoking that is relevant to biologic plausibility for causal associations between involuntary smoking and disease. The reviews included in this report cover evidence identified through search strategies set out in each chapter. Of necessity, the evidence on mechanisms was selectively reviewed. However, an attempt was made to cover all health studies through specified target dates. Because of the substantial amount of time involved in preparing this report, lists of new key references published after these cut-off dates are included in an Appendix. Literature reviews were extended when new evidence was sufficient to possibly change the level of a causal conclusion.

Major Conclusions

This report returns to involuntary smoking, the topic of the 1986 Surgeon General's report. Since then, there have been many advances in the research on secondhand smoke, and substantial evidence has been reported over the ensuing 20 years. This report uses the revised language for causal conclusions that was implemented in the 2004 Surgeon General's report (USDHHS 2004). Each chapter provides a comprehensive review of the evidence, a quantitative synthesis of the evidence if appropriate, and a rigorous assessment of sources of bias that may affect interpretations of the findings. The reviews in this report reaffirm and strengthen the findings of the 1986 report. With regard to the involuntary exposure of nonsmokers to tobacco smoke, the scientific evidence now supports the following major conclusions:

1. Secondhand smoke causes premature death and disease in children and in adults who do not smoke.

2. Children exposed to secondhand smoke are at an increased risk for sudden infant death syndrome (SIDS), acute respiratory infections, ear problems, and more severe asthma. Smoking by parents causes respiratory symptoms and slows lung growth in their children.

3. Exposure of adults to secondhand smoke has immediate adverse effects on the cardiovascular system and causes coronary heart disease and lung cancer.

4. The scientific evidence indicates that there is no risk-free level of exposure to secondhand smoke.

5. Many millions of Americans, both children and adults, are still exposed to secondhand smoke in their homes and workplaces despite substantial progress in tobacco control.

6. Eliminating smoking in indoor spaces fully protects nonsmokers from exposure to secondhand smoke. Separating smokers from nonsmokers, cleaning the air, and ventilating buildings cannot eliminate exposures of nonsmokers to secondhand smoke.

Chapter Conclusions

Chapter 2. Toxicology of Secondhand Smoke

Evidence of Carcinogenic Effects from Secondhand Smoke Exposure

1. More than 50 carcinogens have been identified in sidestream and secondhand smoke.

2. The evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and its condensates and tumors in laboratory animals.

3. The evidence is sufficient to infer that exposure of nonsmokers to secondhand smoke causes a significant increase in urinary levels of metabolites of the tobacco-specific lung carcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK). The presence of these metabolites links exposure to secondhand smoke with an increased risk for lung cancer.

4. The mechanisms by which secondhand smoke causes lung cancer are probably similar to those observed in smokers. The overall risk of secondhand smoke exposure, compared with active smoking, is diminished by a substantially lower carcinogenic dose.

Mechanisms of Respiratory Tract Injury and Disease Caused by Secondhand Smoke Exposure

5. The evidence indicates multiple mechanisms by which secondhand smoke exposure causes injury to the respiratory tract.

6. The evidence indicates mechanisms by which secondhand smoke exposure could increase the risk for sudden infant death syndrome.

Mechanisms of Secondhand Smoke Exposure and Heart Disease

7. The evidence is sufficient to infer that exposure to secondhand smoke has a prothrombotic effect.

8. The evidence is sufficient to infer that exposure to secondhand smoke causes endothelial cell dysfunctions.

9. The evidence is sufficient to infer that exposure to secondhand smoke causes atherosclerosis in animal models.

Chapter 3. Assessment of Exposure to Secondhand Smoke

Building Designs and Operations

1. Current heating, ventilating, and air conditioning systems alone cannot control exposure to secondhand smoke.

2. The operation of a heating, ventilating, and air conditioning system can distribute secondhand smoke throughout a building.

Exposure Models

3. Atmospheric concentration of nicotine is a sensitive and specific indicator for secondhand smoke.

4. Smoking increases indoor particle concentrations.

5. Models can be used to estimate concentrations of secondhand smoke.

Biomarkers of Exposure to Secondhand Smoke

6. Biomarkers suitable for assessing recent exposures to secondhand smoke are available.

7. At this time, cotinine, the primary proximate metabolite of nicotine, remains the biomarker of choice for assessing secondhand smoke exposure.

8. Individual biomarkers of exposure to secondhand smoke represent only one component of a complex mixture, and measurements of one marker may not wholly reflect an exposure to other components of concern as a result of involuntary smoking.

Chapter 4. Prevalence of Exposure to Secondhand Smoke

1. The evidence is sufficient to infer that large numbers of nonsmokers are still exposed to secondhand smoke.

2. Exposure of nonsmokers to secondhand smoke has declined in the United States since the 1986 Surgeon General's report, *The Health Consequences of Involuntary Smoking*.

3. The evidence indicates that the extent of secondhand smoke exposure varies across the country.

4. Homes and workplaces are the predominant locations for exposure to secondhand smoke.

5. Exposure to secondhand smoke tends to be greater for persons with lower incomes.

6. Exposure to secondhand smoke continues in restaurants, bars, casinos, gaming halls, and vehicles.

Chapter 5. Reproductive and Developmental Effects from Exposure to Secondhand Smoke

Fertility

1. The evidence is inadequate to infer the presence or absence of a causal relationship between maternal exposure to secondhand smoke and female fertility or fecundability. No data were found on paternal exposure to secondhand smoke and male fertility or fecundability.

Pregnancy (Spontaneous Abortion and Perinatal Death)

2. The evidence is inadequate to infer the presence or absence of a causal relationship between maternal exposure to secondhand smoke during pregnancy and spontaneous abortion.

Infant Deaths

3. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and neonatal mortality.

Sudden Infant Death Syndrome

4. The evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and sudden infant death syndrome.

Preterm Delivery

5. The evidence is suggestive but not sufficient to infer a causal relationship between maternal exposure to secondhand smoke during pregnancy and preterm delivery.

Low Birth Weight

6. The evidence is sufficient to infer a causal relationship between maternal exposure to secondhand smoke during pregnancy and a small reduction in birth weight.

Congenital Malformations

7. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and congenital malformations.

Cognitive Development

8. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and cognitive functioning among children.

Behavioral Development

9. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and behavioral problems among children.

Height/Growth

10. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and children's height/growth.

Childhood Cancer

11. The evidence is suggestive but not sufficient to infer a causal relationship between prenatal and postnatal exposure to secondhand smoke and childhood cancer.

12. The evidence is inadequate to infer the presence or absence of a causal relationship between maternal exposure to secondhand smoke during pregnancy and childhood cancer.

13. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke during infancy and childhood cancer.

14. The evidence is suggestive but not sufficient to infer a causal relationship between prenatal and postnatal exposure to secondhand smoke and childhood leukemias.

15. The evidence is suggestive but not sufficient to infer a causal relationship between prenatal and postnatal exposure to secondhand smoke and childhood lymphomas.

16. The evidence is suggestive but not sufficient to infer a causal relationship between prenatal and postnatal exposure to secondhand smoke and childhood brain tumors.

17. The evidence is inadequate to infer the presence or absence of a causal relationship between prenatal and postnatal exposure to secondhand smoke and other childhood cancer types.

Chapter 6. Respiratory Effects in Children from Exposure to Secondhand Smoke

Lower Respiratory Illnesses in Infancy and Early Childhood

1. The evidence is sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and lower respiratory illnesses in infants and children.

2. The increased risk for lower respiratory illnesses is greatest from smoking by the mother.

Middle Ear Disease and Adenotonsillectomy

3. The evidence is sufficient to infer a causal relationship between parental smoking and middle ear disease in children, including acute and recurrent otitis media and chronic middle ear effusion.

4. The evidence is suggestive but not sufficient to infer a causal relationship between parental smoking and the natural history of middle ear effusion.

5. The evidence is inadequate to infer the presence or absence of a causal relationship between parental smoking and an increase in the risk of adenoidectomy or tonsillectomy among children.

Respiratory Symptoms and Prevalent Asthma in School-Age Children

6. The evidence is sufficient to infer a causal relationship between parental smoking and cough, phlegm, wheeze, and breathlessness among children of school age.

7. The evidence is sufficient to infer a causal relationship between parental smoking and ever having asthma among children of school age.

Childhood Asthma Onset

8. The evidence is sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and the onset of wheeze illnesses in early childhood.

9. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and the onset of childhood asthma.

Atopy

10. The evidence is inadequate to infer the presence or absence of a causal relationship between parental smoking and the risk of immunoglobulin E-mediated allergy in their children.

Lung Growth and Pulmonary Function

11. The evidence is sufficient to infer a causal relationship between maternal smoking during pregnancy and persistent adverse effects on lung function across childhood.

12. The evidence is sufficient to infer a causal relationship between exposure to secondhand smoke after birth and a lower level of lung function during childhood.

Chapter 7. Cancer Among Adults from Exposure to Secondhand Smoke

Lung Cancer

1. The evidence is sufficient to infer a causal relationship between secondhand smoke exposure and lung cancer among lifetime nonsmokers. This conclusion extends to all secondhand smoke exposure, regardless of location.

2. The pooled evidence indicates a 20 to 30 percent increase in the risk of lung cancer from secondhand smoke exposure associated with living with a smoker.

Breast Cancer

3. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke and breast cancer.

Nasal Sinus Cavity and Nasopharyngeal Carcinoma

4. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and a risk of nasal sinus cancer among nonsmokers.

5. The evidence is inadequate to infer the presence or absence of a causal relationship between secondhand smoke exposure and a risk of nasopharyngeal carcinoma among nonsmokers.

Cervical Cancer

6. The evidence is inadequate to infer the presence or absence of a causal relationship between secondhand smoke exposure and the risk of cervical cancer among lifetime nonsmokers.

Chapter 8. Cardiovascular Diseases from Exposure to Secondhand Smoke

1. The evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and increased risks of coronary heart disease morbidity and mortality among both men and women.

2. Pooled relative risks from meta-analyses indicate a 25 to 30 percent increase in the risk of coronary heart disease from exposure to secondhand smoke.

3. The evidence is suggestive but not sufficient to infer a causal relationship between exposure to secondhand smoke and an increased risk of stroke.

4. Studies of secondhand smoke and subclinical vascular disease, particularly carotid arterial wall thickening, are suggestive but not sufficient to infer a causal relationship between exposure to secondhand smoke and atherosclerosis.

Chapter 9. Respiratory Effects in Adults from Exposure to Secondhand Smoke

Odor and Irritation

1. The evidence is sufficient to infer a causal relationship between secondhand smoke exposure and odor annoyance.

2. The evidence is sufficient to infer a causal relationship between secondhand smoke exposure and nasal irritation.

3. The evidence is suggestive but not sufficient to conclude that persons with nasal allergies or a history of respiratory illnesses are more susceptible to developing nasal irritation from secondhand smoke exposure.

Respiratory Symptoms

4. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and acute respiratory symptoms including cough, wheeze, chest tightness, and difficulty breathing among persons with asthma.

5. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and acute respiratory symptoms including cough, wheeze, chest tightness, and difficulty breathing among healthy persons.

6. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and chronic respiratory symptoms.

Lung Function

7. The evidence is suggestive but not sufficient to infer a causal relationship between short-term secondhand smoke exposure and an acute decline in lung function in persons with asthma.

8. The evidence is inadequate to infer the presence or absence of a causal relationship between short-term secondhand smoke exposure and an acute decline in lung function in healthy persons.

9. The evidence is suggestive but not sufficient to infer a causal relationship between chronic secondhand smoke exposure and a small decrement in lung function in the general population.

10. The evidence is inadequate to infer the presence or absence of a causal relationship between chronic secondhand smoke exposure and an accelerated decline in lung function.

Asthma

11. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and adult-onset asthma.

12. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and a worsening of asthma control.

Chronic Obstructive Pulmonary Disease

13. The evidence is suggestive but not sufficient to infer a causal relationship between secondhand smoke exposure and risk for chronic obstructive pulmonary disease.

14. The evidence is inadequate to infer the presence or absence of a causal relationship between secondhand smoke exposure and morbidity in persons with chronic obstructive pulmonary disease.

Chapter 10. Control of Secondhand Smoke Exposure

1. Workplace smoking restrictions are effective in reducing secondhand smoke exposure.

2. Workplace smoking restrictions lead to less smoking among covered workers.

3. Establishing smoke-free workplaces is the only effective way to ensure that secondhand smoke exposure does not occur in the workplace.

4. The majority of workers in the United States are now covered by smoke-free policies.

5. The extent to which workplaces are covered by smoke-free policies varies among worker groups, across states, and by sociodemographic factors. Workplaces related to the entertainment and hospitality industries have notably high potential for secondhand smoke exposure.

6. Evidence from peer-reviewed studies shows that smoke-free policies and regulations do not have an adverse economic impact on the hospitality industry.

7. Evidence suggests that exposure to secondhand smoke varies by ethnicity and gender.

8. In the United States, the home is now becoming the predominant location for exposure of children and adults to secondhand smoke.

9. Total bans on indoor smoking in hospitals, restaurants, bars, and offices substantially reduce secondhand smoke exposure, up to several orders of magnitude with incomplete compliance, and with full compliance, exposures are eliminated.

10. Exposures of nonsmokers to secondhand smoke cannot be controlled by air cleaning or mechanical air exchange.

Methodologic Issues

Much of the evidence on the health effects of involuntary smoking comes from observational epidemiologic studies that were carried out to test hypotheses related to secondhand smoke and risk for diseases and other adverse health effects. The challenges faced in carrying out these studies reflect those of observational research generally: assessment of the relevant exposures and outcomes with sufficient validity and precision, selection of an appropriate study design, identification of an appropriate and sufficiently large study population, and collection of information on other relevant factors that may confound or modify the association being studied. The challenge of accurately classifying secondhand smoke exposures confronts all studies of such exposures, and consequently the literature on approaches to and limitations of exposure classification is substantial. Sources of bias that can affect the findings of epidemiologic studies have been widely discussed (Rothman and Greenland 1998), both in general and in relation to studies of involuntary smoking. Concerns about bias apply to any study of an environmental agent and disease risk: misclassification of exposures or outcomes, confounding effect modification, and proper selection of study participants. In addition, the generalizability of findings from one population to another (external validity) further determines the value of evidence from a study. Another methodologic concern affecting secondhand smoke literature comes from the use of meta-analysis to combine the findings of epidemiologic studies; general concerns related to the use of meta-analysis for observational data and more specific concerns related to involuntary smoking have also been raised. This chapter considers these methodologic issues in anticipation of more specific treatment in the following chapters.

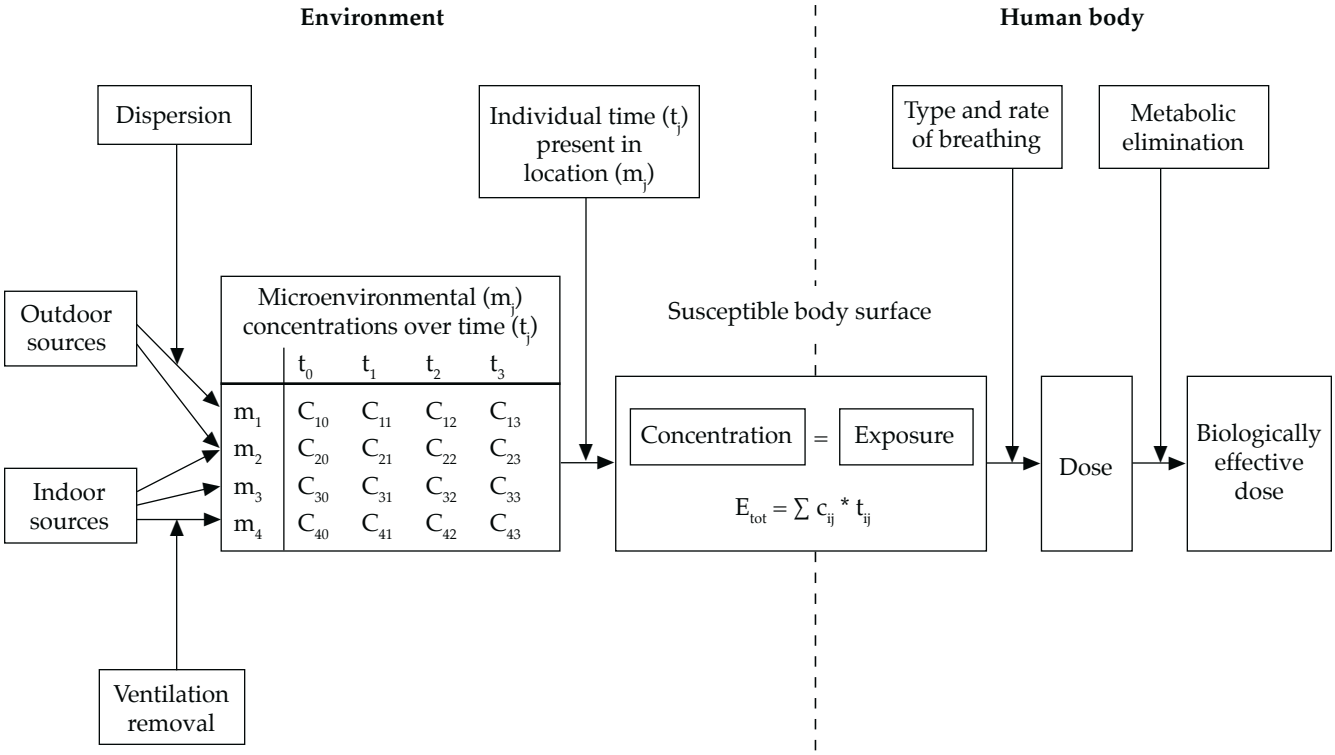
Classification of Secondhand Smoke Exposure

For secondhand smoke, as for any environmental factor that may be a cause of disease, the exposure assessment might encompass the time and place of the exposure, cumulative exposures, exposure during a particular time, or a recent exposure (Jaakkola and Jaakkola 1997; Jaakkola and Samet 1999). For example, exposures to secondhand smoke across the full life span may be of interest for lung cancer, while only more recent exposures may be relevant to the exacerbation of asthma. For CHD, both temporally remote and current exposures may affect risk. Assessments of exposures are further complicated by the multiplicity of environments where exposures take place and the difficulty of characterizing the exposure in some locations, such as public places or workplaces. Additionally, exposures probably vary qualitatively and quantitatively over time and across locations because of temporal changes and geographic differences in smoking patterns.

Nonetheless, researchers have used a variety of approaches for exposure assessments in epidemiologic studies of adverse health effects from involuntary smoking. Several core concepts that are fundamental to these approaches are illustrated in Figure 1.1 (Samet and Jaakkola 1999). Cigarette smoking is, of course, the source of most secondhand smoke in the United States, followed by pipes, cigars, and other products. Epidemiologic studies generally focus on assessing the exposure, which is the contact with secondhand smoke. The concentrations of secondhand smoke components in a space depend on the number of smokers and the rate at which they are smoking, the volume into which the smoke is distributed, the rate at which the air in the space exchanges with uncontaminated air, and the rate at which the secondhand smoke is removed from the air. Concentration, exposure, and dose differ in their definitions, although the terms are sometimes used without sharp distinctions. However, surrogate indicators that generally describe a source of exposure may also be used to assess the exposure, such as marriage to a smoker or the number of cigarettes smoked in the home. Biomarkers can provide an indication of an exposure or possibly the dose, but for secondhand smoke they are used for recent exposure only.

People are exposed to secondhand smoke in a number of different places, often referred to as "microenvironments" (NRC 1991). A microenvironment is a definable location that has a constant concentration of the contaminant of interest, such as secondhand smoke, during the time that a person is there. Some key microenvironments for secondhand smoke include the home, the workplace, public places, and transportation environments (Klepeis 1999). Based

Figure 1.1 The determinants of exposure, dose, and biologically effective dose that underlie the development of health effects from smoking



Source: Samet and Jaakkola 1999. Reprinted with permission.

on the microenvironmental model, total exposure can be estimated as the weighted average of the concentrations of secondhand smoke or indicator compounds, such as nicotine, in the microenvironments where time is spent; the weights are the time spent in each microenvironment. Klepeis (1999) illustrates the application of the microenvironmental model with national data from the National Human Activity Pattern Survey conducted by the EPA. His calculations yield an overall estimate of exposure to airborne particles from smoking and of the contributions to this exposure from various microenvironments.

Much of the epidemiologic evidence addresses the consequences of an exposure in a particular microenvironment, such as the home (spousal smoking and lung cancer risk or maternal smoking and risk for asthma exacerbation), or the workplace (exacerbation of asthma by the presence of smokers). Some studies have attempted to cover multiple microenvironments and to characterize exposures over time. For example, in the multicenter study of secondhand smoke exposure and lung cancer carried out in the United States, Fontham and colleagues (1994) assessed exposures during childhood, in workplaces, and at home during adulthood. Questionnaires that assess exposures have been the primary tool used in epidemiologic studies of secondhand smoke and disease. Measurement of biomarkers has been added in some studies, either as an additional and complementary exposure assessment approach or for validating questionnaire responses. Some studies have also measured components of secondhand smoke in the air.

Questionnaires generally address sources of exposure in microenvironments and can be tailored to address the time period of interest. Questionnaires represent the only approach that can be used to assess exposures retrospectively over a life span, because available biomarkers only reflect exposures

over recent days or, at most, weeks. Questionnaires on secondhand smoke exposure have been assessed for their reliability and validity, generally based on comparisons with either biomarker or air monitoring data as the "gold" standard (Jaakkola and Jaakkola 1997). Two studies evaluated the reliability of questionnaires on lifetime exposures (Pron et al. 1988; Coultas et al. 1989). Both showed a high degree of repeatability for questions concerning whether a spouse had smoked, but a lower reliability for responses concerning the quantitative aspects of an exposure. Emerson and colleagues (1995) evaluated the repeatability of information from parents of children with asthma. They found a high reliability for parent-reported tobacco use and for the number of cigarettes to which the child was exposed in the home during the past week.

To assess validity, questionnaire reports of current or recent exposures have been compared with levels of cotinine and other biomarkers. These studies tend to show a moderate correlation between levels of cotinine and questionnaire indicators of exposures (Kawachi and Colditz 1996; Cal/EPA 1997; Jaakkola and Jaakkola 1997). However, cotinine levels reflect not only exposure but metabolism and excretion (Benowitz 1999). Consequently, exposure is only one determinant of variation in cotinine levels among persons; there also are individual variations in metabolism and excretion rates. In spite of these sources of variability, mean levels of cotinine vary as anticipated across categories of self-reported exposures (Cal/EPA 1997; Jaakkola and Jaakkola 1997), and self-reported exposures are moderately associated with measured levels of markers (Cal/EPA 1997; Jaakkola and Jaakkola 1997).

Biomarkers are also used for assessing exposures to secondhand smoke. A number of biomarkers are available, but they vary in their specificity and in the dynamics of the temporal relationship between the exposure and the marker level (Cal/EPA 1997; Benowitz 1999). These markers include specific tobacco smoke components (nicotine) or metabolites (cotinine and tobacco-specific nitrosamines), nonspecific biomarkers (thiocyanate and CO), adducts with tobacco smoke components or metabolites (4-aminobiphenyl–hemoglobin adducts, benzo[*a*]pyrene–DNA adducts, and polycyclic aromatic hydrocarbon–albumin adducts), and nonspecific assays (urinary mutagenicity). Cotinine has been the most widely used biomarker, primarily because of its specificity, half-life, and ease of measurement in body fluids (e.g., urine, blood, and saliva). Biomarkers are discussed in detail in Chapter 3 (Assessment of Exposure to Secondhand Smoke).

Some epidemiologic studies have also incorporated air monitoring, either direct personal sampling or the indirect approach based on the microenvironmental model. Nicotine, present in the gas phase of secondhand smoke, can be monitored passively with a special filter or actively using a pump and a sorbent. Hammond and Leaderer (1987) first described a diffusion monitor for the passive sampling of nicotine in 1987; this device has now been widely used to assess concentrations in different environments and to study health effects. Airborne particles have also been measured using active monitoring devices.

Each of these approaches for assessing exposures has strengths and limitations, and preference for one over another will depend on the research question and its context (Jaakkola and Jaakkola 1997; Jaakkola and Samet 1999). Questionnaires can be used to characterize sources of exposures, such as smoking by parents. With air concentrations of markers and time-activity information, estimates of secondhand smoke exposures can be made with the microenvironmental model. Biomarkers provide exposure measures that reflect the patterns of exposure and the kinetics of the marker; the cotinine level in body fluids, for example, reflects an exposure during several days. Air monitoring may be useful for validating measurements of exposure. Exposure assessment strategies are matched to the research question and often employ a mixture of approaches determined by feasibility and cost constraints.

Misclassification of Secondhand Smoke Exposure

Misclassification may occur when classifying exposures, outcomes, confounding factors, or modifying factors. Misclassification may be differential on either exposure or outcome, or it may be random (Armstrong et al. 1992). Differential or nonrandom misclassification may either increase or decrease estimates of effect, while random misclassification tends to reduce the apparent effect and weaken the relationship of exposure with disease risk. In studies of secondhand smoke and disease risk, exposure misclassification has been a major consideration in the interpretation of the evidence, although misclassification of health outcome measures has not been a substantial issue in this research. The consequences for epidemiologic studies of misclassification in general are well established (Rothman and Greenland 1998).

An extensive body of literature on the classification of exposures to secondhand smoke is reviewed in this and other chapters, as well as in some publications on the consequences of misclassification (Wu 1999). Two general patterns of exposure misclassification are of concern to secondhand smoke: (1) random misclassification that is not differential by the presence or absence of the health outcome and (2) systematic misclassification that is differential by the health outcome. In studying the health effects of secondhand smoke in adults, there is a further concern as to the classification of the active smoking status (never, current, or former smoking); in studies of children, the accuracy of secondhand smoke exposure classification is the primary methodologic issue around exposure assessment, but unreported active smoking by adolescents is also a concern.

With regard to random misclassification of secondhand smoke exposures, there is an inherent degree of unavoidable measurement error in the exposure measures used in epidemiologic studies. Questionnaires generally assess contact with sources of an exposure (e.g., smoking in the home or workplace) and cannot capture all exposures nor the intensity of exposures; biomarkers provide an exposure index for a particular time window and have intrinsic variability. Some building-related factors that determine an exposure cannot be assessed accurately by a questionnaire, such as the rate of air exchange and the size of the microenvironment where time is spent, nor can concentrations be assessed accurately by subjective reports of the perceived level of tobacco smoke. In general, random misclassification of exposures tends to reduce the likelihood that studies of secondhand smoke exposure will find an effect. This type of misclassification lessens the contrast between exposure groups, because some truly exposed persons are placed in the unexposed group and some truly unexposed persons are placed in the exposed group. Differential misclassification, also a concern, may increase or decrease associations, depending on the pattern of misreporting.

One particular form of misclassification has been raised with regard to secondhand smoke exposure and lung cancer: the classification of some current or former smokers as lifetime nonsmokers (USEPA 1992; Lee and Forey 1995; Hackshaw et al. 1997; Wu 1999). The resulting bias would tend to increase the apparent association of secondhand smoke with lung cancer, if the misclassified active smokers are also more likely to be classified as involuntary smokers. Most studies of lung cancer and secondhand smoke have used spousal smoking as a main exposure variable. As smoking tends to aggregate between spouses (smokers are more likely to marry smokers), misclassification of active smoking would tend to be differential on the basis of spousal smoking (the exposure under investigation). Because active smoking is strongly associated with increased disease risk, greater misclassification of an actively smoking spouse as a nonsmoker among spouses of smokers compared with spouses of nonsmokers would lead to risk estimates for spousal smoking that are biased upward by the effect of active smoking. This type of misclassification is also relevant to studies of spousal exposure and CHD risk or other diseases also caused by active smoking, although the potential for bias is less because the association of active smoking with CHD is not as strong as with lung cancer.

There have been a number of publications on this form of misclassification. Wu (1999) provides a review, and Lee and colleagues (2001) offer an assessment of potential consequences. A number of models have been developed to assess the extent of bias resulting from the misclassification of active smokers as lifetime nonsmokers (USEPA 1992; Hackshaw et al. 1997). These models incorporate estimates of the rate of misclassification, the degree of aggregation of smokers by marriage, the prevalence of smoking in the population, and the risk of lung cancer in misclassified smokers (Wu 1999). Although debate about this issue continues, analyses show that estimates of upward bias from misclassifying active smokers as lifetime nonsmokers cannot fully explain the observed increase in risk for lung cancer among lifetime nonsmokers married to smokers (Hackshaw et al. 1997; Wu 1999).

There is one additional issue related to exposure misclassification. During the time the epidemiologic studies of secondhand smoke have been carried out, exposure has been widespread and almost unavoidable. Therefore, the risk estimates may be biased downward because there are no truly unexposed persons. The 1986 Surgeon General's report recognized this methodologic issue and noted the need for further data on population exposures to secondhand smoke (USDHHS 1986). This bias was also recognized in the 1986 report of the NRC, and an adjustment for this misclassification was made to the lung cancer estimate (NRC 1986). Similarly, the 1992 report of the EPA commented on background exposure and made an adjustment (USEPA 1992). Some later studies have attempted to address this issue; for example, in a case-control study of active and involuntary smoking and breast cancer in Switzerland, Morabia and colleagues (2000) used a questionnaire to assess exposure and

identified a small group of lifetime nonsmokers who also reported no exposure to secondhand smoke. With this subgroup of controls as the reference population, the risks of secondhand smoke exposure were substantially greater for active smoking than when the full control population was used.

This Surgeon General's report further addresses specific issues of exposure misclassification when they are relevant to the health outcome under consideration.

Use of Meta-Analysis

Meta-analysis refers to the process of evaluating and combining a body of research literature that addresses a common question. Meta-analysis is composed of qualitative and quantitative components. The qualitative component involves the systematic identification of all relevant investigations, a systematic assessment of their characteristics and quality, and the decision to include or exclude studies based on predetermined criteria. Consideration can be directed toward sources of bias that might affect the findings. The quantitative component involves the calculation and display of study results on common scales and, if appropriate, the statistical combination of these results across studies and an exploration of the reasons for any heterogeneity of findings. Viewing the findings of all studies as a single plot provides insights into the consistency of results and the precision of the studies considered. Most meta-analyses are based on published summary results, although they are most powerful when applied to data at the level of individual participants. Meta-analysis is most widely used to synthesize evidence from randomized clinical trials, sometimes yielding findings that were not evident from the results of individual studies. Meta-analysis also has been used extensively to examine bodies of observational evidence.

Beginning with the 1986 NRC report, meta-analysis has been used to summarize the evidence on involuntary smoking and health. Meta-analysis was central to the 1992 EPA risk assessment of secondhand smoke, and a series of meta-analyses supported the conclusions of the 1998 report of the Scientific Committee on Tobacco and Health in the United Kingdom. The central role of meta-analysis in interpreting and applying the evidence related to involuntary smoking and disease has led to focused criticisms of the use of meta-analysis in this context. Several papers that acknowledged support from the tobacco industry have addressed the epidemiologic findings for lung cancer, including the selection and quality of the studies, the methods for meta-analysis, and dose-response associations (Fleiss and Gross 1991; Tweedie and Mengersen 1995; Lee 1998, 1999). In a lawsuit brought by the tobacco industry against the EPA, the 1998 decision handed down by Judge William L. Osteen, Sr., in the North Carolina Federal District Court criticized the approach EPA had used to select studies for its meta-analysis and criticized the use of 90 percent rather than 95 percent confidence intervals for the summary estimates (*Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Agency*, 857 F. Supp. 1137 [M.D.N.C. 1993]). In December 2002, the 4th U.S. Circuit Court of Appeals threw out the lawsuit on the basis that tobacco companies cannot sue the EPA over its secondhand smoke report because the report was not a final agency action and therefore not subject to court review (*Flue-Cured Tobacco Cooperative Stabilization Corp. v. The United States Environmental Protection Agency*, No. 98-2407 [4th Cir., December 11, 2002], *cited in* 17.7 TPLR 2.472 [2003]).

Recognizing that there is still an active discussion around the use of meta-analysis to pool data from observational studies (versus clinical trials), the authors of this Surgeon General's report used this methodology to summarize the available data when deemed appropriate and useful, even while recognizing that the uncertainty around the meta-analytic estimates may exceed the uncertainty indicated by conventional statistical indices, because of biases either within the observational studies or produced by the manner of their selection. However, a decision to not combine estimates might have produced conclusions that are far more uncertain than the data warrant because the review would have focused on individual study results without considering their overall pattern, and without allowing for a full accounting of different sample sizes and effect estimates.

The possibility of publication bias has been raised as a potential limitation to the interpretation of evidence on involuntary smoking and disease in general, and on lung cancer and secondhand smoke exposure specifically. A 1988 paper by Vandenbroucke used a descriptive approach, called a "funnel plot," to assess the possibility that publication bias affected the 13 studies considered in a review by Wald and colleagues (1986). This type of plot characterizes the relationship between the magnitude of estimates and their precision. Vandenbroucke suggested the possibility of publication bias only in reference to the studies of men. Bero and colleagues (1994) concluded that there

had not been a publication bias against studies with statistically significant findings, nor against the publication of studies with nonsignificant or mixed findings in the research literature. The researchers were able to identify only five unpublished "negative" studies, of which two were dissertations that tend to be delayed in publication. A subsequent study by Misakian and Bero (1998) did find a delay in the publication of studies with nonsignificant results in comparison with studies having significant results; whether this pattern has varied over the several decades of research on secondhand smoke was not addressed. More recently, Copas and Shi (2000) assessed the 37 studies considered in the meta-analysis by Hackshaw and colleagues (1997) for publication bias. Copas and Shi (2000) found a significant correlation between the estimated risk of exposure and sample size, such that smaller studies tended to have higher values. This pattern suggests the possibility of publication bias. However, using a funnel plot of the same studies, Lubin (1999) found little evidence for publication bias.

On this issue of publication bias, it is critical to distinguish between indirect statistical arguments and arguments based on actual identification of previously unidentified research. The strongest case against substantive publication bias has been made by researchers who mounted intensive efforts to find the possibly missing studies; these efforts have yielded little—nothing that would alter published conclusions (Bero et al. 1994; Glantz 2000). Presumably because this exposure is a great public health concern, the findings of studies that do not have statistically significant outcomes continue to be published (Kawachi and Colditz 1996).

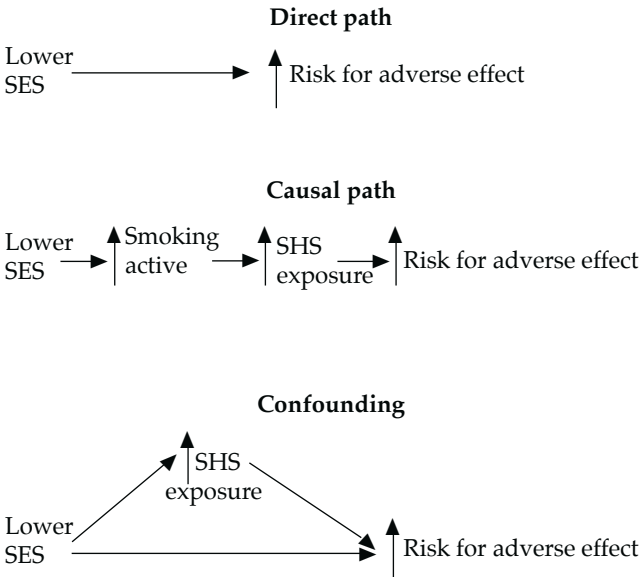
The quantitative results of the meta-analyses, however, were not determinate in making causal inferences in this Surgeon General's report. In particular, the level of statistical significance of estimates from the meta-analyses was not a predominant factor in making a causal conclusion. For that purpose, this report relied on the approach and criteria set out in the 1964 and 2004 reports of the Surgeon General, which involved judgments based on an array of quantitative and qualitative considerations that included the degree of heterogeneity in the designs of the studies that were examined. Sometimes this heterogeneity limits the inference from meta-analysis by weakening the rationale for pooling the study results. However, the availability of consistent evidence from heterogenous designs can strengthen the meta-analytic findings by making it unlikely that a common bias could persist across different study designs and populations.

Confounding

Confounding, which refers in this context to the mixing of the effect of another factor with that of secondhand smoke, has been proposed as an explanation for associations of secondhand smoke with adverse health consequences. Confounding occurs when the factor of interest (secondhand smoke) is associated in the data under consideration with another factor (the confounder) that, by itself, increases the risk for the disease (Rothman and Greenland 1998). Correlates of secondhand smoke exposures are not confounding factors unless an exposure to them increases the risk of disease. A factor proposed as a potential confounder is not necessarily an actual confounder unless it fulfills the two elements of the definition. Although lengthy lists of potential confounding factors have been offered as alternatives to direct associations of secondhand smoke exposures with the risk for disease, the factors on these lists generally have not been shown to be confounding in the particular data of interest.

The term confounding also conveys an implicit conceptualization as to the causal pathways that link secondhand smoke and the confounding factor to

Figure 1.2 Model for socioeconomic status (SES) and secondhand smoke (SHS) exposure



Arrows indicate directionality of association.

disease risk. Confounding implies that the confounding factor has an effect on risk that is independent of secondhand smoke exposure. Some factors considered as potential confounders may, however, be in the same causal pathway as a secondhand smoke exposure. Although socioeconomic status (SES) is often cited as a potential confounding factor, it may not have an independent effect but can affect disease risk through its association with secondhand smoke exposure (Figure 1.2). This figure shows general alternative relationships among SES, secondhand smoke exposure, and risk for an adverse effect. SES may have a direct effect, or it may indirectly exert its effect through an association with secondhand smoke exposure, or it may confound the relationship between secondhand smoke exposure and disease risk. To control for SES as a potential confounding factor without considering underlying relationships may lead to incorrect risk estimates. For example, controlling for SES would not be appropriate if it is a determinant of secondhand smoke exposure but has no direct effect.

Nonetheless, because the health effects of involuntary smoking have other causes, the possibility of confounding needs careful exploration when assessing associations of secondhand smoke exposure with adverse health effects. In addition, survey data from the last several decades show that secondhand smoke exposure is associated with correlates of lifestyle that may influence the risk for some health effects, thus increasing concerns for the possibility of confounding (Kawachi and Colditz 1996). Survey data from the United States (Matanoski et al. 1995) and the United Kingdom (Thornton et al. 1994) show that adults with secondhand smoke exposures generally tend to have less healthful lifestyles. However, the extent to which these patterns of association can be generalized, either to other countries or to the past, is uncertain.

The potential bias from confounding varies with the association of the confounder to secondhand smoke exposures in a particular study and to the strength of the confounder as a risk factor. The importance of confounding to the interpretation of evidence depends further on the magnitude of the effect of secondhand smoke on disease. As the strength of an association lessens, confounding as an alternative explanation for an association becomes an increasing concern. In prior reviews, confounding has been addressed either quantitatively (Hackshaw et al. 1997) or qualitatively (Cal/EPA 1997; Thun et al. 1999). In the chapters in this report that focus on specific diseases, confounding is specifically addressed in the context of potential confounding factors for the particular diseases.

Tobacco Industry Activities

The evidence on secondhand smoke and disease risk, given the public health and public policy implications, has been reviewed extensively in the published peer-reviewed literature and in evaluations by a number of expert panels. In addition, the evidence has been criticized repeatedly by the tobacco industry and its consultants in venues that have included the peer-reviewed literature, public meetings and hearings, and scientific symposia that included symposia sponsored by the industry. Open criticism in the peer-reviewed literature can strengthen the credibility of scientific evidence by challenging researchers to consider the arguments proposed by critics and to rebut them.

Industry documents indicate that the tobacco industry has engaged in widespread activities, however, that have gone beyond the bounds of accepted scientific practice (Glantz 1996; Ong and Glantz 2000, 2001; Rampton and Stauber 2000; Yach and Bialous 2001; Hong and Bero 2002; Diethelm et al. 2004). Through a variety of organized tactics, the industry has attempted to undermine the credibility of the scientific evidence on secondhand smoke. The industry has funded or carried out research that has been judged to be biased, supported scientists to generate letters to editors that criticized research publications, attempted to undermine the findings of key studies, assisted in establishing a scientific society with a journal, and attempted to sustain controversy even as the scientific community reached consensus (Garne et al. 2005). These tactics are not a topic of this report, but to the extent that the scientific literature has been distorted, they are addressed as the evidence is reviewed. This report does not specifically identify tobacco industry sponsorship of publications unless that information is relevant to the interpretation of the findings and conclusions.

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State of California
AIR RESOURCES BOARD

Resolution 06-1

January 26, 2006

Agenda Item No: 06-1-4

WHEREAS, sections 39600 and 39601 of the Health and Safety Code authorize the Air Resources Board (ARB or Board) to adopt standards, rules, and regulations and to do such acts as may be necessary for the proper execution of the powers and duties granted to, and imposed upon, the Board by law;

WHEREAS, Chapter 3.5 (commencing with section 39650) of Part 2 of Division 26 of the Health and Safety Code establishes procedures for the identification of toxic air contaminants by the Board;

WHEREAS, section 39655 of the Health and Safety Code defines a toxic air contaminant as "an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health;"

WHEREAS, section 39662 of the Health and Safety Code directs the Board to list, by regulation, substances determined to be toxic air contaminants, and to specify for each substance listed a threshold exposure level, if any, below which no significant adverse health effects are anticipated;

WHEREAS, the Children's Environmental Health Protection Act of 1999 amended the toxic air contaminant statute to explicitly require consideration of exposures of infants and children to candidate toxic air contaminants, and any evidence on special susceptibilities of infants and children to the effects of candidate toxic air contaminants (Health and Safety Code section 39660(c)(1));

WHEREAS, environmental tobacco smoke (ETS) is a complex mixture of thousands of gases and fine particles mostly less than 1.0 µm in size, and many with known adverse health effects;

WHEREAS, ETS is a significant source of exposure to compounds already identified as toxic air contaminants pursuant to Health and Safety Code sections 39660-39662 including, but not limited to, 1,3-butadiene, acetaldehyde, acrolein, arsenic, benzene, benzo[a]pyrene, cadmium, chromium VI, and formaldehyde;

WHEREAS, despite restrictions on smoking and public awareness of health impacts, ETS exposure continues to be a major public health concern;

WHEREAS, annual ETS emissions in California are estimated to include approximately 40 tons of nicotine, 365 tons of respirable suspended particles, and 1,900 tons of carbon monoxide;

WHEREAS, to obtain current near-source levels of ETS in the ambient air of the state, ARB monitored nicotine (a commonly used surrogate for ETS) concentrations at several outdoor smoking areas in California. Depending on the site location and number of smokers present, the results showed nicotine present in ambient air in concentrations ranging from 0.013 to 3.1 $\mu g/m^3$ for the 8-hour measurements and 0.016 to 4.6 $\mu g/m^3$ for the 1-hour measurements;

WHEREAS, exposure to ETS varies widely among individuals and depends on their daily individual activities and time spent in smoking environments. For Californians who live in non-smoking homes and have only brief encounters with ETS, average 24-hour nicotine exposure concentrations are low, and are estimated to be less than 0.01 $\mu g/m^3$. For those who live in homes with indoor smokers and experience in-vehicle exposures, the average exposure concentration to which they are exposed over 24-hours can range up to 7.4 $\mu g/m^3$;

WHEREAS, infants and children who live with indoor smokers may be exposed to high levels of ETS in their homes, and even higher levels in vehicles. Such exposures are especially of concern for developing young children because they are likely to recur daily and infants and children are especially susceptible to the health effects of ETS;

WHEREAS, pursuant to the request of the Board, the Office of Environmental Health Hazard Assessment (OEHHA) evaluated the health effects of ETS in accordance with section 39660 of the Health and Safety Code;

WHEREAS, the OEHHA report, a comprehensive update of an earlier report first released in 1997 (Cal/EPA, 1997) and later published by the U.S National Cancer Institute (NCI, 1999), describes the health effects of ETS;

WHEREAS, OEHHA staff found that exposure to ETS is directly associated with a variety of adverse health outcomes involving developmental, respiratory, carcinogenic, and cardiovascular effects. These adverse health outcomes in adults include but are not limited to heart disease; lung cancer; nasal sinus cancer; and breast cancer in younger, primarily premenopausal women;

WHEREAS, OEHHA staff found that ETS also has been shown conclusively to be the cause of a number of serious impacts to children's health, such as sudden infant death syndrome (SIDS); pre-term delivery; low birth weight; induction and exacerbation of asthma; chronic respiratory symptoms; and increased acute lower respiratory and middle ear infections;

WHEREAS, upon receipt of the OEHHA evaluation, ARB staff prepared a report including, and in consideration of, the OEHHA evaluation and recommendations and in

the form required by section 39661 of the Health and Safety Code and, in accordance with the provisions of that section, made the report available to the public and submitted it for review to the Scientific Review Panel on Toxic Air Contaminants (SRP) established pursuant to section 39670 of the Health and Safety Code;

WHEREAS, in accordance with section 39661 of the Health and Safety Code, the SRP reviewed the staff report, including the scientific procedures and methods used to support the data in the report, the data itself, and the conclusions and assessments on which the report was based; considered the public comments received regarding the report; and on June 24, 2005, the SRP approved the report and adopted its findings (Attachment A) for submittal to the Board;

WHEREAS, OEHHA, based on available scientific evidence, did not find an ETS exposure level below which no significant adverse health effects are anticipated;

WHEREAS, because of the convincing evidence of childhood exposure to ETS, which may be higher under certain scenarios, and because of the conclusive evidence of associations with a number of illnesses in infants and children, the SRP concluded that exposure to ETS “may cause infants and children to be especially susceptible to illness”; and, upon listing as a toxic air contaminant by the Board, the SRP recommended that OEHHA propose to add ETS to the list of toxic air contaminants that may cause infants and children to be especially susceptible to illness, as stipulated by the Children’s Environmental Health Protection Act of 1999 (Health and Safety Code section 39669.5);

WHEREAS, the SRP found the report to be based on sound scientific knowledge, methods and practices and was a complete and balanced assessment of current scientific understanding, and recommended that ARB list ETS as a toxic air contaminant;

WHEREAS, ETS meets the definition of a toxic air contaminant as defined in section 39655 of the Health and Safety Code;

WHEREAS, the California Environmental Quality Act (CEQA), section 21080.5 of the Public Resources Code and Board regulations at title 17, California Code of Regulations, section 60006, require that no project which may have significant adverse environmental impacts be adopted as originally proposed if feasible alternatives or mitigation measures are available to reduce or eliminate such impacts;

WHEREAS, a public hearing and other administrative proceedings have been held in accordance with the provisions of Chapter 3.5 (commencing with section 11340), Part 1, Division 3, title 2 of the Government Code;

WHEREAS, in consideration of the Initial Statement of Reasons, written comments, and public testimony it has received, the Board finds that:

The proposed identification of ETS as a toxic air contaminant is authorized by California law and satisfies the requirements of Chapter 3.5 (commencing with section 39650) of Part 2 of Division 26 of the Health and Safety Code;

ETS is present in the ambient air of the state and was confirmed by the near-source air monitoring for nicotine conducted by ARB staff at several outside smoking areas and concentrations can range from 0.013 to 4.6 µg/m3;

Infants and children who live with indoor smokers may be exposed to high levels of ETS in their homes, and even higher levels in vehicles;

Pursuant to the request of the Board, OEHHA evaluated the health effects of ETS in accordance with section 39660 of the Health and Safety Code;

OEHHA found that exposure to ETS is directly associated with a variety of adverse health outcomes such as heart disease; lung cancer; nasal sinus cancer; and breast cancer in younger, primarily premenopausal women;

OEHHA staff also found that ETS has been shown to conclusively cause a number of serious impacts to children's health: SIDS, pre-term delivery, low birth weight, induction and exacerbation of asthma, chronic respiratory symptoms, and increased acute lower respiratory and middle ear infections;

The ETS report was reviewed and approved by the SRP pursuant to Health and Safety Code section 39661;

ETS meets the definition of a toxic air contaminant specified in Health and Safety Code section 39655 and that there is not a threshold exposure level below which no significant adverse health effects are anticipated;

The proposed action will not directly have any economic impact on sources of ETS because the act of identifying a toxic air contaminant does not mandate any specific risk management action; and

No reasonable alternative considered or that has otherwise been identified and brought to the attention of ARB would be more effective in carrying out the purpose for which the identification of ETS as a toxic air contaminant are proposed, or be as effective and less burdensome to affected private persons and businesses than the proposed action of identifying ETS as a toxic air contaminant.

WHEREAS, the Board further finds, based on its independent judgment and analysis of the entire record before it, that with respect to the requirements of Health and Safety Code sections 39660-39662, the proposed identification of ETS as a TAC will not have a significant adverse environmental impact.

NOW, THEREFORE, BE IT RESOLVED that, pursuant to Health and Safety Code section 39662, the Board finds that ETS meets the definition of a toxic air contaminant contained in Health and Safety Code section 39655 and hereby identifies ETS as a toxic air contaminant without a threshold exposure level below which no significant adverse health effects are anticipated and adopts the proposed regulatory amendment to section 93000, title 17, California Code of Regulations, as set forth in Attachment B hereto.

BE IT FURTHER RESOLVED that the Board directs the staff to begin the risk management phase of the program for ETS and directs the staff to conduct a needs assessment according to Health and Safety Code section 39665 to determine if any additional actions are warranted to reduce further public exposure to ETS.

I hereby certify that the above is a true and correct copy of Resolution 06-1, as adopted by the Air Resources Board.

_____
Lori Andreoni, Clerk of the Board

Resolution 06-1

January 26, 2006

Identification of Attachments to the Resolution

Attachment A: Findings of the Scientific Review Panel, as set forth in Appendix II of the Initial Statement of Reasons released December 9, 2005

Attachment B: Amendment to section 93000, title 17, California Code of Regulations, as set forth in Appendix I of the Initial Statement of Reasons released December 9, 2005

STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY
AUGUST 11, 2006

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. The identification number indicated in the following list is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing. The date refers to the initial appearance of the chemical on the list. For easy reference, chemicals which are shown underlined are newly added. Chemicals or endpoints shown in strikeout were placed on the Proposition 65 list on the date noted, and have subsequently been removed.

Chemical	Type of Toxicity	CAS No.	Date Listed
A-alpha-C (2-Amino-9H-pyrido [2,3-b]indole)	cancer	26148685	January 1, 1990
Acetaldehyde	cancer	75070	April 1, 1988
Acetamide	cancer	60355	January 1, 1990
Acetazolamide	developmental	59665	August 20, 1999
Acetochlor	cancer	34256821	January 1, 1989
Acetohydroxamic acid	developmental	546883	April 1, 1990
2-Acetylaminofluorene	cancer	53963	July 1, 1987
Acifluorfen	cancer	62476599	January 1, 1990
Acrylamide	cancer	79061	January 1, 1990
Acrylonitrile	cancer	107131	July 1, 1987
Actinomycin D	cancer developmental	50760	October 1, 1989 October 1, 1992
AF-2;[2-(2-furyl)-3-(5-nitro-2-furyl)] acrylamide	cancer	3688537	July 1, 1987
Aflatoxins	cancer	---	January 1, 1988
Alachlor	cancer	15972608	January 1, 1989
Alcoholic beverages, when associated with alcohol abuse	cancer	---	July 1, 1988
Aldrin	cancer	309002	July 1, 1988
All-trans retinoic acid	developmental	302794	January 1, 1989
~~Allyl chloride~~ Delisted October 29, 1999	~~cancer~~	~~107051~~	~~January 1, 1990~~
Alprazolam	developmental	28981977	July 1, 1990
Altretamine	developmental, male	645056	August 20, 1999
Amantadine hydrochloride	developmental	665667	February 27, 2001
Amikacin sulfate	developmental	39831555	July 1, 1990
2-Aminoanthraquinone	cancer	117793	October 1, 1989
p-Aminoazobenzene	cancer	60093	January 1, 1990
o-Aminoazotoluene	cancer	97563	July 1, 1987
4-Aminobiphenyl (4-amino-diphenyl)	cancer	92671	February 27, 1987
1-Amino-2,4-dibromo-anthraquinone	cancer	81492	August 26, 1997
3-Amino-9-ethylcarbazole hydrochloride	cancer	6109973	July 1, 1989

2-Aminofluorene	cancer	153786	January 29, 1999
Aminoglutethimide	developmental	125848	July 1, 1990
Aminoglycosides	developmental	---	October 1, 1992
1-Amino-2-methylanthraquinone	cancer	82280	October 1, 1989
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	cancer	712685	July 1, 1987
4-Amino-2-nitrophenol	cancer	119346	January 29, 1999
Aminopterin	developmental, female	54626	July 1, 1987
Amiodarone hydrochloride	developmental, female, male	19774824	August 26, 1997
Amitraz	developmental	33089611	March 30, 1999
Amitrole	cancer	61825	July 1, 1987
Amoxapine	developmental	14028445	May 15, 1998
Anabolic steroids	female, male	---	April 1, 1990
Analgesic mixtures containing phenacetin	cancer	---	February 27, 1987
Angiotensin converting enzyme (ACE) inhibitors	developmental	---	October 1, 1992
Aniline	cancer	62533	January 1, 1990
Aniline hydrochloride	cancer	142041	May 15, 1998
o-Anisidine	cancer	90040	July 1, 1987
o-Anisidine hydrochloride	cancer	134292	July 1, 1987
Anisindione	developmental	117373	October 1, 1992
Antimony oxide (Antimony trioxide)	cancer	1309644	October 1, 1990
Aramite	cancer	140578	July 1, 1987
Areca nut	cancer	---	February 3, 2006
Aristolochic acids	cancer	---	July 9, 2004
Arsenic (inorganic arsenic compounds)	cancer	--	February 27, 1987
Arsenic (inorganic oxides)	developmental	---	May 1, 1997
Asbestos	cancer	1332214	February 27, 1987
Aspirin (NOTE: It is especially important not to use aspirin during the last three months of pregnancy, unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery.)	developmental, female	50782	July 1, 1990
Atenolol	developmental	29122687	August 26, 1997
Auramine	cancer	492808	July 1, 1987
Auranofin	developmental	34031328	January 29, 1999
Azacitidine	cancer	320672	January 1, 1992
Azaserine	cancer	115026	July 1, 1987
Azathioprine	cancer developmental	446866	February 27, 1987 September 1, 1996
Azobenzene	cancer	103333	January 1, 1990
Barbiturates	developmental	---	October 1, 1992
Beclomethasone dipropionate	developmental	5534098	May 15, 1998
Benomyl	developmental, male	17804352	July 1, 1991
Benz[a]anthracene	cancer	56553	July 1, 1987
Benzene	cancer developmental, male	71432	February 27, 1987 December 26, 1997
Benzidine [and its salts]	cancer	92875	February 27, 1987
Benzidine-based dyes	cancer	---	October 1, 1992
Benzodiazepines	developmental	---	October 1, 1992

Benzo[b]fluoranthene	cancer	205992	July 1, 1987
Benzo[j]fluoranthene	cancer	205823	July 1, 1987
Benzo[k]fluoranthene	cancer	207089	July 1, 1987
Benzofuran	cancer	271896	October 1, 1990
Benzo[a]pyrene	cancer	50328	July 1, 1987
Benzotrichloride	cancer	98077	July 1, 1987
Benzphetamine hydrochloride	developmental	5411223	April 1, 1990
Benzyl chloride	cancer	100447	January 1, 1990
Benzyl violet 4B	cancer	1694093	July 1, 1987
Beryllium and beryllium compounds	cancer	---	October 1, 1987
Betel quid with tobacco	cancer	---	January 1, 1990
Betel quid without tobacco	cancer	---	February 3, 2006
2,2-Bis(bromomethyl)-1,3-propanediol	cancer	3296900	May 1, 1996
Bis(2-chloroethyl)ether	cancer	111444	April 1, 1988
N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornapazine)	cancer	494031	February 27, 1987
Bischloroethyl nitrosourea (BCNU) (Carmustine)	cancer developmental	154938	July 1, 1987 July 1, 1990
Bis(chloromethyl)ether	cancer	542881	February 27, 1987
Bis(2-chloro-1-methylethyl)ether, technical grade	cancer	---	October 29, 1999
Bitumens, extracts of steam-refined and air refined	cancer	---	January 1, 1990
Bracken fern	cancer	---	January 1, 1990
Bromacil lithium salt	developmental male	53404196	May 18, 1999 January 17, 2003
Bromate	cancer	15541454	May 31, 2002
Bromodichloromethane	cancer	75274	January 1, 1990
Bromoethane	cancer	74964	December 22, 2000
Bromoform	cancer	75252	April 1, 1991
1-Bromopropane (1-BP)	developmental, female, male	106945	December 7, 2004
2-Bromopropane (2-BP)	female, male	75263	May 31, 2005
Bromoxynil	developmental	1689845	October 1, 1990
Bromoxynil octanoate	developmental	1689992	May 18, 1999
Butabarbital sodium	developmental	143817	October 1, 1992
1,3-Butadiene	cancer	106990	April 1, 1988
1,3-Butadiene	developmental, female, male	106990	April 16, 2004
1,4-Butanediol dimethanesulfonate (Busulfan)	cancer developmental	55981	February 27, 1987 January 1, 1989
Butylated hydroxyanisole	cancer	25013165	January 1, 1990
Butyl benzyl phthalate (BBP)	developmental	85687	December 2, 2005
beta-Butyrolactone	cancer	3068880	July 1, 1987
Cacodylic acid	cancer	75605	May 1, 1996
Cadmium	developmental, male	---	May 1, 1997
Cadmium and cadmium compounds	cancer	---	October 1, 1987
Caffeic acid	cancer	331395	October 1, 1994
Captafol	cancer	2425061	October 1, 1988
Captan	cancer	133062	January 1, 1990
Carbamazepine	developmental	298464	January 29, 1999
Carbazole	cancer	86748	May 1, 1996
Carbon black (airborne, unbound particles	cancer	1333864	February 21, 2003

of respirable size)			
Carbon disulfide	developmental, female, male	75150	July 1, 1989
Carbon monoxide	developmental	630080	July 1, 1989
Carbon tetrachloride	cancer	56235	October 1, 1987
Carbon-black extracts	cancer	---	January 1, 1990
Carboplatin	developmental	41575944	July 1, 1990
N-Carboxymethyl-N-nitrosourea	cancer	60391926	January 25, 2002
Catechol	cancer	120809	July 15, 2003
Ceramic fibers (airborne particles of respirable size)	cancer	---	July 1, 1990
Certain combined chemotherapy for lymphomas	cancer	---	February 27, 1987
Chenodiol	developmental	474259	April 1, 1990
Chinomethionat (Oxythioquinox)	developmental	2439012	November 6, 1998
Chlorambucil	cancer	305033	February 27, 1987
	developmental		January 1, 1989
Chloramphenicol	cancer	56757	October 1, 1989
Chlorcyclizine hydrochloride	developmental	1620219	July 1, 1987
Chlordane	cancer	57749	July 1, 1988
Chlordecone (Kepone)	cancer	143500	January 1, 1988
	developmental		January 1, 1989
Chlordiazepoxide	developmental	58253	January 1, 1992
Chlordiazepoxide hydrochloride	developmental	438415	January 1, 1992
Chlordimeform	cancer	6164983	January 1, 1989
Chlorendic acid	cancer	115286	July 1, 1989
Chlorinated paraffins (Average chain length, C12;approximately 60 percent chlorine by weight)	cancer	108171262	July 1, 1989
p-Chloroaniline	cancer	106478	October 1, 1994
p-Chloroaniline hydrochloride	cancer	20265967	May 15, 1998
~~Chlorodibromomethane~~ Delisted October 29, 1999	~~cancer~~	~~124481~~	~~January 1, 1990~~
Chloroethane (Ethyl chloride)	cancer	75003	July 1, 1990
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU) (Lomustine)	cancer	13010474	January 1, 1988
	developmental		July 1, 1990
1-(2-Chloroethyl)-3-(4-methylcyclohexyl) -1-nitrosourea (Methyl-CCNU)	cancer	13909096	October 1, 1988
Chloroform	cancer	67663	October 1, 1987
Chloromethyl methyl ether (technical grade)	cancer	107302	February 27, 1987
3-Chloro-2-methylpropene	cancer	563473	July 1, 1989
1-Chloro-4-nitrobenzene	cancer	100005	October 29, 1999
4-Chloro-*o*-phenylenediamine	cancer	95830	January 1, 1988
Chloroprene	cancer	126998	June 2, 2000
Chlorothalonil	cancer	1897456	January 1, 1989
p-Chloro-*o*-toluidine	cancer	95692	January 1, 1990
p-Chloro-*o*-toluidine, strong acid salts of	cancer	---	May 15, 1998
5-Chloro-*o*-toluidine and its strong acid salts	cancer	---	October 24, 1997
Chlorotrianisene	cancer	569573	September 1, 1996
Chlorozotocin	cancer	54749905	January 1, 1992
Chlorsulfuron	developmental, female, male	64902723	May 14, 1999
Chromium (hexavalent compounds)	cancer	---	February 27, 1987
Chrysene	cancer	218019	January 1, 1990
C.I. Acid Red 114	cancer	6459945	July 1, 1992

C.I. Basic Red 9 monohydrochloride	cancer	569619	July 1, 1989
C.I. Direct Blue 15	cancer	2429745	August 26, 1997
C.I. Direct Blue 218	cancer	28407376	August 26, 1997
C.I. Solvent Yellow 14	cancer	842079	May 15, 1998
Ciclosporin (Cyclosporin A; Cyclosporine)	cancer	59865133 79217600	January 1, 1992
Cidofovir	cancer, developmental, female, male	113852372	January 29, 1999
Cinnamyl anthranilate	cancer	87296	July 1, 1989
Cisplatin	cancer	15663271	October 1, 1988
Citrus Red No. 2	cancer	6358538	October 1, 1989
Cladribine	developmental	4291638	September 1, 1996
Clarithromycin	developmental	81103119	May 1, 1997
Clobetasol propionate	developmental, female	25122467	May 15, 1998
Clofibrate	cancer	637070	September 1, 1996
Clomiphene citrate	developmental	50419	April 1, 1990
Clorazepate dipotassium	developmental	57109907	October 1, 1992
Cobalt metal powder	cancer	7440484	July 1, 1992
Cobalt [II] oxide	cancer	1307966	July 1, 1992
Cobalt sulfate	cancer	10124433	May 20, 2005
Cobalt sulfate heptahydrate	cancer	10026241	June 2, 2000
Cocaine	developmental, female	50362	July 1, 1989
Codeine phosphate	developmental	52288	May 15, 1998
Coke oven emissions	cancer	---	February 27, 1987
Colchicine	developmental, male	64868	October 1, 1992
Conjugated estrogens	cancer developmental	---	February 27, 1987 April 1, 1990
Creosotes	cancer	---	October 1, 1988
p-Cresidine	cancer	120718	January 1, 1988
Cupferron	cancer	135206	January 1, 1988
Cyanazine	developmental	21725462	April 1, 1990
Cycasin	cancer	14901087	January 1, 1988
Cycloate	developmental	1134232	March 19, 1999
~~Cyclohexanol~~ Delisted January 25, 2002	~~male~~	~~108930~~	~~November 6, 1998~~
Cycloheximide	developmental	66819	January 1, 1989
Cyclophosphamide (anhydrous)	cancer developmental, female, male	50180	February 27, 1987 January 1, 1989
Cyclophosphamide (hydrated)	cancer developmental, female, male	6055192	February 27, 1987 January 1, 1989
Cyhexatin	developmental	13121705	January 1, 1989
Cytarabine	developmental	147944	January 1, 1989
Cytembena	cancer	21739913	May 15, 1998
D&C Orange No. 17	cancer	3468631	July 1, 1990
D&C Red No. 8	cancer	2092560	October 1, 1990
D&C Red No. 9	cancer	5160021	July 1, 1990
D&C Red No. 19	cancer	81889	July 1, 1990
Dacarbazine	cancer developmental	4342034	January 1, 1988 January 29, 1999
Daminozide	cancer	1596845	January 1, 1990
Danazol	developmental	17230885	April 1, 1990

Dantron (Chrysazin; 1,8-Dihydroxy-anthraquinone)	cancer	117102	January 1, 1992
Daunomycin	cancer	20830813	January 1, 1988
Daunorubicin hydrochloride	developmental	23541506	July 1, 1990
2,4-D butyric acid	~~developmental~~, male	94826	June 18, 1999
DDD (Dichlorodiphenyldichloroethane)	cancer	72548	January 1, 1989
DDE (Dichlorodiphenyldichloroethylene)	cancer	72559	January 1, 1989
DDT (Dichlorodiphenyltrichloroethane)	cancer	50293	October 1 , 1987
o,p'-DDT	developmental, female, male	789026	May 15, 1998
p,p'-DDT	developmental, female, male	50293	May 15, 1998
DDVP (Dichlorvos)	cancer	62737	January 1, 1989
~~2,4-DP (dichloroprop)~~ Delisted January 25, 2002	~~developmental~~	~~120365~~	~~April 27, 1999~~
N,N'-Diacetylbenzidine	cancer	613354	October 1, 1989
2,4-Diaminoanisole	cancer	615054	October 1, 1990
2,4-Diaminoanisole sulfate	cancer	39156417	January 1, 1988
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	cancer	101804	January 1, 1988
2,4-Diaminotoluene	cancer	95807	January 1, 1988
Demeclocycline hydrochloride (internal use)	developmental	64733	January 1, 1992
Diaminotoluene (mixed)	cancer	---	January 1, 1990
Diazepam	developmental	439145	January 1, 1992
Diazoaminobenzene	cancer	136356	May 20, 2005
Diazoxide	developmental	364987	February 27, 2001
Dibenz[a,h]acridine	cancer	226368	January 1, 1988
Dibenz[a,j]acridine	cancer	224420	January 1, 1988
Dibenz[a,h]anthracene	cancer	53703	January 1, 1988
7H-Dibenzo[c,g]carbazole	cancer	194592	January 1, 1988
Dibenzo[a,e]pyrene	cancer	192654	January 1, 1988
Dibenzo[a,h]pyrene	cancer	189640	January 1, 1988
Dibenzo[a,i]pyrene	cancer	189559	January 1, 1988
Dibenzo[a,l]pyrene	cancer	191300	January 1, 1988
1,2-Dibromo-3-chloropropane (DBCP)	cancer male	96128	July 1, 1987 February 27, 1987
2,3-Dibromo-1-propanol	cancer	96139	October 1, 1994
Dichloroacetic acid	cancer	79436	May 1, 1996
p-Dichlorobenzene	cancer	106467	January 1, 1989
3,3'-Dichlorobenzidine	cancer	91941	October 1, 1987
3,3'-Dichlorobenzidine dihydrochloride	cancer	612839	May 15, 1998
1,4-Dichloro-2-butene	cancer	764410	January 1, 1990
3,3'-Dichloro-4,4'-diaminodiphenyl ether	cancer	28434868	January 1, 1988
1,1-Dichloroethane	cancer	75343	January 1, 1990
Dichloromethane (Methylene chloride)	cancer	75092	April 1, 1988
Dichlorophene	developmental	97234	April 27, 1999
Dichlorphenamide	developmental	120978	February 27, 2001
Diclofop methyl	developmental	51338273	March 5, 1999
1,2-Dichloropropane	cancer	78875	January 1, 1990
1,3-Dichloropropene	cancer	542756	January 1, 1989
Dicumarol	developmental	66762	October 1, 1992
Dieldrin	cancer	60571	July 1, 1988
Dienestrol	cancer	84173	January 1, 1990
Diepoxybutane	cancer	1464535	January 1, 1988

Diesel engine exhaust	cancer	---	October 1, 1990
Di(2-ethylhexyl)phthalate (DEHP)	cancer	117817	January 1, 1988
	developmental, male		October 24, 2003
1,2-Diethylhydrazine	cancer	1615801	January 1, 1988
Diethylstilbestrol (DES)	cancer	56531	February 27, 1987
	developmental		July 1, 1987
Diethyl sulfate	cancer	64675	January 1, 1988
Diflunisal	developmental, female	22494424	January 29, 1999
Diglycidyl resorcinol ether (DGRE)	cancer	101906	July 1, 1989
Dihydroergotamine mesylate	developmental	6190392	May 1, 1997
Dihydrosafrole	cancer	94586	January 1, 1988
Di-*n*-butyl phthalate (DBP)	developmental, female, male	84742	December 2, 2005
Di-*n*-hexyl phthalate (DnHP)	female, male	84753	December 2, 2005
Diisopropyl sulfate	cancer	2973106	April 1, 1993
Diltiazem hydrochloride	developmental	33286225	February 27, 2001
3,3'-Dimethoxybenzidine (*o*-Dianisidine)	cancer	119904	January 1, 1988
3,3'-Dimethoxybenzidine dihydrochloride (*o*-Dianisidine dihydrochloride)	cancer	20325400	October 1, 1990
3,3'-Dimethoxybenzidine-based dyes metabolized to 3,3'-dimethoxybenzidine	cancer	---	June 11, 2004
3,3'-Dimethylbenzidine-based dyes metabolized to 3,3'-dimethylbenzidine	cancer	---	June 11, 2004
4-Dimethylaminoazobenzene	cancer	60117	January 1, 1988
trans-2-[(Dimethylamino)methyl-imino]-5-[2-(5-nitro-2-furyl)vinyl]-1,3,4-oxadiazole	cancer	55738540	January 1, 1988
7,12-Dimethylbenz(a)anthracene	cancer	57976	January 1, 1990
3,3'-Dimethylbenzidine (ortho-Tolidine)	cancer	119937	January 1, 1988
3,3'-Dimethylbenzidine dihydrochloride	cancer	612828	April 1, 1992
Dimethylcarbamoyl chloride	cancer	79447	January 1, 1988
1,1-Dimethylhydrazine (UDMH)	cancer	57147	October 1, 1989
1,2-Dimethylhydrazine	cancer	540738	January 1, 1988
Dimethyl sulfate	cancer	77781	January 1, 1988
Dimethylvinylchloride	cancer	513371	July 1, 1989
m-Dinitrobenzene	male	99650	July 1, 1990
o-Dinitrobenzene	male	528290	July 1, 1990
p-Dinitrobenzene	male	100254	July 1, 1990
3,7-Dinitrofluoranthene	cancer	105735715	August 26, 1997
3,9-Dinitrofluoranthene	cancer	22506532	August 26, 1997
1,6-Dinitropyrene	cancer	42397648	October 1, 1990
1,8-Dinitropyrene	cancer	42397659	October 1, 1990
Dinitrotoluene (technical grade)	female, male	---	August 20, 1999
Dinitrotoluene mixture, 2,4-/2,6-	cancer	---	May 1, 1996
2,4-Dinitrotoluene	cancer	121142	July 1, 1988
	male		August 20, 1999
2,6-Dinitrotoluene	cancer	606202	July 1, 1995
	male		August 20, 1999
Dinocap	developmental	39300453	April 1, 1990
Dinoseb	developmental, male	88857	January 1, 1989
1,4-Dioxane	cancer	123911	January 1, 1988
Diphenylhydantoin (Phenytoin)	cancer	57410	January 1, 1988
	developmental		July 1, 1987
Diphenylhydantoin (Phenytoin), sodium salt	cancer	630933	January 1, 1988

Di-*n*-propyl isocinchomeronate (MGK Repellent 326)	cancer	136458	May 1, 1996
Direct Black 38 (technical grade)	cancer	1937377	January 1, 1988
Direct Blue 6 (technical grade)	cancer	2602462	January 1, 1988
Direct Brown 95 (technical grade)	cancer	16071866	October 1, 1988
Disodium cyanodithioimidocarbonate	developmental	138932	March 30, 1999
Disperse Blue 1	cancer	2475458	October 1, 1990
Diuron	cancer	330541	May 31, 2002
Doxorubicin hydrochloride (Adriamycin)	cancer	23214928	July 1, 1987
Doxorubicin hydrochloride (Adriamycin)	developmental, male	23214928	January 29, 1999
Doxycycline (internal use)	developmental	564250	July 1, 1990
Doxycycline calcium (internal use)	developmental	94088854	January 1, 1992
Doxycycline hyclate (internal use)	developmental	24390145	October 1, 1991
Doxycycline monohydrate (internal use)	developmental	17086281	October 1, 1991
Endrin	developmental	72208	May 15, 1998
Environmental tobacco smoke (ETS)	developmental	---	June 9, 2006
Epichlorohydrin	cancer	106898	October 1, 1987
	male		September 1, 1996
Ergotamine tartrate	developmental	379793	April 1, 1990
Erionite	cancer	12510428/ 66733219	October 1, 1988
Estradiol 17B	cancer	50282	January 1, 1988
Estragole	cancer	140670	October 29, 1999
Estrogens, steroidal	cancer	---	August 19, 2005
Estrone	cancer	53167	January 1, 1988
Estropipate	cancer, developmental	7280377	August 26, 1997
Ethinylestradiol	cancer	57636	January 1, 1988
Ethionamide	developmental	536334	August 26, 1997
Ethoprop	cancer	13194484	February 27, 2001
Ethyl acrylate	cancer	140885	July 1, 1989
Ethyl alcohol in alcoholic beverages	developmental	---	October 1, 1987
Ethylbenzene	cancer	100414	June 11, 2004
Ethyl dipropylthiocarbamate	developmental	759944	April 27, 1999
Ethyl-4,4'-dichlorobenzilate	cancer	510156	January 1, 1990
Ethylene dibromide	cancer	106934	July 1, 1987
	developmental, male		May 15, 1998
Ethylene dichloride (1,2-Dichloroethane)	cancer	107062	October 1, 1987
Ethylene glycol monoethyl ether	developmental, male	110805	January 1, 1989
Ethylene glycol monoethyl ether acetate	developmental, male	111159	January 1, 1993
Ethylene glycol monomethyl ether	developmental, male	109864	January 1, 1989
Ethylene glycol monomethyl ether acetate	developmental, male	110496	January 1, 1993
Ethyleneimine	cancer	151564	January 1, 1988
Ethylene oxide	cancer	75218	July 1, 1987
	female		February 27, 1987
Ethylene thiourea	cancer	96457	January 1, 1988
	developmental		January 1, 1993
Ethyl methanesulfonate	cancer	62500	January 1, 1988
Etodolac	developmental, female	41340254	August 20, 1999
Etoposide	developmental	33419420	July 1, 1990
Etretinate	developmental	54350480	July 1, 1987

Fenoxaprop ethyl	developmental	66441234	March 26, 1999
Fenoxycarb	cancer	72490018	June 2, 2000
Filgrastim	developmental	121181531	February 27, 2001
Fluazifop butyl	developmental	69806504	November 6, 1998
Flunisolide	developmental, female	3385033	May 15, 1998
Fluorouracil	developmental	51218	January 1, 1989
Fluoxymesterone	developmental	76437	April 1, 1990
Flurazepam hydrochloride	developmental	1172185	October 1, 1992
Flurbiprofen	developmental, female	5104494	August 20, 1999
Flutamide	developmental	13311847	July 1, 1990
Fluticasone propionate	developmental	80474142	May 15, 1998
Fluvalinate	developmental	69409945	November 6, 1998
Folpet	cancer	133073	January 1, 1989
Formaldehyde (gas)	cancer	50000	January 1, 1988
2-(2-Formylhydrazino)-4-(5-nitro-2-furyl) thiazole	cancer	3570750	January 1, 1988
Fumonisin B_1	cancer	116355830	November 14, 2003
Furan	cancer	110009	October 1, 1993
Furazolidone	cancer	67458	January 1, 1990
Furmecyclox	cancer	60568050	January 1, 1990
Fusarin C	cancer	79748815	July 1, 1995
Ganciclovir sodium	cancer, developmental, male	82410320	August 26, 1997
Gasoline engine exhaust (condensates/extracts)	cancer	---	October 1, 1990
Gemfibrozil	cancer female, male	25812300	December 22, 2000 August 20, 1999
Glasswool fibers (airborne particles of respirable size)	cancer	---	July 1, 1990
Glu-P-1 (2-Amino-6-methyldipyrido [1,2- a:3',2'-d]imidazole)	cancer	67730114	January 1, 1990
Glu-P-2 (2-Aminodipyrido [1,2-a:3',2'-d]imidazole)	cancer	67730103	January 1, 1990
Glycidaldehyde	cancer	765344	January 1, 1988
Glycidol	cancer	556525	July 1, 1990
Goserelin acetate	developmental, female, male	65807025	August 26, 1997
Griseofulvin	cancer	126078	January 1, 1990
Gyromitrin (Acetaldehyde methylformylhydrazone)	cancer	16568028	January 1, 1988
Halazepam	developmental	23092173	July 1, 1990
Halobetasol propionate	developmental	66852548	August 20, 1999
Haloperidol	developmental, female	52868	January 29, 1999
Halothane	developmental	151677	September 1, 1996
HC Blue 1	cancer	2784943	July 1, 1989
Heptachlor	cancer developmental	76448	July 1, 1988 August 20, 1999
Heptachlor epoxide	cancer	1024573	July 1, 1988
Herbal remedies containing plant species of the genus Aristolochia	cancer	---	July 9, 2004
Hexachlorobenzene	cancer	118741	October 1, 1987

	developmental		January 1, 1989
Hexachlorocyclohexane (technical grade)	cancer	---	October 1, 1987
Hexachlorodibenzodioxin	cancer	34465468	April 1, 1988
Hexachloroethane	cancer	67721	July 1, 1990
2,4-Hexadienal (89% trans, trans isomer; 11% cis, trans isomer)	cancer	---	March 4, 2005
Hexamethylphosphoramide	cancer	680319	January 1, 1988
	male		October 1, 1994
Histrelin acetate	developmental	---	May 15, 1998
Hydramethylnon	developmental, male	67485294	March 5, 1999
Hydrazine	cancer	302012	January 1, 1988
Hydrazine sulfate	cancer	10034932	January 1, 1988
Hydrazobenzene (1,2-Diphenylhydrazine)	cancer	122667	January 1, 1988
1-Hydroxyanthraquinone	cancer	129431	May 27, 2005
Hydroxyurea	developmental	127071	May 1, 1997
Idarubicin hydrochloride	developmental, male	57852570	August 20, 1999
Ifosfamide	developmental	3778732	July 1, 1990
Iodine-131	developmental	10043660	January 1, 1989
Indeno[1,2,3-cd]pyrene	cancer	193395	January 1, 1988
Indium phosphide	cancer	22398807	February 27, 2001
IQ (2-Amino-3-methylimidazo [4,5-f] quinoline)	cancer	76180966	April 1, 1990
Iprodione	cancer	36734197	May 1, 1996
Iron dextran complex	cancer	9004664	January 1, 1988
Isobutyl nitrite	cancer	542563	May 1, 1996
Isoprene	cancer	78795	May 1, 1996
Isosafrole	cancer	120581	October 1, 1989
Isotretinoin	developmental	4759482	July 1, 1987
Isoxaflutole	cancer	141112290	December 22, 2000
Lactofen	cancer	77501634	January 1, 1989
Lasiocarpine	cancer	303344	April 1, 1988
Lead	developmental, female, male	---	February 27, 1987
Lead and lead compounds	cancer	---	October 1, 1992
Lead acetate	cancer	301042	January 1, 1988
Lead phosphate	cancer	7446277	April 1, 1988
Lead subacetate	cancer	1335326	October 1, 1989
Leuprolide acetate	developmental, female, male	74381536	August 26, 1997
Levodopa	developmental	59927	January 29, 1999
Levonorgestrel implants	female	797637	May 15, 1998
Lindane and other hexachloro-cyclohexane isomers	cancer	---	October 1, 1989
Linuron	developmental	330552	March 19, 1999
Lithium carbonate	developmental	554132	January 1, 1991
Lithium citrate	developmental	919164	January 1, 1991
Lorazepam	developmental	846491	July 1, 1990
Lovastatin	developmental	75330755	October 1, 1992
Lynestrenol	cancer	52766	February 27, 2001
Mancozeb	cancer	8018017	January 1, 1990

Maneb	cancer	12427382	January 1, 1990
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido[2,3-b]indole)	cancer	68006837	January 1, 1990
Mebendazole	developmental	31431397	August 20, 1999
Medroxyprogesterone acetate	cancer	71589	January 1, 1990
	developmental		April 1, 1990
Megestrol acetate	developmental	595335	January 1, 1991
MeIQ (2-Amino-3,4-dimethyl-imidazo[4,5-f]quinoline)	cancer	77094112	October 1, 1994
MeIQx (2-Amino-3,8-dimethyl-imidazo[4,5-f]quinoxaline)	cancer	77500040	October 1, 1994
Melphalan	cancer	148823	February 27, 1987
	developmental		July 1, 1990
Menotropins	developmental	9002680	April 1, 1990
Meprobamate	developmental	57534	January 1, 1992
Mercaptopurine	developmental	6112761	July 1, 1990
Mercury and mercury compounds	developmental	---	July 1, 1990
Merphalan	cancer	531760	April 1, 1988
Mestranol	cancer	72333	April 1, 1988
Methacycline hydrochloride	developmental	3963959	January 1, 1991
Metham sodium	cancer	137428	November 6, 1998
	developmental		May 15, 1998
Methazole	developmental	20354261	December 1, 1999
Methimazole	developmental	60560	July 1, 1990
Methotrexate	developmental	59052	January 1, 1989
Methotrexate sodium	developmental	15475566	April 1, 1990
5-Methoxypsoralen with ultraviolet A therapy	cancer	484208	October 1, 1988
8-Methoxypsoralen with ultraviolet A therapy	cancer	298817	February 27, 1987
2-Methylaziridine (Propyleneimine)	cancer	75558	January 1, 1988
Methylazoxymethanol	cancer	590965	April 1, 1988
Methylazoxymethanol acetate	cancer	592621	April 1, 1988
Methyl bromide, as a structural fumigant	developmental	74839	January 1, 1993
Methyl carbamate	cancer	598550	May 15, 1998
Methyl chloride	developmental	74873	March 10, 2000
3-Methylcholanthrene	cancer	56495	January 1, 1990
5-Methylchrysene	cancer	3697243	April 1, 1988
4,4'-Methylene bis(2-chloroaniline)	cancer	101144	July 1, 1987
4,4'-Methylene bis(N,N-dimethyl) benzenamine	cancer	101611	October 1, 1989
4,4'-Methylene bis(2-methylaniline)	cancer	838880	April 1, 1988
4,4'-Methylenedianiline	cancer	101779	January 1, 1988
4,4'-Methylenedianiline dihydrochloride	cancer	13552448	January 1, 1988
Methyleugenol	cancer	93152	November 16, 2001
Methylhydrazine and its salts	cancer	---	July 1, 1992
Methyl iodide	cancer	74884	April 1, 1988
Methyl mercury	developmental	---	July 1, 1987
Methylmercury compounds	cancer	---	May 1, 1996
Methyl methanesulfonate	cancer	66273	April 1, 1988
2-Methyl-1-nitroanthraquinone (of uncertain purity)	cancer	129157	April 1, 1988
N-Methyl-N'-nitro-N-nitrosoguanidine	cancer	70257	April 1, 1988
N-Methylolacrylamide	cancer	924425	July 1, 1990

N-Methylpyrrolidone	developmental	872504	June 15, 2001
Methyltestosterone	developmental	58184	April 1, 1990
Methylthiouracil	cancer	56042	October 1, 1989
Metiram	cancer	9006422	January 1, 1990
	developmental		March 30, 1999
Metronidazole	cancer	443481	January 1, 1988
Michler's ketone	cancer	90948	January 1, 1988
Midazolam hydrochloride	developmental	59467968	July 1, 1990
Minocycline hydrochloride (internal use)	developmental	13614987	January 1, 1992
Mirex	cancer	2385855	January 1, 1988
Misoprostol	developmental	59122462	April 1, 1990
Mitomycin C	cancer	50077	April 1, 1988
Mitoxantrone hydrochloride	developmental	70476823	July 1, 1990
Monocrotaline	cancer	315220	April 1, 1988
5-(Morpholinomethyl)-3-[(5-nitrofurfuryl-idene)-amino]-2-oxazolidinone	cancer	139913	April 1, 1988
Mustard Gas	cancer	505602	February 27, 1987
MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone)	cancer	77439760	December 22, 2000
Myclobutanil	developmental, male	88671890	April 16, 1999
Nabam	developmental	142596	March 30, 1999
Nafarelin acetate	developmental	86220420	April 1, 1990
Nafenopin	cancer	3771195	April 1, 1988
Nalidixic acid	cancer	389082	May 15, 1998
Naphthalene	cancer	91203	April 19, 2002
1-Naphthylamine	cancer	134327	October 1, 1989
2-Naphthylamine	cancer	91598	February 27, 1987
Neomycin sulfate (internal use)	developmental	1405103	October 1, 1992
Netilmicin sulfate	developmental	56391572	July 1, 1990
Nickel (Metallic)	cancer	7440020	October 1, 1989
Nickel acetate	cancer	373024	October 1, 1989
Nickel carbonate	cancer	3333673	October 1, 1989
Nickel carbonyl	cancer	13463393	October 1, 1987
	developmental		September 1, 1996
Nickel compounds	cancer	---	May 7, 2004
Nickel hydroxide	cancer	12054487; 12125563	October 1, 1989
Nickelocene	cancer	1271289	October 1, 1989
Nickel oxide	cancer	1313991	October 1, 1989
Nickel refinery dust from the pyrometallurgical process	cancer	---	October 1, 1987
Nickel subsulfide	cancer	12035722	October 1, 1987
Nicotine	developmental	54115	April 1, 1990
Nifedipine	developmental, female, male	21829254	January 29, 1999
Nimodipine	developmental	66085594	April 24, 2001
Niridazole	cancer	61574	April 1, 1988
Nitrapyrin	cancer	1929824	October 5, 2005
	developmental		March 30, 1999
Nitrilotriacetic acid	cancer	139139	January 1, 1988
Nitrilotriacetic acid, trisodium salt monohydrate	cancer	18662538	April 1, 1989

5-Nitroacenaphthene	cancer	602879	April 1, 1988
5-Nitro-*o*-anisidine	cancer	99592	October 1, 1989
o-Nitroanisole	cancer	91236	October 1, 1992
Nitrobenzene	cancer	98953	August 26, 1997
4-Nitrobiphenyl	cancer	92933	April 1, 1988
6-Nitrochrysene	cancer	7496028	October 1, 1990
Nitrofen (technical grade)	cancer	1836755	January 1, 1988
2-Nitrofluorene	cancer	607578	October 1, 1990
Nitrofurantoin	male	67209	April 1, 1991
Nitrofurazone	cancer	59870	January 1, 1990
1-[(5-Nitrofurfurylidene)-amino]-2-imidazolidinone	cancer	555840	April 1, 1988
N-[4-(5-Nitro-2-furyl)-2-thiazolyl] acetamide	cancer	531828	April 1, 1988
Nitrogen mustard (Mechlorethamine)	cancer	51752	January 1, 1988
	developmental		January 1, 1989
Nitrogen mustard hydrochloride (Mechlorethamine hydrochloride)	cancer	55867	April 1, 1988
	developmental		July 1, 1990
Nitrogen mustard N-oxide	cancer	126852	April 1, 1988
Nitrogen mustard N-oxide hydrochloride	cancer	302705	April 1, 1988
Nitromethane	cancer	75525	May 1, 1997
2-Nitropropane	cancer	79469	January 1, 1988
1-Nitropyrene	cancer	5522430	October 1, 1990
4-Nitropyrene	cancer	57835924	October 1, 1990
N-Nitrosodi-*n*-butylamine	cancer	924163	October 1, 1987
N-Nitrosodiethanolamine	cancer	1116547	January 1, 1988
N-Nitrosodiethylamine	cancer	55185	October 1, 1987
N-Nitrosodimethylamine	cancer	62759	October 1, 1987
p-Nitrosodiphenylamine	cancer	156105	January 1, 1988
N-Nitrosodiphenylamine	cancer	86306	April 1, 1988
N-Nitrosodi-*n*-propylamine	cancer	621647	January 1, 1988
N-Nitroso-N-ethylurea	cancer	759739	October 1, 1987
3-(N-Nitrosomethylamino)propionitrile	cancer	60153493	April 1, 1990
4-(N-Nitrosomethylamino)-1-(3-pyridyl)1-butanone	cancer	64091914	April 1, 1990
N-Nitrosomethylethylamine	cancer	10595956	October 1, 1989
N-Nitroso-N-methylurea	cancer	684935	October 1, 1987
N-Nitroso-N-methylurethane	cancer	615532	April 1, 1988
N-Nitrosomethylvinylamine	cancer	4549400	January 1, 1988
N-Nitrosomorpholine	cancer	59892	January 1, 1988
N-Nitrosonornicotine	cancer	16543558	January 1, 1988
N-Nitrosopiperidine	cancer	100754	January 1, 1988
N-Nitrosopyrrolidine	cancer	930552	October 1, 1987
N-Nitrososarcosine	cancer	13256229	January 1, 1988
o-Nitrotoluene	cancer	88722	May 15, 1998
Norethisterone (Norethindrone)	cancer	68224	October 1, 1989
	developmental		April 1, 1990
Norethisterone acetate (Norethindrone acetate)	developmental	51989	October 1, 1991
Norethisterone (Norethindrone) /Ethinyl estradiol	developmental	68224/57636	April 1, 1990
Norethisterone (Norethindrone)/Mestranol	developmental	68224/72333	April 1, 1990
Norethynodrel	cancer	68235	February 27, 2001

Norgestrel	developmental	6533002	April 1, 1990
Ochratoxin A	cancer	303479	July 1, 1990
Oil Orange SS	cancer	2646175	April 1, 1988
Oral contraceptives, combined	cancer	---	October 1, 1989
Oral contraceptives, sequential	cancer	---	October 1, 1989
Oxadiazon	cancer	19666309	July 1, 1991
	developmental		May 15, 1998
Oxazepam	cancer	604751	October 1, 1994
	developmental		October 1, 1992
Oxydemeton methyl	female, male	301122	November 6, 1998
Oxymetholone	cancer	434071	January 1, 1988
	developmental		May 1, 1997
Oxytetracycline (internal use)	developmental	79572	January 1, 1991
Oxytetracycline hydrochloride (internal use)	developmental	2058460	October 1, 1991
Oxythioquinox	cancer	2439012	August 20, 1999
Paclitaxel	developmental, female, male	33069624	August 26, 1997
Palygorskite fibers (> 5µm in length)	cancer	12174117	December 28, 1999
Panfuran S	cancer	794934	January 1, 1988
Paramethadione	developmental	115673	July 1, 1990
Penicillamine	developmental	52675	January 1, 1991
Pentachlorophenol	cancer	87865	January 1, 1990
Pentobarbital sodium	developmental	57330	July 1, 1990
Pentostatin	developmental	53910251	September 1, 1996
Phenacemide	developmental	63989	July 1, 1990
Phenacetin	cancer	62442	October 1, 1989
Phenazopyridine	cancer	94780	January 1, 1988
Phenazopyridine hydrochloride	cancer	136403	January 1, 1988
Phenesterin	cancer	3546109	July 1, 1989
Phenobarbital	cancer	50066	January 1, 1990
Phenolphthalein	cancer	77098	May 15, 1998
Phenoxybenzamine	cancer	59961	April 1, 1988
Phenoxybenzamine hydrochloride	cancer	63923	April 1, 1988
Phenprocoumon	developmental	435972	October 1, 1992
o-Phenylenediamine and its salts	cancer	95545	May 15, 1998
Phenyl glycidyl ether	cancer	122601	October 1, 1990
Phenylhydrazine and its salts	cancer	---	July 1, 1992
o-Phenylphenate, sodium	cancer	132274	January 1, 1990
o-Phenylphenol	cancer	90437	August 4, 2000
PhiP(2-Amino-1-methyl-6-phenylimidazol[4,5-b]pyridine)	cancer	105650235	October 1, 1994
Pimozide	developmental, female	2062784	August 20, 1999
Pipobroman	developmental	54911	July 1, 1990
Plicamycin	developmental	18378897	April 1, 1990
Polybrominated biphenyls	cancer	---	January 1, 1988
	developmental		October 1, 1994
Polychlorinated biphenyls	cancer	---	October 1, 1989
	developmental		January 1, 1991

Polychlorinated biphenyls (containing 60 or more percent chlorine by molecular weight)	cancer	---	January 1, 1988
Polychlorinated dibenzo-*p*-dioxins	cancer	---	October 1, 1992
Polychlorinated dibenzofurans	cancer	---	October 1, 1992
Polygeenan	cancer	53973981	January 1, 1988
Ponceau MX	cancer	3761533	April 1, 1988
Ponceau 3R	cancer	3564098	April 1, 1988
Potassium bromate	cancer	7758012	January 1, 1990
Potassium dimethyldithiocarbamate	developmental	128030	March 30 1999
Pravastatin sodium	developmental	81131706	March 3, 2000
Prednisolone sodium phosphate	developmental	125020	August 20, 1999
Primidone	cancer	125337	August 20, 1999
Procarbazine	cancer	671169	January 1, 1988
Procarbazine hydrochloride	cancer developmental	366701	January 1, 1988 July 1, 1990
Procymidone	cancer	32809168	October 1, 1994
Progesterone	cancer	57830	January 1, 1988
Pronamide	cancer	23950585	May 1, 1996
Propachlor	cancer	1918167	February 27, 2001
1,3-Propane sultone	cancer	1120714	January 1, 1988
Propargite	cancer developmental	2312358	October 1, 1994 June 15, 1999
beta-Propiolactone	cancer	57578	January 1, 1988
Propoxur	cancer	114261	August 11, 2006
Propylene glycol mono-*t*-butyl ether	cancer	57018527	June 11, 2004
Propylene oxide	cancer	75569	October 1, 1988
Propylthiouracil	cancer developmental	51525	January 1, 1988 July 1, 1990
Pyridine	cancer	110861	May 17, 2002
Pyrimethamine	developmental	58140	January 29, 1999
Quazepam	developmental	36735225	August 26, 1997
Quinoline and its strong acid salts	cancer	---	October 24, 1997
Quizalofop-ethyl	male	76578148	December 24, 1999
Radionuclides	cancer	---	July 1, 1989
Reserpine	cancer	50555	October 1, 1989
Residual (heavy) fuel oils	cancer	---	October 1, 1990
Resmethrin	developmental	10453868	November 6, 1998
Retinol/retinyl esters, when in daily dosages in excess of 10,000 IU, or 3,000 retinol equivalents. (NOTE: Retinol/retinyl esters are required and essential for maintenance of normal reproductive function. The recommended daily level during pregnancy is 8,000 IU.)	developmental	---	July 1, 1989
Ribavirin	developmental male	36791045	April 1, 1990 February 27, 2001

Riddelliine	cancer	23246960	December 3, 2004
Rifampin	developmental, female	13292461	February 27, 2001
~~Saccharin~~ Delisted April 6, 2001	~~cancer~~	~~81072~~	~~October 1, 1989~~
~~Saccharin, sodium~~ Delisted January 17, 2003	~~cancer~~	~~128449~~	~~January 1, 1988~~
Safrole	cancer	94597	January 1, 1988
Salicylazosulfapyridine	cancer	599791	May 15, 1998
Secobarbital sodium	developmental	309433	October 1, 1992
Selenium sulfide	cancer	7446346	October 1, 1989
Sermorelin acetate	developmental	---	August 20, 1999
Shale-oils	cancer	68308349	April 1, 1990
Silica, crystalline (airborne particles of respirable size)	cancer	---	October 1, 1988
Sodium dimethyldithiocarbamate	developmental	128041	March 30 1999
Sodium fluoroacetate	male	62748	November 6, 1998
Soots, tars, and mineral oils (untreated and mildly treated oils and used engine oils)	cancer	---	February 27, 1987
Spironolactone	cancer	52017	May 1, 1997
Stanozolol	cancer	10418038	May 1, 1997
Sterigmatocystin	cancer	10048132	April 1, 1988
Streptomycin sulfate	developmental	3810740	January 1, 1991
Streptozocin (streptozotocin)	developmental, female, male	18883664	August 20, 1999
Streptozotocin (streptozocin)	cancer	18883664	January 1, 1988
Strong inorganic acid mists containing sulfuric acid	cancer	---	March 14, 2003
Styrene oxide	cancer	96093	October 1, 1988
Sulfallate	cancer	95067	January 1, 1988
Sulfasalazine	male	599791	January 29, 1999
Sulindac	developmental, female	38194502	January 29, 1999
Talc containing asbestiform fibers	cancer	---	April 1, 1990
Tamoxifen and its salts	cancer	10540291	September 1, 1996
Tamoxifen citrate	developmental	54965241	July 1, 1990
Temazepam	developmental	846504	April 1, 1990
Teniposide	developmental	29767202	September 1, 1996
Terbacil	developmental	5902512	May 18, 1999
Terrazole	cancer	2593159	October 1, 1994
Testosterone and its esters	cancer	58220	April 1, 1988
Testosterone cypionate	developmental	58208	October 1, 1991
Testosterone enanthate	developmental	315377	April 1, 1990
2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD)	cancer developmental	1746016	January 1, 1988 April 1, 1991
1,1,2,2-Tetrachloroethane	cancer	79345	July 1, 1990
Tetrachloroethylene (Perchloroethylene)	cancer	127184	April 1, 1988
p-*a*,*a*,*a*-Tetrachlorotoluene	cancer	5216251	January 1, 1990
Tetracycline (internal use)	developmental	60548	October 1, 1991
Tetracyclines (internal use)	developmental	---	October 1, 1992
Tetracycline hydrochloride (internal use)	developmental	64755	January 1, 1991
Tetrafluoroethylene	cancer	116143	May 1, 1997
Tetranitromethane	cancer	509148	July 1, 1990

Thalidomide	developmental	50351	July 1, 1987
Thioacetamide	cancer	62555	January 1, 1988
4,4'-Thiodianiline	cancer	139651	April 1, 1988
Thiodicarb	cancer	59669260	August 20, 1999
Thioguanine	developmental	154427	July 1, 1990
Thiophanate methyl	female, male	23564058	May 18, 1999
Thiouracil	cancer	141902	June 11, 2004
Thiourea	cancer	62566	January 1, 1988
Thorium dioxide	cancer	1314201	February 27, 1987
Tobacco, oral use of smokeless products	cancer	---	April 1, 1988
Tobacco smoke	cancer	---	April 1, 1988
Tobacco smoke (primary)	developmental, female, male	---	April 1, 1988
Tobramycin sulfate	developmental	49842071	July 1, 1990
Toluene	developmental	108883	January 1, 1991
Toluene diisocyanate	cancer	26471625	October 1, 1989
o-Toluidine	cancer	95534	January 1, 1988
o-Toluidine hydrochloride	cancer	636215	January 1, 1988
~~para-Toluidine~~	~~cancer~~	~~106490~~	~~January 1, 1990~~
Delisted October 29, 1999			
Toxaphene (Polychlorinated camphenes)	cancer	8001352	January 1, 1988
Treosulfan	cancer	299752	February 27, 1987
Triadimefon	developmental, female, male	43121433	March 30, 1999
Triazolam	developmental	28911015	April 1, 1990
Tributyltin methacrylate	developmental	2155706	December 1, 1999
Trichlormethine (Trimustine hydrochloride)	cancer	817094	January 1, 1992
Trichloroethylene	cancer	79016	April 1, 1988
2,4,6-Trichlorophenol	cancer	88062	January 1, 1988
1,2,3-Trichloropropane	cancer	96184	October 1,1992
Trientine hydrochloride	developmental	38260014	February 27, 2001
Triforine	developmental	26644462	June 18, 1999
Trilostane	developmental	13647353	April 1, 1990
Trimethadione	developmental	127480	January 1, 1991
2,4,5-Trimethylaniline and its strong acid salts	cancer	---	October 24, 1997
Trimethyl phosphate	cancer	512561	May 1, 1996
Trimetrexate glucuronate	developmental	82952645	August 26, 1997
Triphenyltin hydroxide	cancer developmental	76879	July 1, 1992 March 18, 2002
Tris(aziridinyl)-*p*-benzoquinone (Triaziquone)	cancer	68768	October 1, 1989
Tris(1-aziridinyl)phosphine sulfide (Thiotepa)	cancer	52244	January 1, 1988
Tris(2-chloroethyl) phosphate	cancer	115968	April 1, 1992
Tris(2,3-dibromopropyl)phosphate	cancer	126727	January 1, 1988
Trp-P-1 (Tryptophan-P-1)	cancer	62450060	April 1, 1988
Trp-P-2 (Tryptophan-P-2)	cancer	62450071	April 1, 1988
Trypan blue (commercial grade)	cancer	72571	October 1, 1989
Unleaded gasoline (wholly vaporized)	cancer	---	April 1, 1988
Uracil mustard	cancer developmental, female, male	66751	April 1, 1988 January 1, 1992
Urethane (Ethyl carbamate)	cancer	51796	January 1, 1988

	developmental		October 1, 1994
Urofollitropin	developmental	97048130	April 1, 1990
Valproate (Valproic acid)	developmental	99661	July 1, 1987
Vanadium pentoxide (orthorhombic crystalline form)	cancer	1314621	February 11, 2005
Vinblastine sulfate	developmental	143679	July 1, 1990
Vinclozolin	cancer	50471448	August 20, 1999
	developmental		May 15, 1998
Vincristine sulfate	developmental	2068782	July 1, 1990
Vinyl bromide	cancer	593602	October 1, 1988
Vinyl chloride	cancer	75014	February 27, 1987
4-Vinylcyclohexene	cancer	100403	May 1, 1996
4-Vinyl-1-cyclohexene diepoxide (Vinyl cyclohexene dioxide)	cancer	106876	July 1, 1990
Vinyl fluoride	cancer	75025	May 1, 1997
Vinyl trichloride (1,1,2-Trichloroethane)	cancer	79005	October 1, 1990
Warfarin	developmental	81812	July 1, 1987
2,6-Xylidine (2,6-Dimethylaniline)	cancer	87627	January 1, 1991
Zileuton	cancer, developmental, female	111406872	December 22, 2000
~~Zineb~~ Delisted October 29, 1999	~~cancer~~	~~12122677~~	~~January 1, 1990~~

Date: August 11, 2006

PubMed

Display Settings: Abstract

J Air Waste Manag Assoc. 2007 May;57(5):522-34.

Real-time measurement of outdoor tobacco smoke particles.

Klepeis NE[1], Ott WR, Switzer P.

Author information

Abstract

The current lack of empirical data on outdoor tobacco smoke (OTS) levels impedes OTS exposure and risk assessments. We sought to measure peak and time-averaged OTS concentrations in common outdoor settings near smokers and to explore the determinants of time-varying OTS levels, including the effects of source proximity and wind. Using five types of real-time airborne particle monitoring devices, we obtained more than 8000 min worth of continuous monitoring data, during which there were measurable OTS levels. Measurement intervals ranged from 2 sec to 1 min for the different instruments. We monitored OTS levels during 15 on-site visits to 10 outdoor public places where active cigar and cigarette smokers were present, including parks, sidewalk cafés, and restaurant and pub patios. For three of the visits and during 4 additional days of monitoring outdoors and indoors at a private residence, we controlled smoking activity at precise distances from monitored positions. The overall average OTS respirable particle concentration for the surveys of public places during smoking was approximately 30 microg m(-3). OTS exhibited sharp spikes in particle mass concentration during smoking that sometimes exceeded 1000 microg m(-3) at distances within 0.5 m of the source. Some average concentrations over the duration of a cigarette and within 0.5 m exceeded 200 microg m(-3), with some average downwind levels exceeding 500 microg m(-3). OTS levels in a constant upwind direction from an active cigarette source were nearly zero. OTS levels also approached zero at distances greater than approximately 2 m from a single cigarette. During periods of active smoking, peak and average OTS levels near smokers rivaled indoor tobacco smoke concentrations. However, OTS levels dropped almost instantly after smoking activity ceased. Based on our results, it is possible for OTS to present a nuisance or hazard under certain conditions of wind and smoker proximity.

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Tob Control. 2011 May;20(3):212-8. doi: 10.1136/tc.2010.041277. Epub 2010 Dec 21.

Not just 'a few wisps': real-time measurement of tobacco smoke at entrances to office buildings.

Kaufman P[1], Zhang B, Bondy SJ, Klepeis N, Ferrence R.

Author information

Abstract

INTRODUCTION: An unintended consequence of indoor smoking restrictions is the relocation of smoking to building entrances, where non-smokers may be exposed to secondhand smoke, and smoke from outdoor areas may drift through entrances, exposing people inside. Tobacco smoke has been linked to numerous health effects in non-smokers and there is no safe level of secondhand smoke (SHS) exposure. This paper presents data on levels of tobacco smoke inside and outside entrances to office buildings.

METHODS: Real-time air quality monitors were used to simultaneously measure respirable particulate matter (PM(2.5); air pollutant particles with a diameter of 2.5 μg or less) as a marker for tobacco smoke, outside and inside 28 entrances to office buildings in downtown Toronto, Ontario, in May and June 2008. Measurements were taken when smoking was and was not present within 9 m of entrances. Background levels of PM(2.5) were also measured for each session. A mixed model analysis was used to estimate levels of PM(2.5), taking into account repeated measurement errors.

RESULTS: Peak levels (10 s averages) of PM(2.5) were as high as 496 μg/m(3) when smoking was present. Mixed model analysis shows that the average outdoor PM(2.5) with smoking was significantly higher than the background level ($p<0.0001$), and significantly and positively associated with the number of lit cigarettes ($p<0.0001$). The average level of PM(2.5) with ≥ 5 lit cigarettes was 2.5 times greater than the average background level.

CONCLUSIONS: These findings support smoke-free policies at entrances to buildings to protect non-smokers from exposure to tobacco smoke.

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Original investigation

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Comparison of Indoor Air Quality in Smoke-Permitted and Smoke-Free Multiunit Housing: Findings From the Boston Housing Authority

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Abstract

Introduction. Secondhand smoke remains a health concern for individuals living in multiunit housing, where smoke has been shown to easily transfer between units. Building-wide smoke-free policies are a logical step to minimize smoke exposure in these settings. This evaluation sought to determine whether buildings with smoke-free policies have less secondhand smoke than similar buildings without such policies. Further, the study assessed potential secondhand smoke transfer between apartments with and without resident smokers.

Methods. Fine particulate matter ($PM_{2.5}$), airborne nicotine, and self-reported smoking activity were recorded in 15 households with resident smokers and 17 households where no one smoked in 5 Boston Housing Authority developments. Of these, 4 apartment pairs consisted of adjacent apartments with and without resident smokers. Halls between apartments and outdoor air were also monitored to capture potential smoke transfer and provide background $PM_{2.5}$ concentrations.

Results. Households within buildings with smoke-free policies showed lower $PM_{2.5}$ concentrations compared to buildings without these policies (median: 4.8 vs. 8.1 μg/m^3). Although the greatest difference in $PM_{2.5}$ between smoking-permitted and smoke-free buildings was observed in households with resident smokers (14.3 vs. 7.0 μg/m^3), households without resident smokers also showed a significant difference (5.1 vs. 4.0 μg/m^3). Secondhand smoke transfer to smoke-free apartments was demonstrable with directly adjacent households.

Conclusion. This evaluation documented instances of secondhand smoke transfer between households as well as lower $PM_{2.5}$ measurements in buildings with smoke-free policies. Building-wide smoke-free policies can limit secondhand smoke exposure for everyone living in multiunit housing.

Introduction

The Surgeon General reports that there is no risk-free level of exposure to secondhand smoke and that it can cause premature death and disease in nonsmokers.[1] Previous research has demonstrated that levels of fine particulate matter ($PM_{2.5}$) in the air are three times higher in smoke-permitted homes than in smoke-free homes

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and that confining smoking to certain living spaces does not offer protection from secondhand smoke.[2–4] Children living in multiunit housing have more exposure to secondhand smoke than those living in free-standing homes.[5] Furthermore, people living in multiunit housing have little control over their exposure to secondhand smoke since much of the air entering their apartments originates somewhere else in the building.[6,7] Low-income urban populations are especially susceptible to these issues. For example, in Boston, both the prevalence of smoking (34.4% vs. 20.6%) and current asthma symptoms (19.2% vs. 9.0%) are significantly higher among public housing residents compared with other residents.[8] Therefore, interventions that specifically influence the public housing setting could address health disparities. Digenis-Bury et al.[8] demonstrated that public housing residents in Boston were more likely to have children, less likely to have completed high school or college, and more likely to be unemployed or unable to work compared with other Boston residents. Models controlling for gender, age, race/ethnicity, level of education, and income revealed higher rates of hypertension, asthma, and diabetes among Boston public housing residents (prevalence odds ratio: 1.5–1.8). Many of these disparities can exacerbate vulnerability to secondhand smoke exposure.

In September 2012, in an effort to protect vulnerable residents from exposure to secondhand smoke, the Boston Housing Authority (BHA) implemented a smoke-free policy throughout its entire public housing portfolio, which houses 27,000 people in 14,000 units in 64 developments. The policy development process took place over several years, entailing resident involvement and signing of lease addenda acknowledging the policy change. Informational summits were held, residents were surveyed about their level of support for the policy change, and free on-site tobacco cessation counseling was offered to public housing residents and staff. In part because Americans spend the majority of their time in their own homes, smoke-free policies can have meaningful impact on smoke exposure and may thus experience greater reductions in personal exposure.[1,9,10]

Multiple environmental markers exist for the assessment of secondhand smoke; fine particulate matter is one measurable environmental marker, which can estimate secondhand smoke exposure magnitude, duration, and frequency.[1,11] Aerosol monitors measure these $PM_{2.5}$ particles, which have diameters less than 2.5 μm and are easily drawn deep into the lungs where they can damage the cardiovascular system.[12,13] These monitors have been used to investigate secondhand smoke in multiunit housing communities.[14,15] The specificity of nicotine sampling, conducted alongside aerosol monitoring, supports the conclusion that observed particulates originated primarily from tobacco smoke in settings with active smoking.[4] Studies with real-time aerosol monitoring and nicotine sampling taking place concurrently have validated aerosol monitoring as a method of measuring secondhand smoke.[16] The BHA smoke-free policy presents a unique ecological opportunity for assessing changes in indoor air quality.

The purpose of this evaluation is two-fold: to assess whether there are measurable differences in aerosol levels in BHA buildings with and without smoke-free policies in place and to compare coincident and temporal trends in aerosol levels in the homes of smoking and nonsmoking residents in order to understand how secondhand smoke may transfer between them. This cross-sectional analysis will further describe how smoke-free policies benefit both smoking and nonsmoking populations.

Methods

Sampling Plan

Prior to the portfolio-wide smoke-free policy implementation in September 2012, multiple smoke-free pilot sites were in place. We identified five BHA developments from which we could create pairs of comparable building type (3-story walk-up, mid-rise, and high-rise) with and without smoke-free policies in place prior to September 2012. One development had 3-story walk-up entryways with and without smoke-free policies in place prior to September 2012 and served as its own paired grouping. Although two mid-rise developments were not subject to the pending smoke-free policy due to separate funding and management structures, one already had a building-wide smoke-free policy in place and the other did not. The remaining two high-rise developments transitioned to having a building-wide smoke-free policy as of September 30, 2012 (Table 1). All sampling occurred from August to December 2012, and each sampling event was categorized according to the policy of record on the date of sampling. Household units within each development were selected based on volunteer interest (provided they were adults who comprehended English). We sought to enroll 40 households—20 with and 20 without smoking residents—from these five housing developments and paired them by proximity. Ideal pairs were directly adjacent, but nonadjacent neighbor pairs (with and without smoking residents) who shared a hallway or stairwell were also included. On six occasions, unoccupied units were used in place of nonsmoking households if these locations afforded closer proximity to a household with smoking residents. A smoking household was defined as one that contained at least one smoking resident who agreed to participate in data collection regardless of his or her development's smoke-free policy. These households were designated smoking whether or not the resident smoker(s) abided by the development's smoke-free policy. A nonsmoking household was defined as one that contained no smokers residing in the home as reported by the study participant, regardless of the development's smoke-free policy.

Participant Recruitment

Participants were recruited through community meetings, community liaisons, and door knocking. Each participant gave oral consent to participate in the air quality study, and our confidentiality agreement included protecting residents from being reported to BHA even if they had smoked in designated smoke-free spaces. Participation included keeping a resident log of events, which would affect air quality (e.g., cooking, open windows, lit candles or cigarettes, etc.) during the air sampling period and allowing both the $PM_{2.5}$ monitor and passive nicotine sampler to be placed in the home for a 72-hr sampling period. Participants received $25 gift cards as compensation. Approval of human subjects research was granted by the Boston University Medical Center Institutional Review Board.

Equipment

Co-calibrated DUSTTRAK, DUSTTRAK II, and SidePak aerosol monitors (models 8520, 8530, and AM510, TSI, Inc.) were used to measure $PM_{2.5}$ concentrations in the air. The aerosol monitors were set to record measurements ($PM_{2.5}$ concentration in mg/m^3) at 1-min intervals, which were the average of the previous 60 s of sampling. Manufacturer-specified flow rates were used: 1.7 L/min for model 8520, 1.0 L/min for model 8530, and 1.7 L/min for the SidePak model. We used the size selective inlets provided by the manufacturer of the

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Table 1. Characteristics of Areas Sampled for Particulate Matter

					Area sampled for particulate matter			
Smoke-free policy	Development	Building type	Residential type	Proximity	Units by resident smoking status		Public areas	
Yes	A	3-Story	Family	Nonadjacent	Smoker	Nonsmoker	Hall	Outdoor
Yes	A	3-Story	Family	Nonadjacent	Smoker	Unoccupied unit	Hall	Outdoor
Yes	A	3-Story	Family	Nonadjacent	Smoker	Unoccupied unit	Hall	Outdoor
No	A	3-Story	Family	Nonadjacent	Smoker	Unoccupied unit	Hall	Outdoor
No	B	High-rise	Elderly/disabled	Nonadjacent	Smoker	Nonsmoker	Hall	Outdoor
No	B	High-rise	Elderly/disabled	Nonadjacent	Smoker	Unoccupied unit	Hall	Outdoor
No	B	High-rise	Elderly/disabled	Nonadjacent	Smoker	Nonsmoker	Hall	Outdoor
No	C	High-rise	Elderly/disabled	Adjacent	Smoker	Unoccupied unit	Hall	Outdoor
No	C	High-rise	Elderly/disabled	Nonadjacent	Smoker	Nonsmoker	Hall	Outdoor
No	C	High-rise	Elderly/disabled	Nonadjacent	Smoker	Unoccupied unit	Hall	Outdoor
Yes	D	Mid-rise	Family	Adjacent	Smoker	Nonsmoker	Hall	Outdoor
Yes	D	Mid-rise	Family	Adjacent	Smoker	Nonsmoker	Hall	–
Yes	D	Mid-rise	Family	Nonadjacent	Smoker	Nonsmoker	Hall	Outdoor
No	E	Mid-rise	Family	Adjacent	Smoker	Nonsmoker	Hall	Outdoor
No	E	Mid-rise	Family	Nonadjacent	Smoker	Nonsmoker	Hall	Outdoor
No	E	Mid-rise	Family	Nonadjacent	–	Two nonsmokers	Hall	Outdoor

Note. Developments B and C transitioned to having a building-wide smoke-free policy as of September 30, 2012.

DUSTTRAK and SidePak. We conducted side-by-side comparisons between all the devices which were used in this study prior to them being deployed. We recorded $PM_{2.5}$ concurrently for 72 hr in each of four settings: smoking home, nonsmoking or unoccupied neighboring unit, common entryways or hallway, and outdoors sample. Monitors were connected to an electrical source and placed in the primary living space of the home away from windows or vents. If a table or shelf was unavailable, static-free plastic tubing 4 ft in length was attached to the monitor inlet and affixed to a position closer to breathing level. In all instances, the monitor keypad was locked during the sampling period to prevent tampering or accidental termination.

We placed passive nicotine samplers in all of these same settings to confirm the presence of tobacco smoke. Both positive (double concurrent sampling) and negative (unopened sampler) controls were submitted alongside the other environmental samplers for processing at the University of California at Berkeley.

Data Analysis

Particulate matter aerosol data were downloaded from the $PM_{2.5}$ monitors using TSI TrakPro software (version 4.5.1.0, TSI Inc.) and imported into SAS (version 9.1.3, SAS Institute), where they were analyzed alongside resident log information. $PM_{2.5}$ concentration values were limited to those between 0 $\mu g/m^3$ and the 99th percentile in order to eliminate extreme outliers. Our calibration factors (0.366 for indoor $PM_{2.5}$ data and 0.635 for outdoor $PM_{2.5}$ data) were based on a separate dataset of concurrent aerosol monitoring and gravimetric analysis in BHA public housing.[15] These calibration factors control for differences in humidity, which affects the particle size distribution in these settings.

Data from these monitors were used to make four analyses: (a) comparisons of median $PM_{2.5}$ levels between smoke-permitted and smoke-free buildings, (b) comparisons of median $PM_{2.5}$ levels between smoker-occupied and nonsmoker-occupied settings, (c) correlations of nicotine concentrations with $PM_{2.5}$ levels to support evidence that $PM_{2.5}$ levels contained tobacco-related contamination, and (d) real-time instances of smoke transfer between smoker-occupied and nonsmoker-occupied households.

The primary outcome of interest was the median $PM_{2.5}$ level in a given setting.[14] We tested whether levels differed between smoke-permitted and smoke-free buildings. Buildings were considered smoke-free if that was their policy of record at the time of sampling. We also compared $PM_{2.5}$ levels in homes with and without smoking residents during hours in which smoking participants reported smoking occurrences on their resident log compared with hours in which no smoking occurrences were reported. We used the Wilcoxon–Mann–Whitney test to determine whether these nonparametrically distributed sample populations were significantly different from each other.

Real-time instances of smoke transfer from smoking to nonsmoking households were initially explored graphically. This transpired when the resident log documented cigarette use in the smoking household at a time corresponding with increased $PM_{2.5}$ measurements, and when minutes later, an increase in $PM_{2.5}$ levels was measured in the home without smoking residents in the absence of any other type of documented air contaminant. We also assessed air quality in common entryways or shared hallways where smoking was not permitted and expected to see intermediate measurements between those recorded in the homes of smoking and nonsmoking residents.

Finally, we used passive nicotine samplers to absorb ambient nicotine in all of the same settings where the $PM_{2.5}$ monitors were placed in order to confirm that higher levels of particulate matter in the air were correlated with elevated environmental tobacco smoke levels. Nicotine concentrations were calculated based on the duration of deployment. We used the Spearman rank correlation coefficient to determine whether $PM_{2.5}$ levels correlated with nicotine concentration absorbed by passive nicotine samplers, where $r_s = 1$ is perfect positive correlation.

Results

$PM_{2.5}$ levels were sampled from 32 households in 5 BHA developments; 15 of these were inhabited by smokers, 11 by nonsmokers, and 6 were unoccupied units used as nonsmoking proxies (Table 1). Households with smoking residents averaged 2.0 inhabitants including 0.5 children per unit with a median age of 38.5 years (range:

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1–74). Households without smoking residents averaged 1.6 inhabitants including 0.5 children per unit with a median age of 24.5 years (range: 5–76). Both household types had an average of three-and-a-half rooms (excluding kitchens and bathrooms). Continuous $PM_{2.5}$ data were collected for an average of 78.1 hr in smoking households and 77.0 hr in nonsmoking households.

The five housing developments included two high-rise, two mid-rise, and one 3-story walk-up building. Four of the 16 sampling pairs included a nonsmoking or unoccupied unit directly adjacent to the enrolled smoking household (Table 1). One sampling pair in Development D did not include an outdoor site due to equipment malfunction. In one sampling pair in Development E, an eligible smoking participant could not be recruited, so instead an additional nonsmoking household was included within this smoke-permitted building. These values contributed to the pooled nonsmoking $PM_{2.5}$ samples but could not be used to inform us about smoke transfer between households. Median $PM_{2.5}$ concentrations for each sampled setting revealed that households with resident smokers had the highest levels (10.6 μg/m^3), followed by outdoor spaces (8.3 μg/m^3), hallways/shared entryways (5.1 μg/m^3), and lastly nonsmoking/unoccupied units (4.8 μg/m^3); these distributions were significantly different ($p < .0001$).

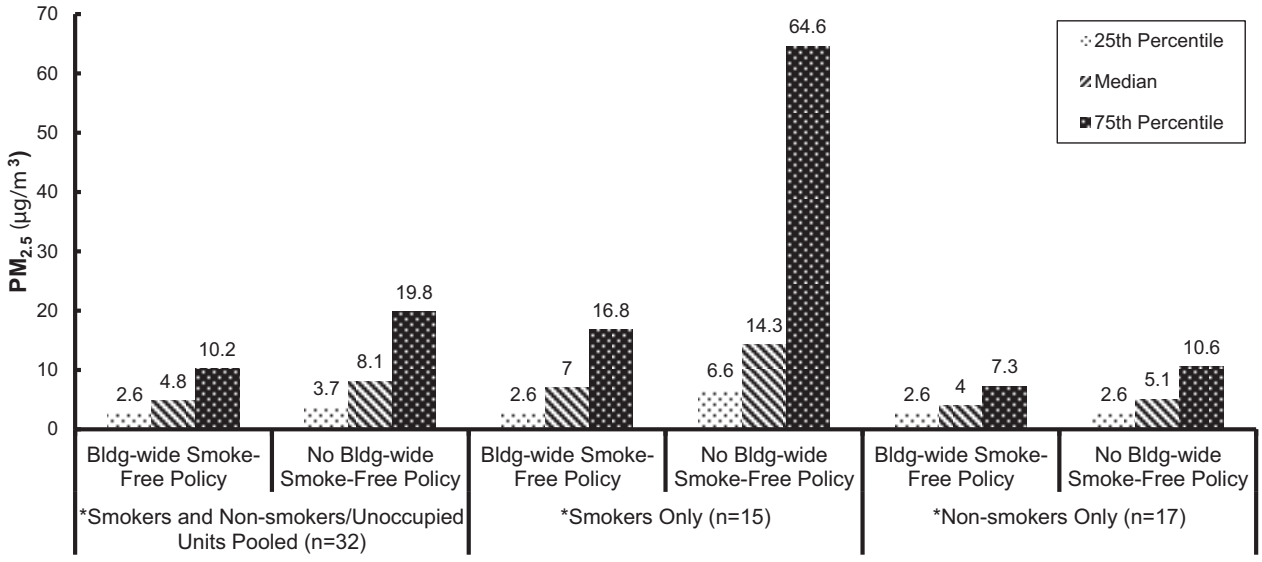
Comparisons of Median $PM_{2.5}$ Levels Between Smoke-Permitted and Smoke-Free Buildings

Figure 1 shows the differences in $PM_{2.5}$ distributions between buildings with smoke-permitted and smoke-free policies in place. Pooled $PM_{2.5}$ data from both smoking and nonsmoking/unoccupied units showed buildings with smoke-free policies in place had lower $PM_{2.5}$ concentrations at each quartile, with a median of 4.8 μg/m^3 compared with 8.1 μg/m^3 in buildings with smoke-permitted policies. The differences are most striking at the 75th percentile: 10.2 μg/m^3 compared with 19.8 μg/m^3.

Comparisons of Median $PM_{2.5}$ Levels Between Smoker-Occupied and Nonsmoker-Occupied Settings

These differences were also demonstrated when apartments with smoking residents and those without smoking residents were pooled separately. Median $PM_{2.5}$ concentrations in apartments with smoking residents were lower in buildings with smoke-free policies (14.3 vs. 7.0 μg/m^3). Unoccupied apartments or those with no resident smokers also had lower median $PM_{2.5}$ concentrations in buildings with smoke-free policies in place (5.1 vs. 4.0 μg/m^3). All differences were significant using the Wilcoxon–Mann–Whitney test ($p < .0001$).

Median $PM_{2.5}$ levels measured in both the smoking and adjacent nonsmoking households during hours in which the participant smoker reported smoking compared with hours during which no smoking was reported showed significant differences (Table 2). The households with smoking participants demonstrated sharp differences in $PM_{2.5}$ levels between those hours with reported smoking (29.6 μg/m^3) and those without (9.2 μg/m^3, $p < .0001$). Nonsmoking households located directly adjacent to these smoking participants also experienced differences in $PM_{2.5}$ levels during hours in which their smoking neighbor reported smoking (5.9 μg/m^3) compared with hours in which no smoking was reported (3.3 μg/m^3, $p < .0001$). This relationship is not observed with nonadjacent pairs of smoking and nonsmoking/unoccupied households, in which a small, statistically significant difference in $PM_{2.5}$ levels was observed during smoking hours (4.0 μg/m^3) and nonsmoking hours (4.4 μg/m^3). This opposing relationship explains the nonsignificant difference in $PM_{2.5}$ levels when all nonsmokers are combined. Common areas also showed a significant, but small magnitude difference in $PM_{2.5}$ levels in hours with reported smoking (5.9 μg/m^3) compared with hours in which no smoking was reported (5.1 μg/m^3).



*Distributions between building-wide and no building-wide smoke-free policy were significantly different using Wilcoxon-Mann-Whitney ($p < .0001$)

Figure 1. $PM_{2.5}$ distributions by smoke-free policy.

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Correlations of Nicotine Concentrations With $PM_{2.5}$ Levels to Support Evidence That $PM_{2.5}$ Levels Contained Tobacco-Related Contamination

Smoking households had the highest mean nicotine concentrations (3.07 μg/m³) compared with common areas (0.43 μg/m³), nonsmoking/unoccupied households (0.04 μg/m³), and outdoor settings (0.02 μg/m³, which was the lowest concentration detected by these nicotine samplers; data not shown in tables). Higher $PM_{2.5}$ levels were correlated with higher nicotine concentrations in all sampling settings (r_s = .58, p < .0001), but particularly so within smoking households (r_s = .90, p < .0001).

Real-Time Instances of Smoke Transfer Between Smoker-Occupied and Nonsmoker-Occupied Households

In Figure 2, we display an instance consistent with tobacco smoke from a smoking participant infiltrating an adjacent unoccupied unit some minutes later. Arrows indicate times at which smoking was self-reported, and the unoccupied unit's $PM_{2.5}$ levels show a steady increase shortly thereafter. There was no other known source of air contamination in this unoccupied unit. Note the different y-axis scales of the smoking and nonsmoking household $PM_{2.5}$ levels. The smoking household's $PM_{2.5}$ levels of higher amplitude show more dynamic response to the smoking events, with higher peaks followed by sharper declines. In contrast, the unoccupied unit shows gradual increases at lower amplitude, which are sustained longer. Specific instances such as these with clear occurrences of smoke transfer corroborated by resident log were rare.

Discussion

This evaluation demonstrates that indoor air pollution is lower in apartments covered by building-wide smoke-free policies compared to apartments in buildings without these policies. These findings lend support to the potential effectiveness of residential smoke-free policies in multiunit housing and bolster existing evidence indicating that smoke cannot be confined to designated smoking areas within buildings. Segregating smokers and nonsmokers by entire buildings with different smoking policies is not a favorable alternative to

Table 2. Comparisons of $PM_{2.5}$ (μg/m³) Aerosol Levels Measured During Hours When Smokers Self-Reported Smoking or Nonsmoking

Area observed	Smoking or nonsmoking hours reported by smoker	25th Percentile	Median	75th Percentile	90th Percentile	*p* value[a]
Smokers	Nonsmoking hours	3.7	9.2	23.4	92.6	<.0001
	Smoking hours	8.1	29.6	113.1	230.2	
All nonsmokers	Nonsmoking hours	2.6	4.4	7.7	15.0	.581
	Smoking hours	2.2	4.0	8.1	16.1	
Nonsmokers living adjacent to smoker	Nonsmoking hours	2.2	3.3	8.8	27.1	<.0001
	Smoking hours	2.6	5.9	24.2	64.8	
Nonsmokers not living adjacent to smoker	Nonsmoking hours	2.9	4.4	7.7	12.4	<.0001
	Smoking hours	2.2	4.0	7.7	12.1	
Common areas	Nonsmoking hours	2.9	5.1	8.8	15.7	<.0001
	Smoking hours	2.9	5.9	10.2	16.1	

[a]Wilcoxon–Mann–Whitney test.

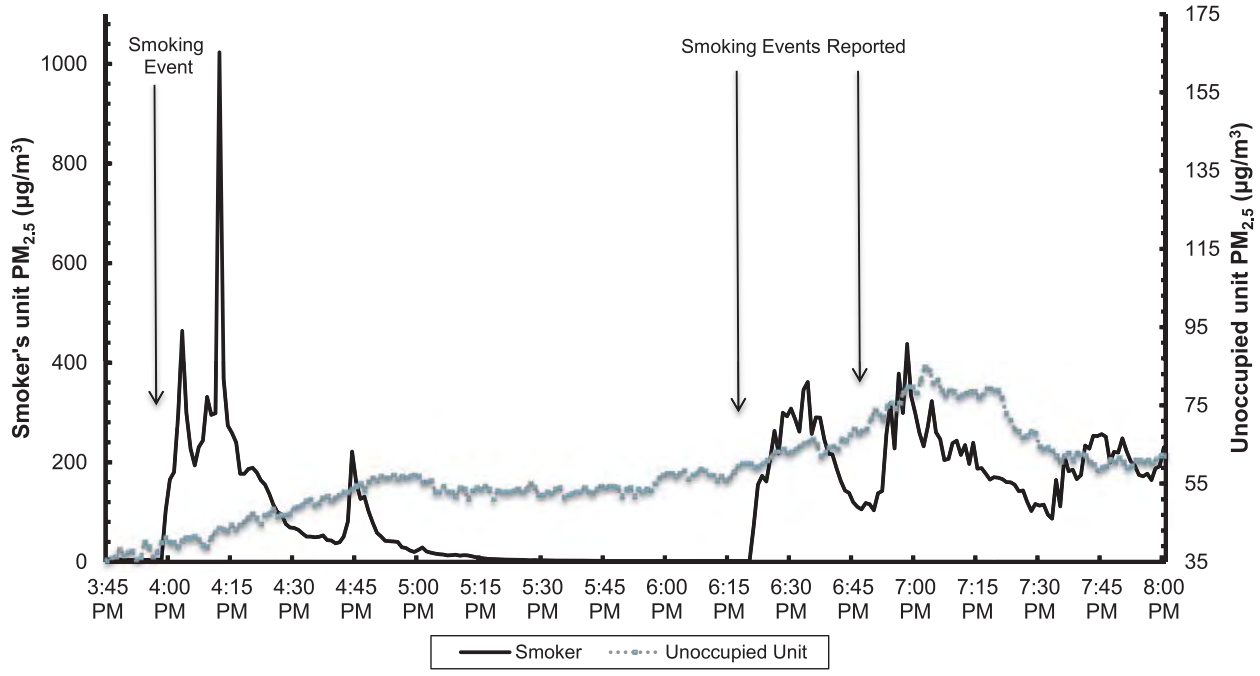

Figure 2. Overlay of two real-time $PM_{2.5}$ axes: levels in smoker's unit and adjacent unoccupied unit.

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removing the source throughout the property because it increases the smoke exposure to both smoking and nonsmoking residents in those smoking-permitted buildings.

In buildings with smoke-free policies in place, households with resident smokers had over 50% lower median $PM_{2.5}$ concentrations. This difference suggests that smoke-free policies may reduce indoor smoking and exposure to secondhand smoke. Differences were even more striking at the higher percentiles, consistent with the episodic nature of smoking-associated increases in secondhand smoke-related pollutants. Even small magnitude changes in annual aerosol exposure (i.e., 10 μg/m^3) are associated with health impacts and increased risk of all-cause mortality.[18–21] Of note, the U.S. Environmental Protection Agency's health-based $PM_{2.5}$ annual standard is 12 μg/m^3.[22] The 3-day sampling period medians in this evaluation cannot be directly correlated with annual means, but it is possible that these differences cumulated over a longer time period might have meaningful health implications.

We attribute the higher $PM_{2.5}$ concentrations in smoking-permitted households directly to tobacco smoke. Ambient nicotine concentrations showed the strongest correlation in smoking homes where aerosol levels were also the highest. Using self-reported instances of smoking to classify each hour as a "smoking hour" or "nonsmoking hour" was another measure of the direct impact smoking had on aerosol levels. Smoking households, directly adjacent units, and shared hallways or stairwells all showed significantly higher aerosol levels during hours in which smoking was reported. Classifying a whole hour as smoking or nonsmoking created a conservative estimate for imprecise reporting of the time of smoking events and built in a "lag time" for smoke to transfer to other areas.

Similar to previous studies that measured $PM_{2.5}$ in multiunit housing, we observed significantly higher aerosol levels in smoking compared with nonsmoking households.[14,15] These apartments with resident smokers had more than twice the $PM_{2.5}$ concentration of nonsmoking/unoccupied units regardless of whether some of these smokers may have chosen to smoke outside their homes. Our findings, embedded in building-wide policy differences, underscore the importance of building-wide smoke-free policies since households with self-imposed smoke-free policies in smoking-permitted buildings demonstrated higher levels of $PM_{2.5}$ than did nonsmoking households in buildings with smoke-free policies in place. We attribute this, in part, to smoke transfer within the building.

We acknowledge that our survey of air quality was limited to concurrent sampling in four settings for each sampling period in the five housing developments. We cannot account for contaminants that may have transferred from a nonparticipating smoker in the same vicinity as our grouped smoking/nonsmoking pairs. Therefore, evidence of peaks in $PM_{2.5}$ in nonsmoking/unoccupied units in response to documented smoking activity represents an underestimate of smoke transfer. We relied on self-reported logs of smoking activity, which is susceptible to variably precise record-keeping, which we addressed by broadening each smoking event to an hour. Although we chose building pairs that were of similar building style and construction, there are still inter-building differences which account for changes in how air is transferred between spaces. Additionally, sampling occurred during warm and cold weather periods of variable humidity, which may affect monitor performance and human behavior (e.g., opening/closing windows, smoking frequency, etc.). Furthermore, this cross-sectional survey has limited generalizability due to its use of a convenience sample and the fact that $PM_{2.5}$ itself is not specific to secondhand smoke.

Despite advances in smoke-free policy adoption in public places, exposure to secondhand smoke in the home continues to impose a risk to vulnerable populations who live in multiunit housing. The department of Housing and Urban Development has urged housing authorities to adopt complete smoke-free policies across the country, and BHA is one of the first large housing authorities to implement this far-reaching policy recommendation.[23] The implications of this evaluation are that the implementation of a smoke-free policy would reduce secondhand smoke in multiunit housing.

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Declaration of Interests

None declared.

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BENEFITS OF SMOKE-FREE REGULATIONS IN OUTDOOR SETTINGS: BEACHES, GOLF COURSES, PARKS, PATIOS, AND IN MOTOR VEHICLES

James L. Repace†

Some persons feel that although establishing smoke-free buildings is justified, establishing smoke-free areas outdoors is not. This paper discusses the toxicity of tobacco smoke, the factors determining its concentration, and argues that tobacco smoke in places where people live, work, or congregate, whether indoors or outdoors, poses a nuisance to many, and both an acute and chronic health hazard to some. Thus, local governments are justified in establishing smoke-free zones outdoors.

Tobacco smoke contains at least 172 toxic substances, including 3 regulated outdoor air pollutants, 33 hazardous air pollutants, 47 chemicals restricted as hazardous waste, and 67 known human or animal carcinogens.[1] The law of conservation of

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1. JAMES L. REPACE, EXPOSURE ANALYSIS 203 (Wayne R. Ott et al. eds., 2006).

mass dictates that this must be true whether tobacco smoke is inhaled in the act of smoking, or inhaled by nonsmokers out of the air indoors or outdoors, known as secondhand smoke (SHS).

The concentration of tobacco smoke pollution in buildings and in vehicles is proportional to the density of smokers, and inverse to the ventilation rate.[2] Tobacco smoke pollution outdoors (outdoor tobacco smoke—or OTS), is far more complicated, being determined by the density and distribution of smokers, the wind velocity (direction and speed), and the stability of the atmosphere.[3] High SHS concentrations are produced by high smoker density, low wind velocities, and stable atmospheric conditions. SHS concentrations persist for hours after smoking ceases indoors, while OTS concentrations dissipate rapidly after smoking ceases outdoors.[4] However, during smoking, OTS levels outdoors may be as high as SHS indoors, especially in close proximity to smokers.

I. STATE AND LOCAL OUTDOOR SMOKING BAN POLICIES

Several states have taken steps to restrict smoking in outdoor locations and even in automobiles where children are present. As a result of research conducted by the state, culminating in the listing of OTS as a Toxic Air Contaminant, some of the most restrictive ordinances have been passed in California.

The City Council of Calabasas, California, passed an ordinance that took effect January 1, 2007, "prohibit[ing] smoking in all public places, indoor or outdoor, where anyone might be exposed to secondhand smoke."[5] The outdoor ban "includes outdoor cafes, bus stops, soccer fields, condominium pool decks, parks and sidewalks."[6] "Smoking in one's car is allowed, unless the windows

2. James L. Repace, *Fact Sheet: Outdoor Air Pollution from Secondhand Smoke* (2005), *available at* http://www.repace.com/pdf/OTS_FACT_SHEET.pdf.

3. *Id.*

4. Neil E. Klepeis et al., *Real-Time Measurement of Outdoor Tobacco Smoke Particles*, 57 J. AIR & WASTE MGMT. ASS'N 522, 522 (2007); James L. Repace, Address Before the 13th World Conference on Tobacco OR Health: Abstract of Indoor and Outdoor Carcinogen Pollution on a Cruise Ship in the Presence and Absence of Tobacco Smoking (Oct. 17, 2004) (unpublished working paper, on file with author).

5. John M. Broder, *Smoking Ban Takes Effect, Indoors and Out*, N.Y. TIMES, Mar. 19, 2006, at 1; CALABASAS, CAL., MUN. CODE §§ 8.12.030–.040 (2006), *available at* http://www.bpcnet.com/codes/calabasas.

6. Broder, *supra* note 5, at 1.

are open and someone nearby might be affected."[7] Violators face "warnings, fines of up to $500 for repeat offenses, and misdemeanor charges."[8] The ordinance followed a few "weeks after the California Air Resources Board declared secondhand smoke to be a Toxic Air Contaminant that can lead to respiratory infections, asthma, lung cancer, heart disease and death."[9] "Smoking has been prohibited on most Southern California beaches and piers since 2003."[10] Nationwide, in excess of "700 cities . . . have enacted ordinances placing some limits on outdoor smoking, according to the American Nonsmokers' Rights Foundation."[11] California Governor Arnold Schwarzenegger "signed a bill [making] it an infraction to smoke in a vehicle if someone under age 18 is present."[12] Other California smoking prohibitions "include a ban on smoking in enclosed workplaces and within 25 feet of a playground."[13] Legislation banning smoking in cars with young children present was adopted in Arkansas in 2006, and similar smoking bans with children have been introduced in the states of California, Georgia, Michigan, New Jersey, New York, Pennsylvania, and Vermont.[14] Louisiana has limited smoking in cars when children 13 and younger are in the vehicle.[15]

II. STUDIES OF OUTDOOR TOBACCO SMOKE CONCENTRATIONS

A limited number of controlled experiments and field studies of OTS have been conducted in California, Europe, Maryland, and the Carribean. These studies show that OTS levels outdoors are often as high as SHS levels indoors, although there are differences in the persistence of OTS levels once smoking ceases.

7. *Id.*
8. *Id.*
9. *Id.*
10. *Id.* at 2.
11. *Id.*
12. Steve Lawrence, *State Bans Smoking with Kids in Vehicle*, ASSOCIATED PRESS, Oct. 11, 2007.
13. *Id.*
14. Wayne Ott et al., *Air Change Rates of Motor Vehicles and In-Vehicle Pollutant Concentrations from Secondhand Smoke*, 1–14 J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 1, 13 (2007).
15. Vaughn W. Rees & Gregory N. Connelly, *Measuring Air Quality to Protect Children from Secondhand Smoke in Cars*, 31 AM. J. PREVENTIVE MED. 363, 363 (2006).

A. California

The California Air Resources Board (CARB) study measured OTS nicotine concentrations outside an airport, college, government center, office complex, and amusement park.[16] CARB found that at these typical outdoor locations, Californians may be exposed to OTS levels as high as indoor SHS concentrations.[17] CARB found that OTS was strongly affected by the number of smokers, and moderately affected by the size of the smoking area and the measured wind speed.[18] The CARB study concluded that OTS concentrations are detectable and are sometimes comparable to indoor concentrations. The study also demonstrated that the number of cigarettes being smoked (i.e., total source strength), the position of smokers relative to the receptor, and atmospheric conditions can all lead to substantial variation in average exposures.[19] CARB concluded that OTS is a "Toxic Air Contaminant."[20]

A Stanford University study measured OTS respirable particle concentrations in outdoor patios, on airport and city sidewalks, and in parks.[21] It also conducted controlled experiments of SHS indoors and OTS outdoors.[22] It found that mean SHS particle concentrations outdoors can be comparable to SHS indoors.[23] Within about 2 feet of a smoker, OTS was quite high and comparable to SHS concentrations measured indoors.[24] The study found that levels measured in 2 sidewalk cafés were detectable at distances beyond 13 feet.[25] It further found that, in contrast to SHS, OTS does not accumulate and that OTS peaks are more

16. *See* CAL. ENVTL. PROT. AGENCY: AIR RESOURCES BOARD, PROPOSED IDENTIFICATION OF ENVIRONMENTAL TOBACCO SMOKE AS A TOXIC AIR CONTAMINANT (2005), http://repositories.cdlib.org/tc/surveys/CALEPA2005.

17. *Id.* at 5–12.

18. *Id.* at 23.

19. *Id.* at 82–91.

20. *Id.* at 25.

21. Klepeis et al., *supra* note 4, at 525 (study conducted via "15 on-site field visits to 10 public outdoor locations containing smokers").

22. *Id.* at 525–26.

23. *Id.* at 531.

24. *Id.* at 532 ("Generally, average levels within 0.5 m[eters] from a single cigarette source were quite high and comparable to indoor levels . . . .") (0.5 meters equals approximately 1.64 feet).

25. *Id.* ("[D]uring 2 on-site proximity experiments . . . OTS was still detectable . . . at distances of approximately 3–4 m[eters] from a single cigarette on sidewalk patios.") (4 meters equals approximately 13.12 feet).

sensitive to source-receptor proximity and wind velocity.[26] Thus, long-term averages for OTS concentrations are averaged over a large number of transient peaks, which only occur when smokers are active, whereas indoor concentrations remain high long after smoking has ceased. The total dose to a person indoors from each cigarette will be greater than that received from each cigarette smoked outdoors. The study found upwind OTS concentrations very low and downwind OTS much higher.[27]

B. Denmark

Boffi measured OTS respirable particle pollution in a car park (open space), outdoors in front of a conference center with smokers under a roof (18 smokers during a measurement time of 35 minutes), indoors in the nonsmoking conference center, along the motorway to Copenhagen city centre, and inside a Copenhagen restaurant where smoking was allowed.[28] He found that mean values observed with smokers in front of the conference center were significantly higher than the outdoor parking place, indoor conference center, motorway, and Copenhagen outdoor official data.[29]

C. Finland

Repace and Rupprecht measured OTS respirable particle pollution in 5 outdoor cafés and on city streets in downtown Helsinki.[30] They found that air pollution levels during August 2003 in Helsinki outdoor cafés with many smokers were 5 to 20 times higher than on the sidewalks of busy streets polluted by bus, truck, and auto traffic.[31]

26. *Id.* at 530–32.
27. *Id.* at 532.
28. R. Boffi et al., *A Day at the European Respiratory Society Congress: Passive Smoking Influences Both Outdoor and Indoor Air Quality*, 27 EUR. RESPIRATORY J. 862, 862 (2006).
29. *Id.* at 863.
30. James L. Repace & Ario Alberto Rupprecht, Paper Presented at the 13th World Conference on Tobacco OR Health: Outdoor Air Pollution from Secondhand Smoke (July 14, 2006).
31. *Id.*

D. Maryland

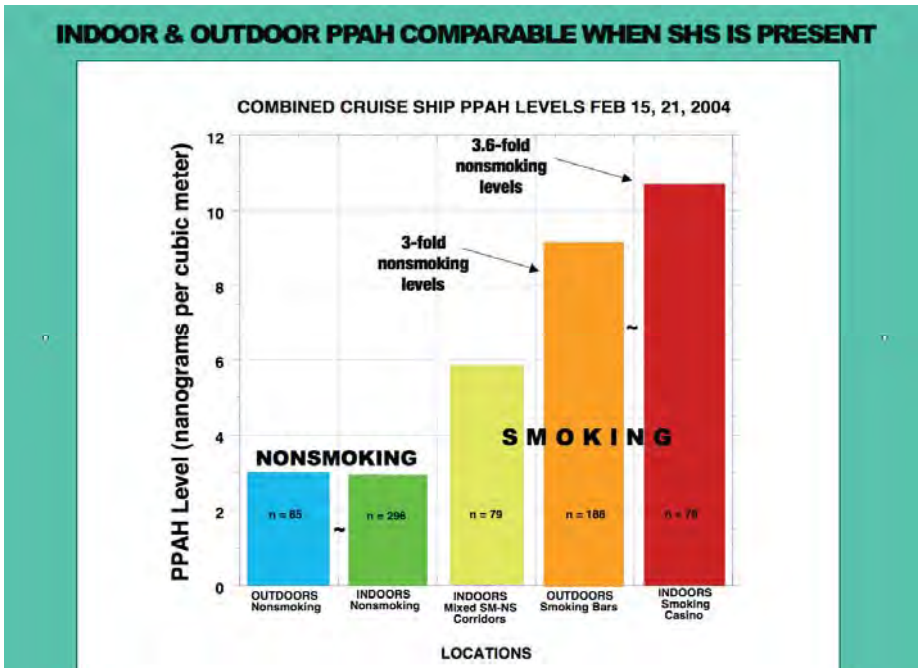
Repace measured outdoor fine particle and carcinogen concentrations from OTS on the campus of the University of Maryland in Baltimore County.[32] Using controlled experiments, Repace found that cigarette smoke respirable particulate (RSP) concentrations decline approximately inversely with distance downwind from the point source, whereas cigarette smoke carcinogen concentrations decline approximately inversely as the square of the distance from source to receptor.[33] The experiments showed that OTS smoke levels did not approach background levels either for fine particles or carcinogens until about 23 feet from the source.[34] Levels of irritation begin as low as 4 micrograms per cubic meter ($\mu g/m^3$) SHS-RSP, and levels of odor detection are as low as 1 $\mu g/m^3$.[35] Thus SHS odor would be detectable in these experiments as far as 7 meters from the source, and levels of irritation would begin at 4 meters from the source.[36]

E. The Caribbean

Experiments conducted on a cruise ship underway at 20 knots at sea in the Caribbean showed that OTS in various smoking-permitted outdoor areas of the ship tripled the level of carcinogens to which nonsmokers were exposed relative to indoor and outdoor areas in which smoking did not occur, despite the strong breezes and unlimited dispersion volume.[37] Moreover, outdoor smoking areas were contaminated with carcinogens to nearly the same extent as a popular casino on board in which smoking was permitted.[38]

32. Repace, *supra* note 2.
33. *Id.* at 9.
34. *Id.* at 10.
35. Martin H. Junker et al., *Acute Sensory Responses of Nonsmokers at Very Low Environmental Tobacco Smoke Concentrations in Controlled Laboratory Settings*, 109 ENVTL. HEALTH PERSP. 1045, 1050–51 (2001).
36. *See id.* at 1049–50.
37. James L. Repace, Address at the 14th Annual Conference of the International Society of Exposure Analysis: Indoor and Outdoor Carcinogen Pollution on a Cruise Ship (Oct. 2004).
38. *Id.*

Figure 1. Indoor and Outdoor Carcinogen Pollution on a Cruise Ship[39]



Outdoor carcinogen levels in the presence of smoking in a ship underway at sea at 20 knots of speed is comparable to indoor levels in the ship's casino, again showing a strong proximity effect despite the open air and strong breezes.[40]

F. Smoking in Cars

Two studies have shown that secondhand smoke in the small volumes of cars leads to very high exposures. Ott, Klepeis, and Switzer measured carbon monoxide (CO) and fine particle ($PM_{2.5}$) from multiple cigarettes smoked inside of 4 motor vehicles under both moving and stationary conditions, and found high particle concentrations inside cars with smokers due to the small volumes of the passenger compartments, and found that the concentrations become extremely high with the low air change rates caused by

39. *Id.*
40. *Id.*

closing windows and air conditioning.[41] They concluded that these extremely high particle concentrations constitute a serious health risk for adults and children who are passengers in a car with a smoker.[42] These findings were echoed by a Harvard School of Public Health report, concluding that SHS in cars can be up to 10 times more of a health risk than SHS in a home.[43] At least 20 states and a number of municipalities have considered limiting smoking in cars where minors are present.[44]

III. DISCUSSION

Individual cigarettes are point sources of air pollution; smokers in groups become an area source of SHS pollution. Outdoor air pollutants from individual point sources are subject to plume rise if the temperature of the smoke plume is hotter than the surrounding air; however if the plume has a small cross-section, as for a cigarette, it will rapidly cool and lose its upward momentum, and then will subside, as the combustion particles and gases are heavier than air.[45] Thus, in the case of no wind, the cigarette plume will rise to a certain height and then descend, and for a group of smokers, for example, sitting in an outdoor café, on a hospital patio, or in stadium seats, their smoke will tend to saturate the local area with SHS.

In the case where there is wind, the amount of thermally-induced plume rise is inversely proportional to the wind velocity—doubling the wind velocity will halve the plume rise.[46] In this case, the cigarette plume will resemble a cone tilted at an angle to the vertical.[47] The width of the cone and its angle with the ground will depend upon the wind velocity: a higher wind will create a more horizontal but wider cone (due to increased turbulence), with uncertain impact on exposure to SHS for downwind nonsmokers.[48] If there are multiple cigarette sources forming an area source of

41. Ott et al., *supra* note 14, at 15.
42. *Id.*
43. Rees & Connelly, *supra* note 15, at 363. The report concludes that levels of RSP measured in private cars were unsafe for children at prolonged rates. *Id.* at 367. *See also* Lawrence, *supra* note 12.
44. Lawrence, *supra* note 12.
45. Repace, *supra* note 2, at 1.
46. *Id. See generally* SAMUEL J. WILLIAMSON, FUNDAMENTALS OF AIR POLLUTION (1973).
47. WILLIAMSON, *supra* note 46; Repace, *supra* note 2, at 1.
48. WILLIAMSON, *supra* note 46; Repace, *supra* note 2, at 1.

SHS, the downwind concentrations will consist of multiple intersecting cones, i.e., overlapping plumes of increased concentration in the volume of overlap, before re-dissipating with increasing distance from the area source.[49] As the wind direction changes, SHS pollution will be spread in various directions, fumigating downwind nonsmokers.

A. Symptomatic Effects

There are a number of studies that show that nonsmokers suffer both illness and irritation from tobacco smoke exposure. SHS contains a large quantity of respirable particles, which can cause breathing difficulty for those with chronic respiratory diseases, or trigger an asthmatic attack in those with disabling asthma.[50] For the remainder of nonsmokers, Junker et al. report eye, nasal, and throat irritation thresholds for 24 healthy young adult females for repeated exposures over the course of 2 hours, corresponding to an SHS-$PM_{2.5}$ concentration of about 4.4 $\mu g/m^3$.[51] As Figure 2 shows, these levels are exceeded even at distances 3 or 4 meters (10 to 13 feet) downwind of a smoker in a sidewalk café, posing an irritation and annoyance problem even for healthy nonsmokers. With larger numbers of smokers, this irritating cloud of pollution would extend to even greater distances. Thus, there is scientific data to support OTS being both a health threat to asthmatic patients and a public nuisance to nonsmokers in general.

49. WILLIAMSON, *supra* note 46.

50. James Repace, Indoor Air Pollution and the Asthma Epidemic 5 (July 1996) (unpublished working paper, on file with author).

51. Junker et al., *supra* note 35, at 1049.

Figure 2. Outdoor Tobacco Smoke (OTS) In a Sidewalk Café and a Backyard Patio[52]

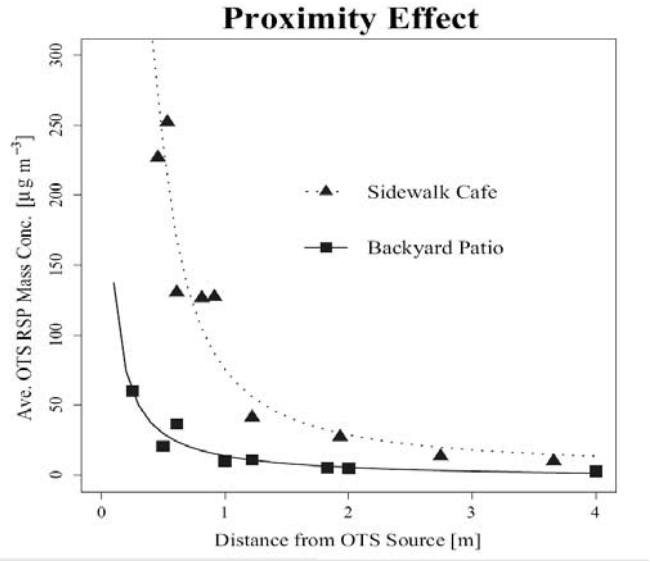


Figure 2. Overall average OTS mass concentrations as a function of proximity to the OTS source measured during experiments on a backyard patio using smoldered cigarettes, and two sidewalk cafés with human-smoked and smoldered cigarettes, for which source proximity was precisely recorded. Background RSP levels were subtracted from all measurements.

Figure 2 illustrates the proximity effect in a sidewalk café: outdoor tobacco smoke was still detectable at distances of approximately 3 to 4 meters from a single cigarette on sidewalk patios. Slightly elevated particle concentrations were detected at a distance of 8 meters from a cluster of burning cigarettes and around the corner of the house during a backyard patio experiment.[53]

Speer investigated subjective reactions of nonsmokers who developed symptoms from passive smoking.[54] Speer divided the nonsmokers into 2 groups: 191 nonsmokers with allergic diseases such as nasal allergy, asthma, and allergic headache, and a control group of 250 non-allergic nonsmokers without such diseases.[55]

52. Klepeis et al., *supra* note 4, at 532, fig. 3.
53. *Id.*
54. *See generally* Frederic Speer, *Tobacco and the Nonsmoker: A Study of Subjective Symptoms*, 16 ARCHIVES ENVTL. HEALTH 443 (1968).
55. *Id.* at 443–44.

Speer concluded that an impressively large number of people complain of symptoms from tobacco smoke, both allergic and non-allergic individuals.[56] The symptoms are summarized in Figure 3 on the following pages.

Figure 3. Known Symptoms of Passive Smoking[57]

Passive Smoking may produce:

- Itching, tearing, burning, reddening, swelling of eyes, blinking—increasing with exposure;
- Sneezing, blocking, running, itching of nose;
- Coughing, wheezing, sore throat—respiratory discomfort might begin within a half hour, persist for 8 to 12 hours;
- Headache, nausea and dizziness;
- Choking sensation;
- Irritation of mucous membranes of nose, throat, lung;
- Respiratory disease exacerbation;
- Respiratory symptoms, depressed pulmonary function.

Passive smoking is the inhalation of secondhand or environmental tobacco smoke (SHS)-polluted air. SHS is the toxic waste of tobacco consumption.

56. *Id.* at 446.

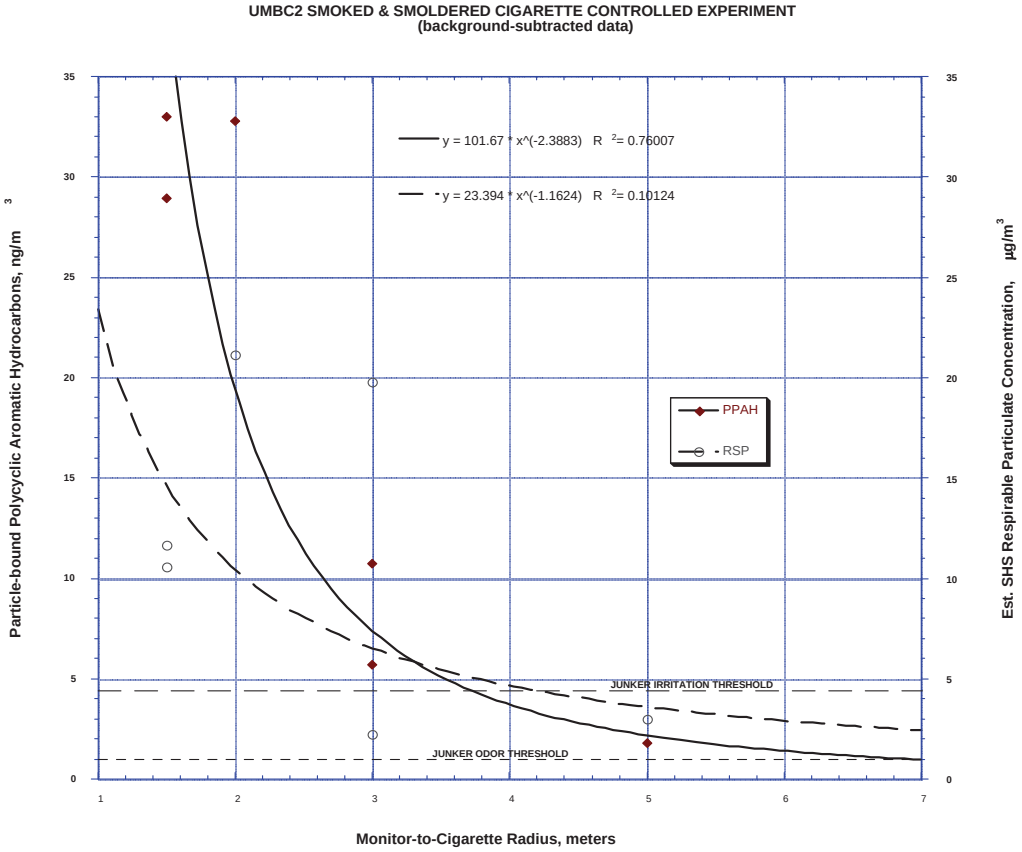
57. *Id.* at 443–46; Herbert Savel, *Clinical Hypersensitivity to Cigarette Smoke*, 21 ARCHIVES ENVTL. HEALTH 146 (1970).

Prevalence of SHS symptoms reported by 10,000 nonsmoking office workers, exposed 8 hours per day[58] • Difficulty working near a smoker (50%) • Forced to move away from desks (36%) • Bothered by SHS (33%) • Eye irritation (48%) • Nasal irritation (35%) • Aggravation of pulmonary disease (25%)	Odor acceptability[59] ~ 1μg/m^3 SHS-RSP; irritation threshold[60]: 4.4 μg/m^3

Savel reported on 8 nonsmokers with clinical hypersensitivity to cigarette smoke; all 8 individuals were allergic nonsmokers, and all developed immediate upper respiratory discomfort after being exposed to cigarette smoke.[61] Savel also reported a number of adverse symptoms, including eye and nose irritation, choking sensation, and both sinus and migraine headaches.[62] Savel concluded that an allergy to cigarette smoke might produce clinically distressing upper respiratory tract symptoms in nonsmokers with allergic backgrounds, exert a depressant effect on the antibacterial defense mechanisms of the lung, exert a toxic effect on lymphocytes, and play a role in the pathogenesis of pulmonary distress.[63]

58. Cary B. Barad, *Smoking on the Job: The Controversy Heats Up*, 48 OCCUPATIONAL HEALTH & SAFETY 21, 21–24 (1979).
59. Junker et al., *supra* note 35, at 1050.
60. *Id.*
61. Savel, *supra* note 57, at 146.
62. *Id.* at 147.
63. *Id.*

Figure 4. Smoked and Smoldered Cigarettes Showing the Cancer-Causing Polycyclic Aromatic Hydrocarbons (PAH) and SHS-RSP Data[64]



The Junker (2001) irritation index shows the median threshold of SHS irritation for healthy nonsmokers.[65] Figure 4 illustrates the proximity effect in an outdoor plaza where students congregated in widely scattered tables on a college campus in Baltimore, Maryland.[66] The proximity effect was studied in a controlled experiment involving 10 college student smokers placed in rings of increasing diameter around 2 air quality monitors so

64. Repace, *supra* note 2.
65. Junker et al., *supra* note 35, at 1045.
66. Repace, *supra* note 2, at 6.

that no matter which way the wind blew, the monitors were always downwind of 1 smoker.[67] Relative to a ring radius of 4 meters (13 feet), where the level is 4 units high, the SHS-RSP exposure concentration at 1.5 meters (5 feet) is 13 units high for particles and 35 units high for PPAH carcinogens, as shown in Figure 4. In this experiment, the proximity effect near a ring-shaped area source increases SHS by a factor of 3 for particles and a factor of nearly 9 for carcinogens.

B. Asthmatic Effects

There is very good evidence that environmental tobacco smoke has direct irritant effects in the case of passive smoking by children under the age of 4; this effect appears to diminish in children aged over 4 years.[68] There is also good evidence that SHS can trigger bronchospasm in some adults with asthma.[69] SHS is associated with wheezing symptoms, medical therapy for wheezing, and wheezing-related emergency department visits by children.[70] A causal association exists between SHS and increased episodes and aggravation of symptoms of children with asthma, affecting 200,000 to 1,000,000 children under the age of 18.[71] More than 14 million Americans reported having asthma in 2000, according to the National Center for Health Statistics.[72] "Asthma is a leading contributor of limited activity and absences from work and school; it also causes 5000 deaths each year in the U.S. The National Heart, Lung, and Blood Institute estimates that the annual direct and indirect costs of asthma were $12.7 billion in 2000."[73] By 2004, 7.1% (20.5 million) of people currently had asthma.[74] Among children under age 18 years, 8.5% (6.2 million) currently had asthma. Among adults 18 years and over, 6.7% (14.4 million) had asthma.[75] According to one report, teenage children exposed to

67. *Id.*
68. Repace, *supra* note 4.
69. *Id.*
70. *Id.*
71. *Id.*
72. Nat'l Heart, Lung, and Blood Inst., Asthma: Frequently Asked Questions, http://www.nhlbi.nih.gov/health/prof/lung/asthma/surveil_faq.htm.
73. Press Release, Nat'l Insts. of Health, NHLBI Funds Centers for Reducing Asthma Disparities (Oct. 30, 2002), *available at* http://www.nhlbi.nih.gov/new/press/02-10-30a.htm.
74. Nat'l Heart, Lung, and Blood Inst., *supra* note 72.
75. *Id.*

tobacco smoke in cars had an even higher risk of persistent wheeze than if they had been exposed at home.[76]

C. Health Risks from Exposure to SHS and OTS

Repeated exposure to a carcinogen, such as air pollution from SHS and OTS, over a lifetime increases the risk of cancer.[77] The U.S. Surgeon General has stated that there is "no risk free exposure to SHS"—chronic risk is proportional to average exposure concentration times duration of exposure times the dose-response relationship.[78] Federal regulatory agencies compute risk over a 70-year standard lifetime (e.g., EPA) or over a working lifetime of 45 years (e.g., OSHA).[79] Typical risks for lung cancer from passive smoking are in the range of 1 to 10 deaths per 1000 persons per lifetime.[80] Typical chronic heart disease risks are 10 times higher.[81] "De minimis" or acceptable risk is typically 1 death per 1,000,000 persons per lifetime.[82] OSHA's "significant risk of material impairment of health" is 1 death or irreversible serious health effect per 1000 workers per 45 year working lifetime.[83] "De manifestis" or obvious risk is 5 deaths or irreversible adverse health effect per 10,000 people at risk.[84] For workers indoors, it would take tornado-like rates of ventilation or air cleaning to reduce risks from chronic workplace exposure to de minimis levels; ergo, there is no risk-free chronic exposure to SHS. This is also likely to be true for waiters in outdoor cafés. Moreover, indoors or outdoors, for persons who have serious asthma, chronic obstructive

76. Peter D. Sly et al., *Exposure to Environmental Tobacco Smoke in Cars Increases the Risk of Persistent Wheeze in Adolescents,* 186 MED. J. AUSTL. 322, 322 (2007).

77. *See* RISK ASSESSMENT FORUM, U.S. ENVTL. PROT. AGENCY, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 5-1 to -7 (2005) (discussing risk characterization as bringing together hazard, dose-response, and exposure analysis).

78. Americans for Nonsmokers' Rights, *Second Hand Smoke: The Science* 1 (Nov. 2006), *available at* http://www.no-smoke.org/pdf/SHS.pdf.

79. *See* JOHN R. FOWLE III & KERRY L. DEARFIELD, U.S. ENVTL. PROT. AGENCY, RISK CHARACTERIZATION HANDBOOK 154 (2000), *available at* http://www.epa.gov/OSA/spc/pdfs/rchandbk.pdf (EPA); James L. Repace et al., *Air Nicotine and Saliva Cotinine as Indicators of Workplace Passive Smoking Exposure and Risk*, 18 RISK ANALYSIS 71, 78 (1998) (OSHA).

80. *See* James L. Repace et al., *A Quantitative Estimate of Nonsmokers' Lung Cancer Risk from Passive Smoking*, 11 ENV'T INT'L 3, 6–9 (1985).

81. Repace et al., *supra* note 79, at 79.

82. Curtis C. Travis et al., *Cancer Risk Management: A Review of 132 Federal Regulatory Decisions*, 21 ENVTL. SCI. & TECH. 415, 418 (1987).

83. Repace et al., *supra* note 79, at 79.

84. Travis et al., *supra* note 82, at 418.

respiratory disease, or heart disease, even brief exposures to SHS could land them in the emergency room or worse. It is generally these patients who died in the notorious outdoor smog episodes in the Meuse Valley in Belgium in 1930, Donora, Pennsylvania in 1948, and London in 1952, which eventually led to stringent regulation of outdoor air pollution.[85]

Arguments against banning smoking in certain outdoor public venues were advanced by Professor Simon Chapman in his presentation at the Tobacco Control Legal Consortium Symposium on the Limits of Tobacco Control Regulation.

> Our focus in this symposium on whether policy and advocacy for the regulation of SHS might sometimes go "too far." [Where] "going too far" in SHS policy means efforts premised on reducing harm to others, which ban smoking in outdoor settings such as ships' decks, parks, golf courses, beaches, outdoor parking lots, hospital gardens and streets. It is also the introduction of misguided policies allowing employers to refuse to hire smokers, including those who obey proscriptions on smoking indoors while at work. Many people are comforted by the smell of camp and log fires, even seeking out such exposures. But the same people will sometimes become outraged by the occasional, fleeting exposure to tobacco smoke. While nearly identical in terms of their noxious content, both forms of smoke have entirely different *meanings*. If radically different concerns about inhaling essentially the same zoo of noxious particles was all that mattered here, we would have to conclude that many people can be frankly irrational. But outrage about some forms of smoke and open acceptance of others is very explicable to sociologists of risk perception. Among the many key determinants of meaning and outrage are whether a noxious agent is seen as voluntary or coerced; natural or artificial; and whether the risk has been amplified by lots of media attention. We don't read much about the dangers of inhaling campfire smoke, smoke from incense or candles or cooking, but we read a lot about the dangers of secondhand cigarette smoke. I emphasize that I am very supportive of preventing smoking in crowded, confined outdoor

85. WILLIAMSON, *supra* note 46. *See also* STEPHEN T. HOLGATE ET AL., AIR POLLUTION & HEALTH (1999).

> settings such as sports stadia, in most outdoor dining sections of (particularly small) restaurants and in unblocking the entrances to buildings by having smokers move further away.[86]

My response to Professor Chapman's arguments follows: We agree completely on the principle of banning smoking in outdoor cafés and sports stadia. However, I disagree that because campfire smoke and smoke from incense, candles, or cooking have not (yet) received the same level of notoriety that SHS has (largely because they have not been researched until recently), that they do not pose both acute and chronic health hazards resulting from the toxicity of fine particles.[87] In fact, smoke from any source in places where people live, work, or congregate is going to pose a nuisance to many and an acute health hazard to some. Smoke from all of these sources is the product of incomplete combustion and is toxic to humans. As with indoor smoking, if enough persons complain about outdoor smoking, local governments will be moved to protect the public, as they have done for decades with factory smoke and auto exhaust, and are scientifically justified in doing so for OTS on the basis of the exposure analysis discussed herein.

IV. CONCLUSIONS AND POLICY IMPLICATIONS

In 1946, a city ordinance urged by concerned citizens was passed in Pittsburgh, Pennsylvania, despite the absence at that time of any scientific evidence of the health effects of outdoor air pollution levels on the population. Thus, early public air pollution policy was formulated on the basis of intuition. Similarly, a wave of restrictions on outdoor smoking has been passed in several U.S. states, despite the absence of health effects studies on OTS and the paucity of data on OTS concentrations. However, data is accumulating in support of the public's intuitive response to OTS. Recent field studies plus controlled experiments demonstrate that, regardless of which way the wind blows, individuals in an outdoor

86. Simon Chapman, Professor of Public Health at the University of Sydney, Austl., Presentation at the Tobacco Control Legal Consortium Symposium on the Limits of Tobacco Control Regulation at William Mitchell College of Law (Oct. 23, 2007).

87. *See generally* Wayne R. Ott & Hans C. Siegmann, *Using Multiple Continuous Fine Particle Monitors to Characterize Tobacco, Incense, Candle, Cooking, Wood Burning, and Vehicular Sources in Indoor, Outdoor, and In-Transit Settings*, 40 ATMOSPHERIC ENV'T 821 (2006).

café, transiting through a building doorway, on a public street, sidewalk or bus stop, even on the open deck of a cruise ship at sea, or otherwise surrounded by a group of smokers, are always downwind from the source and are thus subject to being enveloped in a cloud of obnoxious, irritating, asthmagenic, carcinogenic, and atherogenic fumes.

These studies also show that under a variety of conditions, levels of OTS can be as high as indoor levels of SHS. Smoking in the small volume of cars leads to much higher levels of tobacco smoke air pollution than in other enclosed environments. Individuals who suffer from asthma, especially children, are at acute risk from OTS. Healthy persons are subject to annoyance and increased risk of developing chronic disease from repeated OTS exposure over a lifetime. This new data confirms public intuition, demonstrating that public demand for smoke-free outdoor spaces is not "going too far," and justifies policies banning smoking in outdoor locations, in vehicles, where people congregate in public, or where workers are placed at risk, such as outdoor cafés.

Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems)

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EXECUTIVE SUMMARY

- E-cigarettes are evolving rapidly and being marketed like cigarettes were in the 1950s and 1960s
    - Marketing is back on television and radio
    - Aggressive placement in convenience stores (next to candy) and in other stores (next to medications)
- Youth are rapidly adopting e-cigarettes
    - E-cigarettes contain candy flavors (e.g., cherry, chocolate, turkish delight)
    - High levels of dual use
    - Youth who use e-cigarettes are heavier (not lighter) smokers
    - Youth who use e-cigarettes are much less likely to have stopped smoking (OR 0.1-0.2)
    - The temporal and causal relationships between e-cigarette use and smoking have not been determined
- E-cigarettes have not been proven to help people quit smoking
    - Longitudinal population studies show that e-cigarette use is associated with a lower odds of quitting
    - The randomized trial comparing e-cigarettes to nicotine patch shows that in the context of low level behavioral support, the quit rate for those using e-cigarettes is low and similar to those using a nicotine patch
- There is a high level of dual use of e-cigarettes and conventional cigarettes among adults
- The hope that e-cigarettes will reduce harm by delivering "clean" nicotine will not be realized in continuing dual users
    - Continuing to smoke any conventional cigarettes confers essentially the full cardiovascular risk
    - Cancer risk may only be modestly affected because smoking duration is more important than intensity
- E-cigarettes deliver lower levels of toxins than conventional cigarettes, but they still deliver some toxins
- E-cigarettes pollute the air less than conventional cigarettes, but they pollute the air
    - They do not just emit "harmless water vapor"
- People passively exposed to e-cigarettes aerosol absorb nicotine (measured as cotinine), with one study showing levels comparable to passive smokers
- There is little research on direct health effects
    - One study shows short-term pulmonary effects
    - Evidence of cytotoxicity in animal and human *in vitro* test systems
- While the original e-cigarette companies were competing with conventional cigarette companies, all the major cigarette companies are now in the e-cigarette business

- E-cigarette companies are using the same political and public relations strategies as cigarette companies (most notably organizing users, similar to how the cigarette companies organized smokers)
- E-cigarette policy making in many countries is dominated by assumptions about their use (utility as a smoking cessation aid or for harm reduction) that are not supported by the evidence available to date

At minimum, these policies should be implemented immediately:

- Prohibit the use of e-cigarettes anywhere where the use of conventional cigarettes is prohibited
- Apply the same restrictions on e-cigarette advertising and promotion as apply to conventional cigarettes
- Ban the use of characterizing flavors in e-cigarettes
- Prohibit claims that e-cigarettes are effective smoking cessation aids until such time as there is convincing scientific evidence that such claims are true for e-cigarettes as they are actually used in the general population.
- Regulate e-cigarettes to set standards for product performance in order to minimize risks to users and bystanders

Because the product, the market, and the associated scientific evidence surrounding e-cigarettes are all evolving rapidly:

- All legislation and regulations related to e-cigarettes should allow for flexibility to adapt regulations expeditiously in response to new science, including evaluation of different models for regulating e-cigarettes, as it accumulates
- No country or subnational jurisdiction should be compelled to permit the sale of e-cigarettes
- Legislation and regulations regarding e-cigarettes need to take into account the fact that, unlike conventional cigarettes and other tobacco products and medicinal nicotine replacement therapies, e-cigarettes can be altered by users to change the nicotine delivery and be used to deliver other drugs
- There should be transparency in the role of the e-cigarette and tobacco companies in advocating for and against legislation and regulation, both directly and through third parties
- FCTC Article 5.3 should be respected when developing and implementing legislation and regulations related to e-cigarettes

TABLE OF CONTENTS

This document served as one input for discussion on ENDS at the WHO Study Group on Tobacco Product Regulation (TOBREG) meeting in Rio in December, 2013. The interpretation of results and recommendations in the present document represent the opinions of the authors and not necessarily WHO or TOBREG.

BACKGROUND

E-cigarettes (also known as electronic nicotine delivery systems or ENDS) are a class of products intended to deliver nicotine-containing aerosol (incorrectly commonly called “vapor”) to a user by heating a solution typically comprised of propylene glycol and/or glycerol (glycerin), nicotine and flavoring agents (Figure 1). E-cigarettes without nicotine are also available. The first of these devices that started the trend in use we describe in this report was invented by a Chinese pharmacist, Hon Lik, in 2003. The U.S. patent application for the device states that the product is "An electronic atomization cigarette that functions as substitutes (sic) for quitting smoking and cigarette substitutes." (Patent #8,490,628 B2) E-cigarette sales have risen rapidly since they entered the marketplace in2007.(Pauly et al., 2007, Cobb et al., 2010) These products are marketed as healthier alternatives to tobacco smoking, useful in quitting smoking and reducing cigarette consumption, and a method for circumventing smokefree laws and enabling users to "smoke anywhere."(Grana and Ling, in press) Interest in the products has been increasing(Ayers et al., 2011) and an exponential rise in sales over the past 3 years (2010-2013) has been due, at least in part, to widespread advertising via television commercials and print advertisements, that often feature celebrities, for the most popular brands, including those owned by tobacco companies.(Felberbaum, 2013)

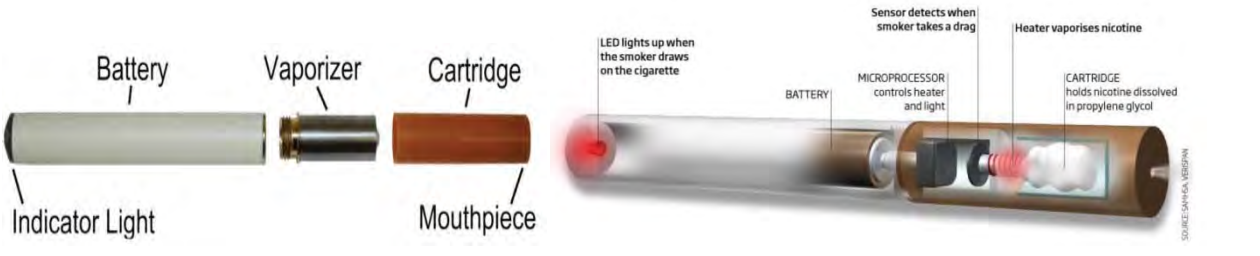

Figure 1. Diagrams of electronic cigarette design

In 2009, the WHO Study Group on Tobacco Product Regulation (TobReg) addressed the emerging regulatory issues pertaining to e-cigarettes. TobReg noted that there was very little published scientific evidence on the health effects of e-cigarettes, or their efficacy for smoking cessation (stated in TobReg Report 955)(World Health Organization, 2009) and that there was not sufficient evidence to support the cessation and health claims made by companies and those in the public health community who were advocating e-cigarettes for harm reduction. The report states (p.7), "In addition to nicotine dependence, the sensory effects of the product, social and

marketing forces and perceptions of harmfulness and potential benefits should be considered in examining the initiation, patterns of use and development of addiction."(World Health Organization, 2009) Meanwhile, e-cigarette prevalence has increased dramatically (Table 1, bottom of document)

Both the 2009 TobReg Report 955 and the 2012 World Health Organization Framework Convention on Tobacco Control (FCTC) Conference of the Parties report on e-cigarettes (November 2012)(FCTC/COP/5/13, 2012) articulated concerns about how the products may create interference with implementation of the FCTC articles that address non-price measures to reduce demand for tobacco products, particularly Articles 8(protection from tobacco smoke exposure), 9 (tobacco product content regulation), 10 (regulation of tobacco product disclosures), 11 (regulation of tobacco product packaging), 13 (tobacco advertising, promotion and sponsorship), because e-cigarettes mimic tobacco cigarettes, and thus may interfere with limits on the indirect promotion of tobacco use/products. E-cigarettes may hinder protection from exposure to tobacco smoke (Article 8) because, while the limited published research suggests that e-cigarettes emit much less and lower levels of toxicants into the environment than conventional cigarettes, they still subject bystanders to passive exposure (called “passive vaping” in Schripp et al., 2012)(Schripp et al., 2012) E-cigarettes are widely advertised and promoted (often inaccurately) as being exempt from clean indoor air laws. The similar appearance of people using e-cigarettes and those using conventional cigarettes can complicate enforcement of restrictions on smoking conventional cigarettes. Moreover, the e-cigarette aerosol has not been proven safe for inhalation by bystanders. A main concern with the products stated in the 2009 WHO report was lack of data on the safety of the ingredients in the e-cigarette solution, especially the safety of repeated inhalation of a heated mixture of propylene glycol and other chemicals.(World Health Organization, 2009) In 2009, TobReg recommended that if e-cigarettes were to be considered medicines or tobacco products, they would be subject to the labeling and warnings requirements in Articles 10 and 11. The TobReg report placed great emphasis on the products’ potential interference with Article 13, which addresses advertising and sponsorship by industry. Both Articles 8 and 13 can have the effect of denormalizing the use of tobacco products and indirect promotion of tobacco products through limiting exposure to tobacco smoke in public places (Article 8) and thus the modeling of smoking behavior in public and limiting advertising

Table 1. Prevalence of e-cigarette use in various countries as measured by published population-based surveys										
Authors	**Country, sample description, n**	**Ever use among general population (%)**					**Ever use among smokers (%)**			
		2009	2010	2011	2012		2009	2010	2011	2012
Regan et al. 2013	U.S., Adults 18+, n=10587 (2009); n= 10328 (2010), ConsumerStyles nationally-representative survey	0.6	2.7	--	--		Not reported	18.2	--	--
King et al. 2012	U.S., Adults, 18+, HealthStyles survey nationally-representative, mail-back (n=4,184) andonline (n=2505) modes n=6689 in 2010, online only n=4050 in 2011	--	2.1 mail, 3.3 online	6.2 online	--		--	6.8 mail, 9.8 online	21.2 online	--
Pearson et al. 2012	U.S., Adults 18+ , 2 samples									
	Nationally-representative online sample (Knowledge Networks), 2010, n=2649	--	3.4	--	--		--	11.4	--	--
	Legacy Longitudinal Study of Smokers (smokers and former smokers), 2010, n=3648	--	--	--	--		--	6.4	--	--
McMillen et al. 2013	U.S., Adults 18+, nationally-representative samples recruited via 2 survey modes: telephone-based (n=1504) and online (n=1736), Social Climate on Tobacco Control survey, 2010	--	1.8	--	--		--	14.4	--	--
Dockrell et al. 2013	U.K., Adults 18+, nationally-representative online panel (YouGov), 2010: n=12597 adults; 2010 n=12432	--	--	--	--		--	--	--	21.6
Adkison et al. 2013	ITC 4-country survey, Adults 18+,* July 2010-June 2011*									
	U.S. (n=1520)	--	--	--	--			20.4		
	Canada (n=1581)	--	--	--	--			10.0		
	U.K. (n=1325)	--	--	--	--			17.7		
	Australia (n=1513)	--	--	--	--			11.0		

Popova and Ling 2013	U.S., Adults 18+, nationally-representative online sample (Knowledge Networks), current and former smokers, n=1836	--	--	--	--		--	--	20.1	--
Cho et al. 2011	Korea, Adolescents, middle school and high school, n=4,341, national survey in 2008*	0.5*	--	--	--		--	--	--	--
Lee et al. 2013 (in press)	Korea, Adolescents, middle school and high school, grades 7-12, ages 13-18, (Korean Youth Risk Behaviour Study) n=75,643			9.4%						
CDC NYTS 2013	U.S., Adolescents, middle and high school, 2011, 2012 National Youth Tobacco Survey (n's not reported)	--	--	MS: 1.4 HS: 4.7	MS: 2.7 HS: 10.0		--	--	--	--

and sponsorship by tobacco companies (Article 13). These policy measures could be undermined by the permitted use of a cigarette-like product that produces a smoke-like aerosol in public and widespread, unrestricted advertising of such products in ways that have been restricted for cigarettes and other tobacco products by the implementation of Article 13.

There has been rapid e-cigarette product innovation in the marketplace despite many unanswered questions about their safety, efficacy for harm reduction and cessation, and total impact on public health. Several commentaries and editorials have been published in the scientific press debating these issues (e.g.,(Britton, 2013, Benowitz and Goniewicz, 2013, Chapman, 2013, Cobb et al., 2010, Etter, 2013, Wagener et al., 2012)) and the number of scientific studies on e-cigarettes is growing. Both the individual risks and benefits and the total impact of these products occur in the context of the widespread and continuing availability of conventional cigarettes and other tobacco products, with high levels of "dual use" of e-cigarettes and conventional cigarettes at the same time among both adults(Adkison et al., 2013, King et al., 2013, Dockrell et al., 2013, Pearson et al., 2012, Regan et al., 2013) and youth.(Centers for Disease Control and Prevention, 2013) This dual use raises questions about the possible harm reduction benefits. It is important to assess e-cigarette toxicant exposure and individual risk as well as health effects of e-cigarettes as they are actually used in order to ensure safety and to develop evidence-based policies and a regulatory scheme that protects the entire population, children and adults, smokers and non-smokers, in the context of how the tobacco industry is marketing and promoting these products.

This report reviews the literature on e-cigarettes available as of September 2013, as well as an update of tobacco industry involvement in the e-cigarette market, research recommendations, global regulations pertaining to e-cigarettes, and potential options for regulation.

METHODS

Initial searches were conducted via the PubMed electronic database using keywords to identify studies describing electronic cigarettes (electronic cigarette, e-cigarette, electronic nicotine delivery systems). The initial searches yielded 153 studies, of which 125 were identified as relevant to electronic cigarettes (Figure 1). Seventy-eight published papers retrieved from those searches were formally reviewed to meet the aims of the present report. Seventy-five

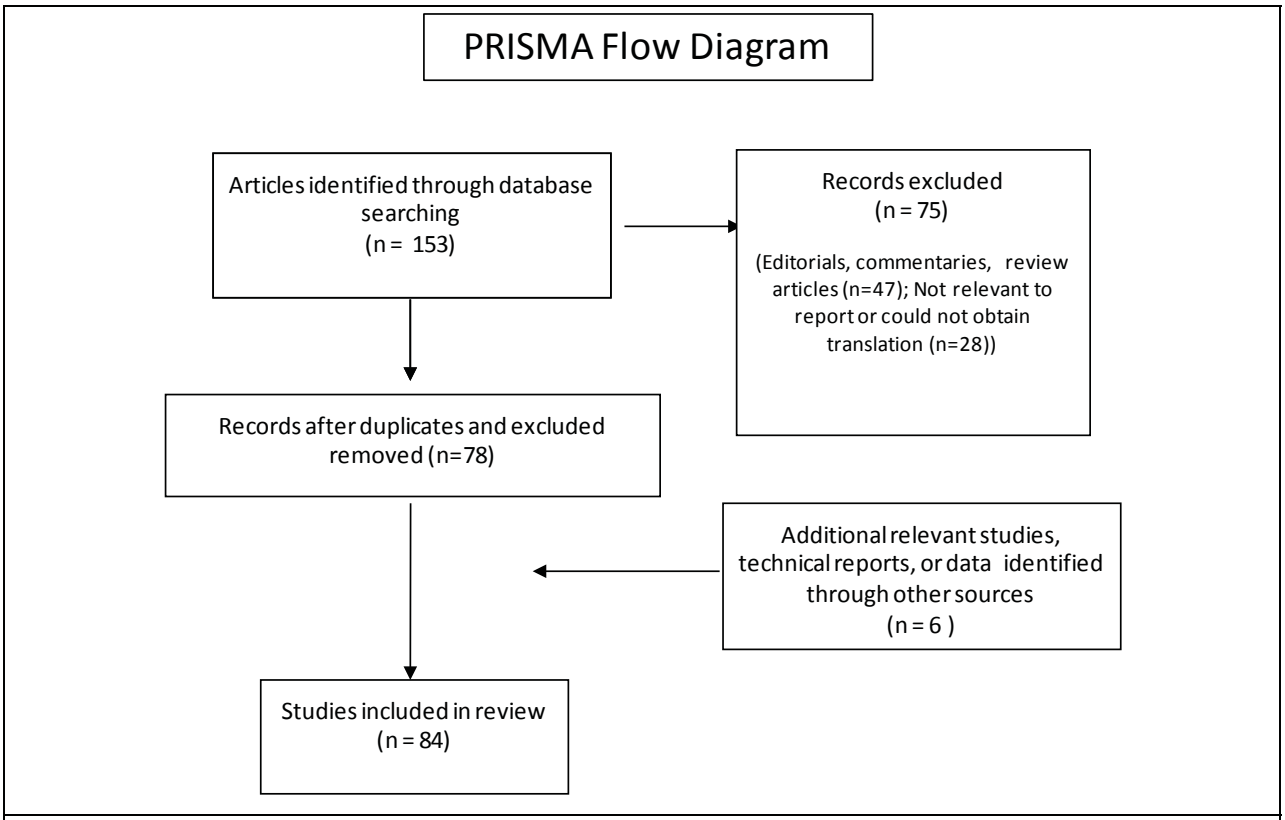

Figure 1. Studies screened and selected for inclusion.

studies were excluded from systematic review were commentaries that did not provide original data, (they are cited to provide background and context.) Searches using the same search terms as above were conducted in the WHO regional databases (electronic cigarette, e-cigarette, electronic nicotine delivery systems). Relevant papers were located in only one database, BIBLIOTECA Virtual em Salude Latin America and Caribbean, and all of the results were already retrieved by the initial searches in PubMed. In addition, the authors, working with WHO, reached out to investigators in the field in an effort to locate studies that had not yet been published (submitted or in press). Each study included in the systematic review was analyzed for content, quality and industry funding (tobacco or e-cigarette companies). After review, each study was categorized according to the main subject headings: marketing and media, prevalence, chemical analyses, biological effects, cessation of conventional cigarettes. Some articles were discussed in other sections of the report: product engineering and product performance and risks to users and bystanders.

Authors also reviewed and included non-peer-reviewed documents, including the World Health Organization Study Group on Tobacco Product Regulation, Technical Report Series 955,(World Health Organization, 2009) a FCTC Conference of the Parties report: “Electronic nicotine delivery systems, including electronic cigarettes. Report by the Convention Secretariat,”(FCTC/COP/5/13, 2012) German Cancer Research Center report, “Electronic Cigarettes – An Overview,”(German Cancer Research Center, 2013)a technical report: “Peering through the mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks?”(Burstyn, 2013) Several published news articles and relevant websites are cited to provide supporting documentation and context to the scientific review.

PRODUCTS (TYPES, ENGINEERING)

E-cigarettes have many names, including electronic cigarettes, ENDS and e-hookah. For the purposes of this report all these products will be referred to as e-cigarettes. Product engineering has been evolving since the first e-cigarettes were documented as arriving on the global market in 2007(Pauly et al., 2007). As of late 2013, there was wide variability in product engineering, including varying concentrations of nicotine in the solution that e-cigarette use to generate the aerosol (also called "e-liquid"), varying volumes of solution in the product, different carrier compounds (most commonly propylene glycol with or without glycerol (glycerin), a wide range of additives and flavors, and battery voltage. Battery voltage differences and unit circuitry can result in great variability in the products' ability to heat and convert the nicotine solution to an aerosol and, consequently, may affect actual nicotine delivery and other chemicals delivered to users and emitted in the exhaled aerosol. Products come in a variety of nicotine strengths (including some without nicotine), usually expressed in mg/ml of solution or percent concentration. Williams and Talbot (2011) measured e-cigarette products' performance across three indicators: airflow rate required to generate aerosol, pressure drop , and aerosol density via three different protocols, finding that air flow and pressure drop required to activate e-cigarette products is quite variable between brands.(Williams and Talbot, 2011) Moreover, the products are "smoked" differently than cigarettes. Hua and colleagues conducted an analysis of 9 videos with tobacco smoking and 64 with e-cigarette "vaping" to assess differences in "smoking" topography between e-cigarette users and conventional cigarette users. Authors found that average length of a puff taken from an e-cigarette was significantly longer than that of tobacco

users (4.3 seconds vs. 2.4 seconds, respectively) and there was a wide range in puffing duration for e-cigarettes (2 to 8.3 seconds).(Hua et al., 2013b)

Quality of product functioning and performance is highly variable and inconsistent,(Trtchounian and Talbot, 2011) and users can modify many of the products. In addition, as the types and design of products and their contents continue to evolve rapidly, it is increasingly difficult to determine what an e-cigarette "is," what it may contain, and what it is delivering to the user and the surrounding environment. The rapid and continual evolution of products makes it difficult to conduct research on the products and generalize study findings to all products because they may become quickly outdated.

The first e-cigarettes were cigarette-shaped, plastic or metal devices comprising three parts: a battery, a reservoir for e-cigarette solution (usually containing nicotine) often with a fibrous material on which the solution is placed, and a heating element (sometimes referred to as an atomizer) which attaches to the battery and converts the liquid into an aerosol (Figure 1). In subsequent models the cartridge was called a cartomizer, which combined the e-liquid reservoir with the wick/fiber and heating element into a single unit (Figure 2). The cigarette-shaped and sized devices are often called “mini” e-cigarettes or "cig-a-likes" by users (who often call themselves “vapers”). There are disposable and rechargeable e-cigarette models (Figure 2). More recent designs are larger models that are pen-shaped and sized with cartomizers (Figure 2) that often hold more nicotine solution to reduce the amount of times a user needs to refill throughout the day. Some cartridges, called clearomizers and "tank systems," hold several ml of e-liquid, are transparent, and allow the user to monitor the level of fluid they contain. There are also much larger capacity and technologically sophisticated tank system devices (Figure 2) that have various mechanical and/or digital display features. One such feature is a larger metal casing for the batteries, which is able to be opened and the batteries replaced according to user preferences. In some tank devices the heating elements and batteries can be replaced with more powerful batteries or lower electrical resistance heaters that allow the user to control how the e-liquid is vaporized (these devices are often referred to as variable voltage devices by users). Furthermore, since the first e-cigarette products appeared on the market, users have been modifying the devices and creating their own; instructions to do so are widely available on the Internet on e-cigarette forum sites and YouTube. A concerning trend that has been occurring at least in the U.S. and is owed largely to the refillable nature of e-cigarettes, is the use of the devices to smoke

Product	Description	Some Brands
Disposable e-cigarette 	Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution (with or without nicotine). Not rechargeable or refillable and is intended to be discarded after product stops producing aerosol. Sometimes called an e-hookah.	NJOY OneJoy, Aer Disposable, Flavorvapes
Rechargeable e-cigarette 	Cigarette-shaped device consisting of a battery that connects to an atomizer used to heat a solution typically containing nicotine. Often contains an element that regulates puff duration and /or how many puffs may be taken consecutively.	Blu, GreenSmoke, EonSmoke
Pen-style, medium-sized rechargeable e-cigarette 	Larger than a cigarette, often with a higher capacity battery, may contain a prefilled cartridge or a refillable cartridge (often called a clearomizer). These devices often come with a manual switch allowing to regulate length and frequency of puffs.	Vapor King Storm, Totally Wicked Tornado
Tank-style, large-sized rechargeable e-cigarette 	Much larger than a cigarette with a higher capacity battery and typically contains a large, refillable cartridge. Often contains manual switches and a battery casing for customizing battery capacity. Can be easily modified.	Volcano Lavatube

Figure 2. Examples of different e-cigarette products

marijuana in the form of a liquid and wax dabs (a concentrated form of marijuana, mainly comprising THC).(Givens and Cheng, October 11, 2013, Shuman and Burns, May 24, 2013)

E-liquids are offered in a variety of flavors. A content analysis of 59 e-cigarette websites conducted in 2012,(Grana and Ling, in press) e-cigarettes and the nicotine solution were found to come in tobacco (95%), menthol (97%), coffee (61%), fruit (73%), candy (71%) and alcohol (10%) flavors, as well as more unusual flavors such as “cola” and “Belgian waffle.” Flavor is an important product characteristic in determining who is attracted to a product and the ability to get started on a product. The 2012 US Surgeon General’s Report, Preventing Tobacco Use among Adolescents and Young Adults, found that flavored tobacco products are disproportionately used by youth and initiators (U.S. Department of Health and Human Services, 2012). Since flavors

play a key role in promoting youth tobacco use, cigarettes with these characterizing flavors (with the exception of menthol) have been banned in the U.S. and a flavor ban on nicotine containing products (which includes e-cigarettes) was included in the proposed revision of the EU Tobacco Products Directive (TPD) produced by the European Commission. On 8 October 2013 the EU Parliament deleted this provision, which would allow flavored e-cigarettes (European Parliament, 2013). As of November 2013 there were ongoing negotiations between the European Parliament, the European Council and the European Commission over the final wording of the TPD. To the best of our knowledge, there were no restrictions on flavored e-cigarettes anywhere in the world.

PRODUCT PERFORMANCE AND POTENTIAL RISKS TO USERS AND BYSTANDERS

E-cigarette devices are manufactured mainly in China. There are concerns about risks posed by e-cigarette and e-cigarette solution. Trtchounian and Talbot (2011) examined 6 brands of products for design, content, labeling, quality and product information including warnings.(Trtchounian and Talbot, 2011) Most of the e-cigarette starter kits purchased came with some instructions. Most provided information about the battery and how to connect the parts of the devices, but did not come with a list of product ingredients, or health warning messages. Most of the products leaked when handled and cartridges came with fluid leaked on them, creating the potential for dermal nicotine exposure and potential nicotine poisoning.(Trtchounian and Talbot, 2011)

Propylene glycol and glycerin comprise the main base ingredients of the e-liquid and helps to generate the aerosol used to deliver nicotine and other compounds to the user. This aerosol looks like smoke. There is concern about potential health effects of chronic inhalation of the vaporized base components of the e-liquid.

As first summarized in the report on electronic cigarettes produced by the German Cancer Research Center in 2013,“Electronic Cigarettes – An Overview,” these chemicals are approved for ingestion in food, cosmetics and some drug preparations by many government regulating agencies (U.S., E.U.(German Cancer Research Center, 2013)). Ingestion is a different mode of administration than inhalation so these safety decisions may not be relevant to e-

cigarette use. Glycerin (also called glycerol), is also approved for use in food and cosmetics, is also not explicitly approved for human inhalation.(German Cancer Research Center, 2013)

Regarding inhalation, a Master Data Safety Sheet, guidance for the industrial use of propylene glycol by Sciencelab.com, Inc., states it can cause eye and respiratory irritation and "Prolonged or repeated inhalation may affect behavior/CNS (with symptoms similar to ingestion), and spleen."(Sciencelab.com Inc., 2013)A major manufacturer of propylene glycol, the Dow Chemical Company, states in its product safety materials that the "inhalation exposure to [propylene glycol] mists should be avoided"(Dow Chemical Company, 2013) and the American Chemistry Council warns against its use in theater fogs due to its potential to cause eye and respiratory irritation.(The American Chemistry Council, July 2001) When heated and vaporized, propylene glycol can form propylene oxide, an IARC class 2B carcinogen.(Laino T et al., 2012) and glycerol forms acrolein, which can cause upper respiratory tract irritation.(U.S. EPA, Henderson TR et al., 1981)

Major injuries and illness have resulted from e-cigarette use, which may be related to lack of basic safeguards in the product design and manufacturing process, as well as the contents of the solution. Tobacco product adverse events can be reported to the Food and Drug Administration (FDA), Center for Tobacco Products (CTP). Chen (2012) summarized the 47 adverse event reports filed with the FDA CTP between 2008 and early 2012 regarding e-cigarettes; finding that 8 of these 47 adverse events were serious health issues with examples including hospitalization due to congestive heart failure, hypotension, pneumonia, chest pain and "possible infant death secondary to choking on e-cig cartridge."(Chen, 2013) Reporting of an adverse event does not indicate causation, but it does raise questions of biological plausibility that need to be addressed. Examples of less serious adverse events include nausea, vomiting and sore throat. Moreover, one e-cigarette company also instructs users to draw on the product differently from a cigarette because they might experience adverse reactions, stating: "If you find yourself smoking your e-cigarette the way you smoke a traditional cigarette, you are doing something wrong. **As a matter of fact, if you vape your e-cig as you smoke your cigarette you will find yourself with a sore throat, sore lungs, an incessant cough and irritation in your mouth and throat.**[bold in original]"(Metro E-cigarette Website)

An18-month old girl in the U.S. became seriously ill after drinking e-cigarette liquid in a refill container that was left in the child's reach and did not come with a child-proof cap.(Shawn

and Nelson, 2013) A child in Israel died of nicotine poisoning from drinking her grandfather's e-cigarette solution.(Winer, May 29, 2013) e-cigarettes have exploded and caught fire, causing serious injury. A man in Florida suffered severe burns and lost half his tongue due to an e-cigarette battery exploding in his face.(CBS NEWS, February 16, 2012) A woman in Atlanta escaped serious injury from an e-cigarette that exploded in her home, starting a fire.(Strickland, 2013) These problems are common enough that e-cigarette internet forums and some retail websites advise that the lithium batteries may explode or overheat when left to charge for long periods of time or in direct heat exposure or if charged with the wrong charger or a powerful electrical source. An e-cigarette forum (www.e-cigarette-forum.com) has a section in which advice is given about the risks of specific battery types.(E-cigarette-forum) Because e-cigarette are not regulated there is no systematic collection of information on these issues, which is likely to result in under-reporting. It is also unknown to what extent these problems could be eliminated by stronger regulatory standards on the product itself.

MARKETING AND MEDIA RESEARCH

While most attention from the biomedical community has been on the e-cigarette device, the aerosol that it delivers to users (and, to a lesser extent, bystanders), and the potential of e-cigarettes for cessation of conventional cigarettes, much of the public discourse and popular understanding about use of e-cigarettes has been determined by how they have been marketed and covered in the news media. In order to understand patterns of product use, it is important to understand the marketing claims promoted to the public about e-cigarettes and how products and marketing is designed to attract different segments of the population (such as never users of nicotine or tobacco products, youth, current smokers, and former smokers). Consumer perceptions of the risks and benefits posed by e-cigarettes, both independent risks and relative to cigarettes and other tobacco products, are important factors in determining uptake and consequently the total public health burden due to tobacco use. For example, claims that e-cigarettes are less harmful than cigarettes may encourage adoption by non-smokers (potentially children) as well as smokers seeking to quit conventional cigarettes. Promotion of e-cigarettes as a convenient alternative to cigarettes when a smoker cannot light up would blunt the effect of smokefree laws on smoking cessation. The explicit promotion of dual use (as has also been done

with snus) for places where people cannot smoke cigarettes (Figure 3) has important implications for the ultimate use patterns and health impact of introducing e-cigarettes into the marketplace.

Grana and Ling (in press) systematically reviewed a sample of single-brand e-cigarette retail websites (n=59) that were online in 2012 to determine the main marketing messages, type

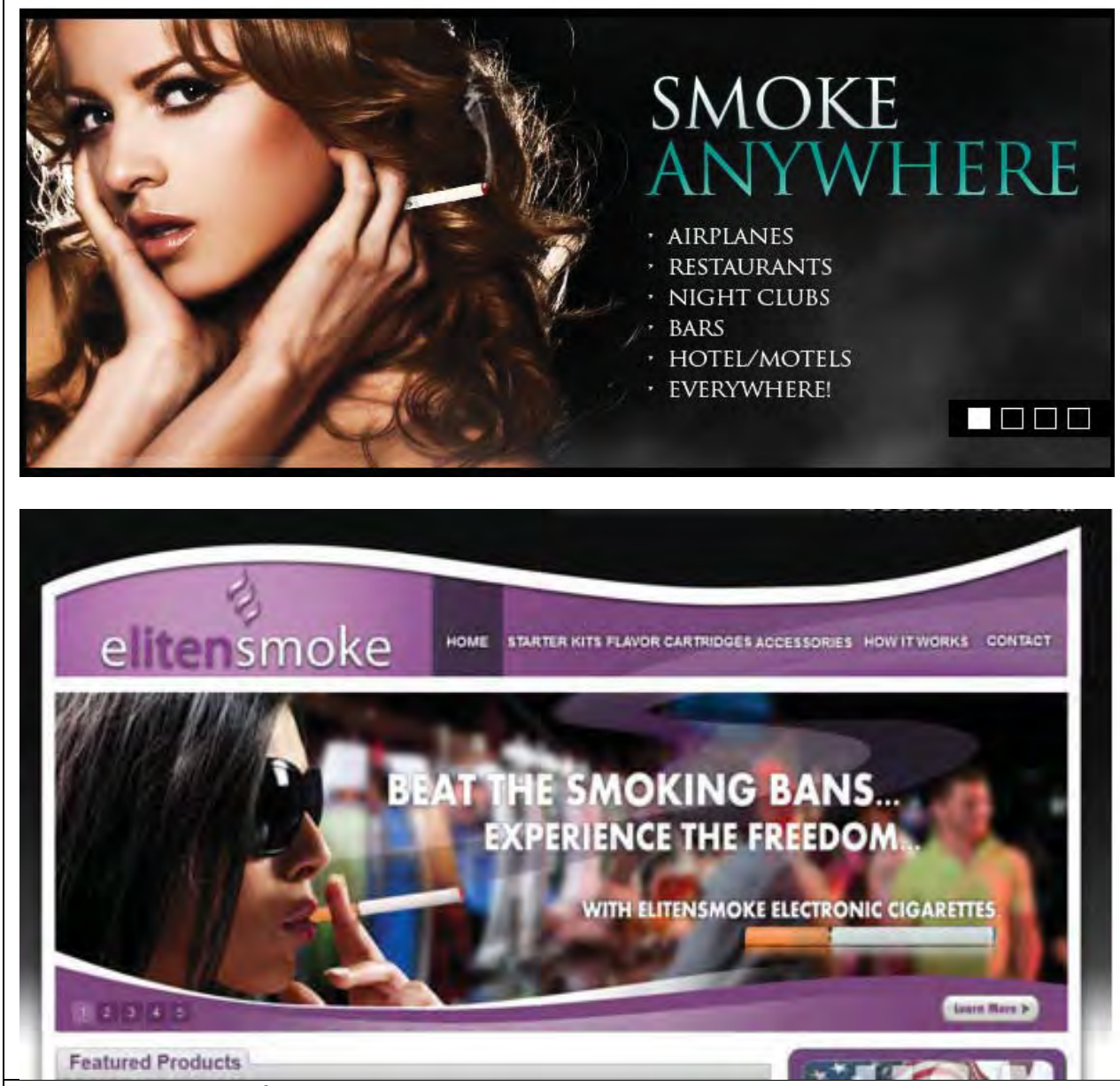

Figure 3. Examples of marketing claims to use e-cigarettes to "smoke anywhere" and "circumvent smokefree laws" (www.smokingeverywhere,com; www.elitensmoke.com) June 2012

of products sold and unique marketing features on the sites.(Grana and Ling, in press) They found that the most popular claims were that the products are healthier (95%), cheaper (93%) and cleaner (95%) than cigarettes, can be smoked anywhere (88%), can be used to circumvent smokefree policies (71%), do not produce secondhand smoke (76%), and are modern (73%). Health claims were also made through pictorial and video representations of doctors, which were present on 22% of sites. Cessation-related claims (ranging from overt statements that one can use the product to quit smoking to indirect claims such as "you'll never want to smoke tobacco cigarettes again") were found on 64% of sites. Claims about effects on bystanders frequently included statements that e-cigarettes emit "only water vapor" that is harmless to others.

Another more subtle way e-cigarettes are presented as a healthier option than conventional cigarettes on e-cigarette-related websites is through information and claims about nicotine.(Tobacco Vapor Electronic Cigarette Association) When mentioning that the products contain nicotine, sites often offer information that nicotine is not the harmful substance in cigarettes. In addition, information about the characteristics of nicotine is presented in a misleading way, with sites presenting nicotine as derived from plants other than tobacco, including eggplant and tomatoes, where the levels are so low that it would require eating pounds a day to take in nicotine in amounts to rival that of nicotine from a secondhand smoke exposure, and also presenting positive aspects of nicotine use on cognition.

Some e-cigarette websites (as well as some scientific commentators)(Phillips and Rodu, Britton, 2013) trivialize the addictive properties of nicotine by comparing it to caffeine. For example, one e-cigarette shop website includes this information in a section called "About the E-Cig:"

> **Is Nicotine harmful?**
>
> Nicotine is not the harmful ingredient in tobacco, it is the smoke that kills: the smoke and combustion artefacts cause lung cancer, heart disease and many other illnesses. Also, everyone tests positive for nicotine in the bloodstream, in very small amounts, since it is a common ingredient in vegetables. A related material, nicotinic acid, is a vitamin Niacin or Vitamin B3 so to say it is universally harmful is obviously untrue. Without the smoke, smoking is likely to be far less harmful, as nicotine may be as harmful as the caffeine in coffee. Nicotine is best avoided by those who are pregnant or have heart disease. You may want to avoid it if you also do not take caffeine or alcohol by drinking coffee, tea, wine or beer. Like these substances, it should probably not be started in the first place. Some people however find their lives are dysfunctional without nicotine, and an electronic cigarette is probably as good a way as any to supply it. www.itisvapor.com, Last accessed November 24, 2013

While nicotine is not the only or most dangerous thing in conventional cigarette smoke, claims that nicotine is harmless is not supported by the scientific evidence as summarized in the 1988 Surgeon General's Report on *The Health Consequences of Smoking: Nicotine Addiction*, addressed this comparison directly:

> Most categories of drugs which have been found to cause widespread drug dependence in the nonlaboratory setting have been tested with animals and humans in laboratory settings. Results of these studies have been reviewed in detail elsewhere Several categories of drugs have been found to be self-administered by humans and animals in the laboratory settings, to meet criteria as positive reinforcers, and to exhibit orderly relations as a function of drug dose, drug pretreatment, and other factors known to affect the intake of dependence-producing drugs. These include alcohol, morphine, pentobarbital, amphetamine, cocaine, and nicotine in the forms of cigarettes and i.v. injection.
>
> Self-administration studies with animals are much more extensive and have also been reviewed in detail elsewhere. In brief, drug self-administration studies in animals in the 1960s showed that a range of drugs including opioids, amphetamines, barbiturates, certain organic solvents, alcohol, cocaine, and nicotine were self-administered. All of these drugs were found to maintain powerful chains of drug-seeking behavior, even when insufficient drug was taken to produce a clinically significant degree of physical dependence. *Drugs that did not serve as reinforcers in these studies included caffeine*…" [emphasis added, citations deleted](U.S. Department of Health and Human Services, 1988)

It is not reasonable to state or imply an equivalence between nicotine and caffeine.

The use of celebrities in product marketing has been occurring since at least 2009.(Grana et al., 2011) In Poland, a popular ad (as of March 2012) featured a famous actor with the tagline 'You can smoke wherever you want.' In the U.S., Katherine Heigl, a famous U.S. actress went on the David Letterman Show, a popular late night program in the U.S. and spent much of her interview discussing her quit attempt with the e-cigarette and even used an e-cigarette on stage with Mr. Letterman (Figure 4). At the time, she had a relationship with the company where a portion of sales of an e-cigarette called the Pitbull were donated to a charity of her choice, Compassion Revolution. The video of the interview with David Letterman was on the site as well as posted on other websites and widely used in many online press releases and advertorials.

Rooke and Amos (2013) conducted a thematic analysis of newspaper and online media coverage about electronic cigarettes in the UK and Scotland from July 2007 to June 2012 (n=119 articles, editorials and columns; 44 from July 2007- June 2010, 75 from July 2010- July

Figure 4. Katherine Heigl smoking an e-cigarette on the set of the David Letterman Show, a popular late-night national television program in the United States, September 2009)

2012).(Rooke and Amos, 2013) Five themes emerged: "healthier choice" (71 articles), "getting around smokefree" (44 articles), "celebrity use" (41 articles), "price" (41 articles), and "risk and uncertainty" (31 articles). They found that the articles published earlier focused on e-cigarettes as a way to circumvent clean indoor air policies, with the healthier choice theme appearing as an aside. Authors noted that the smokefree-themed articles were "rebellious" in tone and presented e-cigarettes as a way to "beat" smoking bans and give users the "freedom to smoke where [they] want." The healthier choice theme increased as a main focus of articles over the years included in the study, with e-cigarettes presented as posing less risk to tobacco cigarettes and potential for use as a smoking cessation aid. Authors noted that the healthier choice claims were often presented as a defense to issues of potential risk and uncertainty about the products, focusing on them as a healthier alternative for smokers and for use in quitting smoking. Potential risks related to lack of product and safety information were usually raised by health officials and included concerns about the poisonous nature of nicotine and risks of accidental overdose or ingestion by children. However, authors note that the "healthier" themed articles also focused on e-cigarettes

as part of "safer cigarette" development by the tobacco industry and as part of the concept of tobacco harm reduction, noting that the coverage "suggested official backing for e-cigarettes and highlighted their 'potential to save lives.'" Stories about celebrity use of e-cigarettes appeared after 2009, focusing on e-cigarettes as the latest stylish, "must-have" item and often emphasizing use of the products to get around smokefree laws and to quit smoking. Coverage often included anecdotes about having tried nicotine replacement therapies (NRT), failing to quit and then trying the e-cigarette, thus implying that e-cigarettes are a more effective form of NRT. Specifically, the Katherine Heigl appearance on the David Letterman television program noted above in Grana et al. (2011) is cited as an example in this article, demonstrating its widespread reach through news and marketing channels and thus the widespread reach of the "cessation aid" message.(Grana et al., 2011)

An innovation that e-cigarette companies have employed since their advent is web-based affiliate marketing (e.g., third-party product promotion that leads to sales, often disguised as a press release or news article). Cobb et al.(2013) performed a forensic analysis of e-cigarette Internet marketing practices in order to track the links between affiliate advertising, affiliate marketing sites and the retailer websites selling the products and to compare the therapeutic (smoking cessation) claims on the affiliate marketing and the seller's website.(Cobb et al., 2013) The analysis revealed that affiliate marketing contained therapeutic claims while the retailer website linked to the affiliate did not. A brief descriptive analysis of 20 websites documented that 12 had affiliate programs, 11 made health claims and 4 made cessation claims.(Cobb et al., 2013) Current legal precedent in the U.S. classifies e-cigarettes as tobacco products unless they are marketed with therapeutic claims and many retail website contain a disclaimer usually in fine print at the bottom of the homepage or in the FAQ section that the products are not intended to treat disease or not intended for smoking cessation.

Another innovation employed effectively by e-cigarette marketers and retailers is the use of social media and viral video sharing. In an analysis of e-cigarette-related Youtube videos (n=396) posted from 2007-2011, Paek et al. (2013) found that 85.2% of videos had a clear sponsorship by e-cigarette companies or their affiliate marketers.(Paek et al., 2013) Despite the industry sponsorship, 79% appeared to be user-generated and only 17% were formal advertisements or news clips. The videos communicated health and smoking cessation claims, with 21.4% presenting e-cigarettes as "less harmful than other tobacco products," 12% claiming

they are “healthy,” and 9.3% “can help you quit smoking;” but non-marketer sites presented significantly more health claims than marketer videos. A high level of information about the product was presented in the videos indicating the use of common retailer marketing tactics (product (68%), price (34%), place (65.5%), brand-specific taste (39.5%) and design (18.9%)). In an analysis of viewer preferences, the number of “likes” on each video was counted at time of download and a hierarchical regression was conducted to determine significant predictors of number of likes. Number of views was the strongest statistically significant predictor of likes ($p<.001$), and more weakly associated variables were "not having an obvious advertising message" ($p=05$), "presented a social benefit" ($p=.05$), and those had a "positive valence" ($p<.01$).

In the only published study as of November 2013 on the effects of viewing e-cigarette television advertising on adult smokers and recent quitters (n=519) in an online convenience sample, Kim et al. (2013) found that after viewing a popular TV commercial for Blu e-cigarettes 75.8% of the sample reported the ad made them think about smoking, 74.3% reported it made them think about quitting and 66% said it made them likely to try e-cigarettes in the future.(Kim et al., 2013) In addition after viewing the ad, participants mean reported urge to smoke was 42.1(SD=1.9) on a 100 point scale from “no urge” to the “strongest urge I have ever experienced”). Persons who had used e-cigarettes (34% of the sample) were statistically significantly more likely to think about smoking cigarettes after viewing the ad than non-users (82.7% and 72.2%, respectively). There were no statistically significant differences in urge to smoke and thinking about quitting for e-cigarette ever-users vs. non-users.

While originally promoted almost exclusively on the internet, marketing activities for e-cigarettes have increased dramatically, with the increasing promotion of e-cigarettes on television in some countries (e.g., U.S., U.K.). In the U.S. television advertising is largely by Lorillard, Inc., a multinational tobacco company based in the U.S. and the first of the cigarette companies to enter the e-cigarette business when it purchased Blu brand e-cigarette in 2012(Esterl, April 25, 2012) and the U.K. brand of e-cigarettes, Sky Cig, in 2013.(Esterl, October 1, 2013) As of late 2013, Lorillard has one of the largest U.S. national TV campaigns, which includes use of celebrities to glamorize e-cigarettes and shows them inhaling and exhaling what looks like smoke. Also, in the U.S., the e-cigarette company NJOY aired a commercial in a regional television market during the 2013 National Football League Superbowl game.(Hodge Jr.

et al., 2013) In the U.K. the commercials range from showing young people out enjoying themselves (SkyCig) to older people who are tired of missing out on major life events due to their smoking (E-Lites), a sentiment more associated with the harm reduction or NRT approach. Jenny McCarthy, a TV host and model, appears in a 2013 Blu advertisement that glamorizes e-cigarette use and emphasizes the romantic opportunity it could create (Figure 5). Moreover, this advertisement is set in a bar which recalls the pairing of cigarettes and alcohol and makes that connection for e-cigarettes, and is likely to appeal to older adolescents and young adults, the population that spends disproportionately more time out in bars trying to develop romantic relationships. Blu also has another actor in its commercials, Stephen Dorff, whose rugged good

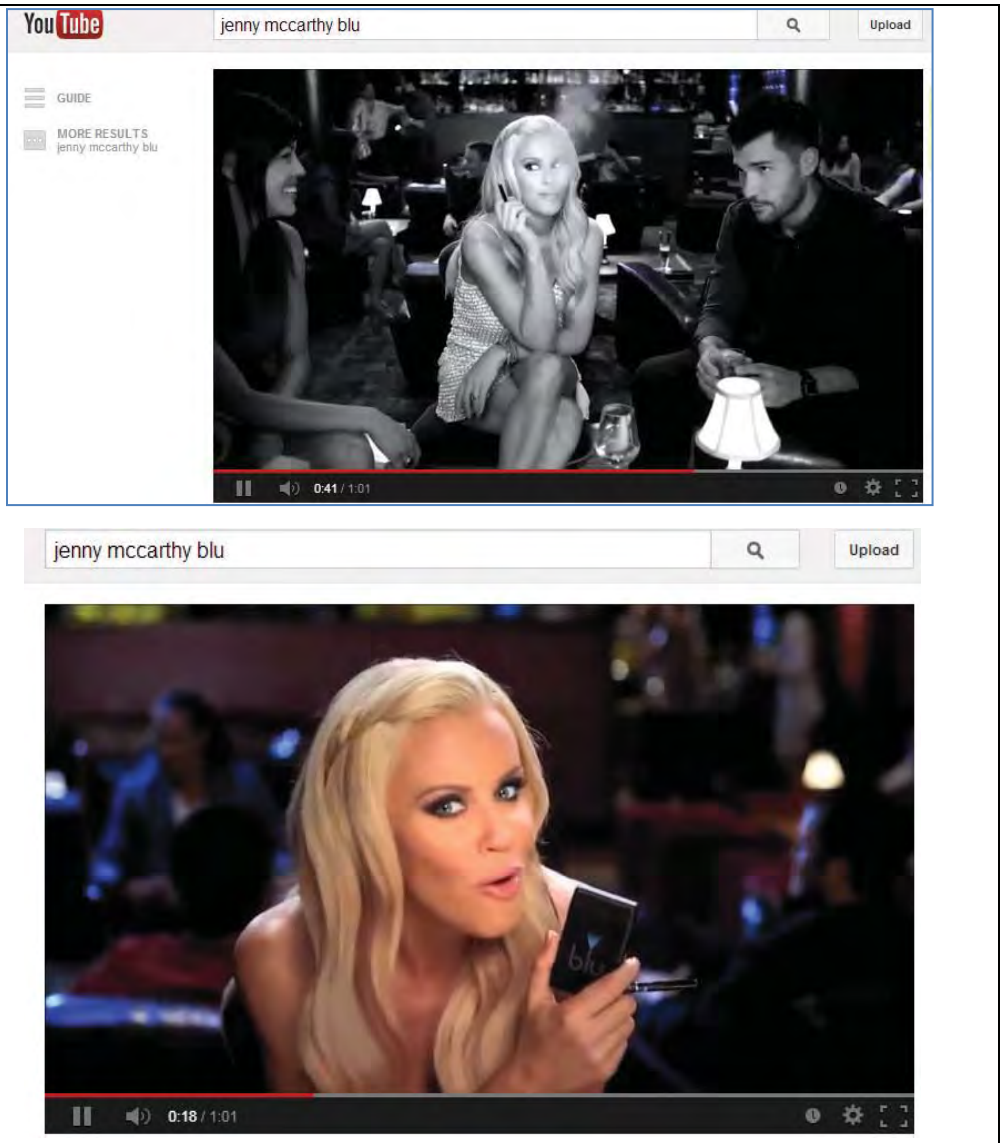

Figure 5. Celebrity Jenny McCarthy in Lorillard's Blu e-cigarette television commercial (as of October 2013)

looks recall the Marlboro Man but in a suit, and e-cigarette brand NJOY uses rebel rockstar Courtney Love.(BluCigs, 2012)

Conclusion

As of 2013, e-cigarette companies (including cigarette companies who have purchased e-cigarette companies) are marketing e-cigarettes using some of the same claims, tactics and media channels – including television and radio -- that were effective at marketing cigarettes to attract young people and deter smokers from quitting before use of these channels to market cigarettes was banned.

The fact that a large majority of e-cigarette retail websites encouraged the use of the products anywhere and everywhere (88%), specifically noting places where cigarette smoking would be banned (71%) and places for socializing, has direct implications for regulation of e-cigarettes and implementation of the FCTC. These messages can be used to undermine the idea of smoking restrictions and existing smokefree laws designed to apply to tobacco smoke. Importantly, it appears that both the e-cigarette companies and tobacco companies are focused on creating positive social norms for the products, encouraging their use "anywhere" and promoting them explicitly to get around smokefree laws (which are effective tobacco control measures), and promoting their use as socially acceptable. The totality of the messaging creates familiarity among smokers by emphasizing the similarity to a cigarette and the smoking experience while simultaneously assuring the smokers and their family and friends (and perhaps kids) that it is entirely different than a cigarette. A 2013 commercial for e-cigarettes, FIN, comes with the tagline “Rewrite the Rules,” and a direct quote from the commercial states, “There was a time when no one was offended by it – that time has come again.”(FIN Electronic Cigarettes, May 25, 2013)

Television and radio have been unavailable to the cigarette and other tobacco companies to market their products in the US (as well as much of the world) since the 1970s. E-cigarette advertising on television and radio is mass marketing of an addictive nicotine product for use in a recreational manner to new generations who have never experienced such marketing. This pervasive marketing may have implications for existing smokers as well as the one published study on this topic indicates that viewing an e-cigarette commercial may induce thoughts about smoking and cue the urge to smoke among adult smokers.(Kim et al., 2013)

PREVALENCE

Adults

International Samples

The Eurobarometer survey in 2012 (n=27 countries, n=26,751) assessed awareness, attitudes toward and prevalence of ever-using e-cigarettes in the European Union.(TNS Opinion & Social, 2012) Male and younger aged respondents had the greatest awareness of e-cigarettes. The greatest awareness was in Finland (92%) and Greece (90%) while the lowest was in Sweden (34%). In general, more Europeans in this survey were unsure if they think e-cigarettes were harmful to health (38%) or think that they are not harmful to health (35%) than thinks they are harmful to health (27%). Seven percent of European Union respondents have tried e-cigarettes at least once, with the highest rate of trial in Bulgaria (11%), Latvia (10%), Denmark (9%), Poland (9%) and the Czech Republic (9%) and highest rate of regular use in Greece, Denmark and Romania (each 2%).

Adkison and colleagues (2013) estimated rates of e-cigarette use and perceptions of the products in 2010 among current and former smokers in the International Tobacco Control Study conducted in U.K, U.S., Australia and Canada.(Adkison et al., 2013) Likely reflecting the fact that e-cigarettes are freely available in the UK and US and not legal for sale with nicotine in Australia and Canada, the highest rates of awareness were in the U.K.(54%) and U.S. (73%), while rates were lower in Australia (40%) and Canada (20%) (all rates were statistically significantly different). Prevalence of e-cigarette trial (among those aware) was 20.4% in U.S., 17.7% in the U.K., 10% in Canada and 11% in Australia. Across countries use was higher among those of younger age, higher income, reporting nondaily smoking and who perceive e-cigarettes as less harmful than cigarettes. Despite larges differences in awareness among the countries, current use did not differ among the countries (p=0.114). In current smokers, a marker of dependence (cigarettes per day) was not associated with ever e-cigarette use or past 30-day use (p value not provided).

United Kingdom

Dockrell et al (2013) analyzed data from a nationally representative survey of UK adults (2010: n=12597 adults, 2297 smokers; 2012 n=12432, 2093 smokers) finding the prevalence of e-cigarette trial and current use doubled from 2010 to 2012.(Dockrell et al., 2013) Ever use in

2010 was not measured among former smokers or never smokers, only current non-daily or daily smokers. In 2010, 5.5% of smokers had tried e-cigarettes but no longer used them, which increased to 15.0% in 2012. Current use of e-cigarettes among smokers rose from 2.7% in 2010 to 6.7% in 2012. Ever e-cigarette use among former smokers in 2012 was 2.7% and current use 1.1%; ever use among never smokers in 2012 (only measured in that year) was 0.4% and current use was 0.1%. About 33% of ever e-cigarette users continued to use in 2010 and in 2012. In a multivariate model which included only ex- and current smokers, being an occasional (OR=4.32 95% CI: 2.89, 6.48) or daily smoker (OR=7.33 95% CI: 5.66, 9.48) increased odds of ever e-cigarette use compared to ex-smokers, while older age (age ≥35) decreased odds of ever e-cigarette use compared to 18-34 year olds (OR=0.58 95% CI: 0.43, 0.78). In the model for current e-cigarette use, only being an occasional (OR=6.04 95% CI: 2.92, 12.49) or daily smoker (OR=6.68 95% CI: 4.15, 10.77) increased odds of current e-cigarette use. Authors also analyzed data from a 2010 survey of smokers (n=1308) that included a special battery of e-cigarette questions. A majority of respondents reported that e-cigarettes: “might satisfy the desire to smoke” (60%), “might help cut down on cigarettes” (55%), and “they might help me give up smoking entirely (51%).”Perceived disadvantages included “might be too expensive” (53%), “might not satisfy the desire to smoke enough” (39%), and might be mistaken for cigarettes therefore frowned upon in public”(35%). Among e-cigarette triers (n=494, 37.7% of sample), the most common reason for trying e-cigarettes was “as a substitute for smoking where smoking is not allowed” (reported by 49% of daily pack a day smokers, 43% of those smoking 10-19 cigarettes per day, and 31% among those smoking 9 or fewer cigarettes per day, p=0.008). Secondary reasons were to cut down (35%) and to quit smoking (31%). The finding that using e-cigarettes to get around smokefree laws is likely reflected in the dominant pattern of dual use in both 2010 and 2012 prevalence data reported in this study.

Switzerland

Douptcheva et al (2013) reported preliminary data analyses of the Cohort Study on Substance Use Risk Factors (C-SURF), a longitudinal study of Swiss men who are interviewed during enrollment in the army, to examine prevalence and predictors of e-cigarette use.(Douptcheva et al., 2013) Among the entire cohort of young men, aged 19-25, 4.9% of participants reported ever trying e-cigarettes. Use differed by smoking status with 9.3% of

current smokers reporting trying e-cigarettes, 1.6% of former smokers and 0.4% of never smokers. Excluding 144 occasional e-cigarette users, they conducted an analysis of e-cigarette use among daily smokers (n=1233) that compared daily dual users (n=25) to daily smokers who never use e-cigarette (n=1064); they found no statistically significant differences in cigarettes per day, nicotine dependence or past year quit attempts.

United States

Using data from U.S.-based ConsumerStyles survey (which is a mail-back survey of a national sample of adults), Regan et al. (2013) found that awareness of e-cigarettes doubled from 2009 to 2010 (16.4% to 32.2%) and ever use of e-cigarettes increased from 0.6% in 2009 to 2.7% in 2010.(Regan et al., 2013) Ever use was most common among men, younger adults and those with lower socioeconomic status. Ever use was higher among smokers than among the general population in 2010 (18.2% v 2.7%, respectively). Current smokers who had tried e-cigarettes did not differ from non-users in intention to quit or past-year quit attempts.

King et al (2013), analyzed data from a companion dataset to the ConsumerStyles, called HealthStyles, collected in 2010 (mail-based and web-based modalities) and 2011 (web-based mode).(King et al., 2013) They found awareness of e-cigarettes had increased from about 40% to about 58% and ever use had doubled from 3.4% to 6.2% between 2010 and 2011. Ever use was higher in current smokers at both waves (6.8% of the 2010 mail-based sample, 9.8% of the 2010 web-based sample and 21% of the 2011 web-based sample). Ever use among former smokers increased dramatically from 2010 to 2011, from 0.6% in 2010 mail sample and 2.5% in 2010 online sample to 7.4% in the 2011 online sample. Authors note data were weighted to be nationally-representative and the Styles surveys typically yield estimates of smoking prevalence that are almost identical to the nationally-representative National Health Interview Survey.(Regan et al., 2013, King et al., 2013) Moreover, a similar percentage of U.S. adults who were aware of e-cigarettes in 2010 were reported by Regan et al and King et al., as the nationally-representative 2010 data reported in Pearson et al. (Pearson et al., 2012) (32.2% Regan,(Regan et al., 2013) 38.5% and 40.9% in King(King et al., 2013) vs. 40.3% in Pearson(Pearson et al., 2012).

Pearson et al (2012) estimated e-cigarette use prevalence in two studies, the Legacy Longitudinal Study of Smokers (LLSS) and a nationally-representative general population online

survey, both conducted in 2010.(Pearson et al., 2012) Smokers in the LLSS and the nationally online sample were similar on all demographics except age (those in the LLSS were on average younger) and smoking characteristics and desire to quit with the exception that a greater proportion of smokers in the LLSS had made more than one quit attempt (69% v 31%, respectively). Overall awareness in the online nationally-representative sample (n=2649) was 40.2% and ever use was 3.4%, while awareness among smokers was 57% and ever use was 11.4%. Among LLSS cohort (n=3648), awareness was 57.0% and ever use was 6.4%. Moreover in the online sample, almost all current use (past 30-day) of e-cigarettes was among current smokers: 4.1%, compared to 0.5% of former smokers and 0.3% of never smokers. (Current use was not measured in the LLSS.) In addition, although a low percentage of former smokers (2%) had used e-cigarettes, that rate was over twice the rate among never smokers (0.77%).In the online nationally-representative survey the odds of being an e-cigarette user was associated with intention to quit in the next 6 months (adjusted OR = 1.74; 95% CI: 1.02, 2.98), compared to never expecting to quit; but this was not evident in the LLSS cohort.

In a 2010 nationally-representative, mixed-mode survey (telephone-based n=1504, online n=1736; total n=3240), McMillen et al. (2012) assessed the ever use of emerging tobacco products including e-cigarettes among adults in the U.S.(McMillen et al., 2012) Ever use of e-cigarettes among all respondents was 1.8%, with highest rates of use among daily (6.2%), and non-daily (8.2%) smokers. Past 30-day (current) e-cigarette use did not exceed 1% for any of the "emerging tobacco products, which included e-cigarettes, but 19.7% of ever e-cigarette users reported past 30-day use.

Popova and Ling (2013) found that among a nationally representative panel of current and recent former smokers, 20.1% had ever used e-cigarettes.(Popova and Ling, 2013) Ever e-cigarette use was more common in women than men (OR=0.79, 95% CI: 0.63-0.99), persons of Asian ethnicity than white (OR=2.76, 95% CI: 1.03, 7.39), and those aged 18-29 years compared to 60 years or older (OR=2.32, 95% CI: 1.57, 3.42). Among smokers, those with some college education compared to those with a bachelors degree (OR=2.09; 95% CI: 1.13, 3.86) and those with incomes less than $15,000 compared to those with incomes of $60,000 or greater were more likely to be current (past 30-day) e-cigarette users (OR=1.95, 95% CI: 1.17, 3.25). Respondents who had ever tried e-cigarettes were significantly more likely to have tried to quit conventional

cigarettes in the past year and failed than persons who had not tried to quit (OR=1.78, 95% CI: 1.25, 2.53).

U.S. Regional Samples

Choi and Forster (2013) found that among young adults aged 20-28 in the Midwestern US surveyed in 2011, ever use of e-cigarettes was 7.0% and past 30-day use was 1.2%.(Choi and Forster, 2013) Among those aware of e-cigarettes, most believe e-cigarettes are less harmful than conventional cigarettes (52.9%) and 44% believe they can help with quitting smoking. Ever use was more common among 20-24 year olds (25-28 year olds), men, current smokers, and those who believe e-cigarettes are less harmful than conventional cigarettes and can be used for in smoking cessation. In a focus group study more broadly focused on young adult perceptions of novel tobacco products that included e-cigarettes, Choi et al. (2012), found that about 50% of the sample of young adult smokers and non-smokers indicated interest in trying e-cigarettes if offered by a friend.(Choi et al., 2012)

Sutfin and colleagues (2013) found that among college students in North Carolina surveyed in 2009, ever use of e-cigarettes was 4.5% while past 30-day use was 1.5%, with highest use among current smokers.(Sutfin et al., 2013) Importantly, they found that 12% of e-cigarette users were never smokers. E-cigarette use was not associated with intention to quit smoking.

A cross-sectional study of Hawaiian daily smokers (n=1567) conducted from 2010-2012, examined e-cigarette use prevalence and associations with quitting attitudes and behaviors.(Pokhrel et al., 2013) Thirteen percent of participants reported having ever used e-cigarette to quit smoking (authors did not assess any other reason for using the products). Smokers who had used e-cigarettes to quit were younger, more highly motivated to quit, had greater self-efficacy for quitting, and reported a longer recent quit duration than smokers who had not used e-cigarettes to quit. In the multivariate logistic regression analyses, greater quit motivation (OR = 1.14; 95% CI: 1.08, 1.21), quitting self-efficacy (OR = 1.18; 95% CI: 1.06, 1.36) and having ever used FDA-approved therapies (OR = 3.72; 95% CI: 2.67, 5.19) were significantly associated with greater likelihood of having used e-cigarettes to quit smoking, whereas age (OR=0.98; 95% CI: 0.97, 0.99) and Native Hawaiian ethnicity (OR = 0.68; 95% CI: 0.45, 0.99) were inversely associated with greater likelihood of using e-cigarettes for quitting.

Convenience Samples of Users: Prevalence, User perceptions

There have also been several studies with convenience samples that may provide information about motivations for using e-cigarettes, attitudes and behavior. Due to study methodology, these studies were likely biased toward recruitment of persons motivated to quit and enthusiastic about e-cigarettes, limiting the generalizability of the findings.

In an online survey of 81 users of cessation websites and e-cigarette forums conducted in 2009, authors found that most respondents perceived the products as less harmful than cigarettes and used the products to quit smoking or to cut down on conventional cigarette smoking.(Etter, 2010) In a subsequent study conducted in 2010, Etter and Bullen (2011) surveyed 3587 adults from several countries that were recruited from e-cigarette forums and smoking cessation websites, and employed a similar questionnaire as Etter 2010.(Etter and Bullen, 2011b, Etter, 2010) Most respondents were former smokers (71%) at time of survey, using a nicotine e-cigarette (97%) and an average of 120 puffs/day. Top reasons for using e-cigarettes were: perceive them as less toxic than tobacco (84%), to help with quitting or relapsing (77%), to ameliorate cravings for and withdrawal from cigarettes (67%) for use in situations where smoking is restricted (39%) .(Etter and Bullen, 2011b) A subset of this sample who gave their email address for follow-up (n=779) completed a one-month (n=477) and a one-year follow-up (n=367) survey.(Etter and Bullen, 2013)As at baseline, a majority of participants at follow-up were former smokers (72%). Seventy-six percent of participants reported using e-cigarettes daily (17% were never users of e-cigarettes), and users took an average of 150 puffs/day and most commonly reported using 16 mg/ml nicotine strength e-liquids. A majority of people who were e-cigarette users at baseline remained e-cigarette users at one month and one year (98% at one month and 89% at one year among daily users. The relapse rate among former smokers who daily e-cigarette users at baseline was 6% by one-month follow-up and 6 percent by one- year follow-up. Of the daily smokers at baseline, 91% were still using e-cigarettes daily at one-month follow-up and 72% were using daily at one-year follow-up. Almost all of the former smokers using e-cigarettes daily at baseline were still using e-cigarettes daily at follow-up (99% at one-month and 92% at one-year). E-cigarette uptake was seen at follow-up among never-users of e-cigarettes at baseline (15% at one -month and 13% at one-year). Twenty-two percent of smokers (occasional and daily) at baseline had quit smoking at one-month and 46% had quit at one year. Authors note that respondents were older, higher income, more likely to be former smokers and

to report daily e-cigarette use compared to non-respondents. Daily smokers retained at follow-up reported higher motivation to quit smoking.

Two of the earliest studies were conducted with attendees of meetings in the U.S. of electronic cigarette enthusiasts and retailers. McQueen et al. (2011) conducted in-person interviews (n=15) with attendees of Vapefest and a MidWest Vapers Group meeting.(McQueen et al., 2011) Respondents were described as experienced e-cigarette users, many of whom were former smokers who had unsuccessfully tried to quit in the past with approved smoking cessation therapies and reported finding e-cigarettes "a vast improvement."Respondents reported perceived benefits of e-cigarette use to include that it is cheaper, has health benefits, less offensive odor, and women reported using nicotine and non-nicotine e-cigarettes to control weight and "snacking." Respondents reported finding the use of Internet forums "invaluable" to find products and assess quality of the diverse range of products. Some interviewees had begun selling the products in the previous 6 months and some indicated they were "unpaid evangelists" who had set up websites for visitors to gain information about e-cigarettes, tips for caring for and modifying the devices, and a way for visitors to purchase the products. Participants reported that the time required to learn how to use an e-cigarette device and how to "vape" with the devices, as well as device defects, present barriers to converting smokers to e-cigarette users. Participants reported starting with a cigarette-shaped device filled with tobacco or menthol e-liquid to maintain familiarity with cigarettes and then moving on to a device with a "larger and/or higher voltage battery" that can vaporize a larger amount of liquid to produce "throat hit" and tapering nicotine over time. They were enthusiastic about the products and supportive of research, particularly on the safety and efficacy of the products.

In another study, Foulds et al. recruited 104 Vapefest attendees at to respond to a survey administered in person that included questions about demographics, e-cigarettes and tobacco history, and beliefs about e-cigarettes.(Foulds et al., 2011) They found that 73% of users started with intention to quit smoking and 88% reported being "ex-smokers," with an average of 9 quit attempts before using e-cigarettes. Two-thirds had tried previously to quit by using FDA-approved cessation devices and 99% felt the e-cigarettes helped with quit attempt. Only 8% used the most widely sold brands, suggesting most built their own devices or bought non-name brand products over the Internet.

Siegel et al. (2011) obtained a list of purchasers of Blu brand electronic cigarettes from the company and invited them to complete a survey 6 months after making their first purchase (5000 purchasers, 4.5% response rate, sample n=222) in 2010.(Siegel et al., 2011) They found that 31% reported they were not smoking tobacco cigarettes at the 6 month survey timepoint. This study is limited by selection bias (purchasers of one particular product) and very low response rate (4.5%).

In 2011, Dawkins et al., (2012) conducted an online survey of 1347 adults recruited from an electronic cigarette retail website.(Dawkins et al., 2013) Participants were 70% men, mean aged 43 years, 96% white (72% European), and most (72%) used a "tank" type of e-cigarettes with nicotine-filled solution (1% reported using no-nicotine). Seventy-four percent of respondents who had used an e-cigarette reported not smoking for at least a few weeks. Results show that users perceive e-cigarettes as healthier than smoking and pleasant to use. In an analysis of self-reported ex-smokers, "'time to first vape' was significantly longer than 'time to first cigarette' ($p<0.001$)."

Goniewicz and colleagues (2012) surveyed Polish e-cigarette users recruited from online forums and retail sites in 2010 (n=179) and found that a majority of e-cigarette users were cigarette smokers when they initiated e-cigarette use (86%).(Goniewicz et al., 2012) Participants reported using the products as a less harmful alternative to smoking (41%) or to quit smoking (41%) and 66% reported no conventional tobacco cigarette smoking at the time of the survey. Fourteen percent of the sample were never smokers before they tried e-cigarettes. Twenty percent of that group reported they now also smoke tobacco cigarettes, suggesting e-cigarette use can be a gateway to smoking and dual use.

Farsalinos et al. (2013) conducted one-time interviews with Greek e-cigarette users (n=111) who were biochemically confirmed abstinence from conventional cigarettes (by level of blood carboxyhemoglobin) to characterize their experience with using e-cigarettes as a complete substitute for conventional cigarettes for at least one month.(Farsalinos et al., 2013b) Participants were recruited from a hospital where the researchers work and from e-cigarette forums, 84% men, and formerly heavy smokers. Although, 35% of participants initiated e-cigarette use with a cigarette-like e-cigarettes, most participants reported using devices with eGo batteries (90.9%) or "variable voltage" "mod" devices (9.1%) during their attempt at complete substitution. Forty-two percent reported that they achieved complete substitution in the first month of using the devices,

reported being abstinent for a median of 6 months (IQR: 4-11) and e-cigarette use for a median of 8 months (IQR: 4-13). With regard to the level of nicotine in the cartridges or e-liquid they used, all participants reported starting by using a nicotine level higher than 5mg/ml, with a large majority (74%) using 15mg/ml or higher and 16.2% reported having to increase the nicotine level in their device to help them completely substitute e-cigarettes for conventional cigarettes. Participants reported using a median of 18mg/ml (IQR: 18-18) nicotine concentration "to stop smoking" and then reducing the nicotine level used in their device after achieving complete substitution. In a logistic regression, controlling for nicotine level used to stop smoking, duration of e-cigarette use was statistically significantly associated with having reduced the nicotine level used in the device. Participants rated their dependence on smoking (when they smoked) as higher (79/100) than their current dependence on e-cigarettes (59/100).

In the Czech Republic, Kralikova et al (2012), surveyed 1738 (86% response rate) people they identified as currently smoking or buying conventional cigarettes in 2012.(Kralikova et al., 2013, Cho et al., 2011) Forty-six point seven percent had heard of e-cigarettes but never tried them, 23.9% had tried them once, 16.6% had tried them repeatedly, and 9.7% reported using them regularly. Of the 50% of respondents who had ever tried an e-cigarette, 18.3% reported regular use and 14% reported using them daily. A positive initial experience with e-cigarette use was much higher among those who use e-cigarettes regularly compared to those who only tried them once (68.5% v 15.2%, respectively). Of those who tried only once or repeatedly, “not satisfying” was the top reason given by both groups followed by “poor taste.”In depth analyses were conducted for the sample of regular users (n=158). Among regular users, reasons for trying e-cigarettes were to cut down (39%), use where smoking is not allowed (28%) and to quit smoking (27%) (5.3% gave another reason). Regular users who reported that e-cigarettes helped them cut down (n=93) smoked on average 9.7 (SD=6.5) cigarettes per day, while those who did not report that e-cigarettes helped them cut down (N=61) smoked 13.1 (SD=7.0) cigarettes per day ($p<.005$). Most non-reducers said they used the e-cigarettes to circumvent smokefree laws.

Youth

In a survey of Korean adolescent respondents to the 2008 Health Promotion Fund Project survey (n=4,341), 10.2% of students were aware of e-cigarettes.(Cho et al., 2011) Overall, only 0.5% of students reported having tried an e-cigarette, but there were significant differences in use

by gender (0.91% among males, 0.18% among females, p<0.001) and having ever used conventional cigarettes (2.0% among ever cigarette users, 0.15% among never cigarette users, p<0.001)

A subsequent study of adolescent (aged 13-18) respondents to the 2011 Korean Youth Risk Behaviour Survey (n=75,643) found that prevalence of e-cigarette use had greatly increased in just 3 years to 9.4% ever use and 4.7% past 30 day use.(Lee et al., 2013) Use was also much higher among respondents who used conventional cigarettes: 8.0% ever e-cigarette use among current smokers, 1.4% ever e-cigarette use among non-smokers or former smokers and 3.6% current (past 30-day) use among smokers, 1.1% current use among non-smokers or former smokers). The relationship between e-cigarette use and current (past 30 day) smoking, quit attempts, and no longer using cigarettes was analyzed with logistic regression.(Lee et al., 2013) They found that after adjusting for demographics, current cigarette smokers were much more likely to use e-cigarettes than non-smokers. Among current cigarette smokers, those who smoked more frequently were more likely to be current e-cigarette users. Odds of being an e-cigarette user was 1.58 times (95% CI: 1.39-1.79) higher among students who had made a quit attempt than those who had not. Students no longer using cigarettes were rare among current e-cigarette users (OR 0.10, 95% CI: 0.09-0.12).

In the U.S., Pepper et al, 2013 found high levels of awareness of e-cigarettes (67%) but little use among a sample of 228 adolescent males who participated in an online survey in 2011 (less than 1 percent had tried an e-cigarette).(Pepper et al., 2013) However, in the multivariate logistic regression only current smoking was strongly associated with increased willingness to try an e-cigarette (OR=10.25, CI: 2.88, 36.46). In the bivariate logistic regression, holding a negative opinion of “the typical smoker” was associated with less willingness to try an e-cigarette (OR=0.58, 95% CI: 0.43, 0.79). These findings demonstrate that adolescent boys who use cigarettes are also susceptible to using e-cigarettes and that negative perceptions of being a smoker may be protective against e-cigarette smoking.

Camenga and colleagues (2013) assessed current (past 30-day) e-cigarette use among high school students in 2 high schools in Connecticut and New York (U.S.) (Camenga et al., 2013) Three cross-sectional waves of data were included in analyses (February 2010 (n=1719), October 2010 (n=1702) and June 2011 (n=1345). Analyses showed that past 30-day e-cigarette use increased from 0.9% in February 2010 to 1.7% in October 2010 to 2.3% in June 2011, and

dual use with cigarettes increased from 0.8%, 1.4% to 1.9%, respectively. At all 3 times, the majority of e-cigarette use was dual use with conventional cigarettes (87.5% in February 2010, 82.8% in October 2010 and 83.9% in June 2011). In separate multivariate models for each wave, current cigarette smokers had a statistically significant increased odds of past 30-day e-cigarette use (adjusted for demographics, school and location).

The first national estimates of e-cigarette use among U.S. youth from the National Youth Tobacco Survey document rapid growth of e-cigarette use of e-cigarette use among middle school and high school students in the U.S. from 2011-2012.(Centers for Disease Control and Prevention, 2013) Among middle school youth (grades 6-8), prevalence of ever trying an e-cigarettes doubled from 1.4% in 2011 to 2.7% in 2012. Similarly, current use (past 30-day use) rose from 0.6% to 1.1%. Among high school youth, ever use doubled from 4.7% in 2011 to 10.0% in 2012, with current use rising from 1.5% in 2011 to 2.8% in 2012. Notably, dual use with cigarette smoking accounts for most of the past 30-day e-cigarette use among middle school youth (61.1%) and high school youth (80.5%). Initiation of nicotine exposure with e-cigarettes is evidenced by the fact that 20% of middle school youth who had tried an e-cigarette and 7.2% of high school youth who had tried an e-cigarette had not tried a conventional tobacco cigarette yet.

Dutra and Glantz (in press) further examined e-cigarette use and conventional cigarette smoking using the 2011 NYTS data w (n=18,644).(Dutra and Glantz, in press) This is a cross-sectional study, which presents associations and does not permit causation. Among experimenters with conventional cigarettes (>1 puff, <100 cigarettes), ever e-cigarette use was associated with higher odds of ever smoking (>100 cigarettes; (OR=7.68, 95% CI [5.45-10.83]) and current smoking (OR=7.44, [5.39-10.27]). Current e-cigarette use was associated with increased odds of ever smoking (OR=7.27 [3.99-13.25]) and current smoking (OR=6.68 [3.82-11.68]). Among experimenters, ever use of e-cigarette was also associated with a decreased odds of abstinence from cigarette smoking (past 30-day (OR=0.22 [0.16-0.30]), 6-month (OR=0.22 [0.16-0.29]), and 1-year (OR=0.22 [0.15-0.32]). Similarly, current e-cigarette use was also associated decreased odds of smoking abstinence in the past 30-days (OR=0.15 [0.08-0.28]), 6-month (OR=0.17 [0.07-0.40]), and 1-year (OR=0.15 [0.07-0.34]). Among ever smokers (>100 cigarettes), ever e-cigarette use approached significance for the odds of abstaining from smoking in the past 30 days in 2011 (OR=0.55 [0.31-1.01]). Thus, in this cross-sectional population-based

study, e-cigarette use was associated with higher odds of ever or current cigarette smoking and lower odds of abstinence from conventional cigarettes.

Goniewicz studied e-cigarette use among 20,240 students enrolled at 176 high schools and universities in Poland.(Goniewicz and Zielinska-Danch, 2012) Surveys were administered September 2010 to June 2011. 23.5% of Polish teens aged 15-19 had ever used e-cigarettes and 8.2% reported past 30-day use. Among 20-24 year olds attending universities, 19.0% had ever used an e-cigarette and 5.9% reported past 30-day use. In the whole sample, 3.2% of never smokers had tried an e-cigarette.

E-cigarette use has been assessed in 2 countries via the Global Youth Tobacco Surveys (GYTS) in 2011 and 2012. Results from analyses of the GYTS data for Latvia (2011), revealed that 9.1% of 13-15 year olds are current e-cigarette users (10.3% boys and 7.7% girls). Analyses of the GYTS in Finland (2012) showed that 17% of 13-15 year olds have ever used e-cigarettes (20% boys and 14% girls) and 4.7% are current e-cigarette users (4.2% boys and 5.2% girls).(Reddy, November 12, 2013)

Conclusion

Awareness of and e-cigarette trial has at least doubled among both adults and adolescents, in the countries where data are available from 2008 to 2012. In the U.S., awareness is more prevalent among men, but trying e-cigarettes is more prevalent among women. Almost the same percent of European Union and US adult respondents to national surveys reported having tried e-cigarettes (7% in 2012 vs. 6.2% in 2011, respectively).(TNS Opinion & Social, 2012, King et al., 2013) All population-based studies of adult use show the highest rate of e-cigarette use among current smokers, followed by former smokers, with little use among nonsmokers, although e-cigarette trial and use rose in all of these categories over the past few years (Table 1; note Eurobarometer report did not assess e-cigarette use by smoking status). Therefore epidemiologic, population-based studies indicate that, across countries, e-cigarette are most commonly being used concurrently with conventional tobacco cigarettes, referred to as dual use. Moreover, in some of the European studies (e.g., U.K., Swiss, Czech) the most common reasons given to try e-cigarettes was to use them in places where smoking is restricted and to cut down on smoking, followed by to help with quitting.(Dockrell et al., 2013, Douptcheva et al., 2013, Kralikova et al., 2013) Few of the population-based studies reported on variables that

could be related to self-selection to use e-cigarettes among smokers in the samples, such as dependence, motivation to quit, and previous use of smoking cessation therapies; however, in the studies that did report on such variables, there was mixed evidence to support associations between e-cigarette use and those factors.(Regan et al., 2013, Pearson et al., 2012, Pokhrel et al., 2013, Lee et al., 2013)

Studies of users recruited through e-cigarette-related venues (websites, festivals and purchaser lists) reveal that the motivations for using e-cigarettes are primarily to cut down or reduce smoking and to quit smoking, and show some successful quitting.(McQueen et al., 2011, Goniewicz et al., 2012, Dawkins et al., 2013, Etter and Bullen, 2011b, Farsalinos et al., 2013b, Siegel et al., 2011) These studies indicate that persons motivated to try e-cigarettes have also tried other smoking cessation methods. These studies are limited by self-selection bias inherent in the e-cigarette and smoking cessation-related recruitment methods, which may attract more enthusiastic users and successful quitters.

The data on e-cigarette use among adolescents is more limited but, like adults, shows rapid increases in awareness and use in 5 countries (U.S., Poland, Latvia, Finland and Korea), with higher rates of trial and current use in European countries than the U.S. or Korea.(Reddy, November 12, 2013, Lee et al., Goniewicz and Zielinska-Danch, 2012, Centers for Disease Control and Prevention, 2013, Dutra and Glantz, in press) As with adult population-based studies, data suggest that e-cigarette use is most appealing and prevalent among youth who are also experimenting with or current users of tobacco cigarettes. Dual use with conventional cigarettes is the predominant pattern of e-cigarette use - 61% in middle school students and 80% among high school students. Among middle school youth, 20% of those who had tried e-cigarettes had never tried a tobacco cigarette, which raises the concern that some youth could be initiating nicotine addiction with e-cigarettes. Although it is unclear if e-cigarette use among youth leads to tobacco smoking, this possibility should be strongly considered given the widespread availability of combustible tobacco products including cigarettes, little cigars, cigarillos, bidis as well as smokeless tobacco products. These results indicate rapid market penetration of e-cigarettes among youth, with trial among high school students (10.0%) in 2012 even higher than the 2011 rate for adults, 6.2%.(King et al., 2013) Moreover, although youth who had tried to quit were more likely to use e-cigarettes, most adolescent e-cigarette users are

dual users with conventional smoking, suggesting that e-cigarettes are not leading to abstinence from smoking among adolescents.

These findings are troubling for what they suggest about the trajectory of developing tobacco use. In a longitudinal cohort study of Swedish adolescents that examined trajectories of tobacco use, adolescents who initiated tobacco use with both cigarettes and snus had a significantly elevated risk of progression to current smoking at 18 years old compared to snus initiators (OR= 2.54 (95% CI: 1.68-3.91).(Galanti et al., 2008) A study of U.S. Air Force recruits sheds light on the trajectory of use with different product initiation. Of those who were never smokers when they entered basic training, 5.1% were current users and 2.5% past users of smokeless tobacco. At one-year follow-up the recruits who were current or ever smokeless tobacco users were over 2 times more likely to have started smoking than nonusers.(Haddock et al., 2001) Post et al. (2010) examined tobacco use and nicotine dependence in Swedish adolescents and found that dual users reported the greatest odds of endorsing the dependence symptoms.(Post et al., 2010) These adolescent dual users also had the highest level of endorsing withdrawal symptoms when trying to quit.

ANALYSES OF E-CIGARETTE E-FLUID AND AEROSOL

Chemical Constituents

In 2009, the U.S. Food and Drug Administration (FDA) released a statement that analyses of ENDS products revealed the presence of tobacco-derived impurities and one cartridge contained a toxic contaminant used in antifreeze (diethylene glycol).(Food and Drug Administration, 2009) Two studies from FDA scientists presented analyses of e-cigarette product constituents.(Hadwiger et al., 2010, Trehy et al., 2011) Trehy et al. (2011) conducted an analysis of 4 e-cigarette products for nicotine and minor tobacco alkaloids in liquids and in aerosol generated from the e-cigarettes.(Trehy et al., 2011) Minor alkaloids refer to alkaloids found in tobacco other than nicotine which are present in much smaller quantities than nicotine. The products that were purchased included NJOY, Smoking Everywhere, CIXI and Johnson Creek e-liquid. (It is not clear in which year the products were purchased.) The puffing procedure was 100 ml puffs taken every 60 seconds for 30 puffs. They found that the amount of nicotine measured in the aerosol was impacted by the temperature to which the solution was heated, with repeated heating of the liquid in short intervals (triggered by short puff intervals) enhancing

nicotine release. Thus the amount of nicotine delivered to the user is likely to be dependent on temperature achieved by the heat source and inter-puff interval performed by the user. The analysis of nicotine content of cartridge e-liquid from three of the brands revealed poor concordance of labeled and actual nicotine content, including two labeled as having 0mg nicotine that had nicotine in them. Analysis of the refill solutions from the U.S. e-liquid company Johnson Creek showed good agreement (100-110% of advertised content) between labeled and actual content. Liquids tested from one manufacturer contained minor tobacco alkaloids, including myosmine, anatabine, anabasine and in some cases cotinine and beta nicotyrine. It is likely that these alkaloids were extracted along with nicotine from tobacco as part of the manufacturing process. The analysis of simulated e-cigarette use found that individual puffs contained from 0 µg to 35µg nicotine per puff. Assuming a high nicotine delivery of 30 µg/puff, it would take about 30 puffs to deliver the 1 mg of nicotine typically delivered by smoking a conventional cigarette. A Marlboro cigarette was tested and found to deliver 152-193µg/puff, so 6 or 7 puffs would deliver 1 mg. The levels of minor alkaloids in aerosol were below the limit of detection for both e-cigarettes, although levels could be measured from the smoke of a Marlboro. Two products from CIXI labeled as Cialis and Rimonabant flavor contained amino-tadalafil and rimonabant, medicines to treat erectile dysfunction and a cannabinoid (THC) receptor antagonist, respectively.(Hadwiger et al., 2010) These studies demonstrates inconsistency in nicotine amount compared to labeled content of these e-cigarette products and indicate that in this study, the nicotine in a puff of the highest nicotine e-cigarette contained 20% of the nicotine than contained in a puff of a conventional cigarette. Actual nicotine delivery from an e-cigarette would likely be impacted by users' smoking behavior.

Goniewicz et al. (2012) analyzed 16 brands of e-cigarette products, and 20 samples across brands.(Goniewicz et al., 2013) They measured nicotine content in e-liquid and used an adapted smoking machine to measure the nicotine content in 300 puffs of aerosol generated from each product. The amount of nicotine measured in the e-liquid extracted from the cartridges varied from labeled nicotine content by more than 20% in 9 of 20 samples. Similarly, a 20% difference in marked content vs. actual content was found in 3 of 15 e-cigarette refill liquid samples. Across products, nicotine content ranged from 0.5 mg (SD=0.1) to 15.4 mg(SD=2.1).

Cameron et al. (2013) analyzed 7 e-cigarette solutions (e-liquids) to determine concordance between advertised or labeled and actual nicotine content.(Cameron et al., 2013)

Among the 7 samples of e-liquid, 2 were labeled as containing 24mg/ml of nicotine and 5 were not marked with a specific nicotine content, but as "low," "medium," "high" and "super high." For samples with only strength descriptors, expected concentrations were obtained from information on the brands' websites (low=6-14mg/ml, medium=10-18mg/ml, high and super high=25-36mg/ml). They found that, while all the samples contained nicotine, only 2 were in the expected range and 4 were lower than specified.

Goniewicz et al (2013) analyzed the aerosol from 12 brands of e-cigarettes for toxic and carcinogenic compounds, including carbonyls, volatile organic compounds, tobacco-specific nitrosamines.(Goniewicz et al., 2013 (online first)) They also compared results from the e-cigarette aerosol to the puffs from a medicinal nicotine inhaler. They found varying levels of carbonyls (e.g., formaldehyde, acetealdehyde and acrolein), volatile organic compounds (e.g., toluene) and tobacco-specific nitrosamines present in the e-cigarette aerosol. E-cigarette products varied widely in toxicant content per 150 puffs averaged across sampling timepoints (e.g., formaldehyde range: 3.2-56.1 µg; acrolein: 0-41.9 µg, TABLE 2). The levels of toxicants in the aerosol were 9-450 times lower than the same volume cigarette smoke, supporting the idea that e-cigarette aerosol is much less hazardous than cigarette smoke (Table 2). Goniewicz et al. also compared the e-cigarette aerosol to the aerosol delivered by the nicotine inhaler, a medicine marketed but not widely used to aid smoking cessation. Depending on brand, some toxicants were found in the e-cigarette aerosol at higher levels than the nicotine inhaler (e.g.,o-methylbenzaldehyde and formaldehyde). Five of the 11 toxicants measured were not detected in the nicotine inhaler at all, including acrolein, toluene, p,m,-xylene, NNN, and NNK. They also report the presence of trace amounts of three metals (cadmium, nickel, and lead) in the e-cigarette aerosol as well as in the nicotine inhaler. Whether the levels of toxicants in e-cigarette aerosol indicate an actual health risk compared to the nicotine inhaler is unknown, but toxicant deliveries from both were far lower than from conventional cigarettes.

Kim et al. (2012) developed a liquid chromatography-tandem mass spectrometry method for analyzing TSNAs in electronic cigarette replacement fluids.(Kim and Shin, 2013) They applied their method to 105 refill fluids from 11 different companies in the Korean market. They specifically quantified NNN, NNK, NAT, and NAB, and they present data on total TSNAs in each product. They found nearly a three order of magnitude variation in TSNA concentrations among e-cigarette refill fluids, with total TSNA concentration ranging from 330 µg/ml to 8600

TABLE 2. Levels of toxicants in e-cigarette aerosol compared to nicotine inhaler and cigarette smoke			
Toxicant	Content in nicotine inhaler mist per 15 puffs*	Range in content in aerosol from 12 e-cigarettes samples per 15 puffs*	Range in content in conventional cigarette micrograms (µg) in mainstream smoke from 1 cigarette
Formaldehyde (µg)	0.2	0.2-5.61	1.6-52
Acetaldehyde (µg)	0.11	0.11-1.36	52-140
Acrolein (µg)	ND	0.07-4.19	2.4-62
o-methylbenzaldehyde (µg)	0.07	.13-.71	--
Toluene(µg)	ND	ND-0.63	8.3-70
p,m-xylene (µg)	ND	ND - 0.2	--
NNN (ng)	ND	ND - 0.00043	0.0005-0.19
NNK (ng)	ND	ND-0.00283	0.012-0.11
Cadmium (ng)	0.003	ND - 0.022	--
Nickel (ng)	0.019	0.011-0.029	--
Lead (ng)	0.004	0.003-0.057	--
* 15 puffs was selected to approximate the same nicotine delivery of 1 conventional cigarette; µg=microgram, ng=nanogram ND=Not Detected -- = Not measured Data were taken from Tables 3 and 4 in Goniewicz et al. 2013.(Goniewicz et al., 2013 (online first))Lowest and highest values reported in each table were used for the range presented for each toxicant			

µg/ml. Their data demonstrate significant variability in TSNA composition and quantity among different e-cigarette brands and illustrate the importance of screening numerous products to obtain an overview of product variability.

E-cigarettes do not burn or smolder, so aerosol emitted into the environment is exhaled by the user. Schripp et al. (2012) analyzed the aerosol exhaled by users to determine the presence of toxicants and address the question of secondhand aerosol exposure.(Schripp et al., 2012) Three studies are described. In the first, a smoker puffed 6 puffs from an e-cigarette separated by 60 seconds each time in an $8m^3$ stainless steel chamber with an air exchange rate of 0.3/hr. This puffing regimen in the chamber was repeated with 3 e-liquids (0mg nicotine, apple flavor, 18mg nicotine, apple flavor, 18mg nicotine, tobacco flavor) and one tobacco cigarette. In the second protocol, aerosol from three different types of e-cigarettes puffed for 3 seconds each was pumped into a 10 L glass chamber with an air exchange rate of 3/hr. In the third protocol an

e-cigarette consumer exhaled one e-cigarette puff into a glass chamber. Three e-cigarette devices were used for these experiments – two that used a "tank" system which is directly filled with e-liquid and one that used a cartridge with a cotton fiber on which to drip the e-liquid. Authors found that aerosol from the $8m^3$ chamber analysis contained low levels of formaldehyde, acetaldehyde, isoprene, acetic acid,2-butanodione (MEK), acetone and proponal (Table 3). Analyses of the aerosol in the second protocol (10-l glass chamber) revealed high levels of 1,2-propanediol (propylene glycol), 1,2,3-propanetriol, diacetin (from flavorings), traces of apple oil (3- methylbutyl-3-methylbutanoate), and nicotine. When e-cigarette aerosol was directly pumped into a glass chamber, propylene glycol was the predominant element, with lower levels of others. Nicotine release was 0.1 to 0.2 µg/puff.

Pellegrino et al. (2012) analyzed the chemical composition of the e-liquid and resulting aerosol generated from one Italian brand, of e-cigarettes, Aria, both the nicotine and non-nicotine versions. The e-liquid and aerosol in both nicotine and non-nicotine e-cigarettes was primarily comprised of propylene glycol and glycerol (glycerin) and low levels of flavoring agents and).

Table 3. Concentrations of selected compounds in a test chamber of exhaled e-cigarette aerosol and conventional cigarette secondhand smoke (reproduced from Table 4 of (Schripp et al., 2012))(Schripp et al., 2012)

Table 4 Concentrations ($\mu g/m^3$) of selected compounds during the 8-m^3 emission test chamber measurement of e-cigarette A and conventional cigarette using Tenax TA and DNPH

			E-cigarette			Conventional cigarette
Compounds	CAS	Participant blank	Liquid 1	Liquid 2	Liquid 3	
1,2-Propanediol	57-55-6	<1	<1	<1	<1	112
1-Hydroxy-2-propanone	116-09-6	<1	<1	<1	<1	62
2,3-Butanedione	431-03-8	<1	<1	<1	<1	21
2,5-Dimethylfuran	625-86-5	<1	<1	<1	<1	5
2-Butanone (MEK)	78-93-3	<1	2	2	2	19
2-Furaldehyde	98-01-1	<1	<1	<1	<1	21
2-Methylfurane	534-22-5	<1	<1	<1	<1	19
3-Ethenyl-pyridine[a]	1121-55-7	<1	<1	<1	<1	24
Acetic acid	64-19-7	<1	11	13	14	68
Acetone	67-64-1	<1	17	18	25	64
Benzene	71-43-2	<1	<1	<1	<1	22
Isoprene	78-79-5	8	6	7	10	135
Limonene	5989-27-5	<1	<1	<1	<1	21
m,p-Xylene	1330-20-7	<1	<1	<1	<1	18
Phenol	108-95-2	<1	<1	<1	<1	15
Pyrrole	109-97-7	<1	<1	<1	<1	61
Toluene	108-88-3	<1	<1	<1	<1	44
Formaldehyde[b]	50-00-0	<1	8	11	16	86
Acetaldehyde[b]	75-07-0	<1	2	2	3	119
Propanal[b]	123-38-6	<0.2	<0.2	<0.2	<0.2	12

[a]Quantified on the basis of toluene response.
[b]DNPH method.

nicotine (in the nicotine e-cigarettes

McAuley et al (2012) conducted a published risk assessment of e-cigarettes funded by the Consumer Advocates for Smoke-free Alternatives Association, CASAA, a pro- e-cigarette advocacy group.(McAuley et al., 2012) Key details about the protocol for conducting their risk assessment are not described, as there are obvious problems with the study that do not warrant its review in this report. In fact, a technical report(Burstyn, 2013) (below) reviewing the existing data on e-cigarette constituents that was also funded by CASAA excluded this study due to its poor quality, stating:

> Although the quality of reports is highly variable, if one assumes that each report contains some information, this asserts that quite a bit is known about composition of ENDS liquids and aerosols. The only report that was excluded from consideration was work of McAuley et al.[23] because of clear evidence of cross-contamination – admitted to by the authors – with cigarette smoke and, possibly, reagents. The results pertaining to non-detection of tobacco-specific nitrosamines (TSNAs) are potentially trustworthy, but those related to PAH are not since it is incredible that cigarette smoke would contain fewer polycyclic aromatic hydrocarbons (PAH; arising in incomplete combustion of organic matter) than aerosol of e-cigarettes that do not burn organic matter [23]. In fairness to the authors of that study, similar problems may have occurred in other studies but were simply not reported, but it is impossible to include a paper in a review once it is known for certain that its quantitative results are not trustworthy.(Burstyn, 2013)

Other problems with the analysis and findings include the fact that they did not detect any benzo(a)pyrene in the conventional cigarette smoke despite the fact that it has been established for over 50 years that benzo(a)pyrene is an important carcinogen in cigarette smoke. The most unreliable conclusion in the paper (on page 855, second column, 11 lines from the top) is that “neither vapor from e-liquids or cigarette smoke analytes posed a condition of ‘Significant Risk’ of harm to human health via the inhalation route of exposure." Given the authors' analysis found that conventional cigarettes did not pose significant risk, there is likely a fatal error in the data, analysis, or both. This paper's conclusions about e-cigarette toxicity does not appear credible as it concludes that cigarettes are not dangerous to inhale.

In the technical report funded by CASAA examining the constituents in e-cigarette cartridges and liquid, Burstyn (2013) employs occupational threshold limit values (TLVs) to evaluate the potential risk posed by various toxins at various levels in e-cigarettes.(Burstyn, 2013) In reviewing the evidence of risk due to propylene glycol or glycerine exposure the report

states that assuming a high level of consumption around 5-25ml of solution a day could produce levels of exposure to propylene glycol and glycerin to justify concern. The author noted that the assessment is limited by "the quality of much of the data that was available for [the] assessment was poor." Based on calculated levels of inhalation, the author concludes that

> …there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (contaminants plus declared ingredients), if it were an emission from industrial process, creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.(Burstyn, 2013)

TLVs are an approach to assessing health effects for occupational chemical exposures that are generally much higher (often orders of magnitude higher) than levels considered acceptable for ambient or population-level exposures.(Employing an occupational standard to evaluate risk to the general population is the same approach to risk assessment as those conducted for secondhand smoke by those affiliated with the tobacco industry, which concluded that secondhand tobacco smoke could not produce any adverse health effects.) Occupational exposures also do not consider exposure to sensitive subgroups, such as people with medical conditions, children and infants, who might be exposed to secondhand e-cigarette emissions, most notably nicotine.

Particulate Matter

Particle size is an important determinant of where inhaled particles will be deposited in the respiratory system and the resulting adverse health effects of particulate exposure (U.S. EPA http://www.epa.gov/pm/). All particles less than or equal to 10 microns in aerodynamic diameter (i.e., PM_{10}) reach the respiratory system and potentially cause health problems in the circulatory and respiratory systems (http://www.epa.gov/pm/health.html). Those whose diameter falls between 2.5 and 10 microns are considered the “inhalable coarse fraction” and impact the large central airway. Fine particles with an aerodynamic diameter are defined as particles less than equal to 2.5 microns and are termed $PM_{2.5}$. Ultrafine particles (also called nanoparticles) are particles less than or equal to 0.1 micron (0.1 micron = 100 nm). (For reference, conventional cigarette smoke particles have a median size of 200-400 nm.) For ultrafine particles between

approximately 10 and 300 nm in diameter, roughly 10 – 50% are deposited in the furthest reaches of the lungs – the alveoli (FIGURE 4, below). Ultrafine liquid particles would coalesce with lung fluid to form a film, and constituents would be absorbed after deposition, as for larger particles. Solid ultrafine or nano-particles (carbonaceous or metal) can penetrate the epithelium and reach circulation. Once in the bloodstream they can be deposited around the body and be absorbed directly into cells through endocytosis. There is also evidence of extrapulmonary translocation of ultrafine particles with various potential toxic effects(Oberdorster et al., 2005) (Oberdorser et al. 2005) including translocation to the central nervous system.(Elder et al., 2006)Frequent low or acute high levels of exposure to fine and ultrafine particles can contribute to pulmonary and systemic inflammatory processes and increase the risk of cardiovascular and respiratory disease and death (Pope et al., 2009, Brook et al., 2010)and respiratory problems.(Mehta et al., 2013)

Because of these health concerns, the U.S. EPA has standards for ambient concentrations of both $PM_{2.5}$ and PM_{10}: http://www.epa.gov/air/criteria.html.Ambient particles can be variable and chemically complex and the specific components responsible for toxicity are generally not known.(Ostro et al., 2007) In particular, the relative importance of particle size and particle composition to toxicity is not known. Given these uncertainties, it is not clear to what extent the ultrafine particles delivered by e-cigarettes will have similar health effects and toxicity as ambient fine particles such as those generated by conventional cigarette smoke or secondhand

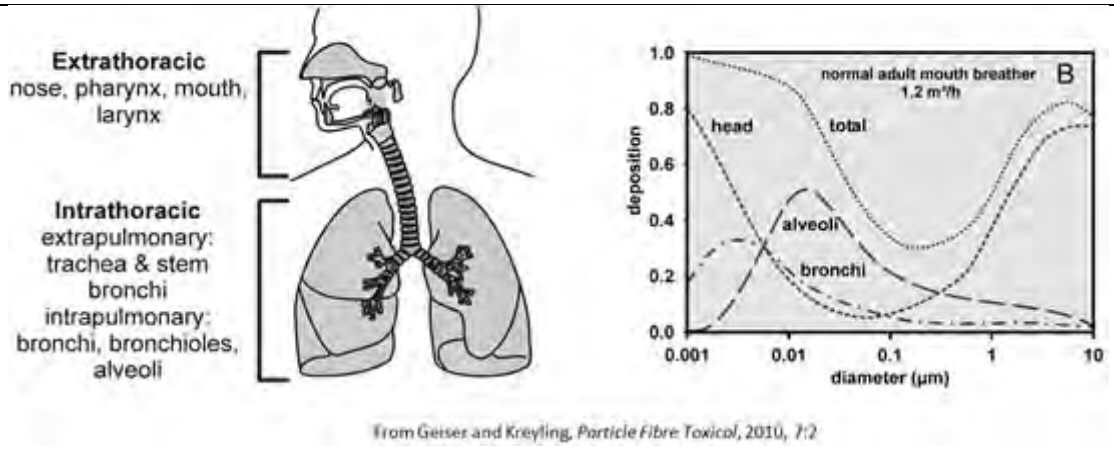

FIGURE 4. Particle deposition in the human body by size (reproduced from Geiser and Kreyling, 2010)(Geiser and Kreyling, 2010)

smoke; e-cigarette particles could be more, less or of equal toxicity as other particles of similar size.

Schripp et al. (2012) observed particles in exhaled e-cigarette aerosol, around and below 100 nm.(Schripp et al., 2012), the range of sizes that are efficiently deposited to alveoli (Figure 4). The number of particles was observed to decrease as a function of time with specified time intervals, 1, 5, 10 minutes in both the $8m^3$chamber and the glass 10 liter chamber, perhaps due to deposition in the container. Exhaled e-cigarette aerosol contained mostly propylene glycol and smaller amounts of related VOCs, apple oil (flavorant) and nicotine. The authors conclude that *"'passive vaping' must be expected from the consumption of e-cigarettes."* Like secondhand cigarette smoke, levels of these chemicals in real environments where e-cigarettes are being used will depend on the density of users and properties of the ventilation system.

Pellegrino et al. (2012) compared pollution levels in a chamber of particulate matter from a nicotine-containing e-cigarettes and a non-nicotine e-cigarettes and a conventional cigarette via evaluation of the concentration of suspended particulate (TSP) and particles sized $\leq$ 10, 7.5, 2.5 and 1 μg.(Pellegrino et al., 2012) All measurements to determine TSP was taken over a 3 minute periodwith "a portable laser operated aerosol mass analyser (Aerocet 531, Metone Instruments Inc, USA) in an air volume of $11m^{3"}$. The e-cigarettes were attached to a device which drew 4 puffs per minute over the 3 minutes, but it was unclear from a description of the methods whether the conventional cigarette was left burning for the study period of 3 minutes or the same number of puffs were elicited. (The very high levels of TSP after 3 minutes, around 900 $\mu g /m^3$, suggests that the conventional cigarettes were allowed to burn continuously.) It is also not clear whether the authors were comparing mainstream e-cigarette aerosol with total or sidestream conventional cigarette smoke. Authors found greater concentrations of larger compared to smaller particles in e-cigarette and cigarette emissions. The authors also reported much larger particles than the other particle size studies. Particle concentrations were much higher (15 times) in air polluted by cigarette smoke than either nicotine or non-nicotine e-cigarettes for all sizes of particles. There are several methodological concerns about this study and the results are very different from the other papers on this topic.(Fuoco et al., 2014, Ingebrethsen et al., 2012, Schripp et al., 2012, Zhang et al., 2013, Williams et al., 2013)

Zhang et al. (2103) examined the size of e-cigarette aerosol particles and likely deposition in the human body. They examined e-cigarette aerosol produced by a single brand of

e-cigarettes (BloogMaxXFusion) using both propylene glycol and vegetable glycerin-based liquids.(Zhang et al., 2013) They generated the aerosol by using a smoking machine that was altered to take 25ml aerosol samples for analysis. In order to assess the likely deposition of particles in the human respiratory system, they used two factors: particle size and lung ventilation rates (one for a "reference worker" one for a "heavy worker," 1.2 m^3/hr and 1.688 m^3/hr, respectively). They found that e-cigarettes and tobacco cigarettes produce aerosols with similar particle size, with some particles in the nanoparticle range. Their human deposition model estimated that 73-80% of particles are distributed into the exhaled aerosol, while 7%–18% of particles would be deposited in alveoli resulting in arterial delivery and 9%–19% would be deposited in the head and airways, resulting in venous delivery.(Zhang et al., 2013) As expected, the heavy worker model showed more alveolar delivery across puffs compared to the reference worker who would have more head and airway delivery.(Zhang et al., 2013) In total, about 20-27% of particles are estimated to be deposited in the circulatory system and into organs from e-cigarette aerosol, which is comparable to the 25-35% for conventional cigarette smoke.

Ingebrethsen et al. (2012) (authors employed at RJ Reynolds tobacco company) conducted a study of particle size in e-cigarette aerosol using three methods (spectral transmission, electric mobility, and gravimetric).(Ingebrethsen et al., 2012) and found the aerosol particles to average 250–450 nm in size, which is comparable to conventional cigarettes. Testing two brands of e-cigarettes (one disposable, one rechargeable) and one tobacco cigarette, authors found that the geometric mean particle size ranged from 238 to 387 nm, and was similar for e-cigarettes and tobacco cigarettes. (The authors did not describe the composition of the e-liquids, which can potentially affect particle size and concentration.)

Fuoco et al. examined particle number concentration and distribution as well as a volatility analysis of the e-cigarette aerosol generated from 3 different devices(2 rechargeable and 1 disposable) using 4 different refill e-liquids with varying levels of nicotine and flavorants. The authors used state-of-the art methods to measure particle number concentration and size distribution (condensation particle counter and a fast mobility particlesizer spectrometer, respectively). Comparisons of particle number concentration in the aerosol from different nicotine content e-liquids, revealed that the higher the nicotine content in the e-liquids the higher

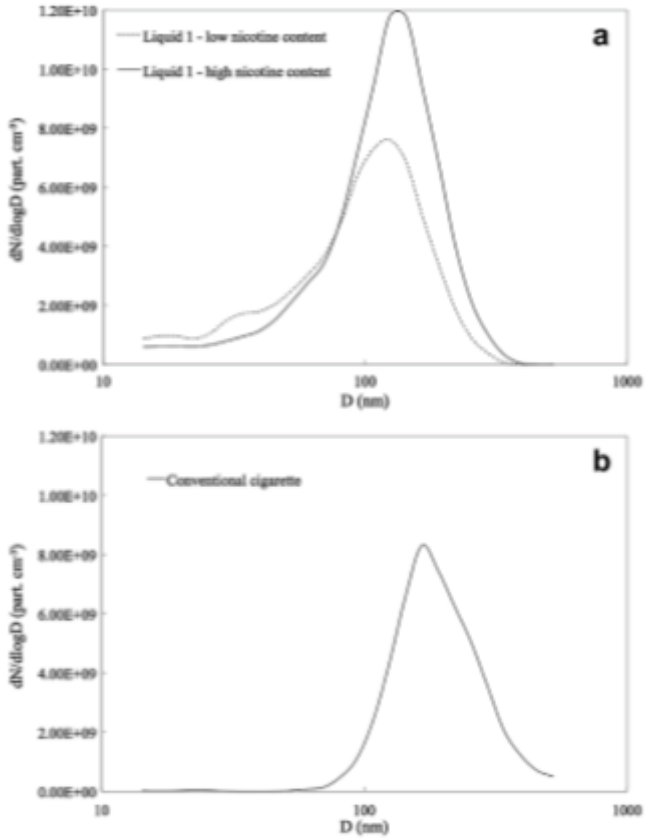

Fig. 3. Particle number distribution measured through the FMPS 3091 (after thermodilution at 37 °C) of the mainstream aerosol from the Liquid 1 (a) and from the conventional tobacco cigarette (b).

Figure 5. Particle number distribution from a) mainstream aerosol in e-liquid 1 and from b) conventional cigarette (reproduced from Figures 3 in Fuoco et al., 2013(Fuoco et al., 2014))

the particle number in the resulting aerosol with little effect on the particle size distribution. Longer puffing time resulted in more particles. Flavor was not associated with differences in particle number or size distribution. The particle size distribution (with modes around 120-165nm range) was similar to conventional cigarettes, with some e-cigarettes delivering more particles than conventional cigarettes.The particle size distributions were similar to that found in Schripp et al. and Ingebrethesen et al. (Figure 5)

Metals in e-cigarette liquid and aerosol were studied by Williams et al (2013) who performed various laboratory analyses on 22 dissected cartomizers (the atomizer and cartridge combined into a single component).(Williams et al., 2013) They examined metal content and quantity in both e-liquid (from cartomizers) and the corresponding aerosol using electron microscopy and energy dispersive x-ray spectroscopy. Both the e-liquid and the Poly-fil fibers

that are used to absorb the e-liquid for heating and conversion to an aerosol andcome into contact with heating elements in the cartomizers, contained heavy metals (tin, nickel, copper, lead, chromium).(Williams et al., 2013) Tin, which appeared to originate from solder joints, was found in the form of both particles and tin whiskers in cartomizer fluid and Poly-fil. E-cigarette fluid containing tin was cytotoxic to human pulmonary fibroblasts.(Williams et al., 2013) E-cigarette aerosol also contained other metals. Levels of nickel were measured that were 2-100 times *higher* than found in Marlboro cigarette smoke. The nickel and chromium possibly originated from the heating element, which conventional cigarettes do not have. Some nickel, tin and chromium in the aerosol were in the form of nanoparticles (<100 nm). This study analyzed e-cigarette models that employ Poly-fil fiber to contain the e-liquid, which is not used in some "tank" systems, where liquid surrounds a heating element or wick. It is likely that the engineering features, including the nature of the battery and the heating temperature of the liquid, the type of heating element and reservoir, will influence the nature of particles that are produced, how many and at what size. These metal nanoparticles can deposit into alveolar sacs in the lung, potentially causing local respiratory toxicity and/or becoming translocated into the circulation.

Cytotoxicity

Bahl et al (2012) screened 41 e-cigarette refill fluids obtained from 4 companies (year of purchase not reported) for cytoxicity (measured as the ability to kill half of the cells in a culture using the 3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide (MTT) assay procedure) to three cell types: human pulmonary fibroblasts, human embryonic stem cells, and mouse neural stem cells.(Bahl et al., 2012) The latter two cells types were chosen as early prenatal and early postnatal models. A hierarchy of cytotoxicity was determined based on e-cigarette liquid that killed 50% of the cells (IC_{50}) for the human embryonic stem cells, which were the most sensitive of the three cell types tested. Results showed that: (1) cytoxicity varied among products with some being highly toxic and some having low or no cytoxicity, (2) nicotine did not cause cytotoxicity, (3) all companies had some products that were non-cytotoxic and some that were highly cytotoxic, (4) one company had products that were non-cytotoxic to pulmonary fibroblasts but cytotoxic to both types of stem cells, (5) cytotoxicity was related to the concentration and number of flavorings used. The finding that the stem cells were more sensitive

than the differentiated adult pulmonary fibroblasts cells suggests that adult lungs are probably not the most sensitive system to the effects of exposure to e-cigarette aerosol. These findings also raise concerns about pregnant women who use e-cigarette or are exposed secondhand e-cigarette aerosol.

In a study funded by FlavorArt e-cigarette liquid manufacturers, Romagna and colleagues (2013) compared the cytotoxicity of aerosol produced from 21 flavored (12 tobacco flavored and 9 fruit or candied flavored; all contained nicotine) brands of e-cigarette liquid to smoke from a reference conventional tobacco cigarette.(Romagna et al., 2013) Samples were analyzed for cytotoxicity using an embryonic mouse fibroblast cell line (3T3) via the MTT assay according to UNI ISO 10993-5 standards, which defines cytoxicity as a 30% decrease in viability of treated cells vs. untreated controls. Only aerosol from coffee-flavored e-liquid produced a cytotoxic effect average of 51% viability at 100% concentration of solution). They concluded that e-cigarette aerosol is much less toxic than cigarette smoke and could be useful products in tobacco harm reduction.

Farsalinos et al. (2013) analyzed the aerosol generated by e-cigarettes and a conventional cigarette for cytotoxicity to cultured rat myocardial cells.(Farsalinos et al., 2013a) Study authors tested 20 refill solutions from 5 manufacturers containing 6 to 24mg/ml of nicotine; 17 tobacco flavored, 3 fruit or candy flavors), a "base" only solution (50% propylene glycol and 50% glycerol)and smoke from a cigarette (0.8mg nicotine, 10mg tar, 10 mg carbon monoxide) in an e-cigarette cartridge and atomizer with a low-voltage battery (3.7 volts) attached and one with a high voltage battery (4.7 volts) attached (the high voltage battery contained an "electronic circuit by which the voltage applied to the atomizer can be adjusted"). The aerosol extract, base only and cigarette smoke solutions were tested on cardiac myoblasts (H9c2) at 100% and 4 dilutions (50%, 25%, 12.5%, 6.25%)and cytotoxicity was measured after a 24 hour incubation period by the ISO 10993-5 <70%. The aerosol from 3 refill fluids was cytotoxic at 100% and 50% dilution, two were tobacco flavored and one was cinnamon cookie flavored. Cigarette smoke was cytotoxic at 100% and all dilutions except 6.25%.

Conclusion

The studies of what is in e-cigarettes are limited by the selection of a handful of products tested (from the hundreds on the market) and by puffing protocol which may or may not reflect

actual users puffing behavior. Considering these limitations, the published research demonstrates a lack of standards for e-cigarettes, mislabeled nicotine content and wide variability in e-cigarette constituents and toxicants.(Trehy et al., 2011, Goniewicz et al., 2013, Hadwiger et al., 2010, Cameron et al., 2013) The e-liquid that is aerosolized in e-cigarette devices is not uniform in ingredient content and proportion; some do not even include nicotine. Studies have detected varying levels of nicotine content from labeled amounts, and the presence of volatile organic compounds, tobacco-related carcinogens, metals and chemicals. For the carbonyl compounds (formaldehyde) and the VOCs, the data show much lower levels than a cigarette but higher levels than the nicotine inhaler.(Goniewicz et al., 2013 (online first)) In addition, the data in Table 2 demonstrate that, depending on brand and sample, an e-cigarette possibly delivers several toxins which were not detected in the nicotine inhaler (the reference for this study). Some of the chemicals, particularly some flavoring agents, in e-cigarette aerosol are cytotoxic to human and rat cells, particularly human embryonic cells. Several chemicals that have been found in e-cigarette aerosol and e-liquid are on California's official list of known human carcinogens or reproductive toxicants,, including nicotine, acetaldehyde, formaldehyde, nickel, lead, toluene.(California Office of Environmental Health Hazard Assessment (OEHHA), November 8, 2013)

Studies that have measured the diameter of the particles comprising e-cigarette aerosol have detected small (<10microns in diameter), fine (<2.5microns in diameter) and ultrafine/nanoparticles (<1 micron in diameter).(Williams et al., 2013, Schripp et al., 2012, Zhang et al., 2013) The size of particles is important for how they can deposit in the body's bloodstream, cells and organs. The smaller the particle size, the easier it is for chemicals to enter the bloodstream and cells, potentially effecting damage or changes. Very small particles mostly get inhaled and exhaled. However some fraction of these particles, at least of certain types, may be absorbed directly. Medium sized particles (cigarette smoke size) are optimal to impact and release their constituents into the airways, and then be absorbed.

The particle size distribution and number of particles delivered by e-cigarettes is similar to that of conventional cigarettes, with most of the particles in the ultrafine range (modes around 100 -200 nm). The particle delivery appears to depend on nicotine level in the e-cigarette liquid, with more particles delivered in higher nicotine e-cigarettes, but not as impacted by the presence of flavors. Users exhale some of these particles, which exposes bystanders to "passive vaping."

Like cigarettes, e-cigarette particles are small enough to reach deep into the lungs and cross from lungs into blood and be absorbed into body tissues.

Based on the data from all these studies one would expect that e-cigarette aerosol could be inhaled into the deep lung, similarly to a tobacco cigarette. The particle concentrations ($10^9/cm^3$) were also similar for e-cigarette and conventional tobacco cigarettes.

At minimum, these studies show that e-cigarette aerosol is not merely "water vapor" as is often claimed in the marketing for these products. Based on these studies, the e-cigarettes tested have much lower levels of most toxicants – but not particles -- than conventional cigarettes. The thresholds for human toxicity of potential toxicants in e-cigarette aerosol are not known, and the possibility of health risks to primary users of the products and those exposed passively to the product emissions must be considered.

BIOLOGICAL EFFECTS

Nicotine Absorption

Vansickel et al. (2010) conducted a study with 32 healthy smokers to examine nicotine absorption from e-cigarettes, cardiovascular effects on craving and withdrawal after using an e-cigarette.(Vansickel et al., 2010) (Results with a subset of these participants were published in *Tobacco Control* as a research letter prior to this study being published and reported similar findings.(Eissenberg, 2010)) Participants with no prior e-cigarette use were asked to participate in each of 4 product use protocols (own brand of cigarette, 18mg NJOY “NPRO” e-cigarette, 16mg Crown Seven “Hydro” e-cigarette, and sham-unlit cigarette) separated by 48 hours and after 12 hours of abstinence from tobacco smoking. The flavor of e-cigarette cartridge was matched to the type of tobacco cigarette usually used by the participant (e.g., menthol or non-menthol). Biological measures were blood plasma nicotine and expired air carbon monoxide (CO); heart rate and subjective measures of craving and withdrawal were also assessed. They found that 5 minutes of puffing on both e-cigarettes and sham cigarette resulted in little or no change from baseline in blood plasma nicotine levels but the expected increased occurred with own brand of tobacco cigarettes (18.8ng/ml) (Figure 6 reproduced from their article). After 5 minutes of puffing, heart rate increased reliably for own cigarette brand only, from 65.7(SD=10.4) to 80.3(SD=10.9) beats per minute. Neither e-cigarette product nor sham smoking increased expired air CO concentration, but own cigarette brand smoking increased CO

as expected. E-cigarette use, with or without nicotine, decreased some nicotine/tobacco abstinence withdrawal symptoms, including cigarette craving, although not to as great an extent as smoking a conventional cigarette. This study shows that smokers could experience some modest relief of some withdrawal symptoms and positive subjective effects with e-cigarette use despite minimal systemic delivery of nicotine.

In a cross-over trial, (Bullen et al 2010) 40 adult smokers were randomized to the following groups at different times: e-cigarette (Ruyan V8) 16mg nicotine, 0mg e-cigarette, Nicorette inhalator, or their usual cigarette for four days (with three days in between test

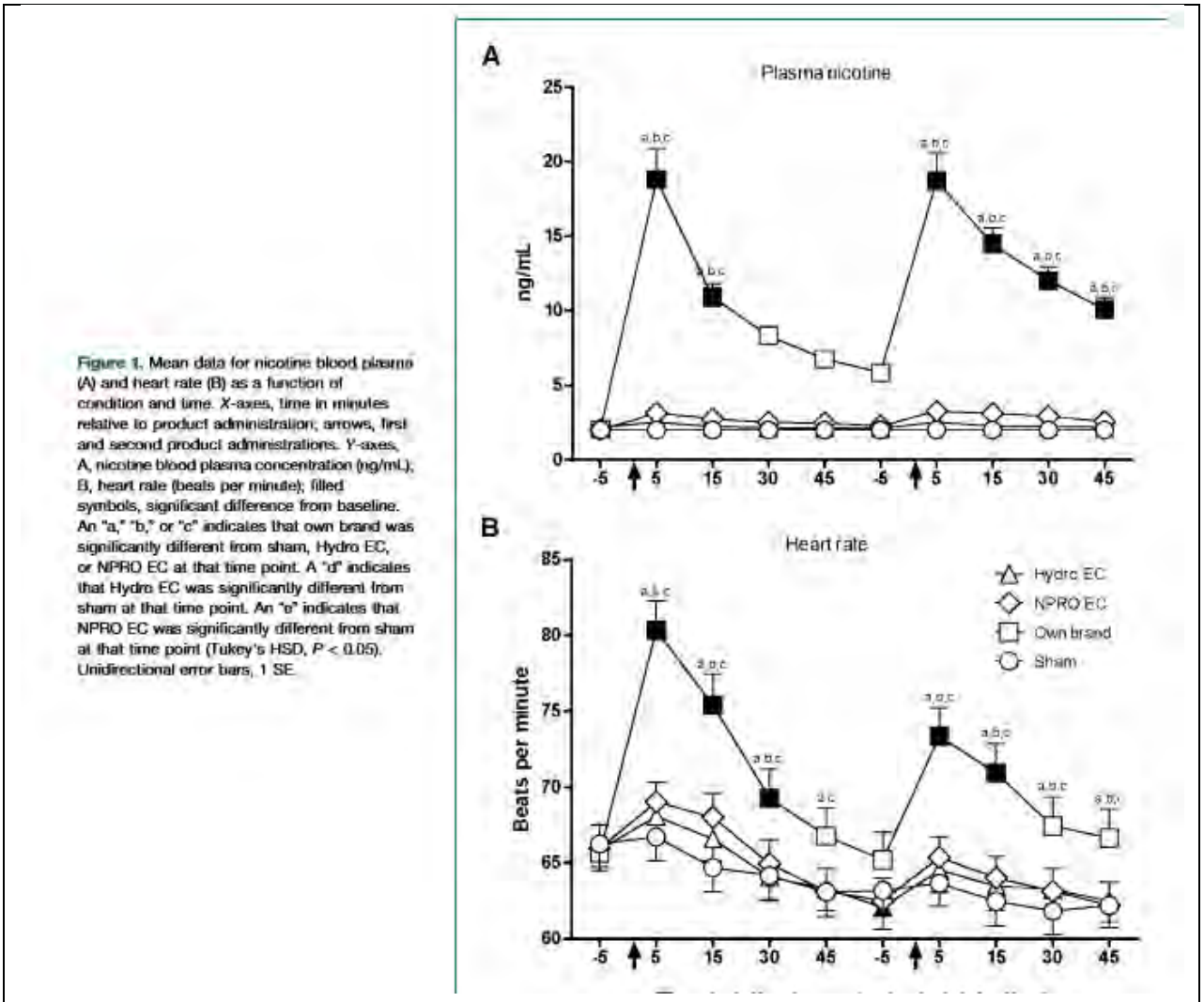

Figure 1. Mean data for nicotine blood plasma (A) and heart rate (B) as a function of condition and time. X-axes, time in minutes relative to product administration; arrows, first and second product administrations. Y-axes, A, nicotine blood plasma concentration (ng/mL); B, heart rate (beats per minute); filled symbols, significant difference from baseline. An "a," "b," or "c" indicates that own brand was significantly different from sham, Hydro EC, or NPRO EC at that time point. A "d" indicates that Hydro EC was significantly different from sham at that time point. An "e" indicates that NPRO EC was significantly different from sham at that time point (Tukey's HSD, $P < 0.05$). Unidirectional error bars, 1 SE.

Figure 6. Levels of blood plasma nicotine concentration and heart rate over time by condition in participants in a 4-arm cross-over study (reproduced from Vansickel et al. (2010))(Vansickel et al., 2010)

rounds).(Bullen et al., 2010) The 16mg e-cigarette resulted in similar serum level of nicotine as the Nicorette inhalator in a similar amount of time (1.3ng/ml at 19.6 min and 2.1ng/ml at 32.0 min, respectively), with the inhaler taking longer to reach peak levels. However, both the e-cigarette and the nicotine inhaler achieved much lower peak serum nicotine levels with a longer time to peak concentration compared to a tobacco cigarette, which increased serum nicotine to 13.4ng/ml at 14.3 min. The 16mg e-cigarette and nicotine inhalator reduced desire to smoke over the 60 minute puffing period more than the 0mg e-cigarette (Figure 7 reproduced from their paper). Both 16mg e-cigarette and the nicotine inhalator reduced the desire to smoke and withdrawal symptoms, with no statistically significant differences. Respondents reported a similarly low level of "satisfaction" with both the 16mg e-cigarette and the nicotine inhalator (approximately 3 on a 10 point scale, exact number not reported), but rated the 16mg e-cigarette as more "pleasant to use" than the inhalator by 1.49 units on a 10 point visual analog scale (VAS) scale (p=0.016).The cross-over design is a strength of the study as it tests the effects of each condition within the same person. However, authors noted that the 16mg e-cigarette failed to deliver nicotine to one-third of participants and participants reported failure of the device to

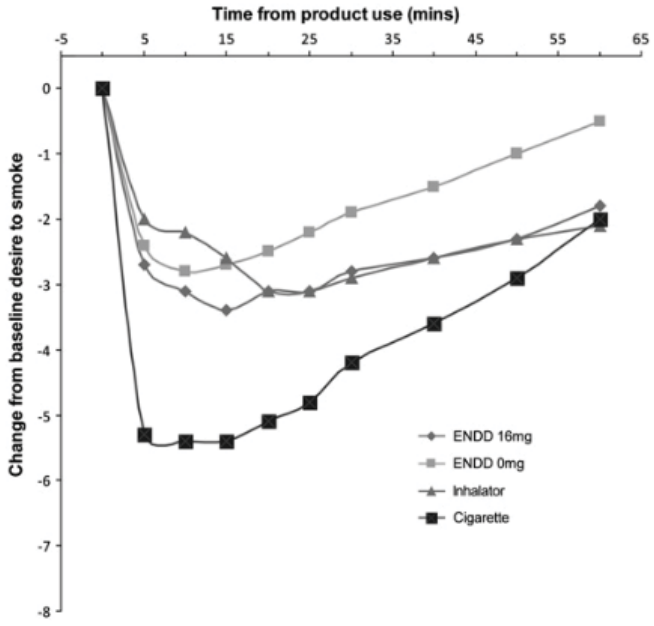

Figure 2 Change in desire to smoke from baseline over the first hour after each product use.

Figure 7. Change in desire to smoke among participants in a 4-arm cross-over trial of 16mg and 0mg nicotine e-cigarette use, inhalator and conventional cigarette (Reproduced from Bullen et al. (2011)(Bullen et al., 2010)

function and produce aerosol (which the authors noted that they discussed with the e-cigarette company supplying the products). This study may also be limited by lack of a “practice period” for participants to become familiar with how to use the e-cigarette or nicotine inhalator, as participants had never used them and only 2 participants had ever used the nicotine inhalator. (This study was funded by the e-cigarette manufacturer, Ruyan Group Holdings Limited through Health New Zealand Ltd., a company owned by one of the authors, M. Laugesen.)

Vansickel and Eissenberg (2013) conducted a second study of nicotine delivery and craving suppression, this time in former smokers who were experienced e-cigarette users (n=8; at least 3 months of regular use) and brought their own e-cigarette device for use during a single, 5-hr. session.(Vansickel and Eissenberg, 2013) For the first part of the protocol, plasma nicotine, heart rate and subjective effects were assessed at baseline and 5 and 15 minutes after users took 10 puffs (at 30 second intervals) followed by a one-hour ad lib puffing session, where blood was sampled every 15 minutes and during a 2-hour rest (no puffing) session where blood was sampled every 30 minutes. Seven of the eight participants used e-cigarette devices that "did not resemble tobacco cigarettes, contained cartomizers, and housed higher voltage and/or longer lasting batteries "than the cigarette-sized e-cigarette products used in the authors' previous work.(Vansickel et al., 2010) Most of the participants used 18 mg/ml nicotine solution (n=6), 1 used 24mg/ml and one used 9mg/ml. Mean blood plasma nicotine level reached 10.3 ng/ml (SEM = 2ng/ml)during the 10-puff protocol, which was much higher than previous studies and comparable to that delivered by conventional cigarette smoking. Blood plasma levels reached an even higher mean after one-hour of ad lib puffing (Figure reproduced form the original article below). During ad lib puffing, heart rate increased from an average of 73.2(SD=2.0beats/min to 78(SD=1.9) within the first 5 minutes and remained elevated throughout the hour, consistent with the expected effects of nicotine. Nicotine withdrawal symptoms (e.g., restlessness) were relieved over the 75minute puffing period (Figure 8, reproduced from their article).(Vansickel and Eissenberg, 2013) Overall, these results show effective nicotine delivery inexperienced users, using their own cartomizer style e-cigarette (with higher battery power than the first generation cigarette-like e-cigarette), with nicotine deliveries comparable to conventional cigarettes, and subjective effects on withdrawal symptoms suggest the e-cigarette relieves symptoms of nicotine physical dependence.

Dawkins et al (2013) assessed nicotine delivery in a study intended to replicate the methodology described above in Vansickel and Eissenberg (2013) in a study funded by SkyCig e-cigarette company.(Dawkins and Corcoran, 2013) Participants (n=14, 6 current smokers, 8 ex-smokers) who were recruited via the SkyCig company website, used at least one 18mg/ml e-cigarette cartridge per day for a minimum of 1 month, were almost all men (3 women), and had a mean age of 37 years. Authors reported difficulty in obtaining samples from half of the participants due to various reasons and consequently only 7 of the 14 participants were able to provide complete blood samples (none of the 3 women were able to provide samples at all time points). Among the 7 participants with complete data, from baseline to 10 minute after taking 10 puffs of the 18 mg/ml e-cigarette, blood plasma nicotine concentration increased from an average concentration of 0.74 ng/ml to 6.77 ng/ml and reached a maximum average peak of 13.91 ng/ml

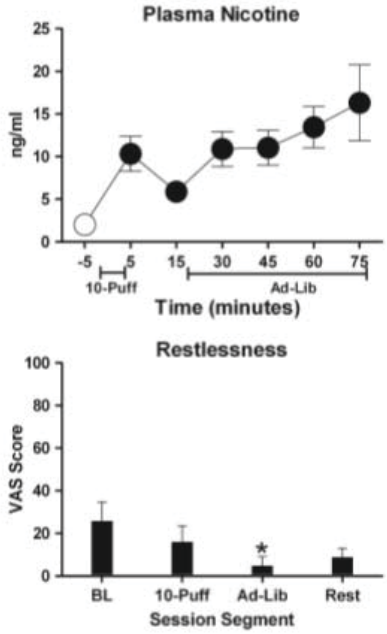

Figure 1. Top panel: *M* (±1 *SEM*) plasma nicotine (assay's limit of quantitation = 2 ng/ml; Breland, Kleykamp, & Eissenberg, 2006) levels at baseline (−5) and during the 10-puff and 1-hr ad lib puffing periods. Filled symbols indicate a significant difference from baseline. Bottom panel: *M* (+1 *SEM*) response to a visual analogue scale item assessing "restlessness" (0–100 scale) at baseline and the end of the 10-puff, ad lib, and rest periods. An asterisk indicates a significant difference from baseline. Data are from eight electronic cigarettes (EC) using participants who abstained from ECs for at least 12 hr before session. Paired *t* tests were used to compare means, $p \leq .05$.

Figure 8. Plasma nicotine concentration and level of restlessness before, during and after e-cigarette use (Reproduced from Vansickel and Eissenberg (2013))(Vansickel and Eissenberg, 2013)

after the 60 minute ad lib session. Participants' tobacco withdrawal symptoms were reduced significantly after e-cigarette use (both the 10 minutes and 60 minute puffing periods).

In another study, Dawkins and colleagues (2013) (Dawkins et al., 2012) also tested the effect of e-cigarette use on withdrawal symptoms, craving and cognition in 86 smokers who had no prior e-cigarette use. (This study was funded by SkyCig e-cigarette company and e-cigarettes were provided by The Electronic Cigarette Company). Participants were randomized to engage in 5 minutes of ad lib puffing on an 18mg/ml "White Super" brand e-cigarette, a 0mg/ml (placebo) "White Super" e-cigarette, or to hold an e-cigarette for 5 minutes without puffing on it and measurements were taken at baseline (time 1), after 5 minutes (time 2) and after 20 minutes (time 3). Authors found that desire to smoke decreased from time 1 to time 3 for both the nicotine and placebo e-cigarette groups compared to the just hold group; declining statistically significantly more in men vs. women. With regard to withdrawal symptom reduction, there were differences in symptoms reduction between men and women. Among men in the nicotine e-cigarette group, symptoms of anxiety, restlessness, poor concentration and irritability were statistically significantly reduced from time 1 to time 3 compared to the participants in placebo e-cigarette and the just hold conditions, but only poor concentration and depression were reduced among women compared to just hold condition. Authors conclude that perhaps nicotine is more important for reducing withdrawal symptoms for men than women. There was no statistically significant difference in performance on the letter cancellation task among the three groups; however those in the nicotine group demonstrated better performance on the Brown-Peterson memory test compared to those in the placebo e-cigarette and just hold condition.(Dawkins et al., 2012)

Nides et al. (2013) examined nicotine delivery and the potential for reduction and cessation among adult smokers provided NJOY King disposable cigarettes over a one-week period (e-cigarettes contained 26 mg nicotine in 0.5 ml of solution each, i.e., 52 mg/ml) (study funded by NJOY e-cigarette company).(Nides et al., 2014) Participants were 25 healthy adult smokers not currently ready to quit smoking (in the next 30 days), mean age 43 years, 66% male, on average smoked 20 cigarettes/day, 45% never e-cigarette users, 7% used more than 10 e-cigarettes in their lifetime. They attended 3 lab visits: visit 1 to screen for eligibility), visit 2 for training which included instructions on how to use the e-cigarettes, provision of a 10-day supply of e-cigarettes (menthol or regular, depending on user preference) and instruction to use them ad

libitum), and visit 3, a follow-up one-week after the training visit. At the screening visit, participants were also instructed to keep a log of cigarettes smoked per day which they returned at visit 2 and at visit 2 were instructed to keep a log of cigarettes smoked and e-cigarette puffs taken per day (using a manual counting device) until visit 3 when they turned in that log. At visit 3, participants came in (abstinent from nicotine for previous 12 hours) and their plasma nicotine, carbon monoxide, heart rate, craving and withdrawal and perception of the products were measured. Blood nicotine levels after 5 minutes of use (10 puffs with 30 seconds between puffs) reached a mean of 3.5 ng/ml (range 0.8-8.5 ng/ml), heart rate increased and craving was reduced by 55% and CO did not increase. During the trial week, most used the e-cigarette daily and participants took a median of 59 puffs each day (range 1.7-400 puffs), 89% decreased cigarettes per day by an average of 39%. Participants rated the e-cigarettes as highly satisfying in terms of looking like a cigarette, safety, ease of use, use to cut down on cigarettes and use to quit smoking. Most common adverse events rated as study-related were "local irritation of the mouth, throat or airways, specifically throat irritation, followed by cough, dry throat, burning sensation on lips," all of which were rated by participants as mild, except one who discontinued use due to throat irritation.

Etter (2011) reported on saliva cotinine levels in experienced e-cigarette users recruited through the smoking cessation and e-cigarette forum websites described in Etter and Bullen 2011.(Etter and Bullen, 2011a) Participants in the original study completed an online questionnaire and 196 participants were mailed saliva collection materials, of which 31 mailed back saliva samples. Thirty participants were former smokers and 1 reported currently trying to quit and smoking 1 cigarette per day. The sample was mean age 41 years, 65% men and reported using 18mg/ml nicotine concentration e-liquid, 5 refills per day and taking a median of 200 puffs per day. Median cotinine among the ex-smokers was 322ng/ml. Investigators concluded that cotinine levels among e-cigarette users were higher the levels reported among those using NRT and similar to the levels reported among smokers.

Abuse Liability

Vansickel et al 2012 conducted a study of the abuse liability of an 18mg e-cigarette (Vapor King brand) with 20 current, daily smokers.(Vansickel et al., 2012) They tested several aspects of abuse liability during a series of four within-subject sessions, 1 of which allowed for

product sampling to familiarize users with the device and 3 of which involved the “multiple choice procedure,” (MCP) a validated procedure in which participants sample a drug and then make two or more choices between it and another drug, or a series of monetary values. The first session involved 6, 10-puff bouts with each puff separated by 30 seconds and each 10-puff bout separated by 30 minutes. During the MCP sessions, participants chose between 10 e-cigarette puffs and varying amounts of money, 10 e-cigarette puffs and a varying number of own brand conventional cigarette puffs, or 10 conventional cigarette puffs and varying amounts of money. The monetary value at which users chose money over the 10 product puffs was considered the "crossover value," or for e-cigarette and conventional cigarette choice condition crossover value was when participants chose conventional cigarette puffs over the e-cigarette puffs. The crossover values were higher for conventional cigarettes compared to e-cigarettes (average of $1.06(SD=$0.16) for 10 e-cigarette puffs and average of $1.50(SD=$0.26) for 10 conventional cigarette puffs ($p<0.003$). E-cigarettes delivered a similar level of nicotine as a cigarette, but more slowly and required a greater number of puffs than cigarettes to achieve the same nicotine level, and reduced withdrawal symptoms. The authors concluded that e-cigarettes deliver nicotine, can reduce withdrawal symptoms and appear have lower abuse potential compared to conventional cigarettes.

Conclusion

The early studies of nicotine absorption found that e-cigarettes delivered a lower level of plasma nicotine than conventional cigarettes(Vansickel et al., 2010, Bullen et al., 2010), while more recent studies demonstrated that when users are experienced and using their own product and engaged in more puff intervals nicotine absorption is similar to that of conventional cigarettes.(Vansickel and Eissenberg, 2013)(Dawkins et al., 2013) As indicated in the Nides et al (2013) study as well, differences in nicotine delivery may be due to a combination of characteristics of the devices and user vaping topography. However, despite the greater efficiency at nicotine delivery in the more recent study by Vansickel et al. (2013) and range of delivery, such as in Nides et al. (2013) all of these studies show that e-cigarettes regardless of nicotine delivery, e-cigarettes can modestly alleviate some symptoms of withdrawal and produce positive subjective appraisal of the e-cigarettes as pleasant to use. Moreover, the one study examining abuse liability found that at least one model of cigarette-shaped 18mg e-cigarette

appeared to have a lower abuse liability than cigarettes.(Vansickel et al., 2012) In the trial comparing nicotine inhalator to e-cigarettes,(Bullen et al., 2010) the nicotine inhalator delivered a similar amount of nicotine as the 16mg e-cigarette, however authors noted that the e-cigarette malfunctioned and did not deliver any nicotine in a third of participants, which did not occur with the nicotine inhalator. These results highlight the need for product regulation in terms of the potential drug delivery and effects, as well as device quality and labeling. Only a few brands and models of e-cigarettes were tested in these studies, limiting the generalizability of the findings to other products.

HEALTH EFFECTS

Vardavas et al. (2012) conducted a study examining pulmonary function after acute *ad lib* puffing of an e-cigarette (Nobacco, medium, 11mg) in a group of healthy cigarette smokers(n=30).(Vardavas et al., 2012) All participants were asked to use the same e-cigarette device (>60% propylene glycol, 11 mg/ml nicotine) as desired for 5 minutes. Participants refrained from smoking tobacco cigarettes for 4 hr prior to study. On another day, 10 participants selected randomly from the 30 participants were asked to sham-smoke an e-cigarette device with the cartridge removed. Three lung function measures were assessed: spirometry, dynamic lung volumes and resistance and expired nitric oxide (NO). E-cigarette use had no effect on spirometric flows (such as FEV1/FVC) but did significantly increase airway resistance (18%) and decrease expired NO (16%). Sham e-cigarette use had no significant effect, as expected. Acute increases in airway resistance, although modest in size, raise concern that more prolonged e-cigarette use could have greater effects, particularly in people with reactive airways disease (asthma). This study is limited by small sample size, the short period of tobacco use abstinence before the protocol was executed, the short length of exposure to e-cigarette aerosol and the lack of comparison to smoking conventional tobacco cigarettes. In addition, smokers in general have high airway resistance with dynamic testing and lower expired NO, likely due to oxidant stress. Despite these limitations, this study suggests that e-cigarette use constricts lung peripheral airways, possibly due to the irritant effects of propylene glycol, which could be of concern particularly in people with chronic lung disease such as asthma, emphysema or chronic bronchitis.

Flouris et al. (2013) assessed the short term effects of active and secondhand e-cigarette and conventional tobacco cigarette use on serum cotinine and pulmonary function in 15 cigarette smokers and 15 never smokers.(Flouris et al., 2013) A single brand of e-cigarettes made in Greece and a single e-liquid (> 60% propylene glycol; 11 mg/ml nicotine) was used. The authors attempted to compute how many e-cigarette puffs would deliver the same amount of nicotine as a conventional cigarette using a number of assumptions, some of which are not valid. For example, authors assume that the smoking machine yield of each person's cigarette indicates amount of nicotine delivered to the smoker, yet neither for conventional cigarettes or e-cigarettes is there evidence of correlation between machine-tested yield and actual systemic delivery. The passive exposure study was conducted in a $60m^3$ chamber. The ventilation (air exchange rate) was not specified. The secondhand cigarette smoke was generated with a target air CO of 23 ppm which is extremely high but which simulates exposure in a very smoky bar. E-cigarette aerosol was generated using a pump that operated for the same duration as the cigarette smoking and aerosol was released into the room. The study limitations include using only type of e-cigarette, studying people who were not regular e-cigarette users, studying a specified puffing (vs *ad lib*) regimen, using extremely high passive exposure conditions, and studying short term pulmonary effects in healthy people (as opposed to asthmatics, who would be expected to be more sensitive to a lung irritant).The authors found a similar rise in serum cotinine with active tobacco cigarette or e-cigarette use immediately after active use (mean increase about 20ng/ml). The passive exposure the serum cotinine increase was similar for e-cigarette and tobacco cigarette exposure (averaging 0.8ng/ml for the tobacco cigarette and 0.5ng/ml for the e-cigarette). These results show that in cigarette smokers, some e-cigarette devices deliver similar amounts of nicotine as tobacco cigarette smoking. With very heavy passive exposure there is also similar systemic exposure to nicotine from tobacco and e-cigarettes among bystanders. Active cigarette smoking resulted in a significant decrease in expired lung volume (FEV1/FVC) but not with active e-cigarette or with passive tobacco cigarette or e-cigarette exposure.

Flouris et al. (2012) studied the effects of passive e-cigarette aerosol on white blood cell count. The paper presents additional analyses of data collected in the same study described by Flouris et al 2013,(Flouris et al., 2013)this time with a different biomarker outcome.(Flouris et al., 2012) The effects of tobacco cigarettes and e-cigarettes, both with active use and passive exposure, on white blood cell count were examined. White cell count increases acutely and

chronically following cigarette smoking, the latter reflecting a chronic inflammatory state that is associated with future risk of acute cardiovascular events. As expected, active conventional cigarette smoking and exposure to secondhand conventional cigarette smoke increased the total white blood cell count as well as granulocyte and lymphocyte counts. Active e-cigarette use and passive exposure to e-cigarette aerosol did not result in a statistically significant increase in these biomarkers over one hour of exposure. This study suggests that the increase in white cell count is mediated more by tobacco combustion products than by nicotine. The figure provided in the paper suggests that the change, if any, is very small, and possibly not of clinical significance. Since the protocol is the same as Flouris et al 2013 (respiratory effects),(Flouris et al., 2013) the same limitations apply.

Hua and colleagues (2013) sought to determine the health impact of electronic cigarettes, using an infodemiological approach.(Hua et al., 2013a) They collected information posted on three electronic cigarette forums: Electronic Cigarette Forum, Vapers Forum and Vapor Talk. Posts were reviewed for reports of both positive and negative health impact. Data were then analyzed with Cytoscape. There were 405 symptoms reported, with the majority negative (326 negative, 78 positive and 1 neutral). These effects encompassed twelve anatomical regions/organ symptoms. The majority of the symptoms affected the mouth and throat, and the respiratory system. Overall, examples of potentially serious negative health effects included: increased blood pressure and asthma attack. Some of the symptoms reported appeared opposite, such as increased and decreased blood pressure, indicating that users of the product may be differently affected or that these events are random occurrences and not related to e-cigarette use, as these are self-reported data with no formal analysis of causality.

McCauley and colleagues reported a case of a serious adverse event deemed to be due to e-cigarette use.(McCauley et al., 2012)A42 year old woman who reported the following symptoms: fevers, dyspnea, and productive cough that had lasted for seven months. The patient was found to have exogenous lipoid pneumonia, a lung disease caused by the deposition of oil in the lung tissue. The symptoms coincided with when she began using e-cigarettes. Because no other behavior or exposure could explain her symptoms and because they resolved after she stopped using e-cigarettes, the patient was diagnosed with “exogenous lipoid pneumonia due to e-cigarette use.”

Conclusion

Only a few studies have directly investigated the health effects of exposure to e-cigarette aerosol. Studies have examined effects of acute, short-term e-cigarette use in people who were also cigarette smokers.(Flouris et al., 2013, Flouris et al., 2012, Vardavas et al., 2012) The few studies examining potential effects of second hand aerosol on non-users have tested short-term e-cigarette aerosol exposure conditions, which may not be realistic for indoor spaces where there could be exposure to e-cigarette aerosol for several hours, such as airplanes, bars, and aerosol lounges. One study describes the self-reported health-related events and symptoms reported on e-cigarette forums,(Hua et al., 2013a)another a case of a lung disease due to e-cigarette use(McCauley et al., 2012)and as reviewed above, there have been adverse events reported to the U.S. FDA.(Chen, 2013)Taken together these studies provide a very limited perspective on the health effects from e-cigarettes. Studies are limited to the few products that have been tested, but some do demonstrate the ability for e-cigarette aerosol exposure to result in biological effects. Long-term biological effects are unknown at this time because e-cigarettes have not been in widespread use long enough to assess these effects.

EFFECTS ON CESSATION OF CONVENTIONAL CIGARETTES

As noted above e-cigarettes are promoted as devices to assist in smoking cessation and many adults who use e-cigarettes are doing so because they believe that they will help them quit smoking conventional cigarettes. The assumption that e-cigarettes will be as effective, or more effective, than pharmaceutical nicotine replacement therapy has also motivated support for e-cigarette use among some public health researchers and policy makers and (as discussed later) formed the basis for public policies on the regulation of e-cigarettes.

Population-based studies

There are two longitudinal studies of the association between e-cigarette use and quitting conventional cigarettes (Table 4) and one cross-sectional study.(Popova and Ling, 2013)

In Adkison et al. (2013) (ITC 4-Country Study noted above) authors presented a longitudinal analysis of data from current and former smokers over 2 times separated by one year.(Adkison et al., 2013) E-cigarette users had a statistically significant greater reduction in cigarettes per day from the first time to the second, one year later (e-cigarette users: 20.1cig/day

Table 4. Longitudinal Studies of the Association between e-cigarette use and cessation of conventional cigarette smoking		
Study	**Location and study design**	**Odds of quitting OR, (95% CI)**
Adkison et al. (2013)	U.S., U.K., Canada, Australia (ITC), surveyed at 2 waves, one year apart	One-year follow-up: 0.81 (0.43-1.53)*
Vickerman et al. (2013)	U.S. quitline callers surveyed at enrollment and 7-months post	Seven-months post enrollment in the quitline: 0.50 (0.40-0.63)**
*Odds ratios obtained by contacting authors **Computed by authors of this report based on the numbers reported in the paper		

to 16.3 cig/day; non-users: 16.9 cig/day to 15.0 cig/day). Although 85% of e-cigarette users reported they were using the product to quit smoking at the initial wave, e-cigarette users were no more likely to have quit one year later than non-users (OR=0.81, 95% CI: 0.43-1.53; p=0.52).

Vickerman et al. (2013) collected data about e-cigarette use among quitline callers from 6 U.S. states assessed at 7-months post enrollment.(Vickerman et al., 2013) About 31% reported they had ever tried e-cigarettes in their lifetime and the majority of those who have ever tried them used them for less than one month (67.1%) and 9.2% were using them at 7-month survey (34.6% response rate). Respondents' main reason for using e-cigarettes was tobacco cessation (51.3%), but it is not known whether the ever use occurred as part of a quit attempt in the past 7 months. Nevertheless, those who reported using e-cigarettes were statistically significantly less likely to quit than those who had not used e-cigarettes (21.7% among callers who used for one month or longer, 16.6% among those who used less than one month and 31.4% among never-users; $p<0.001$).(Vickerman et al., 2013) The unadjusted odds of quitting were statistically significantly lower for e-cigarette users compared to non-users (OR=0.50, 95% CI: 0.40-0.63) (computed from the data in the Table 2 in the paper.(Vickerman et al., 2013))

The association between e-cigarette use and conventional smoking cessation has also been examined in one population-based cross-sectional study. Popova and Ling (2013) like earlier research, found that an important reason that adults tried e-cigarettes (as well as other smokeless products) was to help them quit smoking conventional cigarettes. However, the use of e-cigarettes was not associated with being a successful quitter (adjusted OR 1.09; 95% CI 0.72-1.65) but was associated with being an unsuccessful quitter (OR=1.78, 95% CI 1.25-2.53) compared to people who had never tried to quit. This evidence is from a cross-sectional study

(i.e., a snapshot in time) rather than following the same people over time (a longitudinal study), so it does not allow for causal conclusions.

Clinical trials

Four clinical trials have attempted to examine the efficacy of e-cigarettes for smoking cessation (2 with very small samples).(Polosa et al., 2011, Caponnetto et al., 2013b, Caponnetto et al., 2013a, Bullen et al., 2013, Polosa et al., 2013) In 3 of the studies all groups were using an e-cigarette product, some with and some without nicotine; there was no comparison group not using e-cigarettes.(Polosa et al., 2011, Polosa et al., 2013, Caponnetto et al., 2013a, Caponnetto et al., 2013b) The other study compared efficacy of e-cigarettes to a standard of care regimen with 21mg nicotine patch (Bullen 2013). None of the trials were conducted with the level of behavioral support or counseling that accompanies most pharmaceutical trials for smoking cessation.

Polosa et al. (2011) conducted a proof-of-concept study conducted in Italy in 2010 with smokers18-60 year old not intending to quit in the next 30 days were offered 'Categoria' e-cigarettes and instructed to use up to 4 cartridges (7.4mg nicotine content) per day as desired to reduce smoking and to keep a log of cigarettes smoked per day, cartridges used per day and adverse events.(Polosa et al., 2011) (Polosa notes he served as a "consultant for the Arbi Group Srl., the manufacturer of the 'Categoria' e-cigarette used in the study, beginning in February 2011.") Six-month follow-up was completed with 68% (27/40) of participants. At 6-month follow-up, 13 were using both e-cigarettes and tobacco cigarettes, 5 maintained exclusive tobacco cigarette smoking and 9 stopped using tobacco cigarettes entirely and continued using e-cigarettes (Polosa et al., 2011). Cigarette consumption was reduced by at least 50% in the 13 dual users (25 cig/day at baseline to 6 cig/day at 6-months, $p<0.001$). Most common adverse events reported during the trial were throat irritation, dry cough and mouth irritation, followed closely by headache, nausea and dizziness. Participants reported they would recommend the e-cigarettes to a friend yet noted the need for better manufacturing practices as they were frustrated by problems they had operating their devices.

Polosa et al. continued follow-up of this sample at 18 and 24-months post baseline with 23 subjects who could be follow-up (58% of the original 40 enrolled).(Polosa 2013) Among the 23 participants who completed a 24-month visit, 18 continued to smoke; a greater than 50%

reduction in cigarettes per day occurred in 11 of the participants with a statistically significant reduction from an average of 24 to 4 cigarettes per day (p=0.003) and 7 participants reduced by less than 50% (p=0.06). Five participants had quit tobacco cigarettes at 24 months. During the follow-up phase the specific model of the brand of e-cigarettes used in the study was discontinued thus participants were not using that by the last follow-up. Five participants were not using the e-cigarettes provided (it was unclear if they were using another product) but abstinent from smoking and 3 relapsed. Four obtained other e-cigarettes and continued to use them until the end of the study (all were refillable devices and classified as "heavy reducers" by the authors. Study limitations include use of a product that was noted for poor quality during the trial and lack of a comparison or control group, which could make it difficult to determine if quit rates achieved were not due to chance.

A similar study was conducted by Caponnetto et al (2013) with 14 smokers with schizophrenia not intending to quit in the next 30 days.(Caponnetto et al., 2013a)Participants were provided the same “Categoria” e-cigarettes and carbon monoxide, product use, number of cigarettes smoked, and positive and negative symptoms of schizophrenia were assessed at baseline, week-4, week-8, week-12 week-24 and week 52. Sustained 50% reduction in the number of cigarettes per day smoked at week-52 in 7/14 (50%) participants and median of 30 cig/day decreased to 15 cig/day (p = 0.018). Sustained abstinence from smoking occurred with 2 participants (14.3%) by week 52. Most common side effect was dry cough followed by nausea, throat irritation, and headache. Positive and negative aspects of schizophrenia were not increased after smoking cessation in those who quit. The most common outcome was dual use of e-cigarettes with conventional cigarettes. Study findings are not generalizable to smokers with mental illness due to very small sample size and lack of a control group.

Caponnetto et al. (2013) also conducted a randomized, quasi-controlled trial (n=300) to examine efficacy of different strength e-cigarettes for smoking cessation and reduction in three study arms: 12 weeks of treatment with the 7.2mg nicotine e-cigarette, a 12-week nicotine tapering regimen (6 weeks of treatment with a 7.2mg e-cigarette and 6 weeks with 5.4mg e-cigarette), and 12 weeks of treatment with a non-nicotine e-cigarette.(Caponnetto et al., 2013b) Reduction occurred in the median value of cigarettes per day at all study visits among all three treatment arms. At one-year follow-up the reduction in median level of cigarettes per day among participants in the 7.2 mg nicotine e-cigarette group was 19 to 12 cig/day; the tapered e-cigarette

group was 21 to 14 cig/day and the non-nicotine e-cigarette group was 22 to 12 cig/day. Differences in reductions between groups were not significant after week 8 assessment. There was no statistically significant difference in 6-month or one year quit rate among the three conditions (one year rates: 4% for placebo e-cigarette users, 9% for low nicotine e-cigarette users and 13% for high nicotine e-cigarette users) (Capponetto 2013). The authors noted that those who initiated quitting in the first few weeks of the study stayed quit, while those who did not remained dual users throughout the study. In addition, 26% of quitters continued to use e-cigarettes at 1 year. A problem noted in the paper was a lack of product quality (the authors noted the devices malfunctioned often and new ones had to be sent out frequently over the course of the treatment period).

Bullen et al (2013) conducted the first randomized controlled clinical trial of e-cigarette compared to medicinal nicotine replacement therapy in Auckland, New Zealand.(Bullen et al., 2013) Adult smokers who wanted to quit (n=657) were randomized using a 4:4:1 ratio to the 3 study arms (16mg e-cigarette n=289, 21mg NRT patch n=295, no-nicotine e-cigarette n=73).(Bullen et al., 2013) Voluntary telephone counseling was offered to all subjects. Participants had visits at baseline, week 1 (quit day), 12 weeks to 6 months. Fifty-seven percent of participants in the nicotine e-cigarette group reduced their cigarettes per day by≥50% by 6 months compared to 41% in the patch group (p=0.002) and 45% in the non-nicotine e-cigarette group (p=0.08). Those randomized to the nicotine patch group were less adherent to the treatment (46%) than the 16mg e-cigarette group (78%) and the no-nicotine e-cigarette group (82%). It is possible that study methodology may have biased against success in the nicotine patch group. E-cigarettes were provided by mail for free to participants randomized to either the nicotine or no-nicotine e-cigarette group. Participants in the patch group were provided with usual care for quitline callers in New Zealand, where they are mailed cards redeemable for nicotine patches at a pharmacy at a very reduced rate of about $4 USD for 12 weeks of nicotine patches and were also provided with monetary vouchers to compensate for the $4 they had to pay for the patches at time of card redemption. While the protocol for providing the patches represented reasonable “usual care” for New Zealand, where everyone calling the local quitline has the option of receiving a voucher for NRT that can be redeemed at a local pharmacy, the fact that participants randomized to e-cigarettes were sent the e-cigarettes directly whereas participants randomized to NRT only received vouchers that they had to take to a pharmacy to

redeem may have biased the results against the NRT if the study were viewed as a head-to-head comparison of e-cigarettes and NRT for cessation. There were no statistically significant differences in biochemically-confirmed (breath CO) self-reported continuous abstinence from quit day to 6 month follow-up between nicotine e-cigarette (7.3%), nicotine patch (5.8%), and non-nicotine e-cigarette (4.1%). Considering the nicotine patch group as the standard of care, the quit rates in the Bullen study are much lower than quit rates seen for nicotine patches in clinical trials that offer more intensive behavioral support.(Stead et al., 2008) Another limitation with respect to interpreting this study for e-cigarettes broadly is that the product used had poor nicotine delivery.

Conclusion

In the population-based longitudinal studies of the effects of e-cigarette use on cessation of conventional cigarettes, several strengths and limitations should be noted. A strength of the Adkison et al. (2013) and Vickerman et al. (2013) studies is the assessment of why participants were using e-cigarettes. In Adkison et al. (2013), 85% of e-cigarette users, and in Vickerman 66.5% of e-cigarette users, indicated they were using the product to quit or switch "to replace other tobacco," which limits the possibility that lack of effect on quitting is observed due other motivations for using the device. Although quitline callers represent a small population of smokers motivated to quit, these data present a real-world estimate of the potential effectiveness of using e-cigarettes to quit in a population of motivated to quit. However, this study had a low response rate (34.6%) and may be subject to recall bias as e-cigarette use and perceptions were only assessed at 7-month follow-up. As participants are not randomly assigned to use e-cigarettes in the real world, a strength of the Vickerman et al. (2013) study is that it provides information on smoking characteristics, including measures of tobacco dependence, which could potentially be a source of self-selection bias. In the Vickerman study those who tried e-cigarettes did not statistically significantly differ from non-users in cigarettes per day or time to first cigarette, although they were more likely to have tried to quit 2 or more times. However, it is as yet unclear to what extent self-selection is occurring and contributes to quit success or failure.

The quit rates produced in Caponnetto et al. (2013) for the non-nicotine e-cigarette was 4%, tapered nicotine e-cigarette was 9% and 7.4mg e-cigarette was 13%; past 30-day abstinence at one year was not statistically significantly different.(Caponnetto et al., 2013b) Similarly, in

Bullen et al. (2013), the quit rates for 16mg e-cigarette, 21mg nicotine patch and 0mg e-cigarette showed no statistically significant differences in continuous abstinence quit rates at 6 months (7.4%, 5.8%, 4.1% respectively). Neither study found effects of e-cigarette use on quitting, beyond what is seen in unassisted or low-assistance studies of smokers using NRT to quit.(Hughes et al., 2003) Neither the Caponnetto et al. (2013) and the Bullen et al. (2013) randomized trials demonstrated a statistically significant difference in quit rates between nicotine e-cigarette and non-nicotine e-cigarette, but this could be due to low statistical power.(Bullen et al., 2013, Caponnetto et al., 2013b) In determining the effectiveness of a smoking cessation therapy, active drug is considered efficacious when it outperforms its placebo form, therefore the evidence to date demonstrates that e-cigarettes would not be considered efficacious as nicotine replacement to produce cessation. However, it is possible that e-cigarettes even without nicotine act as substitutes for the sensory and behavioral effects of conventional cigarettes. If this is the case the non-nicotine placebo e-cigarettes would be considered an active treatment condition in that e-cigarettes as discussed previously have been shown to reduce withdrawal symptoms.(Bullen et al., 2010, Eissenberg, 2010, Dawkins and Corcoran, 2013, Vansickel et al., 2010) Important limitations of the current research include lack of a control group not using e-cigarettes, the use of e-cigarettes that deliver relatively low levels of nicotine and the provision of minimal to no behavioral counseling. Another important limitation of studies assessing effectiveness of e-cigarettes for smoking cessation is that because they are not approved as a cessation therapy there are no therapeutic instructions for using them as replacements or to quit smoking (e.g. dosage tapering, duration of use, how to combine them with behavioural strategies, guidance for discontinuation).

In contrast to the assumption that e-cigarettes would function as a better form of NRT, population-based longitudinal studies that reflect real-world e-cigarette use found that e-cigarette use is not associated with successful quitting.(Adkison et al., 2013, Vickerman et al., 2013) The one clinical trial examining the effectiveness of e-cigarettes (both with and without nicotine) compared to the medicinal nicotine patch found that e-cigarettes are no better than nicotine patch and all treatments produced very modest quit rates without counseling.(Bullen et al., 2013) Although more participants liked using the e-cigarette compared to patch and would recommend it to a friend trying to quit,(Bullen et al., 2013) taken together these studies suggest that e-cigarette are not associated with higher quit rates in the general population of smokers.

HEALTH IMPLICATIONS OF CIGARETTE REDUCTION IN THE CONTEXT OF DUAL USE

Reductions in cigarettes per day were observed in these several of the clinical studies(Caponnetto et al., 2013b, Bullen et al., 2013, Polosa et al., 2011) and in one population-based study(Adkison et al., 2013) among those who did not quit. In the cigarette reduction analyses presented in some of the studies, many participants were still smoking about half a pack cigarettes/day at the end of the study.

An individual's cigarette smoking behavior, including both total duration of cigarette consumption, (i.e., years of cigarette use), and intensity of cigarette use, (i.e., number of cigarettes smoked per day) influences the risk of negative health effects.(Godtfredsen et al., 2003) Duration was addressed in a 2013 study of adults in the United States, in which those who stopped smoking cigarettes at younger ages had lower age-adjusted mortality compared to those who continued to smoke later into adulthood.(Jha et al., 2013) Findings regarding decreased smoking intensity; however, have been less consistent, with some studies showing lower mortality with reduced daily cigarette consumption(Gerber et al., 2012) and others not finding a significant overall survival benefit.(Tverdal and Bjartveit, 2006) Use of electronic cigarettes by cigarette smokers to cut down on number of cigarettes smoked per day is likely to have small if any beneficial effects on overall survival if it results in continued use of cigarettes, even in smaller amounts, concurrently with electronic cigarettes, as low intensity cigarette exposure still confers substantially increased mortality risks.

Even if smokers reduce cigarette consumption while using e-cigarettes there is unlikely to be much, if any, cardiovascular benefit because of the highly nonlinear dose-response relationship between exposure to fine particles and the and risk of cardiovascular disease.(Pope et al., 2009, Barnoya and Glantz, 2005)(As discussed earlier in this report, e-cigarettes deliver similar loads of fine particles as conventional cigarettes, both in terms of numbers and size distributions.) Light smoking, even 1-4 cigarettes per day, is associated with markedly elevated cardiovascular disease risk(Bjartveit and Tverdal, 2005).

Both smoking duration and intensity determine cancer risk.The relative risk of death from lung cancer among U.S. adults increases with total number of years smoked and more cigarettes smoked per day.(Thun et al., 2013) Similar results have been seen in risks for other malignancies, with greater smoking duration, intensity, and cumulative smoking dose associated

with greater odds of pancreatic cancer(Lynch et al., 2009) and associations between increased smoking duration and intensity and esophageal cancer.(Pandeya et al., 2008) The relative risk of both lung cancer and bladder cancer levels off after a certain number of cigarettes/day,(Vineis et al., 2000) suggesting that above a certain intensity, the specific levels of exposure may not cause significant differences in risk for these cancers. Doll and Peto (1978) found a dose-response relationship between duration of smoking and number of cigarettes smoked per day and risk of lung cancer, with models suggesting the impact of duration to be greater than that of intensity.(Doll and Peto, 1978) Using participants from the Cancer Prevention Study II, Flanders et al. found a greater increase in lung cancer mortality with greater duration of cigarette smoking compared to greater intensity of smoking.(Flanders et al., 2003) Taken together, these data suggest that lung cancer mortality increases more with additional years of smoking compared to additional cigarettes smoked per day and smoking more cigarettes per day for fewer years may pose less lung cancer risk than fewer cigarettes per day for many years. While use of electronic cigarettes to cut down on cigarettes without complete abstinence may result in the latter scenario and thus a reduction in morbidity, particularly with respect to lung cancer, this trend has not been shown with overall mortality.

Thus, if dual use of electronic cigarettes and cigarettes results in reductions in the number of cigarettes smoked per day for current smokers, might mitigate some of the malignancy risk associated with smoking, but the effect will be less than proportional to the reduction in cigarette consumption because of the (likely larger) importance of duration of smoking. There is not likely to be much cardiovascular benefit absent complete cessation.

TOBACCO INDUSTRY INVOLVEMENT

In 2012 and 2013 major tobacco companies – Lorillard, Reynolds American Inc, (which is 42% owned by British American Tobacco), Altria (Philip Morris), British American Tobacco and Imperial Tobacco -- purchased or developed e-cigarette products. Lorillard, Reynolds and Altria's products are marketed by subsidiary companies: Lorillard Vapor Corporation, R.J.Reynolds Vapor Company, and Nu Mark, LLC., which is owned by Altria. Lorillard acquired e-cigarette companies that produced Blu and SkyCig brands marketed under Lorillard Vapor Corporation.(Esterl, October 1, 2013) As of November 2013, Altria's Mark Ten e-cigarette was in test market in Indiana,(Kress, June 11, 2013) Reynolds' product, the Vuse, was

in test market in Colorado and has planned to continue marketing in Utah as the next phase of national distribution.(Carver, November 18, 2013) BAT markets the Vype in the U.K. Imperial Tobacco Group announced plans to market two e-cigarettes in 2014.(Geller, November 5, 2013) In addition, a smaller tobacco company, Swisher, that makes little cigars and cigarillos, also markets an e-cigarette called the e-Swisher.(Swisher Tobacco Company, 2013)

Tobacco companies are marketing or manufacturing e-cigarettes and some tobacco companies claim to want to participate in "harm reduction," despite no evidence of a strategy to phase out their sale of tobacco cigarettes or other tobacco products. Lorillard CEO Murray Kessler stated in an interview with the *Wall Street Journal* that e-cigarettes will provide smokers an unprecedented chance to reduce their risk from cigarettes.(Esterl, August 27, 2013) Also, in *USA Today* he published an op-ed on September 23, 2013 where he stated: “E-cigarettes might be the most significant harm-reduction option ever made available to smokers.”(Kessler, September 22, 2013) However, Lorillard has gained approval from the US Food and Drug Administration to market a new non-mentholated Newport conventional cigarette, demonstrating the inherent inconsistency in messaging and deeds by expanding their cigarette line while touting their ability to offer a product they claim reduces harm from cigarettes. In this way the cigarette companies get to have it both ways, they purport offer an alternative to their products that cause massive death and disease while continuing to market them. In fact, as noted in the 2010 Surgeon General’s Report, "How Tobacco Smoke Causes Disease,"(U.S. Department of Health and Human Services, 2010) the tobacco industry has used every iteration of cigarette design to undermine cessation and prevention.

Moreover, the tobacco companies address e-cigarette issues as part of their policy agenda. As they did in the 1980's and 1990's,(Samuels and Glantz, 1991) some tobacco companies continue to engage in creating and supporting “smokers rights” groups, seemingly independent groups to interact with consumers directly on political involvement in support of their agenda. Altria and R.J. Reynolds Tobacco Company maintain websites called “Citizens for Tobacco Rights” and “Transform Tobacco;” Figure 7) have e-cigarette news and action alerts featured on the homepages of these websites and include instructions for taking action against bills designed to include e-cigarette use in smokefree laws. In addition, e-cigarette companies engage in similar tactics, using the same political and public relations strategies as the tobacco

Figure 7. Tobacco company advocacy websites; Altria, Inc. website: www.tobaccorights.com; Reynolds American website: www.transformtobacco.com

companies (most notably featuring organized "vapers" like the organized smokers). These strategies were successfully deployed in Europe to convince the European Parliament to substantially weaken the proposed EU Tobacco Product Directive in October 2013.(Higgins, November 9, 2013)

E-cigarette market analysis reports by Goldman-Sachs in 2012 and 2013 noted that despite currently comprising <1% total industry sales, there is the potential for e-cigarettes to account for 15% of US tobacco market profit by 2020.(Hong et al., 2012, Hong et al., 2013) Another equity research report noted that “full conversion” from cigarettes to e-cigarettes has not been achieved and most users are dual users with conventional cigarettes, and going on to note that products would have a longer lifespan because its users would have a longer lifespan.(Herzog et al., July 19, 2013) Importantly, the market analysts remained positive on the long term growth of the tobacco industry with e-cigarettes playing a role, not as a total replacement for the tobacco or nicotine products.

Likewise, after evaluating the cigarette companies’ internal documents and public positions on snus as “harm reduction” in Europe, Gilmore et al. (2013)(Peeters S and Gilmore AB, 2013) found that they were entering the market to protect their cigarette business as long as possible. They saw clear lessons for assessing the companies’ involvements in e-cigarettes:

> While such evidence must be considered alongside the broader body of evidence around snus and the fact it is significantly less harmful than smoked tobacco, collectively these issues suggest that legalisingsnus sales in Europe may have considerably less benefit than envisaged and could have a number of harmful consequences. Perhaps of greater concern, however, given that harm reduction using nicotine products is already an established element of tobacco control and recent research suggests scope for benefit via newer nicotine products, are the recent industry investments in pure nicotine products. These raise two concerns. First, one of competition: should such investments continue, competition between cigarettes and clean nicotine products would decrease, limiting the potential for harm reduction to benefit public health and maintaining the status quo of cigarettes. While a nicotine regulatory authority could ensure that regulation was proportional to harm, it would be powerless to address the issue of competition, so this situation needs close observation. Second, they may enable TTCs [transnational tobacco companies], by presenting themselves as purveyors of nicotine rather than tobacco products, to undermine Article 5.3 of the Framework Convention on Tobacco Control which aims to protect public health policy from commercial and other vested interests of the tobacco industry. Finally, if TTCs are genuinely interested in seeing their cigarette consumers switch to snus (or pure nicotine products), rather than creating new snus/nicotine users and/or dual use opportunities, we would expect to see detailed strategic plans and cigarette sales reduction targets at least for the markets where they intend to introduce these products. However, to this date we have yet to see this. [citations eliminated] (Peeters S and Gilmore AB, 2013)

CURRENTSTATE OF GLOBAL REGULATION (NOVEMBER 2013)

Like e-cigarettes themselves, the policy environment related to e-cigarettes is rapidly developing despite the lack of a sufficient base of scientific evidence to support policy development. Policymakers in many countries are under considerable pressure to provide regulatory guidance regarding e-cigarettes and many policies are based on the assumption that e-cigarettes will contribute to reducing the harms of smoking either by serving as a smoking cessation aid or by replacing combusted cigarettes. However, based on interpretations of the data reviewed above, mounting evidence of dual use and youth initiation of e-cigarette use is of increasing concern and relevance to the evaluation of any hypothesized harm reducing effect.

European Union Draft Tobacco Product Directive

As of November 2013, the policy position on e-cigarettes in the European Union was in flux, with three versions of revisions of the European Union Tobacco Product Directive (EU TPD) under consideration. First, in December 2012 the European Commission issued a draft EU TPD that treated e-cigarettes in a separate class of "nicotine containing products" and as medicinal products if they contain nicotine above a certain threshold.(European Commission, 2012) In June 2013, the Council of the European Union released a draft with changes made by consensus among the Member States that accepted the Commission's overall approach and generally strengthened the regulation of e-cigarettes.(Council of the European Union, June 24, 2013) In particular, the Council cut by half the threshold of nicotine that a product can contain and still be treated as a "nicotine containing product" that is sold as a consumer product. (Any devices delivering more than this threshold would be regulated as a medicine.) In October 2013, the European Parliament approved amendments to the Commission draft that substantially weakened the Commission's authority to regulate e-cigarettes.(European Parliament, 2013) The European Parliament's amendments were based on the explicitly stated premise that, "Given the potential of nicotine-containing products to aid smoking cessation, Member States should ensure that they can be made available as widely as tobacco products." The premise that e-cigarettes are established as effective cessation devices is contradicted by the available data reviewed in this report.

The European Commission Draft(December 2012)

The revisions to the EU TPD released 2012,(European Commission, 2012) proposed to regulate e-cigarettes as medicines or consumer products depending on the levels of nicotine content and delivery. E-cigarettes would be authorized as medicines if they contain at least 2mg of nicotine, 4mg/ml nicotine concentration in the e-cigarette liquid, or deliver a peak plasma nicotine level of 4ng/ml. E-cigarettes that deliver lower levels of nicotine would be authorized to be sold as consumer products with "an adapted health warning." The nicotine content and delivery thresholds were established by considering the nicotine content and delivery of existing nicotine replacement therapies on the assumption that e-cigarettes will perform in similar ways and yield similar success rates for smoking cessation as currently regulated pharmaceutical NRT products.

Article 18 of the EU TPD section on nicotine containing products (NCPs), which includes e-cigarettes, does not account for the widespread variation in products available and product engineering. In contrast to cigarettes or conventional nicotine replacement therapies such as patch, gum, lozenge, there are many different e-cigarette -like products in the current marketplace and many are not sold pre-filled and pre-assembled. Even the most similar product, the medical nicotine inhaler, is standardized for use. It has only one cartridge of one nicotine concentration that only fits in one device. It is unclear how the regulations as proposed will address this variability.

The EU TPD is silent on the marketing of e-cigarette devices that do not contain nicotine, so does not create any restrictions on the marketing or sale of these products, particularly to youth. This is an important omission. Since with e-cigarette products, different components of products are sold separately and can be used with several different liquids with varying or no nicotine content, one way that a company could possibly legally evade regulation under the EU TPD would be to sell nicotine-free e-cigarettes as consumer products then sell the nicotine fluid separately, as is done in New Zealand. It is not clear how the nicotine content standards would apply in this context (e.g., bottles of e-liquid, different sized cartridges that can be used on different devices). Moreover, it is not clear how every piece of these devices would be regulated to ensure that they meet safety standards (whether regulated as medicines or consumer products), or even if they would be allowed to be sold separately.

Another issue the Commission draft of the EU TPD does not address is how products would be allowed to be advertised as medicines. By providing these products with their own definition (that is distinct from cigarettes) and creating a nicotine threshold where some products will be medicines and others will be consumer products, none of the restrictions that have been established policy for marketing tobacco products in the EU will apply. The EU TPD is silent on advertising, relying on current EU policy. E-cigarettes could be marketed on television and radio and using celebrities, sports sponsorships, and product placement that would have strong youth appeals. Furthermore, if marketing differs for those that are authorized as medicines and those that are consumer products, it would cause great confusion since the products look identical and produce identical looking smoke-like aerosol.

The Council of the European Union Proposal (June 2013)

The Council of the European Union accepted the overall approach to regulating e-cigarettes proposed in the Commission draft and strengthened several provisions related to e-cigarettes, most notably by decreasing by half the nicotine levels and concentrations for which medical regulation would apply (changed equal to or exceeding 2mg to 1mg for nicotine levels and equal to or exceeding 4mg/ml to 2mg/ml for nicotine concentration) and deleting the provision pertaining to nicotine delivery (i.e., deleted "products whose intended use results in a mean maximum peak plasma concentration exceeding 4ng of nicotine per ml").(Council of the European Union, June 24, 2013)

The Council also strengthened the ability of Member States to introduce stricter national measures in several areas, including those related to e-cigarettes, when justified for public health reasons (as long as they were proportionate and did not constitute a disguised restriction on trade between Member States).

The EU Parliament Amendments (October 2013)

The European Parliament amendments significantly weakened the Commission's authority to regulate e-cigarettes. The amended EU TPD would allow marketing of all NCPs with a nicotine level of 30 mg/ml or less without any screening for their quality, safety, or efficacy if they are not presented with medicinal or therapeutic claims. (NCPs that exceed 30mg/ml are prohibited.) The 30 mg/ml threshold protects almost all e-cigarette products

currently on the market; 36 mg/ml is typically the strongest concentration offered in cartridges and e-liquid bottles. There are e-liquid preparations for sale in very large quantities that exceed this concentration (100 mg/ml),(Wizard Labs, 2013) but in a content analysis of e-cigarette retail websites in 2012, no product over 36 mg/ml was found.(Grana and Ling, in press) The 30mg/ml level is higher than the nicotine content in any of the e-cigarette devices tested in the studies published to date that are reviewed in this report.

The European Parliament amendments would subject e-cigarettes to pre-market authorization only if they are "presented as having properties for treating or preventing disease" (i.e., "medicinal products"). This position is counter to the assumption Parliament added to the EU TPD that *all* e-cigarette products should be available because of their "potential … to aid smoking cessation." This inconsistency within the European Parliament amendments is evident when the amended TPD notes that "Nicotine-containing products - including e-cigarettes - are sold on the Union market. However Member States have taken different regulatory approaches to address health and safety concerns associated with these products. There is a need for harmonized rules, therefore all nicotine-containing products should be regulated under this Directive as a related tobacco product."

To implement this policy, Article 3.7 provides that:

> The proposal removes current legislative divergence between MemberStates and the differential treatment between Nicotine Replacement Therapies and Nicotine Containing Products, increases legal certainty and consolidates the on-going development in Member States. It also encourages research and innovation in smoking cessation with the aim of maximising health gains.(European Parliament, 2013)

Thus, the draft directive accepts as a premise that NCPs, including e-cigarettes, are "medicinal products" within the meaning of Directive 2001/83/EC because they have properties that are useful "for treating or preventing disease" by aiding smoking cessation. As amended, the EU TPD Article 18 which deals with e-cigarettes seems inconsistent with these provisions since it differentiates between NCPs that are "presented as having properties for treating or preventing disease," which are required to get premarket authorization (under Directive 2001/83/EC under paragraph 2 of Article 18), and all other NCPs, which need only follow the notification procedure set out in Article 17.

Both the Commission's and the European Parliament's proposals for Article 6 (which deals with cigarettes) prohibit "*tobacco products* with a characterising flavor;" however, the

European Parliament's proposal for Article 18 (which deals with e-cigarettes) explicitly states that "flavourings are allowed in the [nicotine containing] products," including e-cigarettes. In other words, under the European Parliament amendments additives which may impart a characterizing flavor that increase product appeal to children (e.g., chocolate, cherry, strawberry, licorice, menthol) are explicitly allowed in e-cigarettes, although they are explicitly prohibited from tobacco products (conventional cigarettes).

The EU TPD requires that "each unit packet and any outside packaging of nicotine-containing products carry the following health warning: 'This product is intended for use by existing smokers. It contains nicotine which is a highly addictive substance.'" The size and placement of the warning is the same as for tobacco products for smoking other than cigarettes and roll-your-own tobacco: 30%-35% of the external area of the unit pack and any outside packaging, depending of the number of a Member State's official languages.

The European Parliament's proposal for Article 18 restricts sales of NCP's according to the legal age for sale of tobacco products in Member States, but in no case under age 18. Additionally, the European Parliament's proposed Article 18 states that all nicotine-containing products must be "available to be sold outside of pharmacies." This means that e-cigarettes or other NCPs that might be marketed "for treating or preventing disease" and are registered as "medicinal products" could be sold outside of pharmacies. The Commission's proposal for Article 18 does not add this language.

The European Parliament's proposal for Article 18 added language that nominally provides for public release of ingredient information on the internet by Member States before e-cigarettes (and other NCPs) are placed on the market, but imposes the requirement on Member States to do so "with due regard to the protection of trade secrets." This explicit added protection for trade secrets could create a loophole that would permit companies to avoid this disclosure requirement by claiming that their ingredient lists are trade secrets, as they have done in response to required submissions for tobacco products to the FDA in the United States.

Both the Commission's and the European Parliament's proposals acknowledge that legislative action at the European Union level is necessary to implement the WHO Framework Convention on Tobacco Control (FCTC), and note the particular relevance of the FCTC's Article 13 on advertising. The European Parliament's proposal explicitly provides that the same "limitations on advertising, sponsorship, audiovisual commercial communication and product

placement for tobacco products as set out in Directive 2003/33/EC and Directive 2010/13/EC" shall apply to e-cigarettes. It also prohibits co-branding of e-cigarettes and tobacco products: "tobacco trademarks, brand names and symbols are not used on nicotine-containing products." The ability to co-brand products with a celebrity's "brand" is unclear. The Commission's proposal for Article 18 regarding nicotine-containing products does not include this specific language.

The definition of passive smoking, "'Passive smoking' means the involuntary inhalation of smoke from the combustion of cigarettes or cigars or from the exhalation of one or more smokers," excludes the so-called "vapor" from e-cigarettes, as it only includes the "combustion of cigarettes or cigars." This omission would thus permit the use of ENDS in places that are currently regulated by laws that prohibit "passive smoking."

Perhaps most significantly, the amendments to the EU TPD eliminated the authority of the European Commission to update the regulations related to ENDS as new information about marketing and use patterns and their direct health effects and effects on cigarette consumption develops in the currently rapidly changing market. Specifically, the requirement that:

> The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

was deleted and replaced with a weak requirement for monitoring and preparation of a report after 5 years that could recommend changes to the TPD (but not make any actual changes).

This change effectively insulates the e-cigarette companies from any science-based regulations for at least 5 years and likely much longer, since it moves the issue back into the political sphere where the tobacco companies are strongest.(Neuman et al., 2002, Smith et al., 2010)

The Situation as of November 2013

As of November 2013 there were three different versions of the EU TPD on the table: the European Commission proposal (from 2012),(European Commission, 2012) the Council of the European Union general approach version(Council of the European Union, June 24, 2013) which reflects the views of the Member States (from June 2013), and the European Parliament amendments (from October 2013).(European Parliament, 2013) According to the Lisbon Treaty,

the Commission has the right to propose new legislation and the Council (Member States) and European Parliament are co-legislators. The three institutions were seeking to negotiate a compromise in the so-called "informal trilogue." If they reach a compromise it will be adopted in the European Parliament in the first reading; if not the co-decision procedure will be officially started, which will most likely take another 1-2 years.

United Kingdom

The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) announced a plan to regulate e-cigarettes as medicines. MHRA policy is based on the position that e-cigarettes function like nicotine replacement therapies for smokers wishing to cut down or quit, stating:

> The consistent evidence from a variety of sources is that most electronic cigarettes use is to support stop smoking attempts or for partial replacement to reduce harm associated with smoking. This is comparable to other nicotine replacement products (e.g., gums, patches, inhalator), which are licensed as medicines. The current evidence is that electronic cigarettes have shown promise in helping smokers quit tobacco but the quality of existing NCPs [nicotine containing products, how MHRA labels e-cigarettes] is such that they cannot be recommended for use.(Medicines and Healthcare Products Regulatory Agency, June 12, 2013)

Thus, the MHRA policy appears to be based on three assumptions: (1) harm reduction implemented by shifting cigarette smokers to “cleaner” forms of nicotine delivery is an effective public health; (2) e-cigarettes are a safe and effective form of nicotine replacement; and (3) the widespread introduction of e-cigarettes will increase cigarette cessation and not increase initiation.

The MHRA’s regulatory plans focus on ensuring consistency of nicotine delivery and quality control of the e-cigarette devices. Since March 2011 MHRA reviewed evidence to regarding safety of the devices and e-liquid and their own analysis of four e-cigarette products, finding that existing products on the market are low quality and not assured for safety.(Commission on Human Medicines Working Group on Nicotine Containing Products (NCPs)) Their evidence review found that products have inconsistent nicotine content from labeled values and levels varied for identical products within the same brand and that is just among a selection of brands among the hundreds on the market. The MHRA found diethylene glycol in one product which is likely to be a result of improper processing of propylene glycol. In addition, they found the presence of a toxic contaminant (1,3-bis(3-phenoxyphenooxy) benzene),

which they stated has no plausible reason for being in the products. They concluded that the devices cannot be considered safe or effective nicotine delivery devices as the content and delivery of nicotine differs from brand to brand and even within brand. Moreover, their evidence review acknowledges that low levels of known tobacco-specific carcinogens were found in products, likely from low-quality nicotine extraction processes. All of these findings concur with the published research reviewed in this report.

MHRA noted that their regulation of e-cigarettes as medicines is in accordance with the European Commission's version of the proposed EU TPD, and that they assumed a version of the EU TPDwould be adopted in 2014 and come into effect by 2016. The MHRA specifies that their program seeks to determine four dimensions to establish medicines licensing for e-cigarettes: "the nature, quality and safety of unlicensed NCPs; the actual use of unlicensed NCPs in the marketplace; the effectiveness of unlicensed NCPs in smoking cessation; and modelling of the potential impact of bringing these products into medicines regulation on public health outcomes." It is unclear the specific steps to achieve these aims.

The MHRA does not include any restrictions on e-cigarette marketing. An undated document, "The Regulation of Nicotine Containing Products: Questions and Answers,"(Medicines and Healthcare Products Regulatory Agency, 2013) attempts to address this issue:

> **24. What will be done by the Government to stop manufacturers making their products attractive to young people/children – such as making fruit tasting electronic cigarettes or doing special offers such as two for the price of one?**
>
> Medicines regulation prohibits advertising to children (under 16 years of age).Any licensed medicines would have an age limit – likely to be 18 years of age. One of the reasons for favouring medicines regulation is that it has controls on advertising and promotion and sale and supply. We will look at applications from manufacturers on a case-by-case basis.
>
> If need be, we are able to set particular conditions on the way that products are presented and promoted, especially if they become popular with young people.
>
> At present, we are not aware of any widespread use of e-cigarettes by young people.(Medicines and Healthcare Products Regulatory Agency, 2013)

These assurances provide little or no protection against aggressive marketing of e-cigarettes to youth; the tobacco companies are long-practiced at developing and implementing effective marketing campaigns directed at youth with similar restrictions for decades all over the world. Evidence published after this agency issued their intended policies has shown rapid e-cigarette uptake among adolescents in the US, (with use doubling from 3.4% to 6.8% among all middle school and high school youth from 2011 to 2012, with rates even higher among older youth in high school 4.7% to 10.0%), mostly among current smokers. Similarly, much of the research on the effects of e-cigarette use on smoking cessation summarized earlier in this report was published after the MHRA evidence review(Commission on Human Medicines Working Group on Nicotine Containing Products (NCPs)) was released and provides additional information that contradicts the assumptions upon which these documents were based that should be considered in further designing these regulatory approaches.

As part of what appears to be a broad consensus in the UK that the introduction of e-cigarettes will reduce the harm of smoking, the anti-smoking advocacy group Action on Smoking and Health (ASH) UK has announced that it "does not consider it appropriate to include e-cigarettes under smokefree regulations,"(Action on Smoking and Health, June 2013)supporting one the e-cigarette companies' key marketing messages that e-cigarettes can be used everywhere without the restrictions and social stigma of smoking.(Grana and Ling, in press, McKee, 2013) It is unclear how the UK plans to address the potential interference with enforcement of existing smokefree laws and potential promotion of smoking as these are mimicking products.

United States

In the U.S., as of November 2013, e-cigarette products remained unregulated by any federal authority, particularly the US Food and Drug Administration (FDA). The Sottera Inc. case ruling that was upheld on appeal in U.S. court, found that e-cigarettes could be regulated as tobacco products unless they are marketed with health and therapeutic claims.(D.C. Circuit U.S. Court of Appeals, 2010) The FDA accepted that ruling and issued a letter to stakeholders on April 25, 2011 stating their intent to issue guidance about exercising their deeming authority over e-cigarettes in the future, but, no such deeming authority or guidance had been issued.(FDA, 2011) Frieberg et al. (2012) analyzed the Family Smoking Prevention and Tobacco

Control Act and used existing legal precedent to imagine potential regulatory options in the U.S. for other tobacco products including electronic cigarettes. He posited that the U.S. FDA could extend restrictions on flavors based on evidence for flavored cigarettes as starter products for youth, price restrictions such as free sampling, warning labels, minimum age for purchase, and restrict health claims.(Freiberg, 2012)

The Food and Drug Administration does not have the authority to regulate where e-cigarettes are used; that is the domain of state and local governments, where almost all activity on smokefree laws has occurred. Since e-cigarettes entered the U.S. market in 2008, there has been a rapid increase in the number of municipalities and states that have adopted legislation regulating where e-cigarettes can be used and laws restricting sales to minors. As of November 2013, 25 states have laws restricting sales to minors, 3 states (New Jersey, North Dakota, and Utah) and 100 municipalities restrict use of e-cigarettes in 100% smokefree indoor environments.(American Nonsmokers' Rights Foundation, October 1, 2013) An additional 9 states restrict e-cigarettes in other venues such as school district property, Department of Corrections/prisons, public educational facilities and grounds, and commuter rail systems.(American Nonsmokers' Rights Foundation, October 1, 2013)These figures could be an under count. Many U.S. local and statewide smokefree laws were enacted before the introduction of e-cigarettes and some include language that could be interpreted as including e-cigarettes.

Convention on Tobacco Control (FCTC) Conference of the Parties Report on national e-cigarette policies and regulations

The November 2012 FCTC Conference of the Parties' report by the convention secretariat on e-cigarettes contains data about 33 participating countries" e-cigarette availability and regulatory policies.(FCTC/COP/5/13, 2012) Brazil, Singapore, Canada, the Seychelles and Uruguay ban e-cigarettes from being sold or distributed in their countries. Several countries have two-tiered or three-tiered levels of regulation depending on the product contents and intended use (communicated through company marketing claims and statements). For example, New Zealand and Switzerland allow e-cigarettes without nicotine to be sold, but residents may purchase e-cigarettes and e-liquid with nicotine over the Internet for personal use (may not sell them in the country). Some countries aim to apply a drug delivery device classification for e-

cigarettes with nicotine and that make health claims. For example, in some countries, the regulatory scheme separates e-cigarette products into consumer and medicinal by their nicotine and health claims. If a product contains no nicotine and no health claim it is currently considered a consumer product and allowed to be sold. However, if a product has nicotine in it and is marketed with a health claim, it must go through their drug delivery regulatory scheme to be approved for retail, distribution and advertisement as a medication. Such regulations exist in Hungary, Turkey, Australia, Belgium, New Zealand and Norway where e-cigarette products require pre-market authorization if they contain nicotine and are marketed with a health claim or claim they are intended to be used for smoking cessation. A unique case exists for South Korea, where products *without* nicotine are regulated as quit aid by the Korean Food and Drug Administration and products with nicotine are treated as tobacco products and regulated by Ministry of Finance (Lee et al 2012).

Updated Information

Since the Conference of the Parties report in 2012, several countries updated policies and policy recommendations regarding e-cigarettes. Germany's Supreme Court ruled that e-cigarettes should be treated as tobacco products under the law.(The Local, September 17, 2013)In 2012, Australia had a country-wide policy that e-cigarettes with nicotine and that make therapeutic claimsare subject to regulation as a therapy, but absent those characteristics were unregulated. Since 2012, several states and territories have included e-cigarettes in their current marketing restrictions as applied to products that mimic tobacco products.(Australian Government, 2013)

In contrast to the position ASH UK took in England, the French Health Minister, Marisol Touraine, announced on May 31, 2013 (World No Tobacco Day) that the French government plans to extend existing smoking restrictions to e-cigarettes.(FRANCE 24, May 31, 2013) These restrictions were undertaken to prevent confusion in enforcement of the national smokefree law and prevent modeling of smoking by a product that mimics cigarette smoking. It will also protect bystanders from being exposed to secondhand e-cigarette aerosol. In India e-cigarettes were declared as illegal under Drugs and Cosmetics Act by State Drug Controller in Punjab and the government of India is preparing to ban them.(State Drugs Controlling Authority Food & Drug Administration Punjab India, 2013) In the Philippines, the Food and Drug Administration recently recommended that e-cigarettes should not be used indoors anywhere that smoking is

prohibited.(Food and Drug Administration Philippines, June 26, 2013)Davao is the first city in the Philippines to act on this recommendation and enact a smokefree law that includes e-cigarettes.(Saligumba, Spetember 24, 2012)

OVERALL SUMMARY

While most discussion of e-cigarettes among health authorities has concentrated on the product itself, its potential toxicity and use of e-cigarettes to help people quit smoking, the e-cigarette companies have been rapidly expanding using aggressive marketing messages similar to those used to promote cigarettes in the 1950s and 1960s. Moreover, e-cigarette advertising is on television and radio in many countries that have long-banned similar advertising for cigarettes and other tobacco products. While it may be reasonable to assume that if existing smokers switched completely from conventional cigarettes (with no other changes in use patterns) there would be a lower disease burden caused by nicotine addiction, the evidence available at this time (while limited) points to high levels of dual use of e-cigarettes with conventional cigarettes, little benefit for cessation (either on a population basis or compared to currently regulated nicotine replacement therapy) and rapidly increasing youth initiation with e-cigarettes. Although, some cite a desire to quit smoking by using the e-cigarette, other common reasons respondents give for using the products are to circumvent smokefree laws and to cut down, which may reinforce dual use patterns.

It is unclear what will be the trajectory of the dual use pattern among adults or children, but any uptake in children is very concerning. Nicotine is a highly addictive substance with negative effects on animal and human brain development, which is still ongoing in adolescence.(Dwyer et al., 2008, Liao et al., 2012, Lichtensteiger et al., 1988, Longo et al., 2013) Evidence from published studies examining dual use of smokeless tobacco, snus and conventional cigarettes among youth and adults shows a progression to cigarette smoking and difficulty with quitting among adolescent smokeless tobacco users.(Galanti et al., 2008, Post et al., 2010) Concerns that e-cigarettes could play a similar role in increasing conventional cigarette use are warranted. Furthermore, high rates of dual use may result in greater total public health burden and possibly increased individual risk if a smoker maintains an even low-level tobacco cigarette addiction for many years instead of quitting.

E-cigarette devices and their components should be evaluated for risks posed to consumers by consumer product safety regulatory authorities and consumers should be appropriately warned about risks and proper handling. Although the data are limited, it is clear that e-cigarette aerosol is not "harmless water vapor" as is frequently claimed and can be a source of air pollution. Article 8 of the FCTC focuses on smoke-free policies to afford protections for the public and all workers to breathe clean air. When evaluating the risks of exposure to e-cigarette aerosol, the standard of comparison should not be whether the vapor is better than the toxic chemical mixture in tobacco cigarette smoke (which is already prohibited), it should be whether the product's emissions introduce toxins into clean air, and how they affect existing public health protections. In contrast to the paucity of research on e-cigarettes, there is an extensive scientific literature showing that smokefree policies protect nonsmokers from exposure to toxins and encourage smoking cessation.(U.S. Department of Health and Human Services, 2006) One-hundred percent smoke-free policies have about twice the effect on consumption and smoking prevalence than policies with exceptions or partial coverage.(Fichtenberg and Glantz, 2002) Exceptions for e-cigarettes may similarly decrease the effects of smoke-free policies on smoking cessation, and as noted in the FCTC Conference of the Parties report, use of the products in smokefree environments may also decrease enforcement of Article 13 as e-cigarettes act as cigarette-mimicking products. Introducing e-cigarettes into clean air environments may result in population harm if use of the product reinforces the act of smoking as socially acceptable, and/or if use undermines the effects of smoke-free policies on smoking cessation. Strong smoke-free policies are an integral part of the recognized and proven comprehensive global tobacco control policies.

RESEARCH NEEDS

There are several areas in which additional research would be useful for understanding the effects of e-cigarettes that could guide policymakers and health professionals:

- Systematic surveillance is critical to monitoring trends in use that will determine the net impact of the products on tobacco use.
- Longitudinal studies to determine trajectories of use to obtain better data on patterns of initiation, the stability of dual use behavior and effect on cessation rates and relapse of both conventional cigarettes and e-cigarettes as actually used in the real world.

- Randomized trials of e-cigarettes as part of supervised smoking cessation programs.
- Assessment of the impact of smoking reduction in the context of dual use as a way to promote long-term cigarette abstinence.
- Short- and long-term studies on the health effects of e-liquid aerosol in humans.
- Effects of short- and long-term exposure to fine particles by e-cigarette aerosol
- How e-cigarette advertising is perceived by all segments of the population – youth, naïve nicotine users, smokers and former smokers, both recent and long-term – and how advertising exposure impacts behaviors.
- Studies of the engineering design and functioning of e-cigarettes, including impact of heating temperature, battery size, puffing characteristics and e-liquid composition on the nature of the aerosol and systemic exposure of users to aerosol constituents.
- Policy research on the impact of the different approaches being taken around the world on conventional smoking, e-cigarette use, and the overall burden of nicotine-induced disease.
- Studies of the nature of the reinforcing effects of e-cigarettes, including influences of nicotine content, flavorants and other constituents, and abuse liability.
- Studies to determine optimal nicotine delivery to support transition away from tobacco products but avoid recruitment of new users.

While important research questions, the evidence summarized in this report is adequate to guide policy makers in responding to e-cigarettes. These policies can be refined over time as more research becomes available.

POLICY RECOMMENDATIONS

As noted above, e-cigarettes deliver lower levels of most of the toxins found in cigarette smoke; the main impediment to e-cigarettes making a contribution to reducing the harm caused by cigarette smoking arise from the effects on youth, dual use (among both adults and youth) and renormalization of smoking behavior. The ultimate effect of e-cigarettes on public health will depend on what happens to the tobacco product market, particularly with combustible products. There are conditions in which e-cigarettes could be a public health benefit on a population level:

- No initiation with e-cigarettes

- No youth use of e-cigarettes
- Cigarette smokers switch completely and not continue a dual use pattern of consumption
- Use of e-cigarettes does not negatively impact current cigarette denormalization efforts
- E-cigarettes do not deliver harmful substances besides nicotine
- No youth-oriented marketing
- No secondhand delivery of nicotine

As of November 2013 this situation did not exist. This situation could change if the following policies were implemented:

- Prohibit the use of e-cigarettes anywhere that use of conventional cigarettes is prohibited
- E-cigarettes should not be sold to anyone who cannot legally buy cigarettes or sold in any venues where sale of conventional cigarettes is prohibited
- Ban conventional cigarettes or regulate nicotine to non-addictive levels
- Apply the same restrictions on e-cigarette advertising and promotion as apply to conventional cigarettes
- Ban the use of characterizing flavors in e-cigarettes
- E-cigarettes should not be co-branded with cigarettes or marketed in a way that promotes dual use
- Prohibit claims that e-cigarettes are effective smoking cessation aids until such time as there is convincing scientific evidence that such claims are true for e-cigarettes as they are actually used in the general population
- Regulate e-cigarettes to set standards for product performance in order to minimize risks to users and bystanders

Should these policies be put in place, it is possible that current conventional smokers who will not quit nicotine would shift to e-cigarettes without major dual use or youth initiation to nicotine addiction with e-cigarettes. Absent this change in the policy environment it is reasonable to assume that the behavior patterns that have been observed for e-cigarettes will persist, which makes it unlikely that they will on balance contribute to reducing the harm of tobacco use and could increase harm by perpetuating the life of conventional cigarettes.

Because the product, the market, and the associated scientific evidence surrounding e-cigarettes are all evolving rapidly:

- All legislation and regulations related to e-cigarettes should allow for flexibility to adapt regulations expeditiously in response to new science, including evaluation of different models for regulating e-cigarettes, as it accumulates
- No country or subnational jurisdiction should be compelled to permit the sale of e-cigarettes
- Legislation and regulations regarding e-cigarettes need to take into account the fact that, unlike conventional cigarettes and other tobacco products and medicinal nicotine replacement therapies, e-cigarettes can be altered by users to change the nicotine delivery and be used to deliver other drugs
- There should be transparency in the role of the e-cigarette and tobacco companies in advocating for and against legislation and regulation, both directly and through third parties
- FCTC Article 5.3 should be respected when developing and implementing legislation and regulations related to e-cigarettes

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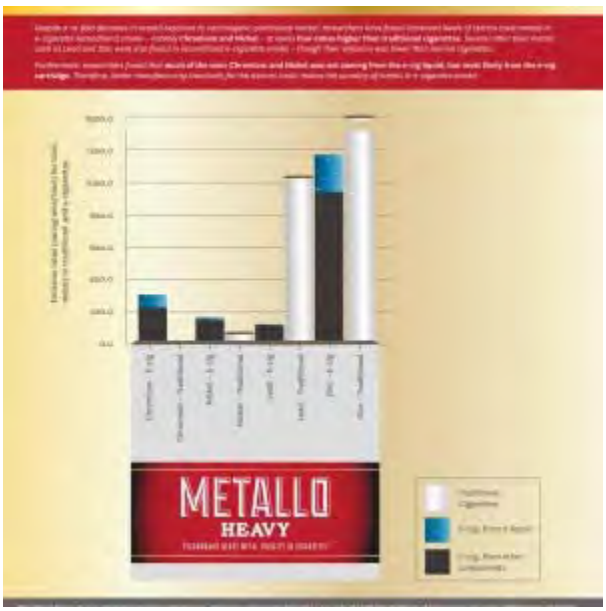
Second-Hand E-Cigarette Smoke: Healthier Than Regular Cigarette Smoke, but Still Contains Some Toxic Elements

August 28, 2014



Despite a 10-fold decrease in overall exposure to carcinogenic particulate matter, researchers find increased levels of certain toxic metals in second-hand smoke from e-cigs

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E-cigarettes are healthier for your neighbors than traditional cigarettes, but still release toxins into the air, according to a new study from USC.

Scientists studying secondhand smoke from e-cigarettes discovered an overall 10-fold decrease in exposure to harmful particles, with close-to-zero exposure to organic carcinogens. However, levels of exposure to some harmful metals in second-hand e-cigarette smoke were found to be significantly higher.

While tobacco smoke contains high levels of polycyclic aromatic hydrocarbons – cancer-causing organic compounds – the level of exposure to these substances was reduced to almost zero in second-hand e-cigarette smoke, due to the fact that they do not burn organic material the way old-fashioned cigarettes do.

However, despite the lack of harmful organic material and a decrease in the majority of toxic metals emissions, e-cigarette smoke contains the toxic element chromium, absent from traditional cigarettes, as well as nickel at levels four times higher than normal cigarettes. In addition, several other toxic metals such as lead and zinc were also found in second-hand e-cigarette smoke – though in concentrations lower than for normal cigarettes.

“Our results demonstrate that overall electronic cigarettes seem to be less harmful than regular cigarettes, but their elevated content of toxic metals such as nickel and chromium do raise concerns,” said Constantinos Sioutas, professor at the USC Viterbi School of Engineering, and corresponding author of the study, which was published online on August 22 by the *Journal of Environmental Science, Processes and Impacts*.

Sioutas and his colleagues at Fondazione IRCCS Instituto Nazionale dei Tumori (National Institute of Cancer Research) in Milan, Italy, began this study with the goal of quantifying the level of exposure to harmful organics and metals in second-hand e-cigarette smoke, in hopes of providing insight for the regulatory authorities.

“The metal particles likely come from the cartridge of the e-cigarette devices themselves – which opens up the possibility that better manufacturing standards for the devices could reduce the quantity of metals in the smoke,” said Arian Saffari, a PhD student at USC Viterbi and lead author of the paper. “Studies of this kind are necessary for implementing effective regulatory measures. E-cigarettes are so new, there just isn’t much research available on them yet.”

For this study, the researchers conducted all of the experiments in offices and rooms. While volunteer subjects were smoking regular cigarettes and e-cigarettes, the researchers collected particles in the indoor air and studied the chemical content and sources of the samples.

“Offices and rooms– not laboratories – are the environments where you’re likely to be exposed to second-hand e-cigarette smoke, so we

did our testing there to better simulate real-life exposure conditions," Saffari said.

Sioutas and Saffari compared the smoke from a common traditional cigarette brand with smoke from an Elips Serie C e-cigarette, one of the most popular European brands. The results could vary based on which type of cigarettes and e-cigarettes are tested, the researchers noted.

Sioutas and Saffari collaborated with researchers from LARS Laboratorio and the Fondazione IRCCS Instituto Nazionale dei Tumori in Milan, Italy, as well as University of Wisconsin-Madison and Cornell University in the United States.

Financial support for the study was provided by the Fondazione IRCCS Instituto Nazionale dei Tumori.

Graphic courtesy of USC Viterbi. Email perkinsr@usc.edu or hazle@usc.edu for a copy.

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Indoor Air. 2013 Feb;23(1):25-31. doi: 10.1111/j.1600-0668.2012.00792.x. Epub 2012 Jul 2.

Does e-cigarette consumption cause passive vaping?

Schripp T[1], Markewitz D, Uhde E, Salthammer T.

Author information

Abstract

Electronic cigarette consumption ('vaping') is marketed as an alternative to conventional tobacco smoking. Technically, a mixture of chemicals containing carrier liquids, flavors, and optionally nicotine is vaporized and inhaled. The present study aims at the determination of the release of volatile organic compounds (VOC) and (ultra)fine particles (FP/UFP) from an e-cigarette under near-to-real-use conditions in an 8-m(3) emission test chamber. Furthermore, the inhaled mixture is analyzed in small chambers. An increase in FP/UFP and VOC could be determined after the use of the e-cigarette. Prominent components in the gas-phase are 1,2-propanediol, 1,2,3-propanetriol, diacetin, flavorings, and traces of nicotine. As a consequence, 'passive vaping' must be expected from the consumption of e-cigarettes. Furthermore, the inhaled aerosol undergoes changes in the human lung that is assumed to be attributed to deposition and evaporation.

PRACTICAL IMPLICATIONS: The consumption of e-cigarettes marks a new source for chemical and aerosol exposure in the indoor environment. To evaluate the impact of e-cigarettes on indoor air quality and to estimate the possible effect of passive vaping, information about the chemical characteristics of the released vapor is needed.

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PMID: 22672560 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms, Substances

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Tob Control. 2014 Mar;23(2):133-9. doi: 10.1136/tobaccocontrol-2012-050859. Epub 2013 Mar 6.

Levels of selected carcinogens and toxicants in vapour from electronic cigarettes.

Goniewicz ML[1], Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, Prokopowicz A, Jablonska-Czapla M, Rosik-Dulewska C, Havel C, Jacob P 3rd, Benowitz N.

Author information

Abstract

SIGNIFICANCE: Electronic cigarettes, also known as e-cigarettes, are devices designed to imitate regular cigarettes and deliver nicotine via inhalation without combusting tobacco. They are purported to deliver nicotine without other toxicants and to be a safer alternative to regular cigarettes. However, little toxicity testing has been performed to evaluate the chemical nature of vapour generated from e-cigarettes. The aim of this study was to screen e-cigarette vapours for content of four groups of potentially toxic and carcinogenic compounds: carbonyls, volatile organic compounds, nitrosamines and heavy metals.

MATERIALS AND METHODS: Vapours were generated from 12 brands of e-cigarettes and the reference product, the medicinal nicotine inhaler, in controlled conditions using a modified smoking machine. The selected toxic compounds were extracted from vapours into a solid or liquid phase and analysed with chromatographic and spectroscopy methods.

RESULTS: We found that the e-cigarette vapours contained some toxic substances. The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product.

CONCLUSIONS: Our findings are consistent with the idea that substituting tobacco cigarettes with e-cigarettes may substantially reduce exposure to selected tobacco-specific toxicants. E-cigarettes as a harm reduction strategy among smokers unwilling to quit, warrants further study. (To view this abstract in Polish and German, please see the supplementary files online.).

KEYWORDS: Carcinogens; Electronic nicotine delivery devices; Harm Reduction; Toxicology

PMID: 23467656 [PubMed - indexed for MEDLINE] PMCID: PMC4154473 [Available on 2015/3/1]

Publication Types, MeSH Terms, Substances, Grant Support

PubMed

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Ann Ig. 2012 Jul-Aug;24(4):279-88.

Electronic cigarettes: an evaluation of exposure to chemicals and fine particulate matter (PM).

Pellegrino RM[1], Tinghino B, Mangiaracina G, Marani A, Vitali M, Protano C, Osborn JF, Cattaruzza MS.

Author information

Abstract

The "electronic (e-)cigarette" generates intense scientific debate about its use. Its popularity is increasing worldwide as a method to reduce/quit smoking, and to smoke indoors when restrictions on smoking tobacco are present. WHO recommends caution, until its effectiveness in helping smokers is clarified, and the possible harm evaluated. The aim of this study was to assess the content of the aromatic liquid mixture and its vapour and the Particulate Matter (PM) emissions of an Italian brand of e-cigarette and to compare its PM emissions with a conventional cigarette. Propylene glycol (66%) and glycerine (24%) were main components in the liquid, while the flavouring substances were less than 0.1%. The same substances were detected in the vapour in similar proportions. Fine and ultrafine PM emissions were higher for the conventional versus the e-cigarette (e.g.: PM10=922 vs 52 microg/m3; PM1=80 vs 14 microg/m3). The e-cigarette seems to give some advantages when used instead of the conventional cigarette, but studies are still scanty: it could help smokers to cope with some of the rituals associated with smoking gestures and to reduce or eliminate tobacco consumption avoiding passive smoking. However, the e-cigarette causes exposure to different chemicals compared with conventional cigarettes and thus there is a need for risk evaluation for both e-cigarettes and passive steam exposure in smokers and non smokers.

PMID: 22913171 [PubMed - indexed for MEDLINE]

MeSH Terms, Substances

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Nicotine Tob Res (2014) doi: 10.1093/ntr/ntu152
First published online: August 30, 2014

Electronic Cigarettes Are a Source of Thirdhand Exposure to Nicotine

Maciej L. Goniewicz, PharmD, PhD and Lily Lee
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Received May 17, 2014.
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Abstract

Introduction: Substances remaining on the surfaces in areas where people have smoked contribute to thirdhand exposure. Nicotine from tobacco smoke has been shown to react with oxidizing chemicals in the air to form secondary pollutants, such as carcinogenic nitrosamines. While previous studies have demonstrated thirdhand exposure to nicotine from tobacco smoke, none has investigated whether nicotine from electronic cigarettes (e-cigarettes) can also be deposited on various surfaces.

Methods: Three brands of e-cigarettes were refilled with varying nicotine concentrations. We released 100 puffs from each product directly into an exposure chamber. Surface wipe samples were taken from five indoor 100cm^2 surfaces (window, walls, floor, wood, and metal) pre and post release of vapors. Nicotine was extracted from the wipes and analyzed using gas chromatography.

Results: Three of four experiments showed significant increases in the amount of nicotine on all five surfaces. The floor and glass windows had the greatest increases in nicotine, on average by a factor of 47 and 6, respectively ($p < .05$). The average amount of nicotine deposited on a floor during each experiment was 205 μg/m^2, and varied from limit of quantitation to 550 μg/m^2.

Conclusions: This study indicates that there is a risk of thirdhand exposure to nicotine from e-cigarettes. Thirdhand exposure levels differ depending on the surface and e-cigarette brand. Future research should explore the potential risks of thirdhand exposure to carcinogens formed from nicotine released from e-cigarettes.

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Press Release

For Immediate Release: Monday, August 25, 2014
Contact: CDC Media Relations (http://www.cdc.gov/media/index.html)
(404) 639-3286

More than a quarter-million youth who had never smoked a cigarette used e-cigarettes in 2013

Study finds youth who have used e-cigarettes are almost twice as likely to have intentions to smoke conventional cigarettes*

(images/p0825-e-cigarettes.jpg)

In 2013, more than a quarter million middle school and high school students never smoked regular cigarettes but had used e-cigarettes three times as many as 2011.
Entire infographic (images/p0825-e-cigarettes.jpg)

More than a quarter of a million youth who had never smoked a cigarette used electronic cigarettes in 2013, according to a CDC study published in the journal *Nicotine and Tobacco Research*. This number reflects a three-fold increase, from about 79,000 in 2011, to more than 263,000 in 2013.

The data, which comes from the 2011, 2012, and 2013 National Youth Tobacco surveys of middle and high school students, show that youth who had never smoked conventional cigarettes but who used e-cigarettes were almost twice as likely to *have intentions** to smoke

conventional cigarettes as those who had never used e-cigarettes. Among non-smoking youth who had ever used e-cigarettes, 43.9 percent said they *have intentions** to smoke conventional cigarettes within the next year, compared with 21.5 percent of those who had never used e-cigarettes.

There is evidence that nicotine's adverse effects on adolescent brain development could result in lasting deficits in cognitive function. Nicotine is highly addictive. About three out of every four teen smokers become adult smokers, even if they intend to quit in a few years.
The analysis also looked at the association between tobacco advertisements and smoking intentions among middle and high school students. Students were asked about whether they had seen tobacco ads on the internet, in magazines and newspapers, in retail stores, and in television programs and movies. Consistent with previous studies, this study found that youth who reported exposure to tobacco ads had higher rates of intention to smoke than those who weren't exposed to such ads.

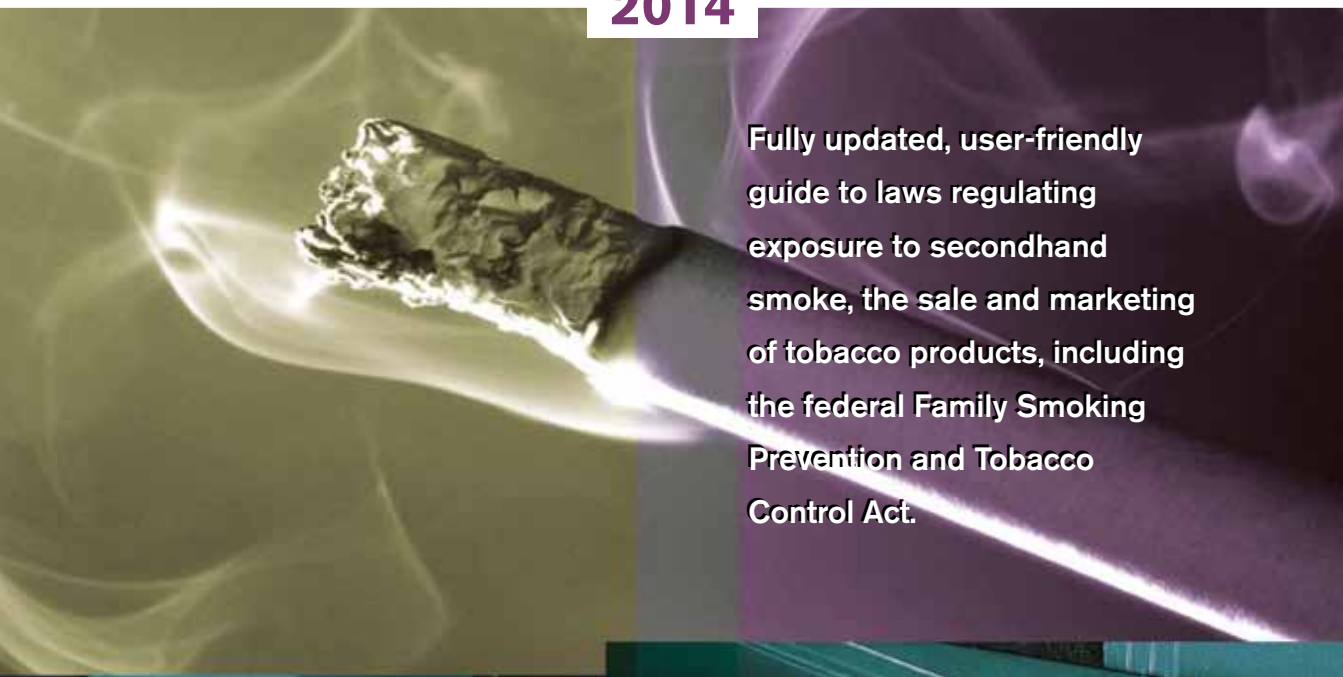
The researchers also found the greater the number of advertising sources to which young people were exposed, the greater their rate of intention to smoke cigarettes. Thirteen percent of students who said they had no exposures to such ads had intentions to smoke, compared to 20.4 percent among those who reported exposures from one to two ad sources and 25.6 percent among those who reported exposures from three to four of the sources.

More than 50 years since the landmark Surgeon General's Report linking cigarette smoking to lung cancer, smoking remains the leading cause of preventable death and disease in the United States. Smoking kills nearly half a million Americans every year. More than 16 million Americans live with a smoking-related disease. Smoking-related diseases cost Americans $132 billion a year in direct health care expenses, much of which comes in taxpayer-supported payments. Each day, more than 3,200 American youth smoke their first cigarette. The Surgeon General has concluded that unless the smoking rate is rapidly reduced, 5.6 million American children alive today – about one in every 13—will die prematurely from a smoking-related disease.

EDITOR'S NOTE:
Researchers used established methods to identify youth who are at risk of future cigarette smoking. In this approach, only youth who have a firm intention to not smoke, that is they reported they would "definitely not" smoke in the next year and reported they would "definitely not" smoke if offered a cigarette by a friend are classified as not having smoking intentions. All others were classified as having smoking intentions. Previous research has demonstrated that even youth who believe they probably will not smoke in the next year, are at heightened risk of initiating smoking in the future. For this reason, they are traditionally included by researchers as having smoking intentions and were in this study as well.

In addition to the primary analysis, the authors performed multiple analyses using alternative classifications of smoking intentions among youth. Even when using a more restrictive classification, which only includes those youth with strongest smoking intentions (responses of "definitely" or "probably" will smoke), the results continue to show that never smoking youth who smoked e-cigarettes are nearly two times more likely to have intentions to smoke conventional cigarettes than those who had never used e-cigarettes.

Tobacco Laws
Affecting California
2014



Fully updated, user-friendly guide to laws regulating exposure to secondhand smoke, the sale and marketing of tobacco products, including the federal Family Smoking Prevention and Tobacco Control Act.

ChangeLab Solutions
www.changelabsolutions.org

This booklet was developed by ChangeLab Solutions with funds received from the California Department of Public Health, under contract #09-11182.

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OVERVIEW

This booklet provides summaries of state and federal tobacco laws that affect California. It is designed as a resource for tobacco control advocates, government attorneys, local law enforcement agencies, and anyone who is working on tobacco control issues. The booklet includes information on California state laws and regulations related to tobacco, including the Stop Tobacco Access to Kids Enforcement Act (known as the STAKE Act), as well as federal laws and regulations that apply within California, such as the Family Smoking Prevention and Tobacco Control Act (known as the Tobacco Control Act).[1] It also summarizes portions of the 1998 Master Settlement Agreement (MSA) between the attorneys general of 46 states (including California) and the major tobacco companies, and the 1998 Smokeless Tobacco Master Settlement Agreement (STMSA) between the attorneys general of 45 states (including California) and U.S. Smokeless Tobacco Company.

In some cases, there are multiple laws covering a particular topic. For example, both California and the federal government ban the sale of tobacco to minors. In that example, selling tobacco to a minor could violate both California and federal law. In other cases, the state and federal law may cover the same topic but have different restrictions. Readers will need to examine the scope of each law closely to determine what is prohibited.

The information in this booklet includes tobacco-related laws that are effective as of May 1, 2014. This booklet replaces all earlier editions and supplements.

This booklet does not contain information on the numerous *local* laws in California that regulate tobacco use, sales, or distribution. Many of these local laws are stricter than state or federal law. For example, local governments in California have passed laws to limit exposure to secondhand smoke in both indoor and outdoor areas where smoking is permitted by state law. Local governments in California also have enacted laws to supplement state laws regarding how tobacco products are sold. For instance, the state tobacco retailer licensing law focuses on protecting state revenue by targeting tax evasion, while numerous communities have local tobacco retailer licensing laws that focus on protecting the public's health.

It is important to review local laws to determine whether a jurisdiction has adopted restrictions to supplement the laws described in this book.

[1] This booklet does not include every instance in which the word *tobacco* is mentioned in state or federal law. However, the booklet contains information on the laws that are relevant to tobacco control implementation and enforcement efforts in California. If you note any omissions in the booklet, please contact ChangeLab Solutions.

PROPOSED FEDERAL REGULATION OF E-CIGARETTES AND OTHER PRODUCTS CONTAINING NICOTINE DERIVED FROM TOBACCO

On April 24, 2014, the U.S. Food and Drug Administration (FDA) issued a proposed rule to extend the reach of the Tobacco Control Act to electronic cigarettes and other products containing nicotine derived from tobacco, including cigars, pipe tobacco, hookah tobacco, gels, and dissolvables. 79 Fed. Reg. 80 (Apr. 24, 2014). At the time of publication, the FDA had only released a proposed rule and solicited comments, and therefore, the scope of any final rule was not known.

The proposed rule consists of two main sections: (1) "deeming" provisions that would deem (or declare) certain products to be tobacco products subject to FDA authority; and (2) additional provisions that would apply to such tobacco products. The proposed rule offers two options with respect to deeming. The first option is a broad provision that applies to "any product made or derived from tobacco that is intended for human consumption" (e.g., products containing nicotine). This would include all cigars. The second option is a narrower provision that excludes certain premium cigars. The narrower option would not extend FDA authority to premium cigars which meet the following criteria (among others): (1) has a retail price (after any discounts or coupons) of at least $10 per cigar (adjusted every two years to account for the price of tobacco products); (2) does not have a characterizing flavor other than tobacco; and (3) weighs more than 6 pounds per 1,000 units. Products that are ultimately determined to be subject to the deeming rule would be subject to the same Tobacco Control Act provisions that apply to cigarettes, roll-your-own tobacco, and smokeless tobacco, including: (1) enforcement action against products determined to be adulterated and misbranded; (2) required submission of ingredient listing and reporting of harmful and potentially harmful constituents for all tobacco products; (3) required registration and product listing for all tobacco products; (4) prohibition against use of modified risk descriptors (e.g., "light," "low," and "mild" descriptors) and claims unless the FDA issues an order permitting their use; (5) prohibition on the distribution of free samples; and (6) premarket review requirements. These provisions would apply automatically to products that are deemed tobacco products.

In addition, the proposed rule would apply three additional provisions to those products that are newly deemed to be subject to the Tobacco Control Act: (1) a restriction on the sale of tobacco products to individuals under 18 years of age; (2) health warnings for product packages and advertisements (which would also apply to cigarettes and roll-your-own tobacco); and (3) a prohibition of vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. For cigars, the proposed health warnings would state health harms caused by cigar smoking; for tobacco products other than cigars, the proposed health warnings would state that the product contains nicotine and that nicotine is an addictive chemical. Under the Tobacco Control Act, the scope of preemption that will apply to state and local regulation of the above tobacco products subject to FDA authority will be the same as for cigarettes. However, the Federal Cigarette Labeling and Advertising Act's

provisions preempting states from regulating the content of advertising or promotion based on smoking and health would continue to apply to cigarettes only (see entries 47 and 52 for more information about preemption). The docket for the proposed rule is available at: **www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-0001**.

The proposed FDA rule as written would affect the following sections of this booklet:

- Section 24 – Sales to Minors: The Tobacco Control Act
- Section 27 – ID Check Requirement: The Tobacco Control Act
- Section 31 – Self-Service Displays: The Tobacco Control Act
- Section 41 – Electronic Cigarettes
- Section 43 – Pre-Market Review of New Tobacco Products: The Tobacco Control Act
- Section 44 – Misbranded Tobacco Products: The Tobacco Control Act
- Section 45 – Modified Risk Tobacco Products: The Tobacco Control Act
- Section 46 – "Light," "Low," and "Mild" Tobacco Products: The Tobacco Control Act
- Section 63 – Content Disclosures to the Public: The Tobacco Control Act
- Section 74 – Samples, Coupons, and Promotional Offers: The Tobacco Control Act
- Section 83 – Cigar Warning Labels
- Section 106 – Registration of Tobacco Establishments: The Tobacco Control Act
- Section 107 – User Fees: The Tobacco Control Act
- Section 108 – Required Disclosures to the FDA: The Tobacco Control Act

FINDING THE ACTUAL LAWS

The full text of the laws and regulations described in this booklet can be found on the following websites:

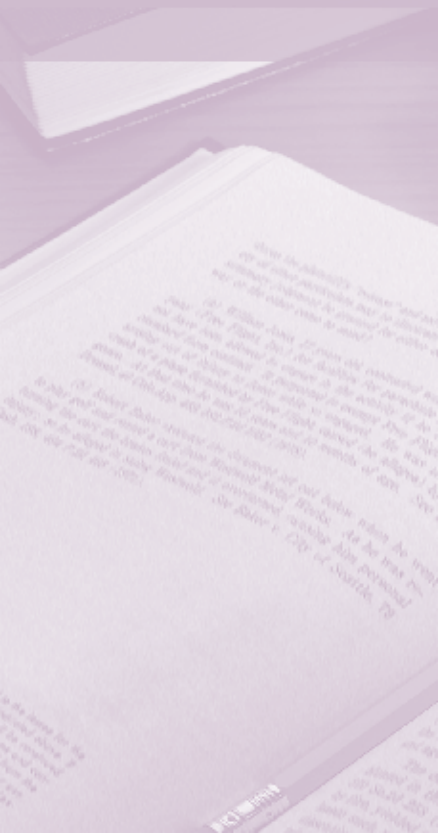
- **California Laws**
  www.leginfo.ca.gov/calaw.html
  This website is the easiest place to find the California laws. To locate a particular code section, check the box next to the type of code (e.g., Penal Code), type the number of the section in the keyword(s) box, and click on the search button under the keyword(s) box. To browse an entire code (as opposed to a particular section), check the box next to the type of code and click on the search button without typing anything into the keyword(s) box.
- **California Regulations**
  http://ccr.oal.ca.gov
  This website provides access to the California Code of Regulations. To find a specific regulation, you can search by key word, by exact citation, or by browsing through the different Titles.
- **Federal Laws**
  http://uscode.house.gov/search/criteria.shtml
  This website contains the full text of the federal laws (the U.S. Code). To pinpoint a particular federal law, you can search by several methods, including keyword, title, and section.
- **Federal Regulations**
  www.gpoaccess.gov/cfr/index.html
  This website provides access to the Code of Federal Regulations (C.F.R.).
- **U.S. Food and Drug Administration (FDA) Guidance, Compliance and Regulatory Information**
  www.fda.gov/tobaccoProducts/guidancecomplianceregulatoryInformation/default.htm
  This website provides access to FDA guidance and compliance information on the 2009 federal Family Smoking Prevention and Tobacco Control Act.
- **Master Settlement Agreement (MSA)**
  http://ag.ca.gov/tobacco/msa.php
  This website contains the entire MSA between the attorneys general of 46 states (including California) and the major tobacco companies.
- **Smokeless Tobacco Master Settlement Agreement (STMSA)**
  http://ag.ca.gov/tobacco/ssa.php
  This website contains the entire STMSA between the attorneys general of 45 states (including California) and U.S. Smokeless Tobacco Company.

DISCLAIMERS

This booklet is provided for general information only and is not offered or intended as legal advice. ChangeLab Solutions and its projects do not enter into attorney-client relationships. Readers should seek the advice of an attorney when confronted with legal issues, and attorneys should perform an independent evaluation of the issues raised in these materials. If you notice any inaccuracies or misstatements, please inform ChangeLab Solutions.

ADDITIONAL COPIES OF THIS BOOKLET

You may download a copy of this booklet from ChangeLab Solutions' website at **www.changelabsolutions.org/publications/tobacco-laws-affecting-california**.



SECONDHAND SMOKE

1. WORKPLACES

California Labor Code Section 6404.5

Scope: It is against the law to smoke in an enclosed space at a place of employment. No employer shall knowingly or intentionally permit smoking in an enclosed space at a place of employment. *Enclosed space* includes lobbies, lounges, waiting areas, elevators, stairwells, and restrooms that are a structural part of the building. A place of employment is any place where employment is carried on.

An employer who permits any nonemployee access to his or her place of employment on a regular basis must take reasonable steps to prevent smoking by a nonemployee, as specified.

Note: At the time of publication, this provision did not prohibit the use of electronic cigarettes. However, local governments are free to regulate the use of electronic cigarettes in areas where smoking is regulated by state law and in additional areas where smoking is prohibited by local law.

Note: This law applies to places of employment at any time of day or night, regardless of whether any employees are present. Legis. Counsel of Cal. Op. 16332, Question No. 18 (May 12, 1995).

Note: A business constitutes a "place of employment" if employment of any kind is carried on at the business location, even if the employment is carried on by individuals who are employed by someone other than the business owner. Thus, this law applies to a business that is operated solely by the owner, and who has no employees, if an individual employed by someone else (e.g., janitor or delivery person) performs work at the business location. Cal. Atty Gen. Op. No. 12-901 (Dec. 20, 2013).

Note: In many cases, volunteers may be considered employees for the purposes of determining whether a space is a place of employment. For instance, a person who provides unpaid services but who receives some other kind of benefit from these services (such as reduced-price admission) may be considered an employee. Legis. Counsel of Cal. Op. 24807, Question No. 3 (Dec. 20, 1997).

Note: Local governments may impose and enforce their own smoking restrictions if they apply to areas not covered by state law. *City of San Jose v. Dep't of Health Services*, 66 Cal. App. 4th 35, 44 (1998). However, to the extent that state law currently prohibits smoking in an enclosed place of employment, a local government may only enforce the state law (and not a similar local law).

Exception: The following places are exempt from the smoking ban:

- Up to 65 percent of hotel/motel guest rooms.

  Note: Hotels and motels may choose to be 100 percent smokefree.

- Up to 25 percent or 50 percent (depending on square footage) of hotel/motel lobbies.

  Note: *Lobby* is defined as a common public area, which has been interpreted to exclude the hotel bar area.

- Meeting and banquet rooms in a hotel/motel, except while food and beverage functions are taking place.
- Retail or wholesale tobacco shops (businesses whose main purpose is the sale of tobacco products) and private smokers' lounges (any enclosed area in or attached to a retail/wholesale tobacco shop dedicated to tobacco use).

  Note: Businesses that serve alcoholic beverages do not qualify for this exception. Cal. Atty Gen. Op. No. 09-507 (Dec. 21, 2011).
- Cabs of trucks or tractors, if nonsmoking employees are not present.
- Warehouse facilities (with more than 100,000 square feet of total floor space, and 20 or fewer full-time employees working at the facility), but not areas utilized as office space.
- Theatrical production sites, if smoking is an integral part of the story.
- Medical research and treatment sites, if smoking is integral to the research and treatment being conducted.
- Private residences, except for those licensed as family day care homes during hours of operation and in those areas where children are present.
- Patient smoking areas in long-term health facilities.
- Employee break rooms designated by employers for smoking, provided they meet all of the following criteria: (1) air from the room is exhausted directly to the outside by an exhaust fan; (2) the employer complies with applicable state and federal ventilation standards; (3) the room is located in a non-work area; and (4) there are sufficient nonsmoking break rooms to accommodate nonsmokers.
- Small businesses (with five or fewer full or part time employees) when all four of the following conditions are met: (1) the smoking area is not accessible to minors; (2) all employees who enter the smoking area consent to permit smoking; (3) air from the smoking area is exhausted directly to the outside by an exhaust fan; and (4) the employer complies with all applicable state and federal ventilation standards.

  Note: This exception is extremely limited and difficult to meet. For example, it does not apply to bars. 82 Ops. Cal. Atty. Gen. 190 (Oct. 8, 1999). In addition, minors may not be excluded arbitrarily in order to meet the first condition. 79 Ops. Cal. Atty. Gen. 8 (Feb. 15, 1996).

Enforcement: This section may be enforced by local law enforcement agencies including local health departments, as determined by the local governing body. The enforcement agency may refer the violation to the California Occupational Safety and Health Administration (Cal/OSHA) for further enforcement; however, Cal/OSHA is not required to respond to a complaint until after a third conviction under California Labor Code Section 6404.5. In addition, under California Labor Code Section 2699, an aggrieved employee or former employee may bring a civil action if Cal/OSHA fails to act upon a complaint.

Penalty: Violators are guilty of an infraction and subject to a fine of up to $100 for a first violation, $200 for a second violation within one year, and $500 for a third or subsequent violation within one year.

Note: Cal/OSHA's fines are potentially much greater; Cal/OSHA has fined a violator over $50,000.

2. MULTI-UNIT RESIDENCES

California Labor Code Section 6404.5

Scope: In apartment and condominium complexes, the indoor common areas (including hallways, stairwells, laundry rooms, and recreation rooms) are subject to the workplace smoking prohibitions contained in Labor Code Section 6404.5 if these areas are places of employment (see entry 1 for a summary of Labor Code Section 6404.5).

Note: An indoor common area may be a place of employment if *any* employment is carried on at the property, even if the employment is carried on by individuals who are employed by someone other than the property owner. Cal. Atty Gen. Op. No. 12-901 (Dec. 20, 2013). Thus, this law may apply to common areas if the property has any employee who works on the property at any time (e.g., manager, security guard, or maintenance worker) regardless of whether the employee is employed directly by the property owner or by a separate business that the property owner hires to perform services.

Note: Landlords and condominium associations may adopt policies further restricting where residents smoke. Such policies could prohibit smoking in indoor and outdoor common areas as well as in individual units.

Note: Tenants or condominium owners with certain disabilities relating to smoke sensitivity may have other legal remedies available to address the problem of drifting smoke entering their units. See entries 118 through 120 for more information on remedies available to people with disabilities.

Enforcement: See entry 1 for a summary of how the California Labor Code may be enforced.

Penalty: See entry 1 for penalties available under the California Labor Code.

California Civil Code Section 1947.5

Scope: A landlord may prohibit the smoking of cigarettes or other tobacco products on the property or in any portion of the building.

Note: Landlords who exercise their authority to prohibit smoking remain subject to all federal, state, and local laws regarding changes to the terms of a lease or rental agreement for all leases or rental agreements that were entered into before the smokefree policy was adopted (e.g., notice requirements, local rent ordinances, etc.). If a landlord prohibits smoking anywhere on the property, any lease or rental agreement entered into on or after January 1, 2012, must include a provision specifying where smoking is prohibited. For a lease or rental agreement entered into before January 2012, a prohibition against smoking in any portion of the property where smoking was previously allowed constitutes a change of the terms of tenancy, requiring adequate notice in writing.

Note: This law explicitly permits local governments to pass ordinances, regulations, and policies that prohibit smoking or tobacco product use in residential dwellings.

Enforcement: Not applicable.

Penalty: Not applicable.

3. STATE, COUNTY, AND CITY BUILDINGS

California Government Code Sections 7596–7598

Scope: Smoking is prohibited:

- inside a public building, which is a building owned and occupied, or leased and occupied, by the state, a county, a city, or a California community college district;
- in an outdoor area within 20 feet of a main exit, entrance, or operable window of a public building; and
- in a passenger vehicle owned by the state.

This law explicitly permits local governments and campuses (e.g., a campus of the University of California, the California State University, or the California community college system) to pass more restrictive ordinances, regulations, and policies.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Exception: The smoking prohibition does not apply to private living areas of public buildings (such as dormitories) or to the parking areas of covered public parking lots. Smoking may be allowed in any outdoor area of a public building unless otherwise prohibited by state or local law and a sign describing the prohibition is posted by the state, county, or city agency, or other appropriate entity.

Enforcement: The governing bodies of the University of California, the California State University and each community college district have the authority to enforce their requirements by citation and fine. If a campus exercises its enforcement and fine authority, it must (and a campus of the University of California may) post signs stating its tobacco use policy and inform employees and students of the policy.

Penalty: The governing bodies of the University of California, the California State University, and each community college district may impose a fine for each offense, with the amount to be determined by the local governing body. Funds shall be allocated to include, but not be limited to, the designated enforcement agency, education and promotion of the policy, and tobacco cessation treatment options. The civil penalty shall not exceed $100.

4. TOT LOTS AND PLAYGROUNDS

California Health and Safety Code Section 104495

Scope: Smoking of tobacco products is prohibited within 25 feet of a playground or tot lot sandbox area. The disposal of tobacco-related waste, such as cigar and cigarette butts, in these areas is also prohibited. A *playground* is defined as a park or recreational area

specifically designed for use by children that has play equipment installed. This includes facilities located on public or private school grounds, or on city, county, or state park grounds. A tot lot sandbox area is a play area within a public park designated for use by children under five years of age. The law allows local governments to pass and enforce stricter laws.

Exception: The law does not apply to private property (except for private schools) or to public sidewalks within 25 feet of a playground or tot lot area.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of an infraction and subject to a fine of $250 per violation.

5. SCHOOLS

20 United States Code Section 6083

Scope: It is illegal under federal law to permit smoking within any indoor facility utilized for kindergarten, elementary, or secondary education or library services for children.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Note: See entries 15 and 16 for summaries of tobacco possession and use restrictions relating to schools.

Enforcement: The U.S. Department of Education is authorized to enforce this law.

Note: A school or library may use its general power over its property to enforce no-smoking rules against visitors and its general power over its terms of employment to enforce no-smoking rules against employees. A school may use its normal disciplinary powers to enforce no-smoking rules against students.

Penalty: Violators may be liable for a civil penalty of up to $1,000 for each violation and/or may be subject to an administrative compliance order. Each day a violation continues constitutes a separate violation.

6. DAY CARE FACILITIES

California Health and Safety Code Sections 1596.795, 1596.890

Scope: California law prohibits smoking on the premises of a licensed day care center and in a licensed family day care home (e.g., a day care for children based in the home of the provider) during the hours of operation as a family day care home and in those areas of the family day care home where children are present. The law allows for more stringent local laws.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Exception: This law does not prohibit smoking in family day care homes before or after hours of operation as a day care facility, but smoking in areas where children are present, even after hours, is still prohibited.

Enforcement: This law may be enforced by the California Department of Social Services or by local law enforcement agencies.

Penalty: Violators are guilty of a misdemeanor punishable by a $1,000 fine and/or imprisonment for no more than 180 days.

20 United States Code Section 6083

Scope: It is illegal under federal law to permit smoking within any indoor facility that is used for federally funded health care, day care, or Head Start services for children or that is used by the employees of the provider of such services.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Exception: This law does not apply to any private residence or to areas used for inpatient hospital treatment for drug or alcohol addiction.

Note: California Health and Safety Code Section 1596.795 prohibits smoking in family day care homes during hours of operation.

Enforcement: The U.S. Department of Education is authorized to enforce this law.

Note: The facilities covered by this law may use their general power over their property to enforce no-smoking rules against visitors and their general power over their terms of employment to enforce no-smoking rules against employees.

Penalty: Violators may be liable for a civil penalty of up to $1,000 for each violation and/or may be subject to an administrative compliance order. Each day a violation continues constitutes a separate violation.

7. FOSTER HOMES

California Health and Safety Code Section 1530.7

Scope: Smoking is prohibited in group homes, foster family agencies, small family homes, transitional housing placement providers, and crisis nurseries licensed pursuant to the California Community Care Facilities Act. Indoor smoking is prohibited in foster family homes and certified family homes; when the child is present, outdoor smoking within these facilities is also prohibited. Moreover, a foster care provider shall not smoke in a vehicle that is regularly used to transport the child.

Enforcement: The California Department of Social Services is authorized to enforce this law.

Penalty: Violation may result in the denial or revocation of a certificate of approval for a certified family home or other disciplinary action against the certified or prospective foster parent.

8. SMOKING IN VEHICLES WITH CHILDREN

California Health and Safety Code Sections 118947–118949

Scope: It is illegal to smoke or possess a lighted pipe, cigar, or cigarette containing tobacco or any other plant in any motor vehicle in which there is a minor (under 18 years of age), regardless of whether the vehicle is in motion or at rest.

Enforcement: A law enforcement officer may not stop a vehicle for the sole purpose of determining whether the driver is violating this prohibition.

Penalty: Violation of this section is an infraction punishable by a fine not exceeding $100 per violation.

9. PUBLIC TRANSIT SYSTEMS

California Health and Safety Code Sections 118925–118945

Scope: Smoking is prohibited on public transportation systems and in any vehicle of an entity receiving transit assistance from the state. A notice prohibiting smoking, displayed as a symbol and in English, must be posted in such vehicles or aircraft, in addition to other sign posting requirements. The law allows for more restrictive local laws.

> **Note:** The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of an infraction and subject to a fine of up to $100 for a first violation, up to $200 for a second violation within one year, and up to $500 for a third and for each subsequent violation within one year.

California Penal Code Section 640

Scope: Smoking is not allowed on public transportation in areas where it is prohibited by that system.

> **Note:** The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of an infraction and subject to a fine of up to $250 and 48 hours of community service.

10. AIRPLANES AND TRAINS

California Health and Safety Code Sections 118925–118945

Scope: Smoking is prohibited on any aircraft or Amtrak train, except to the extent permitted by federal law. The law contains sign posting requirements.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of an infraction and subject to a fine of up to $100 for a first violation, up to $200 for a second violation within one year, and up to $500 for a third or subsequent violation within one year.

49 United States Code Section 41706, 14 Code of Federal Regulations 252

Scope: Smoking is prohibited on domestic U.S. airline flights. Smoking also is prohibited in foreign air travel arriving in or departing from the U.S.

Note: The U.S. Department of Transportation has stated that it views the prohibition on smoking on aircraft to include the use of electronic cigarettes and has also proposed amending the regulatory language to explicitly clarify that electronic cigarette use is prohibited on aircraft. 76 Fed. Reg. 57,008-57,012 (Sept. 15, 2011).

Exception: If a foreign government objects to the prohibition of smoking during foreign air travel, the Secretary of Transportation shall negotiate an alternative.

Enforcement: The Secretary of Transportation shall prescribe regulations necessary to carry out this section.

Penalty: Not specified.

11. YOUTH BUSES AND PUBLIC PARATRANSIT VEHICLES

California Vehicle Code Sections 336, 680, 12523(d)(2), 12523.5(d)(2), 13369(c)(3)

Scope: Drivers of a *youth bus* (a bus other than a school bus used to transport children) may not smoke while operating the bus. Operators of *general public paratransit vehicles* (motor vehicles designed to carry no more than 24 persons that provide local transportation to the public, including students at or below the 12th-grade level to or from a public or private school or school activity) may not smoke.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: The California Department of Motor Vehicles is authorized to enforce this law.

Penalty: A violator may be subject to the denial, suspension, or revocation of a certificate to drive a youth bus or general paratransit vehicle.

12. ADOPTION OF LOCAL SECONDHAND SMOKE LAWS

California Health and Safety Code Section 118910

Scope: A local governing body may completely ban the smoking of tobacco or may regulate smoking in any manner not inconsistent with state law.

Note: Several state laws explicitly permit cities and counties to pass secondhand smoke laws that have stricter restrictions than those imposed by the state laws. (See entries 1, 2, 3, 4, 6, and 9 for summaries of those state laws.) Some cities and counties have passed local laws banning smoking in areas not covered by state law, including parks, beaches, outdoor dining areas, bus stops, and areas within 20 feet of commercial building entryways. These local laws are enforced by various local agencies and impose various penalties.

Enforcement: Not applicable.

Penalty: Not applicable.

POSSESSION AND USE

13. STATE MENTAL HEALTH HOSPITALS

Welfare and Institutions Code Sections 4138, 4139

Scope: Upon receiving a request from the director of a state mental hospital, the state Director of Mental Health may prohibit the possession and use of tobacco products on the grounds of the requesting facility following a phase-in period. The Director must provide an implementation plan to effectuate the prohibition, and must provide any requesting patient with smoking cessation information and assistance. At hospitals where possession and use of tobacco products is prohibited, the facility's store or canteen may not sell tobacco products. This law applies to California's five state mental hospitals: Atascadero State Hospital, Coalinga State Hospital, Metropolitan State Hospital, Napa State Hospital, and Patton State Hospital.

Exception: The prohibition shall not apply on the premises of residential staff housing where patients are not present. Also, departmentally approved religious ceremonies are exempt.

Enforcement: Not specified, but the state mental hospitals are under the jurisdiction of the Department of Mental Health.

Penalty: In a state hospital where the possession of tobacco products by a patient has been prohibited by law or regulation, delivery of tobacco products to a patient or possession of tobacco with the intent to deliver to a patient is a misdemeanor, punishable by a fine not to exceed $1,000 for each item. If a person visiting a patient in a state hospital is found with an item prohibited for patient possession, the item is subject to confiscation but must be returned on the same day unless the item is held as evidence.

14. YOUTH PURCHASE AND POSSESSION

California Penal Code Section 308(b)

Scope: It is unlawful for any person under the age of 18 years to purchase, receive, or possess any tobacco product or paraphernalia. Penal Code Section 308(f) states that no city or county shall adopt any law or regulation inconsistent with this law.

Exception: This provision shall not apply to youth decoys participating in certain enforcement actions. Penal Code Section 308(e) provides immunity to a minor who purchases, receives, or possesses tobacco products or paraphernalia while participating in enforcement activities that comply with the STAKE Act guidelines.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are subject to a fine of $75 or 30 hours of community service.

15. STUDENT POSSESSION AND USE

California Education Code Section 48901

Scope: No elementary or secondary school shall permit its students to smoke or use tobacco or nicotine products including but not limited to, cigarettes, cigars, clove cigarettes, smokeless tobacco, snuff, chew packets, and betel, while the students are on campus, attending school-sponsored activities, or under the supervision and control of school district employees.

Exception: This provision does not prohibit students' use or possession of their own prescription products.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Note: See entry 5 for a summary of the no-smoking law that applies to schools.

Enforcement: Not specified except to say that the governing board of any school district maintaining a high school shall take all steps it deems practical to discourage high school students from smoking.

Note: A school may use its normal disciplinary powers to enforce no-tobacco-use rules against students.

Penalty: Not specified.

California Education Code Sections 48900(h), 48900(s)

Scope: A student who possesses or uses tobacco or nicotine products may be suspended or expelled if the act is related to school activity or attendance (for instance, while on school grounds, while going to or coming from school or a school-sponsored activity, or during the on- or off-campus lunch period). Prohibited products include, but are not limited to, cigarettes, cigars, miniature cigars, clove cigarettes, smokeless tobacco, snuff, chew packets, and betel.

Exception: This provision does not prohibit students' use or possession of their own prescription products.

Enforcement: The superintendent or principal of the school is authorized to enforce this law.

Penalty: The student may be suspended or expelled.

16. TOBACCO-FREE CAMPUS POLICIES

California Health and Safety Code Section 104420(n)(2)

Scope: Each school district and county office of education that receives Proposition 99 tobacco control funding from the State of California must adopt and enforce a tobacco-free campus policy. The policy shall prohibit the use of tobacco products at all times in district-owned/leased buildings, on district property, and in district vehicles. Under the policy, signs

stating Tobacco Use Is Prohibited shall be prominently displayed at all entrances to school property.

Note: See entry 5 for a summary of the no-smoking law that applies to schools.

Enforcement: The California Department of Education monitors the school districts and county offices of education that receive Proposition 99 funding.

Note: A school may use its normal disciplinary powers to enforce no-tobacco-use rules against students, its general power over its property to enforce no-tobacco-use rules against visitors, and its general power over its terms of employment to enforce no-tobacco-use rules against employees.

Penalty: Any school district or county office of education that does not have a tobacco-free policy on July 1 of any given year is not eligible to apply for Proposition 99 funds for that fiscal year (see entry 87 for a summary of Proposition 99).

17. POSSESSION AND USE IN PRISONS

California Penal Code Section 5030.1
California Code of Regulations, Title 15, Sections 3006(c)(18), 3187–3189

Scope: The possession or use of tobacco products, or tobacco cessation products that contain nicotine, by inmates under the jurisdiction of the California Department of Corrections and Rehabilitation is prohibited. The possession or use of tobacco products by anyone on the grounds of any facility under the jurisdiction of the California Department of Corrections and Rehabilitation is prohibited. Tobacco products are considered to be contraband when possessed or used by inmates or by anyone where inmates are housed or detained.

Exception: Inmates may use tobacco products in departmentally approved religious ceremonies. A non-inmate may use tobacco products in certain residential staff housing where inmates are not present. A non-inmate may possess tobacco products in a locked private vehicle for personal use off facility grounds. Tobacco cessation products such as a patch, inhaler, or lozenges are permitted for immediate personal use by staff.

Enforcement: California Department of Corrections and Rehabilitation officials are authorized to enforce this law.

Penalty: Possession of tobacco products by inmates may result in disciplinary action and the confiscation of the tobacco products.

Note: A prison may use its general power over its property to enforce no-tobacco rules against visitors and its general power over its terms of employment to enforce no-tobacco rules against employees.

18. POSSESSION AND USE IN YOUTH CORRECTIONAL FACILITIES

California Welfare and Institutions Code Section 1712.5

Scope: The possession or use of tobacco products by wards and inmates in all institutions and camps under the jurisdiction of the Department of the Youth Authority is prohibited. The use of tobacco products by anyone on the grounds of any institution or facility under the jurisdiction of the Department of the Youth Authority is prohibited.

Exception: Inmates and wards may use tobacco products in departmentally approved religious ceremonies. Tobacco products may be used in residential staff housing where inmates or wards are not present.

Enforcement: Division of Juvenile Facilities officials are authorized to enforce this law.

Penalty: Not specified.

Note: A facility may use its normal disciplinary powers to enforce no-tobacco rules against inmates and wards, its general power over its property to enforce no-tobacco rules against visitors, and its general power over its terms of employment to enforce no-tobacco rules against employees.

19. POSSESSION IN LOCAL CORRECTIONAL FACILITIES

California Penal Code Section 4575

Scope: The possession of any tobacco product by a person housed in a local correctional facility is prohibited if the local board of supervisors has adopted an ordinance or resolution banning tobacco products in its correctional institutions.

Note: See entry 17 for prohibitions and restrictions on tobacco use and possession in state prisons under the jurisdiction of the California Department of Corrections.

Exception: Possession of tobacco products is not prohibited in local correctional institutions in counties where the board of supervisors has not adopted an ordinance banning tobacco products in those facilities.

Penalty: Violation of this section is an infraction, punishable by a fine not to exceed $250.

20. USE IN FOOD SERVICE FACILITIES

California Health and Safety Code Sections 113953.3(a)(5), 113977, 113978, 114390, 114395, 114405

Scope: Food service employees may use tobacco only in designated areas where contamination of food and equipment cannot result. Food service employees shall wash their hands after using tobacco. Owners, managers, and operators are responsible for violations by employees. Food facilities shall have a “no smoking” sign posted in the food preparation, food storage, and dishwashing areas.

Note: The workplace smoking restrictions in California Labor Code Section 6404.5 also apply (see entry 1).

Enforcement: State and local environmental health services officials are authorized to enforce this law. Local law enforcement agencies have the general authority to enforce the misdemeanor penalty under California Penal Code Section 830.1.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of $25 to $1,000 and/or imprisonment for up to six months. A violator may be subject to the suspension or revocation of a permit to operate a food facility.

21. EMPLOYMENT AND OFF-DUTY USE

California Labor Code Sections 98.6, 98.7

Scope: It is illegal for an employer to discriminate against an employee or applicant on the basis of off-duty lawful conduct.

Note: This law applies to off-duty tobacco use so long as the tobacco use is lawful.

Exception: An employer may discriminate against an applicant on the basis of off-duty lawful conduct if the conduct is actually in direct conflict with the essential enterprise-related interest of the employer and if the conduct is prohibited in an employment contract or collective bargaining agreement. An employer may discriminate on the basis of off-duty tobacco use against an applicant for a position as a firefighter. Local and state law enforcement agencies, certain media organizations, and religious associations may discriminate against employees and applicants on the basis of off-duty lawful conduct.

Enforcement: Anyone who believes that he or she has suffered discrimination in violation of the law may file a complaint with the Division of Labor Standards Enforcement of the California Department of Industrial Relations within six months of the alleged occurrence. In addition, under California Labor Code Section 2699, an aggrieved individual may bring a civil action if the California Labor and Workforce Development Agency declines to act upon a complaint.

Penalty: The Division of Labor Standards Enforcement shall order a violator to cease and desist from the violation and may order the violator to take any action deemed necessary to remedy the violation.

TOBACCO SALES

22. SALES TO MINORS: PENAL CODE 308

California Penal Code Section 308(a)

Scope: It is unlawful for any person, firm, or corporation to sell, give, or in any way furnish to a minor any tobacco product or paraphernalia if that person, firm, or corporation knows or should otherwise have grounds to know that the recipient is a minor. This law may be enforced against a business owner or an employee who sold the tobacco product or paraphernalia. Penal Code Section 308(f) states that cities and counties may not adopt any law or regulation that is inconsistent with this law.

> **Note:** A local licensing law that suspends or revokes a license based on a violation of California Penal Code Section 308 is not legally inconsistent with this law, and such local licensing laws are expressly permitted under California Business and Professions Code Section 22971.3 (see entry 93).

Exception: A valid defense to an action under this law is proof that the person who sold or furnished the tobacco products or paraphernalia demanded, was shown, and reasonably relied upon evidence of legal age (such as a driver's license).

Enforcement: A city attorney, county counsel, or district attorney may bring a civil action to enforce the law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

> **Note:** Local law enforcement agencies do not need to use the STAKE Act protocol described in entry 23 when enforcing this law.

Penalty: Violators are subject to either a criminal action for misdemeanor or a civil action punishable by a fine of $200 for a first offense, $500 for a second offense, and $1,000 for a third offense. Each individual franchise or location of a business is treated as a separate entity for purposes of determining liability for the second and subsequent violations of the law.

The prosecuting agency receives 25 percent of penalties collected. Another 25 percent goes to the city or county for the administration and cost of the community-service penalty that applies to minors who purchase, receive, or possess tobacco products or paraphernalia (summarized in entry 14).

A business may not be penalized under both California Penal Code Section 308 and the STAKE Act for the same incident (see entry 23 for a summary of the STAKE Act sales-to-minors law; see entry 97 for license-related penalties that attach to Section 308 violations).

> **Note:** Under California Penal Code Section 308(b), minors who purchase, receive, or possess tobacco products or paraphernalia may be punished by a fine of $75 or 30 hours of community service work (see entry 14).

23. SALES TO MINORS: THE STAKE ACT

California Business and Professions Code Sections 22952, 22957, 22958 (STAKE Act)
California Code of Regulations, Title 17, Section 6903

Scope: It is unlawful for any person, firm, or corporation to sell, give, or in any way furnish any tobacco product or paraphernalia to a person under the age of 18. This law may be enforced only against a business owner and not against an employee who sold the tobacco product or paraphernalia.

Exception: A valid defense to an action under this law is that a youth decoy's appearance was not that which could be generally expected of a person under 18 years of age or that the undercover operation was not carried out in reasonable compliance with the detailed protocol specified in the law. Any failure on the part of the person under 18 years of age to provide true and correct identification, if verbally asked for it, is also a valid defense.

Enforcement: The STAKE Act may be enforced by any defined "enforcing agency," which includes the California Department of Public Health, Attorney General's office, and local law enforcement agencies. The law instructs enforcing agencies to use youth decoys in onsite inspections to determine if retailers are making illegal sales of tobacco products to minors. The law authorizes enforcing agencies to use youth decoys to investigate illegal sales to minors by telephone, mail, or the internet.

An enforcing agency may conduct such inspections at random, in response to public complaints (e.g., on the 1-800-5ASK-4-ID phone line), or at retail sites where violations have previously occurred. The law contains a detailed protocol for an enforcing agency to follow in its undercover operations (the STAKE Act protocol).

Penalty: Violators are subject to a civil penalty of $400-$600 for a first violation; $900-$1,000 for a second violation within a five-year period; $1,200-$1,800 for a third violation within a five-year period; $3,000-$4,000 for a fourth violation within a five-year period; and $5,000-$6,000 for a fifth or subsequent violation within a five-year period.

Violations by one retail location are not counted against other retail locations of the same corporation or business. Violations against a prior owner of a single franchise location are not counted against a new owner of the same single franchise location.

A business owner may not be penalized under both the STAKE Act and California Penal Code Section 308 for the same incident (see entry 22 for a summary of the California Penal Code Section 308 sales-to-minors law).

> **Note:** If an employee sells tobacco to a minor, the business owner can be penalized under the STAKE Act and the employee can be penalized under California Penal Code Section 308 because the owner and employee are not legally the same violator (see entry 95 for license-related penalties that attach to STAKE Act violations).

24. SALES TO MINORS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Section 1140.14(a)

Scope: It is unlawful for any tobacco retailer to sell cigarettes or smokeless tobacco to any person under the age of 18.

Note: The U.S. Food and Drug Administration (FDA) may not establish a minimum age of sale older than 18, although states are free to establish a minimum age of 19 years and older. For example, in December 2013 New York City raised its minimum age requirement for the purchase of tobacco to 21 years.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce this provision.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated

violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

25. SALES TO MINORS: THE SYNAR AMENDMENT

42 United States Code Section 300x-26
45 Code of Federal Regulations Section 96.130

Scope: In order to receive the annual Substance Abuse Prevention and Treatment federal block grant, a state must have and enforce a law prohibiting the sale of tobacco products to individuals under the age of 18. The state must conduct annual youth purchase surveys to ensure compliance with the law and must report the results of these inspections to the U.S. Department of Health and Human Services (HHS).

Note: California enacted the STAKE Act to comply with the Synar Amendment.

Enforcement: HHS is authorized to monitor states' compliance and to reduce the amount of the block grant upon noncompliance.

Penalty: For a state that reports more than a 20 percent rate of illegal sales to youth, the annual Substance Abuse Prevention and Treatment federal block grant will be reduced by up to 40 percent of the amount originally allocated to the state, if the Secretary determines that the state is not in substantial compliance with the law.

26. ID CHECK REQUIREMENT: THE STAKE ACT

California Business and Professions Code Sections 22956, 22957 (STAKE Act)
California Code of Regulations, Title 17, Section 6902(b)

Scope: Retailers must check the identification of tobacco purchasers who reasonably appear to be under 18 years of age.

Enforcement: This requirement may be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Department of Public Health, California Attorney General's office, and local law enforcement agencies.

Penalty: Not specified.

27. ID CHECK REQUIREMENT: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Section 1140.14(b)

Scope: Tobacco retailers must verify that a purchaser of cigarettes or smokeless tobacco is 18 years of age or older through a photo identification card containing the individual's date of birth.

Exception: Verification is not required for any person over the age of 26.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce this provision.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;

- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

28. SIGN POSTING REQUIREMENT: THE STAKE ACT

California Business and Professions Code Sections 22952(b), 22957, 22958(c) (STAKE Act)
California Code of Regulations, Title 17, Section 6902(a)
California Penal Code Section 308(c)

Scope: Every store that sells tobacco must post a boldly printed, contrasting-color sign in a conspicuous place at each point of purchase saying that tobacco products may not be sold to minors.

The sign must contain the following words with initial letters capitalized in the following manner: "The Sale of Tobacco Products to Persons Under 18 Years of Age Is Prohibited by Law and Subject to Penalties. Valid Identification May Be Required. To Report an Unlawful Tobacco Sale, Call 1-800-5ASK-4-ID. Business and Professions Code Section 22952." The sign must be square (at least 5.5 inches by 5.5 inches) or rectangular (at least 3.66 inches by 8.5 inches), and the required notice must meet specified font sizes and typefaces.

Enforcement: This requirement may be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Department of Public Health, California Attorney General's office, and local law enforcement agencies.

Penalty: The STAKE Act authorizes a $200 civil fine for the first violation for failure to post the required signage, and a $500 civil fine for each subsequent violation.

Under Penal Code Section 308(c), violators who fail to post the sign are subject to a fine of $50 for a first offense, $100 for a second offense, $250 for a third offense, and $500 for a fourth or subsequent offense, or by imprisonment for not more than 30 days.

A business owner may not be penalized under both the STAKE Act and California Penal Code Section 308 for the same incident (see entry 95 for license-related penalties that attach to STAKE Act violations).

29. VENDING MACHINES: THE STAKE ACT

California Business and Professions Code Sections 22960, 22958, 22957 (STAKE Act)

Scope: Tobacco products shall not be sold, offered for sale, or distributed from vending machines. This law may be enforced against a business owner only and not against an employee. A local government may pass a law completely banning tobacco vending machines.

Exception: Vending machines may be located where an on-sale public premises license to sell alcoholic beverages (usually a bar) has been issued, provided that the machine is inside the premises and at least 15 feet away from the entrance.

Enforcement: This requirement may be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Department of Public Health, Attorney General's office, and local law enforcement agencies.

Penalty: Violators are subject to a civil penalty of $400-$600 for a first violation; $900-$1000 for a second violation within a five-year period; $1,200-$1,800 for a third violation within a five-year period; $3,000-$4,000 for a fourth violation within a five-year period; and $5,000-$6,000 for a fifth or subsequent violation within a five-year period.

Violations by one retail location are not counted against other retail locations of the same corporation or business. Violations against a prior owner of a single franchise location are not counted against a new owner of the same single franchise location (see entry 95 for license-related penalties that attach to STAKE Act violations).

30. SELF-SERVICE DISPLAYS: THE STAKE ACT

California Business and Professions Code Sections 22958, 22960, 22962 (STAKE Act)

Scope: It is unlawful to sell, offer for sale, or display any tobacco product or paraphernalia through a self-service display, which is an open display of cigarettes that is accessible to the public without the assistance of the clerk. This law may be enforced against a business owner only and not against an employee. The law allows local governments to pass and enforce laws that are stricter than state law.

Exception: Tobacco stores may make available by self-service display pipe tobacco, snuff, chewing tobacco, dipping tobacco, and certain cigars (those that are generally not sold or offered for sale in a sealed package of the manufacturer or importer containing fewer than six cigars). Self-service displays of cigarettes and tobacco paraphernalia are never permitted in a tobacco store. A *tobacco store* is defined as a business that (1) primarily sells tobacco products; (2) generates more than 60 percent of its gross revenue annually from the sale of tobacco products and paraphernalia; (3) prohibits minors unless accompanied by a parent or guardian; and (4) does not sell alcohol or food for consumption on the premises.

> **Note:** This law does not affect the state law allowing tobacco to be sold through vending machines in limited circumstances (see entry 29).

Enforcement: The state Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law.

Penalty: Violators are subject to a civil penalty of $400-$600 for a first violation; $900-$1,000 for a second violation within a five-year period; $1,200-$1,800 for a third violation within a five-year period; $3,000-$4,000 for a fourth violation within a five-year period; and $5,000-$6,000 for a fifth or subsequent violation within a five-year period.

Violations by one retail location are not counted against other retail locations of the same corporation or business. Violations against a prior owner of a single franchise location are not counted against a new owner of the same single franchise location (see entry 95 for license-related penalties that attach to STAKE Act violations).

31. SELF-SERVICE DISPLAYS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Sections 1140.14(c), 1140.16(c)

Scope: Cigarettes and smokeless tobacco may only be sold via a direct, face-to-face exchange. The use of vending machines and self-service displays is not permitted.

Exception: Mail-order sales are permitted. (Mail-order redemption of coupons and distribution of free samples through the mail do not fall within the exception and are prohibited.) Vending machines and self-service displays are permitted in facilities where the retailer ensures that no person under the age of 18 is present or allowed to enter at any time.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce this provision.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

32. BIDIS

California Penal Code Section 308.1

Scope: It is unlawful to sell, offer to sell, distribute, or import *bidis* (also known as beedies), defined as products containing tobacco wrapped in temburni leaf or tendu leaf, or products that are marketed and sold as "bidis" or "beedies."

> **Note:** Bidis are hand-rolled filterless cigarettes that are imported primarily from India and some Southeast Asian countries. They are available in a variety of candylike flavors and often are sold in packs of fewer than 20, which makes them more affordable.

Exception: The law does not apply to businesses that legally prohibit minors on the premises.

Enforcement: The state Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of a misdemeanor and also subject to a civil penalty of $2,000 per violation.

33. SINGLE CIGARETTES

California Penal Code Section 308.2

Scope: No person may sell one or more cigarettes, other than in a sealed and properly labeled package. A sealed and properly labeled package means the original packaging of the manufacturer or importer which meets federal labeling requirements.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of an infraction.

34. MINIMUM PACKAGE SIZE

California Penal Code Section 308.3

Scope: Cigarettes may not be manufactured, distributed, sold, or offered for sale in packages of fewer than 20 cigarettes. Roll-your-own tobacco may not be manufactured, distributed, sold, or offered for sale in a package containing less than 0.60 ounces of tobacco.

Enforcement: A civil action to enforce the law may be brought by the state Attorney General, a district attorney, a county counsel, or a city attorney. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are liable for a civil penalty of $200 for a first violation, $500 for a second violation, and $1,000 for each subsequent violation or are guilty of an infraction.

35. SINGLE ITEMS AND MINIMUM PACKAGE SIZE: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Sections 1140.14(d), 1140.16(b)

Scope: A tobacco retailer may not sell any quantity of cigarettes or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use. Additionally, cigarettes may not be manufactured, sold, or distributed in packages containing fewer than 20 cigarettes.

Enforcement: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. In California, HHS has contracted with the California Department of Public Health's Food and Drug Branch to enforce the provisions that create obligations for tobacco retailers.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated

violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

36. MAIL ORDER/INTERNET SALES: THE STAKE ACT

California Business and Professions Code Section 22963 (STAKE Act)

Scope: No person may sell, distribute, or engage in the *nonsale distribution* of, tobacco products to minors via public or private postal services. The law includes directives designed to ensure that people who order by mail, fax, phone, or the internet are 18 years of age or older. For example, distributors or sellers must either (1) match the name, address, and date of birth provided by the customer to information contained in a database of individuals verified to be 18 or older, or (2) require the customer to submit verification of age, including a copy of a valid form of government identification. The law establishes a two-carton minimum on each order of cigarettes. It also mandates that all applicable purchases must be made by personal check or credit card and that the distributor or seller must call purchasers to confirm their orders.

Nonsale distribution is defined as giving smokeless tobacco or cigarettes to the general public at no cost, or at nominal cost, or to give coupons, coupon offers, gift certificates, gift cards, or other similar offers, or rebate offers for smokeless tobacco or cigarettes to the general public at no cost or at nominal cost. Distribution of tobacco products, coupons, coupon offers, gift certificates, gift cards, or other similar offers, or rebate offers in connection with the sale of another item, including tobacco products, cigarette lighters, magazines, or newspapers shall not constitute nonsale distribution.

Exception: The U.S. Postal Service and other common carriers are exempt from penalties when they deliver a package without any reason to know the package's contents.

Enforcement: A district attorney, city attorney, or the state Attorney General may assess civil penalties against any person or entity that violates this law.

Penalty: Violators who make prohibited sales or distributions are liable for a civil penalty of $1,000-$2,000 for a first violation; $2,500-$3,500 for a second violation; $4,000-$5,000 for a third violation within a five-year period; $5,500-$6,500 for a fourth violation within a five-year period; and $10,000 for a fifth or subsequent violation within a five-year period.

37. MAIL ORDER/INTERNET SALES: THE PACT ACT

15 United States Code Sections 375, 376, 377
18 United States Code Section 1716e

Scope: The Prevent All Cigarette Trafficking Act (the PACT Act) prohibits the delivery of sales of cigarettes (including roll-your-own tobacco) and smokeless tobacco via the U.S. Postal Service. Other common carriers (e.g., UPS, FedEx) may deliver a package containing cigarettes or smokeless tobacco if the package weighs less than 10 pounds and bears stamps and signs verifying that all appropriate local, state, and federal taxes have been paid. Upon delivery, the age and identity of the buyer must be confirmed, and the recipient must be of minimum legal age to purchase tobacco products.

Exception: The U.S. Postal Service restrictions do not apply to sales shipments that begin and end entirely within Alaska or Hawaii and to certain APO/FPO military addresses. Infrequent, lightweight shipments can still be sent via U.S. mail by age-verified adults as long as certain restrictions are met. Additional exceptions apply for authorized business/regulatory purposes, as well as for consumer testing and public health purposes.

Enforcement: The U.S. Postal Service provision is enforced by the Postmaster General with the cooperation of any other federal agency or agency of any state, local, or tribal government, whenever appropriate. The common carrier provisions are enforced by the U.S. Attorney General, state attorneys general, and state tobacco tax administrators.

Penalty: Violators are subject to criminal penalties of up to three years imprisonment. Retailers who violate the law are also subject to civil penalties in an amount not to exceed the greater of $5,000 for a first violation and $10,000 for a subsequent violation, or 2 percent of their gross sales of cigarettes or smokeless tobacco during the one-year period ending on the date of the violation. Common carriers or other delivery services that knowingly violate the new law are subject to civil penalties in an amount not to exceed $2,500 for a first violation and $5,000 for any violation within one year of a prior violation.

Any person found delivering cigarettes or smokeless tobacco through the U.S. Postal Service is subject to an additional civil penalty in the amount equal to 10 times the retail value of the nonmailable cigarettes or smokeless tobacco, including all federal, state, and local taxes.

Any cigarette or smokeless tobacco that is deposited in the mail shall be subject to seizure and forfeiture. Any tobacco products seized and forfeited under this subsection shall be destroyed or retained by the federal government for the detection or prosecution of crimes or related investigations and then destroyed.

38. MAIL ORDER/INTERNET SALES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387f(d)

Scope: The Tobacco Control Act directed the U.S. Department of Health and Human Services (HHS) to issue regulations regarding the remote sale and distribution of tobacco products, such as via the internet or mail order, by December 22, 2010. The Tobacco Control Act also directed HHS to issue regulations regarding the promotion and marketing of tobacco products sold or distributed remotely by June 22, 2011.

> **Note:** In March 2010, Congress enacted the Prevent All Cigarette Trafficking (PACT) Act of 2009, which regulates the remote sale and distribution of tobacco products via the internet or mail order, and made a new HHS regulation largely unnecessary. Specifically, the PACT Act largely prohibits the U.S. Postal Service from shipping tobacco products (see entry 37 for additional information on the PACT Act).
>
> In September 2011, the U.S. Food and Drug Administration (FDA) issued an advanced notice of proposed rulemaking and requested comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the internet, email, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients. 76 Fed. Reg. 55,835 (Sept. 9, 2011).

Enforcement: HHS is authorized to enforce the regulations it issues under this provision with the help of other federal agencies and state governments.

Penalty: At the time of publication, regulations had not yet been issued by the FDA. Once regulations go into effect, the following penalties will apply:

Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;

- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

39. HOME DELIVERY OF UNSOLICITED TOBACCO PRODUCTS

California Penal Code Section 308b

Scope: It is unlawful for a person to knowingly deliver or cause to be delivered any unsolicited tobacco products to any residence in California (see entry 74 for more information on mailing unsolicited samples of smokeless tobacco products).

Exception: It is a defense to a violation of this section that the recipient of the tobacco products is personally known to the sender at the time of the delivery. The law does not impose liability on any U.S. Postal Service employee for actions performed in the scope of his/her employment.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1. Local governments may seek to enforce the nuisance penalty provision using the administrative nuisance abatement procedures commonly found in local laws.

Penalty: Violators are guilty of a misdemeanor, and violations constitute a nuisance within the meaning of California Civil Code Section 3479.

40. FIRE SAFE CIGARETTES

California Health and Safety Code Sections 14950–14960

Scope: It is illegal to sell, offer to sell, or possess for sale cigarettes unless they meet fire safety standards modeled on standards currently in place in New York. Specifically, manufacturers must certify to the state Fire Marshal that their cigarettes have been tested in accordance with standards established by the American Society of Testing and Materials, and that no more than 25 percent of the cigarettes tested in a test trial shall exhibit full-length burns. Cigarettes in compliance with this law shall be marked by the manufacturer on the packaging and case.

Exception: Distributors, wholesalers, or retailers may sell their existing inventory of cigarettes after January 1, 2007, if certain conditions are met.

Enforcement: The state Attorney General may bring a civil action to enforce the law. Any law enforcement agency may seize cigarettes sold, offered for sale, or possessed for sale in violation of the law.

Penalty: Manufacturers or others who knowingly sell or offer cigarettes in violation of these provisions other than through retail sale are subject to a civil penalty of up to $10,000 for each sale. Retailers, distributors and wholesalers who knowingly sell cigarettes in violation of these provisions are subject to a civil penalty of up to $500 for each sale of up to 50 packages of cigarettes and a civil penalty of up to $1,000 for each sale of more than 50 packages of cigarettes. Cigarettes that are sold in violation of these provisions are subject to seizure.

41. ELECTRONIC CIGARETTES

California Health and Safety Code Section 119405

Scope: It is illegal to sell or otherwise furnish an electronic cigarette (e-cigarette) to a person under 18 years of age. An electronic cigarette is a device that can deliver a dose of nicotine to the user through a vaporized solution.

> **Note:** Local governments are allowed to adopt and enforce laws regulating the sale, distribution, and display of electronic cigarettes that are stricter than state law, provided they are not otherwise prohibited by federal law.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are subject to a fine of up to $200 for a first violation; $500 for a second violation; and $1,000 for a third or subsequent violation.

> **Note:** Before this law passed, the California Attorney General entered into settlement agreements with two national retailers of electronic cigarettes—Smoking Everywhere and Sottera—in which the companies agreed to:

- make their websites age-restricted and not to sell flavors attractive to young people;
- stop making false or misleading claims concerning the safety or effectiveness of their products;
- put in place systems for quality control and to place warnings on their products in compliance with Proposition 65 (summarized in entry 119); and
- pay to the state monetary penalties, attorneys' fees, and costs.

Settlements are available on the website for the office of the Attorney General: **http://oag.ca.gov/tobacco/highlights**.

42. TOBACCO PRODUCT STANDARDS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387g

Scope: The U.S. Department of Health and Human Services (HHS) may establish tobacco product standards for the protection of public health. Tobacco manufacturers may no longer use tobacco that contains an unsafe level of pesticide chemical residue, as determined by federal law.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Manufacturers who intentionally misrepresent that they meet tobacco product standards may be subject to civil penalties of up to $250,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice of violation, the violator is subject to a penalty of $250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to $1 million in any 30-day period or $10 million for all such violations ruled on in a single proceeding.

43. PRE-MARKET REVIEW OF NEW TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387e, 387j

Scope: Tobacco products or modified tobacco products not commercially marketed in the U.S. as of February 15, 2007, must be approved by the U.S. Food and Drug Administration (FDA) prior to commercial release. Applications for new products shall be made available to the public. Approval may be withdrawn as information changes and new findings are made.

Exception: A new or modified tobacco product may be exempted from this requirement if the U.S. Department of Health and Human Services (HHS) Secretary issues an order stating that the product is:

1. Substantially equivalent to a tobacco product commercially marketed in the U.S. as of February 15, 2007 ("substantially equivalent"); and
2. Otherwise in compliance with the law.

A modified tobacco product may be exempted from this requirement if the Secretary determines that:

1. The modification would be a minor modification of a tobacco product that can be legally sold; and
2. A report is not necessary to ensure that allowing the tobacco product to be marketed would be appropriate for protection of public health.

A tobacco product that was first introduced into the commercial market between February 15, 2007, and March 22, 2011, may be exempted from this requirement if the manufacturer submitted a report during that period claiming that the product is substantially equivalent to a tobacco product commercially marketed as of February 15, 2007, and if the Secretary does not issue an order to the contrary. If an order is issued finding that such product is not substantially equivalent, the product is adulterated and misbranded. The FDA has indicated that it will take no enforcement action for at least the first 30 days after it issues such an order for products that are in a retailer's current inventory at a specific retail location on the date the order is issued. *Draft Guidance for Industry and Tobacco Retailers: Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent* (Feb. 2014), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM386629.pdf**.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Civil penalty of up to $250,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice, the violator is subject to a penalty of $250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to $1 million in any 30-day period or $10 million for all such violations ruled on in a single proceeding.

44. MISBRANDED TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387c

Scope: A tobacco product is deemed to be misbranded if the package label does not contain all of the following:

1. The name and address of the manufacturer, packer, or distributor;
2. An accurate net quantity statement;
3. The percentage of tobacco that is foreign versus domestic; and
4. The statement "sale only allowed in the United States."

A tobacco product is also misbranded if its labeling is false or misleading. The U.S. Department of Health and Human Services (HHS) may issue regulations requiring prior approval of statements made on the label of a tobacco product.

Exception: Under this provision, HHS shall establish regulations to permit "reasonable variations" and exemptions for "small packages."

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

45. MODIFIED RISK TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387k

Scope: No person may introduce a "modified risk" tobacco product into interstate commerce or commercially market such a product without approval from the U.S. Department of Health and Human Services (HHS). Approval is limited to a five-year term but may be renewed. The agency shall approve modified risk tobacco products only after determining that the product, as it is actually used by consumers, (1) significantly reduces harm and the risk of tobacco-related disease to individual tobacco users, and (2) benefits the health of the population as a whole.

Approval is conditioned on the applicant's agreement to conduct post-market surveillance and studies and to submit the results to HHS annually so that the agency may determine the impact of such marketing on consumer perception, behavior, and health. HHS may also impose additional marketing and label restrictions. Approval may be withdrawn if requirements are not met.

> **Note:** This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the modified risk provision improperly regulated speech and violated the First Amendment.

Exception: In some cases a modified risk tobacco product can be introduced into interstate commerce and yet may not be commercially marketed.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Civil penalty for intentionally purporting to meet tobacco product standards of up to $250,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding. If violations continue after the agency provides written notice, the violator is subject to a penalty of $250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to $1 million in any 30-day period or $10 million for all such violations ruled on in a single proceeding.

46. "LIGHT," "LOW," AND "MILD" TOBACCO PRODUCTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387k

Scope: Descriptors similar to and including "light," "low," and "mild" are prohibited in all advertising, labeling, and marketing of cigarettes and smokeless tobacco products manufactured on or later than June 22, 2010.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on the use of the terms, "low," "light," and "mild," improperly regulated speech and violated the First Amendment.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Civil penalty for intentionally purporting to meet tobacco product standards of up to $250,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding. If violations continue after the agency provides written notice, the violator is subject to a penalty of $250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to $1 million in any 30-day period or $10 million for all such violations ruled on in a single proceeding.

47. BAN ON FLAVORED CIGARETTES OR CIGARETTE COMPONENTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387g

Scope: Cigarettes and their component parts (including the tobacco, filter, or paper) must not contain any artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. The Secretary of the U.S. Department of Health and Human Services (HHS) has the authority to ban menthol or any artificial or natural flavor, herb, or spice not specified in this list.

Exception: Tobacco flavor and menthol are excluded from this provision. This provision does not apply to tobacco products other than cigarettes.

Note: Two federal circuit courts of appeal have held that local governments may enact laws restricting the sale of flavored non-cigarette tobacco products such as cigars and chewing tobacco. See *U.S. Smokeless Tobacco Mfr. Co. v. City of New York,* 708 F.3d 428 (2d Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013). Both courts found that local laws were not preempted by the federal Tobacco Control Act. These decisions are not binding in California but can be influential, and they signal that courts may be more likely to uphold similar laws in other jurisdictions.

Note: The Tobacco Control Act required the U.S. Food and Drug Administration (FDA) Tobacco Products Scientific Advisory Committee (TPSAC) (see entry 114) to submit a report and recommendation to the Secretary on the public health impacts of the use of menthol in cigarettes, including use among children, African Americans, Hispanics, and other racial/ethnic minorities. The TPSAC submitted its report and recommendations to the FDA in March 2011. On July 23, 2013, the FDA issued an advanced notice of proposed rulemaking (ANPR) to solicit public input on menthol in cigarettes. At the time of publication, the FDA had not taken any further action with respect to menthol in cigarettes. The docket for the ANPR is available at: **www.regulations.gov/#!documentDetail;D=FDA-2013-N-0521-0001**.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

48. ORIGIN LABELING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387t

Scope: All tobacco products must bear the statement "sale only allowed in the United States" on all labels, packaging, and shipping containers. This requirement went into effect on July 22, 2010, for non-cigarette tobacco products (or tobacco products other than cigarettes). The Tobacco Control Act stipulated that this requirement will become effective for cigarettes 15 months after the U.S. Department of Health and Human Services (HHS) issues cigarette label and advertising regulations.

Note: The graphic warning labels proposed by the U.S. Food and Drug Administration (FDA) were ruled unconstitutional and were not effective at the time of publication. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). In March 2013, the FDA decided not to appeal the D.C. Circuit Court of Appeals ruling to the U.S. Supreme Court and is instead working on redesigning the warning labels. At the time of publication, the FDA was not enforcing the new warning label requirements and related provisions, including the origin labeling requirement. The FDA had not indicated its timeline for proposing new warning labels.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

ADVERTISING

49. OUTDOOR ADVERTISING: THE MSA

Master Settlement Agreement (MSA) Sections II(ii), II(xx), III(c), III(d), VII(c)
Smokeless Tobacco Master Settlement Agreement (STMSA) Sections II(dd), II(rr), III(c), III(d), VII(c)

Scope: Under the MSA and STMSA, the settling tobacco companies are prohibited from engaging in *outdoor advertising* of tobacco products, defined as (1) billboards; (2) signs and placards in arenas, stadiums, shopping malls, and video game arcades; and (3) any other tobacco advertisements that are outdoors, or on the inside surface of a window but facing outward.

Exception: The MSA and STMSA do not restrict:

- Advertisements that are 14 square feet or smaller, and are either outside a tobacco retail store but on store property, or on the window of a tobacco retail store facing outward;
- Advertisements inside a tobacco retail store that are not placed on a window facing outward;
- Advertisements located inside an adult-only facility (where the operator ensures that no minors are present);
- Outside Advertisements at the site of an adult-only facility advertising the event with a brand name for the duration of the event, and no more than 14 days before the event;
- Billboards advertising a tobacco brand-sponsored event at the site of the event for 90 days before the initial sponsored event and ten days after the last sponsored event; or
- Advertisements outside a tobacco manufacturing facility.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

50. OUTDOOR ADVERTISING: THE STAKE ACT

California Business and Professions Code Sections 22957, 22958, 22961 (STAKE Act)

Scope: No tobacco advertising on any outdoor billboard located within 1,000 feet of any public or private elementary, junior high, or high school, or public playground.

Note: This law currently is not being enforced and is largely made unnecessary by the broader limits on outdoor advertising in the MSA and STMSA. Moreover, the law may be preempted by federal law in light of the U.S. Supreme Court decision in *Lorillard Tobacco Company v. Reilly* (see entry 52 for more information about this decision. *Lorillard Tobacco Company v. Reilly*, 533 U.S. 525 (2001).

Exception: This law does not prohibit a message or advertisement opposing the use of tobacco products.

Enforcement: The Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this section.

Penalty: Violators are subject civil penalties according to Section 22958(d).

51. OUTDOOR ADVERTISING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)

Scope: The Tobacco Control Act directed the U.S. Food and Drug Administration (FDA) to issue a rule regulating outdoor advertising for cigarettes and smokeless tobacco by June 22, 2010. The FDA was instructed to consider any necessary modifications to its proposed 1996 rule prohibiting advertising (i.e., billboards, posters, placards) within 1,000 feet of any public playground or playground areas on public property (e.g., swings, seesaws, baseball diamonds, basketball courts, public schools).

> **Note:** At the time of publication, the FDA had not yet issued rules about outdoor advertising; in March 2010, the FDA issued an advanced notice of proposed rulemaking and request for comments. 75 Fed. Reg. 13,241 (Mar. 19, 2010). This provision in the Tobacco Control Act, among others, was challenged in federal court. The federal district court neither upheld nor struck down this provision, instead ruling that the issue was not properly before the court (i.e., the issue was not ripe because the FDA had not yet issued an outdoor advertising rule). *Commonwealth Brands, Inc. v. United States,* 678 F.Supp.2d 512 (W.D.Ky. 2010), *overruled in part on other grounds by Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013).

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

52. FEDERAL PREEMPTION OF STATE AND LOCAL REGULATION OF CIGARETTE ADVERTISING AND PROMOTION

15 United States Code Sections 1331–1341

Scope: The Federal Cigarette Labeling and Advertising Act (FCLAA) establishes a comprehensive federal program governing cigarette labeling and advertising (for a summary of the FCLAA's warning label requirements and its ban on television advertising, see entries 79 and 60, respectively). The FCLAA also contains a preemption clause that prohibits state and local laws and regulations from imposing any requirements or prohibitions based on smoking and health with respect to the advertising or promotion of cigarettes. 15 United

States Code Section 1334(b). In 2009, the Tobacco Control Act amended FCLAA's preemption clause adding a section expressly allowing state or local governments to impose "specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes." 15 United States Code Section 1334(c).

Note: In the 1990s tobacco companies sued various state and local governments for passing laws that allegedly imposed requirements or prohibitions with respect to the advertising or promotion of cigarettes that are based on smoking and health. In *Lorillard Tobacco Company v. Reilly,* 533 U.S. 525 (2001), the U.S. Supreme Court struck down a Massachusetts regulation banning cigarette advertising within 1,000 feet of schools because it found that the state regulation was preempted by the FCLAA.

Note: The FCLAA only applies to cigarettes. It does not preempt state and local governments from passing laws on the basis of smoking and health that regulate the advertising or promotion of other tobacco products (e.g., cigars, smokeless tobacco, etc.). However, the First Amendment of the U.S. Constitution remains an important consideration regarding the legality of any such law.

Note: The preemption provision of the FCLAA does not apply to the Master Settlement Agreement (MSA) because the MSA is not a state law but instead is a contract to which the tobacco companies have voluntarily agreed to be bound.

Note: In 2012, a federal court of appeals held that the FCLAA preempted a New York City law requiring tobacco retailers to display signs bearing graphic images showing the adverse health effects of smoking. *23-34 9th St. Grocery Corp. v. N.Y.C. Bd. of Health,* 685 F.3d 174 (2d Cir. 2012). The court concluded that requiring graphic warnings to be placed adjacent to product displays impermissibly affected cigarette makers' promotions at retail sites. Although this decision is not binding in California, the case may serve as guidance for California courts examining similar issues. By contrast, a different federal court of appeals held that the FCLAA did not preempt a Providence, RI law that prohibits tobacco retailers from accepting or redeeming coupons and multi-pack discounts for any tobacco products or cigarettes. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence,* 731 F.3d 71 (1st Cir. 2013). The court also held that the law did not conflict with the First Amendment rights of tobacco manufacturers or distributors because it did not prohibit these parties from disseminating coupons or multi-pack offers.

Enforcement: Aggrieved private parties (e.g., tobacco companies or retailers) may bring a civil action against state or local governments in court.

Penalty: A court will invalidate a law that it finds to be preempted by the FCLAA.

Following the ruling upholding Providence's law, in November 2013 New York City adopted a similar law that prohibits tobacco retailers from accepting or redeeming coupons and multi-pack discounts for any tobacco products or cigarettes. New York City's law also set a minimum retail price for the sale of cigarettes, cigars, and little cigars. A lawsuit challenging New York City's law was filed in January 2014. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of New York*, No. 14-CV-577 (S.D.N.Y. Jan. 30, 2014). No ruling had been issued at the time of publication.

53. STOREFRONT ADVERTISING

California Business and Professions Code Sections 25612.5(c)(7), 25617, 25619 (known informally as the Lee Law)

Scope: No more than 33 percent of the square footage of windows and clear (e.g., glass) doors of an alcohol retailer may have advertising signs of any sort, including tobacco.

Note: This law is sometimes referred to as the Lee Law after its original sponsor, Assembly Member Barbara Lee.

This law is not preempted by the Federal Cigarette Labeling and Advertising Act (see entry 52) because it applies generally to advertising of all types, not specifically to advertising of cigarettes.

Exception: The law applies only to retailers with an off-sale premises license to sell alcoholic beverages.

Enforcement: This law may be enforced by the California Department of Alcoholic Beverage Control and by local law enforcement agencies.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of up to $1,000 and/or imprisonment for up to six months.

Note: An officer who refuses or neglects to diligently prosecute persons whom they have reasonable cause to believe have violated this provision is guilty of a misdemeanor under Section 25619.

54. BLUNT WRAPS ADVERTISING

California Business and Professions Code Sections 22958(a), 22962 (STAKE Act) California Penal Code Section 308

Scope: No person or business may place advertising for blunt wraps lower than four feet above the floor. No person or business offering blunt wraps for sale may place blunt wrap advertising within two feet of a candy, snack, or nonalcoholic beverage display. This law may be enforced against a business owner only and not against an employee.

Note: *Blunt wraps* are defined as cigar papers or cigar wrappers that are designed for smoking or ingestion of tobacco products and contain less than 50 percent tobacco.

Enforcement: The state Attorney General, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law.

Penalty: Violators are subject to a civil penalty of $400-$600 for a first violation; $900-$1,000 for a second violation within a five-year period; $1,200-$1,800 for a third violation within a five-year period; $3,000-$4,000 for a fourth violation within a five-year period; and $5,000-$6,000 for a fifth or subsequent violation within a five-year period.

Violations by one retail location are not counted against other retail locations of the same corporation or business. Violations against a prior owner of a single franchise location are

not counted against a new owner of the same single franchise location (see entry 95 for license-related penalties that attach to STAKE Act violations).

55. STATE BUILDING ADVERTISING

California Government Code Section 19994.35

Scope: No tobacco product advertising shall be allowed in any building owned and occupied by the state.

Exception: This law does not apply to tobacco advertising contained in a program, leaflet, newspaper, magazine, or other written material lawfully sold, brought, or distributed within a state building.

Enforcement: Not specified.

Penalty: Not specified.

56. TRANSIT ADVERTISING

Master Settlement Agreement Sections II(xx), III(c)(3)(E), III(d), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections II(rr), III(c)(3)(E), III(d), VII(c)

Scope: The settling tobacco companies are prohibited from placing tobacco *transit advertisements,* defined as advertisements on or within private or public vehicles, and placed at, on, or within a bus stop, taxi stand, transportation waiting area, train station, airport, or similar location.

Exception: This prohibition does not apply to advertisements inside an adult-only facility (where the operator ensures that no minors are present and that the advertisements are not visible to persons outside the facility) or to outside advertisements on the site of an adult-only facility advertising a brand-sponsored event, no more than 14 days before the event, or to vehicles bearing a tobacco brand name used in a brand-sponsored event.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

57. CARTOON CHARACTERS

Master Settlement Agreement Sections II(l), III(b), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections II(j), III(b), VII(c)

Scope: The settling tobacco companies are prohibited from using cartoons in tobacco advertising, promoting, labeling, and packaging.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

58. YOUTH TARGETING

Master Settlement Agreement Sections III(a), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(a), VII(c)

Scope: The settling tobacco companies are prohibited from directly or indirectly targeting youth in tobacco advertising, promotion, and marketing, and from taking any action the primary purpose of which is to initiate, maintain, or increase the incidence of youth smoking.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

59. VIDEO GAMES

California Penal Code Section 308.5

Scope: This law prohibits paid commercial advertising for tobacco (e.g., tobacco product brand names, trademarks, or copyrighted slogans) and alcohol in video games intended for either private use or use in a public establishment, and intended primarily for use by any person under the age of 18 years.

Enforcement: Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1.

Penalty: Violators are guilty of a misdemeanor.

60. TELEVISION/RADIO CIGARETTE ADVERTISING

15 United States Code Sections 1335, 1338, 1339

Scope: This law prohibits advertising cigarettes or little cigars (defined by weight) on any medium of electronic communication subject to the jurisdiction of the U.S. Federal Communications Commission (FCC) (such as television and radio).

Exception: This law does not apply to regular size cigars.

Enforcement: The U.S. Attorney General may seek an injunction in federal court against violators to prevent future violations of this law.

Note: Information on filing complaints to the FCC is located on the FCC's website: **www.fcc.gov/complaints**.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of not more than $10,000.

61. TELEVISION/RADIO SMOKELESS TOBACCO ADVERTISING

15 United States Code Sections 4402, 4404, 4405

Scope: This law prohibits advertising smokeless tobacco on any medium of electronic communication subject to the jurisdiction of the U.S. Federal Communications Commission (FCC) (such as television and radio).

Enforcement: The U.S. Attorney General may seek an injunction in federal court against violators to prevent future violations of this law.

Note: Information on filing complaints to the FCC is located on the FCC's website: **www.fcc.gov/complaints**.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of not more than $10,000.

62. BAN ON MISLEADING CONSUMERS ABOUT U.S. FOOD AND DRUG ADMINISTRATION (FDA) ENDORSEMENTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 331(tt), 333, 372

Scope: It is illegal to make any express or implied statement to consumers in tobacco product labeling or through the media or advertising that would mislead consumers into believing that a tobacco product is:

1. Approved by the FDA;
2. Endorsed by the FDA;
3. Deemed safe by the FDA; or
4. Less harmful due to FDA regulation.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit had alleged that the ban on misleading consumers about FDA endorsements improperly regulated speech and violated the First Amendment.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

63. CONTENT DISCLOSURES TO THE PUBLIC: THE TOBACCO CONTROL ACT

21 United States Code Sections 387d, 387n
15 United States Code Sections 1333, 1336, 1338, 1339

Scope: The U.S. Department of Health and Human Services (HHS) will determine whether tar and nicotine yields of cigarette and tobacco products must be disclosed on all product packages and advertisements. If HHS decides that the levels of any other cigarette or tobacco constituents should be disclosed to benefit the public health, the disclosure may be required through a product package or advertisement insert, or by another approved means.

Exception: Mandatory disclosures of yields of cigarette or tobacco constituents, other than tar or nicotine, cannot appear directly on the face of any cigarette package or advertisement.

Enforcement: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

Note: In April 2012, the U.S. Food and Drug Administration (FDA) issued a notice establishing a list of tobacco product constituents that the agency believes are harmful or potentially harmful to health. The notice includes the criteria the FDA used to develop the list and the reasons the FDA may add or remove constituents from the list. 77 Fed. Reg. 20,034 (Apr. 3, 2012).

Penalty: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of $10,000 or less.

64. PERMISSIBLE FORMS OF LABELING AND ADVERTISING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Section 1140.30(a)

Scope: A manufacturer, distributor, or retailer must notify the U.S. Food and Drug Administration (FDA) 30 days in advance if it seeks to advertise cigarettes or smokeless tobacco in a medium other than: in periodicals or other publications; on billboards, posters, and placards; or in promotional material such as direct mail or point-of-sale material, including audio or video presented at the point of sale. The notice to the FDA must discuss the extent to which the advertising or labeling may be seen by people under the age of 18.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the FDA shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order"

prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

65. EQUAL TREATMENT OF RETAIL OUTLETS: THE TOBACCO CONTROL ACT

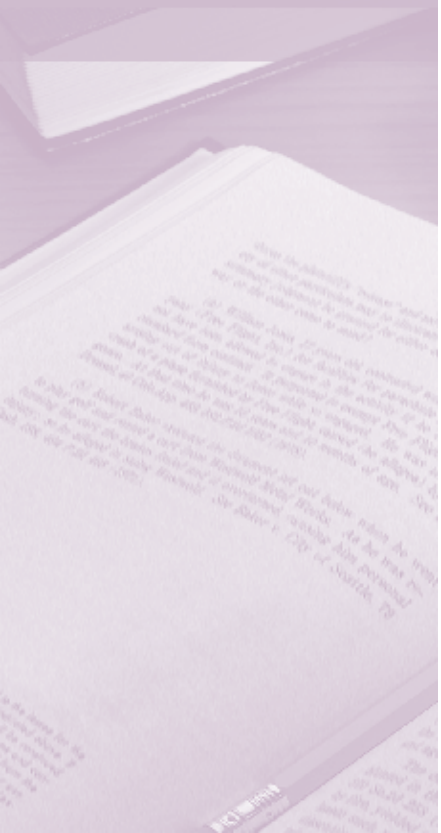
21 United States Code Sections 333, 372, 387m

Scope: The U.S. Department of Health and Human Services (HHS) must issue rules requiring that retail establishments whose primary business is the sale of tobacco products must comply with all advertising restrictions that apply to retail establishments accessible to people under 18 years of age.

Note: This provision ensures that tobacco stores are subject to the same advertising restrictions as other retailers, such as supermarkets and convenience stores.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.



SPONSORSHIP, BRANDING, AND SAMPLING

66. SPONSORSHIP

Master Settlement Agreement (MSA) Sections II(j), III(c), VII(c)
Smokeless Tobacco Master Settlement Agreement (STMSA) Sections II(h), III(c), VII(c)

Scope: Under the MSA and STMSA, each settling tobacco company may engage in only one brand name sponsorship in any 12-month period. A national or multistate series or tour (e.g., Skoal Racing) will count as one brand name sponsorship. The MSA and STMSA prohibit brand name sponsorship of events in which the intended audience is comprised of a significant percentage of youth (*significant percentage* is not defined); events in which paid contestants are under the age of 18; concerts; and football, basketball, soccer, baseball, or hockey games.

The MSA and STMSA prohibit naming a stadium or arena with a brand name and prohibit tobacco companies from paying football, basketball, baseball, soccer, or hockey leagues in exchange for use of a brand name.

Exception: The MSA and STMSA exempt the following sponsorship activities:

- Events at adult-only facilities (where minors are not present and cannot see inside);
- Vehicles bearing a brand name used in a brand-sponsored event;
- Billboards for the brand-sponsored event at the site of the event for 90 days before and 10 days after the event; and
- Corporate name sponsorship.

Note: The corporate name sponsorship exception allows sponsorship in the name of the parent company (e.g., Altria) but not in the name of the brand (e.g., Marlboro).

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://ag.ca.gov/tobacco/contact.php**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

67. SPONSORSHIP: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Section 1140.34(c)

Scope: Manufacturers, distributors, or retailers may not directly or indirectly sponsor any athletic, social, or cultural event, or any entry or team in any event, in the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or anything identifiable with any brand of cigarettes or smokeless tobacco.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on tobacco sponsorships improperly regulated speech and violated the First Amendment.

Exception: Manufacturers, distributors, or retailers are allowed to sponsor events in the name of the corporation that manufactures the tobacco product if: (1) both the corporate name and the corporation were registered and in use in the U.S. prior to January 1, 1995; and (2) the corporate name does not include anything identifiable with any brand of cigarettes or smokeless tobacco.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation.
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of

the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

68. BRAND NAME MERCHANDISE

Master Settlement Agreement Sections III(f), III(c)(3)(C), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(f), III(c)(3)(D), VII(c)

Scope: The settling tobacco companies are prohibited from selling or distributing apparel (e.g., hats, T-shirts) or other merchandise that bears a tobacco product brand name.

Exception: These provisions do not apply to apparel or other merchandise distributed or sold by a third party at the site of a brand name sponsorship, under limited circumstances. These provisions do not apply to coupons or other items used by adults solely in connection with the purchase of tobacco products; and do not apply to apparel or other merchandise used within an adult-only facility that is not distributed (by sale or otherwise) to any member of the general public.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

69. BRAND NAME LIMITATIONS

Master Settlement Agreement Sections III(j), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(j), VII(c)

Scope: Brands of the settling tobacco companies may not be named after any nationally recognized brand or trade name of a non-tobacco product or any nationally recognized sports team, entertainment group, or celebrity.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

70. BRAND NAME LIMITATIONS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1
21 Code of Federal Regulations Section 1140.16(a)

Scope: Brands of cigarettes or smokeless tobacco may not include a trade or brand name of a non-tobacco product.

Exception: This provision does not apply to a tobacco product whose trade or brand name was both a tobacco product and a non-tobacco product that were sold in the U.S. on January 1, 1995.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Note: In May 2010, after the U.S. Food and Drug Administration (FDA) became aware of concerns regarding the constitutionality of this provision, the FDA announced how it would exercise its enforcement discretion with respect to 21 Code of Federal Regulations Section 1140.16(a). Guidance for Industry and *FDA Staff: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco* (May 2010), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM210766.pdf**. The FDA voluntarily suspended enforcement of this provision while the rule is under consideration as long as (1) the trade or brand name of the cigarettes or smokeless tobacco product was registered, or the product was marketed, in the U.S. on or before June 22, 2009; or (2) the first marketing or registration in the U.S. of the tobacco product occurs before the first marketing or registration in the U.S. of the non-tobacco product bearing the same name, as long as the

tobacco and non-tobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities. On November 17, 2011, the FDA published a proposed rule to amend Section 1140.16(a). 76 Fed. Reg. 71,281 (Nov. 17, 2011). The FDA noted that it was aware of concerns raised by the current rule, including its constitutionality, and that, after considering those concerns, it was proposing to narrow the scope of the rule. At the time of publication, the proposal was pending and the FDA's enforcement discretion policy in its 2010 guidance was still in effect. *Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (Aug. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM248241.pdf**.

71. PRODUCT PLACEMENT

Master Settlement Agreement Sections III(e), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(e), VII(c)

Scope: The settling tobacco companies may not pay for product placement in movies, television, theater, video games, music videos, concerts, or other performances.

Exception: These provisions do not apply to media shown in an adult-only facility (where the operator ensures that no minors are present), media not intended for distribution to the public, or instructional media concerning non-conventional cigarettes if viewed only by adult smokers.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

72. SAMPLES, COUPONS, AND PROMOTIONAL OFFERS: CALIFORNIA LAW

California Health and Safety Code Section 118950
California Code of Regulations Title 18, Section 4081

Scope: Free or nominal-cost cigarettes or smokeless tobacco products (or coupons, coupon offers, rebate offers, gift certificates, gift cards, or "other similar offers" for such products) may not be distributed on public grounds or on private grounds that are open to the public.

Note: An example of *public grounds* is a state-owned or county-owned fairground. Examples of *private grounds that are open to the public* are most race tracks or retail outlets.

Note: Every package of legally issued samples must be clearly marked as a sample and must contain the wording "Not for sale. Applicable state tax has been paid." Local governments may pass local laws that are stricter than the state law.

Note: Many local jurisdictions in California have adopted ordinances prohibiting tobacco product sampling. In addition, at the time of publication, two local jurisdictions outside of California – Providence, RI and New York City – had adopted a prohibition on redeeming tobacco product coupons and multi-pack discounts. The Providence, RI ordinance was challenged in federal court and upheld *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013), and the New York City ordinance was similarly challenged in federal court but the case was pending at the time of publication. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of New York*, No. 14-CV-577 (S.D.N.Y. Jan. 30, 2014).

Exception: This law applies only to cigarettes and smokeless tobacco products (e.g., it does not apply to cigars). The law exempts product samples, coupons, coupon offers, rebate offers, gift certificates and gift cards in connection with the sale of another item, including tobacco products, lighters, magazines, or newspapers.

The law does not apply to locations where minors are prohibited by law or to public grounds leased for a private function where minors are denied access to the private function by a peace officer or licensed security guard. Nor does the law apply to a separate distribution area on private property that is open to the public where minors are denied access by a peace officer or licensed security guard. However, the area must be enclosed so as to prevent persons outside the area from seeing the distribution unless they undertake unreasonable efforts to see inside the area.

Enforcement: The state Attorney General may enforce this law.

Penalty: Violators are liable for a civil penalty of not less than $200 for a first item distributed, $500 for a second item, and $1,000 for each item after that. Each distribution of a single package, coupon, coupon offer, gift certificates, gift cards, or other similar offers, or rebate offer to an individual member of the general public in violation of this section shall be considered a separate violation.

California Business and Professions Code Sections 17534, 17535, 17537.3

Scope: Free samples of smokeless tobacco products may not be distributed within a two-block radius of any premises or facility whose primary purpose is directed toward persons under the age of 18, including schools, clubhouses, and youth centers, when those premises are being used for their primary purposes.

Promotional offers of smokeless tobacco that require proof of purchase are prohibited unless the offer states that it is not available to minors. Mail-in and telephone requests for promotional offers must include appropriate efforts to ensure that the person is at least 18 years old, such as asking for the purchaser's birth date.

Mailing unsolicited samples of smokeless tobacco as part of an advertising program is prohibited (see entry 39 for more information on home delivery of unsolicited tobacco products).

Enforcement: Local law enforcement agencies have the general authority to enforce this law under Penal Code Section 830.1. Actions for injunction may be brought by the state Attorney General, district attorney, county counsel, city attorney, or city prosecutor, or by a private individual.

Penalty: Violators (which can be a person, firm, corporation, partnership or association or any employee or agent thereof) are guilty of a misdemeanor.

73. SAMPLES, COUPONS, AND PROMOTIONAL OFFERS: MSA/STMSA

Master Settlement Agreement Sections III(g), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(g), VII(c)

Scope: The settling tobacco companies are prohibited from distributing free samples of tobacco products.

Exception: This prohibition does not apply to the distribution of tobacco products in an adult-only facility (where the operator ensures that no minors are present). Nor does this prohibition apply to tobacco products provided to adults in exchange for proof of purchase or through special promotions such as "two-for-one" offers, or for consumer testing.

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

74. SAMPLES, COUPONS, AND PROMOTIONAL OFFERS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1, 387f(d)
21 Code of Federal Regulations Section 1140.16(d)

Scope: Manufacturers, distributors, and retailers may not distribute (or cause to be distributed) free samples of cigarettes or smokeless tobacco.

Note: This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on tobacco sponsorships improperly regulated speech and violated the First Amendment.

Note: The regulations do not cover other tobacco products (e.g., cigars, little cigars, pipe tobacco). *Guidance for Industry: Compliance With Regulations Restricting*

the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (Aug. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM248241.pdf**.

Exception: This prohibition does not apply to the distribution of free samples of smokeless tobacco in a qualified adult-only facility (QAF), but an adult consumer may only leave with one package (15 grams) of smokeless tobacco. A QAF must:

1. Have a law enforcement officer present to check photo ID and ensure that access is limited only to adults;
2. Be a temporary structure created for the purpose of distributing free samples of smokeless tobacco;
3. Be enclosed by a barrier that prevents people from outside the facility from seeing inside the facility unless they make an unreasonable effort to do so;
4. Not sell, serve, or distribute alcohol;
5. Not be located adjacent to or immediately across from an area used primarily for youth-oriented marketing, promotional, or other activities; and
6. Not have exterior advertising other than brand names in conjunction with a word to identify the QAF.

QAFs are not permitted at any football, basketball, baseball, soccer, or hockey event. The Secretary of Health and Human Services has the authority to add additional types of events to this list in the future.

Note: This provision does not affect the authority of a state or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Retailers who violate this provision and have a training program in place that complies with standards developed by the U.S. Food and Drug Administration (FDA) shall be subject to the following penalties, not to exceed:

- A warning letter for a first violation;
- $250 for a second violation within a 12-month period;
- $500 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Retailers who violate this provision and do not have an approved training program in place shall be subject to civil penalties not to exceed:

- $250 for a first violation;
- $500 for a second violation within a 12-month period;
- $1,000 for a third violation within a 24-month period;
- $2,000 for a fourth violation within a 24-month period;
- $5,000 for a fifth violation within a 36-month period; and
- $10,000 for a sixth or subsequent violation within a 48-month period.

Note: On September 1, 2013, the FDA issued guidance regarding Tobacco Control Act penalties. The guidance discusses the procedures that apply if the FDA seeks civil money penalties and the amount of the penalties that may be assessed. If there is a "repeated violation" of the Tobacco Control Act, the FDA may impose a "no-tobacco-sale order" prohibiting the retailer from selling tobacco products for a specified period. The FDA interprets "repeated violation" to mean that there have been at least five violations of the Tobacco Control Act, each of the five violations represents the second or subsequent violation of a particular requirement, and each of the five violations occurs within 36 months. The FDA states that it generally does not intend to seek a no-tobacco-sale order the first time an inspection identifies violations by a retailer and instead intends to send a warning letter. *Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (Revised) (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf**.

At the time of publication, the FDA had not yet established standards for retailer training programs. Until the FDA establishes standards for retailer training programs, all retailers who violate this provision will be treated as though they have an approved retailer training program in place. However, until the FDA establishes these standards, having a training program in place can nevertheless lead the FDA to further reduce the penalty for violations of the Tobacco Control Act. *Guidance for Industry: Tobacco Retailer Training Programs* (Sept. 2013), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM218906.pdf**.

75. PROOF-OF-PURCHASE GIFTS

Master Settlement Agreement Sections III(h), VII(c)
Smokeless Tobacco Master Settlement Agreement Sections III(h), VII(c)

Scope: The settling tobacco companies are prohibited from giving gifts in exchange for the purchase of a tobacco product (including coupons or credits for a purchase) unless the recipient provides sufficient proof that he or she is an adult (e.g., a photocopy of a driver's license or other government-issued ID card).

Enforcement: The state Attorney General (AG) is authorized to enforce these provisions. Suspected violations can be reported to the AG by calling (916) 565-6486 or by completing an online complaint form at **http://caag.state.ca.us/tobacco/contact.htm**.

Penalty: The AG may seek a court order to enforce these provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

76. LOTTERY

26 United States Code Sections 5723(c), 5762(b)

Scope: Nothing that is or represents a ticket, chance, share, or an interest in a lottery shall be placed in or on any package of tobacco products or cigarette papers.

Enforcement: Not specified.

Penalty: For each offense, violators are subject to a fine of up to $1,000 and/or imprisonment for up to one year.

77. SALE AND DISTRIBUTION OF NON-TOBACCO ITEMS OR SERVICES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387a-1
21 Code of Federal Regulations Section 1140.34(a)

Scope: Manufacturers and distributors of imported cigarettes or smokeless tobacco may not directly or indirectly market, license, distribute, or sell any item or service bearing anything identifiable with any brand of cigarettes or smokeless tobacco, such as the brand name, logo, symbol, motto, or recognizable color or pattern of colors.

> **Note:** This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on the use of cigarette and smokeless tobacco branding improperly regulated speech and violated the First Amendment.

Exception: This provision does not apply to the marketing of cigarettes, smokeless tobacco, or roll-your-own tobacco. This provision does not apply to manufacturers of domestic cigarettes or smokeless tobacco.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

78. JOINT MARKETING: THE TOBACCO CONTROL ACT

21 United States Code Sections 321(rr), 333, 372

Scope: A tobacco product may not be marketed with any other product regulated by the U.S. Food and Drug Administration (FDA), including a drug, food, cosmetic, medical device, or dietary supplement.

> **Note:** This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Commonwealth Brands, Inc. v. United States*, 678 F.Supp.2d 512 (W.D.Ky. 2010), overruled in part on other grounds by *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the prohibition on joint marketing improperly regulated speech and violated the First Amendment.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

WARNING LABELS

79. CIGARETTE WARNING LABELS

15 United States Code Sections 1333, 1334, 1338, 1339

Scope: Under the Federal Cigarette Labeling and Advertising Act, cigarettes may not be manufactured, packaged, or imported for sale or distribution unless they bear one of the Surgeon General's warning labels. It is also unlawful for manufacturers or importers to advertise cigarettes without one of the warning labels.

Note: State and local governments may not create additional cigarette label warning requirements beyond those required by federal law.

Enforcement: The U.S. Federal Trade Commission is responsible for approving labeling plans. The U.S. Attorney General may seek an injunction in federal court against violators to prevent future violations of this law or restrain current violations.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of not more than $10,000.

80. CIGARETTE LABEL AND ADVERTISING WARNINGS: THE TOBACCO CONTROL ACT

21 United States Code Section 387n
15 United States Code Sections 1333, 1336, 1338, 1339

Scope: All cigarette packages made, sold, or distributed within the U.S., and all related advertising and marketing, shall be required to bear one of nine specified warnings regarding associated health risks. The warning labels must adhere to placement and typography restrictions. (For example, the warnings must cover 50 percent of the top front and rear panels of cigarette packages, and must cover at least 20 percent of a newspaper, magazine, or poster advertisement and be in the predominant language of the publication.) The U.S. Department of Health and Human Services (HHS) can make changes to the warning label requirements upon a finding that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

Note: HHS issued regulations on June 22, 2011, specifying that the warning labels would include nine specific graphic images and nine printed warnings depicting the negative consequences of smoking. The graphic warning label requirements were scheduled to go into effect in September 2012; however, the warning label requirement was the subject of two separate lawsuits. Two federal appellate courts issued conflicting rulings regarding the constitutionality of the graphic warning label requirement. The Court of Appeals for the Sixth Circuit held that the label requirement did not violate tobacco companies' First Amendment rights, finding that the graphic warnings were reasonably related to the government's interest in preventing consumer deception. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). By contrast, the Court of Appeals for the District of Columbia held that the warning labels proposed by the U.S. Food and Drug Administration (FDA) violated tobacco companies' First Amendment

rights, finding that the government failed to show that the labels would lower smoking rates. *RJ Reynolds Tobacco Co. v. FDA,* 696 F.3d 1205 (D.C. Cir. 2012). On March 14, 2013, the U.S. Department of Justice declined to appeal the D.C. Circuit ruling. The FDA indicated that it will develop a second set of labels that will address the issues identified by the court. As a result, the agency indefinitely postponed implementation of the graphic warning labels.

Exception: This provision does not apply to tobacco products other than cigarettes or to foreign distribution of cigarettes. A retailer of cigarettes will not be in violation if the packaging contains a warning label, was supplied by a licensed manufacturer or distributer, and was not materially altered by the retailer.

Enforcement: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

Penalty: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of $10,000 or less.

In another ruling involving the First Amendment, a federal trial court finalized the text of several corrective statements that tobacco companies will be required to publish in various media outlets. *United States v. Philip Morris USA, Inc.,* No. 99-2496 (D.D.C. Nov. 27, 2012), appeal docketed, No. 13-5028 (D.C. Cir. Jan. 30, 2013). After years of litigation, the companies were ordered to publish the corrective statements after a court found that the companies deceived the public regarding the addictiveness and health effects of smoking. Examples of the statements include "Smoking is highly addictive" and "There is no safe cigarette." Finding that the corrective statements were factual and uncontroversial, the court rejected the companies' arguments that the statements violated their First Amendment rights. The tobacco companies appealed the court's order, and at the time of publication no final ruling had been issued.

81. SMOKELESS TOBACCO WARNING LABELS

15 United States Code Sections 4402, 4404, 4405

Scope: Smokeless tobacco products may not be manufactured, packaged, or imported for sale or distribution unless they bear one of the warning labels listed in the law. It is also unlawful for manufacturers, packagers, or importers to advertise smokeless tobacco products without one of the warning labels.

Enforcement: The U.S. Federal Trade Commission (FTC) is responsible for approving labeling plans. The U.S. Attorney General or the FTC may seek an injunction in federal court against violators to prevent future violations of this law.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of not more than $10,000.

82. SMOKELESS TOBACCO LABEL AND ADVERTISING WARNINGS: THE TOBACCO CONTROL ACT

21 United States Code Section 387n
15 United States Code Sections 4402, 4404, 4405

Scope: All smokeless tobacco product packages made, sold, or distributed within the U.S. must bear one of four specified warnings regarding associated health risks:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

The warning labels must adhere to placement and typography restrictions. For example, the warning labels must cover 30 percent of each of the two principal display panels of the product. For press and poster advertisements, the warning labels must cover at least 20 percent of the advertisement. Warning labels in a newspaper, magazine or poster advertisement must be in the predominant language of the publication. The U.S. Department of Health and Human Services can make changes to the warning label requirements upon a finding that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

> **Note:** This provision in the Tobacco Control Act, among others, was challenged in federal court and upheld. *Discount Tobacco City & Lottery v. U.S.,* 674 F.3d 509 (6th Cir. 2012), *cert. denied,* 133 S.Ct. 1996 (2013). The lawsuit alleged that the required tobacco label and advertising warnings improperly regulated speech and violated the First Amendment.

Exception: This provision does not apply to tobacco products other than smokeless tobacco or to foreign distribution of smokeless tobacco products. A retailer of smokeless tobacco will not be in violation if the packaging contains a warning label, was supplied by a licensed manufacturer or distributer, and was not materially altered by the retailer.

Enforcement: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

Penalty: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of $10,000 or less.

83. CIGAR WARNING LABELS

FTC Agreements, File Numbers 0023199–00023205

Scope: Pursuant to agreements between the U.S. Federal Trade Commission (FTC) and the seven largest cigar companies (comprising approximately 95 percent of the U.S. cigar market), every signing company's cigar packages and advertisements in the U.S. must clearly and prominently display one of five Surgeon General's health warnings listed in the agreement.

Note: For more information about this agreement, see the FTC's website at **www.ftc.gov/news-events/press-releases/2000/06/ftc-announces-settlements-requiring-disclosure-cigar-health-risks.**

Enforcement: The FTC is charged with enforcing this agreement.

Penalty: Not specified.

California Health and Safety Code Sections 104550–104552

Scope: Cigar manufacturers or importers must label each retail package of cigars with one of the warnings listed in the law. Display boxes or containers used to sell individual cigars must be clearly labeled.

Note: The state Attorney General (AG) has agreed that any cigar company that signed an agreement with the FTC regarding warning labels and that remains in compliance with terms of that agreement is deemed to be in compliance with California Health and Safety Code Sections 104550–104552.

Exception: Warning labels are not required on the cellophane wrappers, tubes, or similar wrappings in which individual cigars are sold.

Enforcement: Actions to enforce this section may be brought by the AG, any district attorney, any city attorney of a city with a population greater than 750,000, or, with permission of the district attorney, by a city prosecutor in any city having a full-time city prosecutor.

Penalty: Violators are subject to a civil penalty up to $2,500 per day for each violation.

TAXATION, LICENSING, AND REPORTING

84. FEDERAL TOBACCO TAX

26 United States Code Sections 5701–5704, 5761–5763

Scope: The manufacturer or importer of tobacco products shall pay taxes in the amount specified for each type of tobacco product. The tax on all tobacco products increased on April 1, 2009. The federal tax on cigarettes is now $1.01 per package. The federal taxes on cigars and smokeless tobacco are calculated according to weight.

Exception: There are four categories of exemptions from the federal tobacco tax: tobacco furnished for employee use or experimental purposes; certain tobacco products transferred or removed from domestic factories and export warehouses; certain tobacco products released from customs custody; and tobacco products exported and returned.

Enforcement: The federal tax laws are enforced by federal law enforcement agencies.

Note: In July 2012, Congress amended the federal Internal Revenue Code's definition of "manufacturer of tobacco products." The revised definition adds retailers who, for commercial purposes, provide consumers with access to roll-your-own tobacco machines. These retailers now must pay the same federal excise taxes and comply with the same permitting processes as mass manufacturers. The amendment closes a tax loophole for retailers that allowed consumers to use high-speed machines to produce cartons of cigarettes that were similar to other mass-produced cigarettes. A "manufacturer of tobacco products" does not include a person who sells a roll-your-own tobacco machine to a consumer for personal home use.

Note: The federal tax status of the entity that provides consumers with access to roll-your-own tobacco machines (i.e. non-profit vs. for-profit) is not relevant in determining whether the entity is providing that access for a "commercial purpose." Federal tax liability can apply to "non-profit" organizations and "social clubs" that make these machines available. *Enforcement Efforts in Connection with Cigarette-Making Machines* (Aug. 2013), **www.ttb.gov/announcements/ttb-announcement-cigarette-making-machines-announcement.pdf**.

Penalty: There are a range of civil and criminal penalties that attach to a failure to comply with the federal tobacco tax laws. In addition, any property intended for use in violating the federal tobacco tax laws is subject to forfeiture.

85. REPORTING REQUIREMENTS: THE JENKINS ACT

15 United States Code Sections 375–378

Scope: The Jenkins Act applies to cigarette sellers who ship or advertise to buyers in another state who are not distributors. Such sellers must make two filings with the state into which they are shipping or advertising. First, sellers must file their name and address. Second, sellers must file a monthly report documenting every shipment into the state. The report must include the name and address of each buyer, the brand, and the quantity shipped.

Enforcement: The Jenkins Act may be enforced by federal law enforcement agencies.

Note: Courts in two states have held that state law enforcement agencies may bring a civil action to enforce the Jenkins Act reporting requirements. See *Washington v. WWW. Dirtcheapcigs.com, Inc.,* 260 F. Supp. 2d 1048, 1053-55 (W.D. Wash. 2003); *Angelica Co. v. Goodman*, 276 N.Y.S.2d 766, 769 (1966). California Code of Civil Procedure Section 1021.10 authorizes the state of California to sue to enforce the Jenkins Act to the extent not expressly prohibited by federal law.

Penalty: Violators are subject to criminal penalties of up to three years imprisonment. Violators are also subject to civil penalties in an amount not to exceed the greater of $5,000 for a first violation and $10,000 for a subsequent violation, or two percent of their gross sales of cigarettes or smokeless tobacco during the one-year period ending on the date of the violation.

86. REPORTING REQUIREMENTS: THE PACT ACT

15 United States Code Sections 375, 376a, 377, 378
18 United States Code Section 1716e

Scope: The Prevent All Cigarette Trafficking Act (the PACT Act) requires cigarette or smokeless tobacco product sellers to make the filings specified in the Jenkins Act with the U.S. Attorney General, who will compile a list of delivery sellers that have not registered or not complied with this law. Common carriers (e.g., UPS, FedEx) are prohibited from delivering packages for delivery sellers that are on the list.

Enforcement: The U.S. Attorney General shall administer and enforce this chapter.

Penalty: Violators are subject to criminal penalties of up to three years imprisonment. Violators are also subject to civil penalties in an amount not to exceed the greater of $5,000 for a first violation and $10,000 for a subsequent violation, or two percent of their gross sales of cigarettes or smokeless tobacco during the one-year period ending on the date of the violation.

Common carriers or other delivery services that intentionally violate the new law are subject to civil penalties in an amount not to exceed $2,500 for a first violation and $5,000 for any violation within one year of a prior violation.

87. CALIFORNIA STATE TOBACCO TAX

California Revenue and Taxation Code Sections 30001–30483
California Health and Safety Code Sections 104350–104480, 104500–104545, 130100–130155

Scope: Under the Cigarette and Tobacco Products Tax Law, California imposes three taxes on the distribution of cigarettes:

- A tax of 12 cents per package of 20 cigarettes, of which 2 cents are earmarked for breast cancer research and control.

- A Proposition 99 surtax of 25 cents per package of 20 cigarettes (with an equivalent surtax on other tobacco products), all of which is allocated to the Cigarette and Tobacco Products Surtax Fund. The revenues are earmarked for tobacco health education, tobacco related disease research, health care for medically indigent families, and certain types of environmental programs. The revenues are deposited according to the following formula: 20 percent in the Health Education Account; 35 percent in the Hospital Services Account; 10 percent in the Physician Services Account; 5 percent in the Research Account; 5 percent in the Public Resources Account; and 25 percent in the Unallocated Account. This surtax became effective on January 1, 1989. Proposition 99 funds are allocated to school-based programs through a single competitive grant process for tobacco education and cessation programs for grades 6 through 12.
- A Proposition 10 surtax of 50 cents per package of 20 cigarettes (with an equivalent surtax on other tobacco products), all of which is allocated to the California Children and Families Program to support early childhood development programs. This surtax became effective on January 1, 1999.

Distributors are responsible for paying state cigarette taxes through the use of tax stamps or meter impressions (see entry 88). In total, each tax stamp or meter impression costs 87 cents per package of cigarettes. Non-cigarette tobacco products are subject to a surtax that is set annually by the state Board of Equalization (BOE). The surtax rate is calculated to be equivalent to the total tax on cigarettes. Distributors are responsible for paying state tobacco taxes.

Exception: Tobacco taxes do not apply to:

- sales to armed services;
- sales to the U.S. Veterans' Administration;
- distributions that are exempt from taxation under federal tax law;
- distributions by a manufacturer to a licensed distributor;
- sales to a law enforcement agency for use in criminal investigations;
- sales to a common carrier engaged in interstate or foreign commerce;
- sales by the original importer to a licensed distributor;
- certain sales or gifts to veterans; or
- use or consumption of untaxed cigarettes brought into the state in a single lot of not more than 400 cigarettes (i.e., two cartons) by an individual for his own use or consumption.

Enforcement: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Anyone who intentionally engages in tax evasion under the Cigarette and Tobacco Products Tax Law is guilty of a misdemeanor if the amount of tax liability is less than $25,000 in any one-year period and is guilty of a felony if the amount of tax liability is $25,000 or

more in any one-year period. (California Revenue and Taxation Code Sections 30477, 30480) Each felony offense is punishable by imprisonment and/or a fine of not less than $5,000 and not more than $20,000. See entries 88-92, 101-102, and 104 for other penalties associated with the violation of state tobacco tax laws.

Note: State law expressly preempts local governments from imposing additional taxes on cigarettes and tobacco products. *See* Cal. Revenue and Taxation Code Sections 30111 & 30462.

88. CIGARETTE TAX STAMPS/METER IMPRESSIONS

California Revenue and Taxation Code Sections 30161–30165
California Code of Regulations Title 18, Sections 4048, 4054, 4081

Scope: Distributors pay cigarette taxes through the use of stamps or meter impressions. The state Board of Equalization (BOE) sells stamps and meter register settings for approved metering machines. A stamp or meter impression must appear on each package of cigarettes prior to distribution. Stamps shall be affixed to the bottom end of each standard package of 20 cigarettes or to the lid or top of each individual package of flats or rounds. Stamps may not be affixed to cartons or larger containers of cigarettes. Meter impressions shall be clearly imprinted on the bottom end of each standard package of 20 cigarettes. Meter impressions may not be imprinted on any other size of package, carton, or container of cigarettes. Stamps and meter impressions may not be affixed to any package of cigarettes if any one of the following occurs:

- The package does not comply with federal laws requiring health warnings (see entries 79 and 80);
- The package is labeled with wording indicating that the manufacturer did not intend that the product be sold in the U.S.;
- The package has been altered by adding or deleting federal warnings or labels;
- The package was imported into the United States after January 1, 2000, in violation of federal tobacco importation law, see 26 United States Code Section 5754; or
- The package bears a brand name of a participating manufacturer in the Master Settlement Agreement (MSA) and is imported by an entity other than the participating manufacturer.

Exception: Stamps or meter impressions need not appear on tobacco products legally given away as samples. However, the manufacturer giving away such samples must notify the BOE in advance of the sampling, report the distribution, and pay the tax due. Each package of samples must be clearly marked as a sample and must contain the wording "Not for sale. Applicable state tax has been paid."

Note: Sampling is restricted under California and federal law (see entries 72–74).

Enforcement: The BOE is authorized to enforce this law.

Penalties: The BOE shall revoke the license issued to a distributor under the California Revenue and Taxation Code if the distributor violates this law. See entries 90–92, 101, and 104 for penalties that attach to various violations relating to tax stamps and meter impressions.

In addition, the penalties listed in entry 102 may apply.

89. MAIL ORDER/INTERNET CIGARETTE TAXATION

California Revenue and Taxation Code Section 30101.7

Scope: In order to sell tobacco products to a person in California over the internet, on the phone, or via any other non-"face-to-face" sales method, the seller must meet all of the following conditions: (1) it must fully comply with all of the requirements of the Jenkins Act (see entry 85); (2) it must obtain and maintain any applicable license under the California Business and Professions Code, as if the delivery sales occurred entirely within California; and (3) it must comply with any applicable state law that imposes escrow or other payment obligations on tobacco product manufacturers.

The state Board of Equalization must provide information to the state Attorney General (AG) regarding a seller's failure or attempt to comply with the Jenkins Act. The AG must provide an annual report to the Legislature regarding all actions taken to comply with, and enforce, the Jenkins Act. The AG may require a seller to report its delivery sales of cigarettes and tobacco products to consumers within California.

Exception: This law does not apply to cigars.

Enforcement: The AG, a city attorney, a county counsel, or a district attorney may bring a civil action to enforce this law.

Penalty: Any violation of the above requirements is a misdemeanor, punishable by a maximum fine of $5,000, imprisonment of up to one year in county jail, or both. Violators are also liable for a civil penalty of between $1,000-$2,000 for a first violation; $2,500-$3,500 for a second violation within a five-year period; $4,000-$5,000 for a third violation within a five-year period; $5,500-$6,500 for a fourth violation within a five-year period; and $10,000 for a fifth or subsequent violation within a five-year period.

90. BLACK MARKET AND COUNTERFEIT CIGARETTES

California Revenue and Taxation Code Sections 30474, 30474.5

Scope: It is illegal to knowingly hold for sale, offer for sale, or sell any packages of cigarettes without the required tax stamp or meter impression (see entry 88 for a summary of the tax stamp and meter impression requirements).

Enforcement: The state Board of Equalization (BOE) and local law enforcement agencies are authorized to enforce this law.

Penalty: Violators are guilty of a misdemeanor punishable by a fine of no more than $25,000 and/or imprisonment for up to one year. Moreover, violators shall pay two fines, each amounting to $100 per violating carton of 200 cigarettes or portion thereof. The first fine shall be divided evenly between the local prosecuting jurisdiction and the BOE. The second fine shall be deposited in the Unlawful Sales Reduction Fund, which shall be used to support local grantees in multi-agency efforts to reduce sales of untaxed cigarettes.

In addition, the penalties listed in entry 102 may apply.

California Revenue and Taxation Code Section 30474.1

Scope: Notwithstanding any other provision of law, the sale or possession for sale of counterfeit tobacco products is illegal. Counterfeit tobacco products include tobacco products with false manufacturing labels and/or fraudulent tax stamps or meter impressions.

Enforcement: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

Penalty: The illegal products are subject to seizure and forfeiture, and violators are guilty of a misdemeanor. If less than two cartons are seized, violators are subject to a fine of up to $5,000 and/or imprisonment not to exceed one year, as well as revocation of a distributor, wholesaler, or manufacturer license. If two or more cartons are seized, violators are subject to a fine of up to $50,000 and/or imprisonment not to exceed one year, as well as revocation of a distributor, wholesaler, or manufacturer license (see entries 96 and 98 for more information on distributor, wholesaler, and manufacturer licenses).

In addition, the penalties listed in entry 102 may apply.

California Business and Professions Code Sections 22974.3(a), 22978.2(a)

Scope: It is illegal to possess, store, own, or sell a package of cigarettes that bears a counterfeit tax stamp or meter impression or that lacks a tax stamp or meter impression (see entry 88 for more information on tax stamps and meter impressions).

Enforcement: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

Penalty: The unstamped packages are subject to seizure and forfeiture, and violators are guilty of a misdemeanor punishable by the following:

- If fewer than 20 packages are seized: For a first violation, a fine of $1,000 and/or imprisonment not to exceed one year; for a second or subsequent violation within five years, a fine of $2,000-$5,000 and/or imprisonment not to exceed one year, and revocation of a retailer, distributor, or wholesaler license (see entries 93 and 96 for more information on retailer, distributor, and wholesaler licenses).
- If 20 or more packages are seized: For a first violation, a fine of $2,000 and/or imprisonment not to exceed one year; for a second or subsequent violation within five years, a fine of $5,000-$50,000 and/or imprisonment not to exceed one year, and

revocation of a retailer, distributor, or wholesaler license (see entries 93 and 96 for more information on retailer, distributor, and wholesaler licenses).

- In addition, the penalties listed in entry 102 may apply.

California Business and Professions Code Sections 22974.3(b), 22978.2(b), 22981

Scope: It is illegal to possess, store, own, or sell a tobacco product on which tax is due. Retailers, distributors, wholesalers, and others in possession of tobacco products have the burden of proving that the tax has been paid.

Enforcement: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

Penalty: Violators are guilty of a misdemeanor punishable by a fine not to exceed $5,000 and/or imprisonment not to exceed one year. Illegal packages are subject to seizure and forfeiture.

In addition, the penalties listed in entries 101 and 102 may apply.

91. FORGERY OF FALSE STAMPS/METER IMPRESSIONS

California Revenue and Taxation Code Section 30473

Scope: It is illegal to fraudulently make, forge, alter, reuse, or counterfeit any tax stamp or meter impression (see entry 88 for more information on tax stamps and meter impressions).

Enforcement: The state Board of Equalization and local law enforcement agencies are authorized to enforce this law.

Penalty: Violators are guilty of a felony and subject to imprisonment for two, three, or four years, and/or to a fine of not less than $1,000 and not more than $25,000.

In addition, the penalties listed in entry 102 may apply.

92. POSSESSION OR SALE OF FALSE STAMPS/METER IMPRESSIONS

California Revenue and Taxation Code Section 30473.5

Scope: It is illegal to possess, sell, or offer to sell or to buy or offer to buy any false or fraudulent tax stamps or meter impressions (see entry 88 for more information on tax stamps and meter impressions).

Enforcement: The state Board of Equalization (BOE) and local law enforcement agencies are authorized to enforce this law.

Penalty: Violators are guilty of a misdemeanor punishable by: (1) for false or fraudulent tax stamps or meter impressions in a quantity of less than 2,000, a fine not to exceed $5,000 and/or imprisonment not to exceed one year; (2) for false or fraudulent tax stamps or meter

impressions in a quantity of 2,000 or greater, a fine not to exceed $50,000 and/or imprisonment not to exceed one year. The BOE shall destroy any stamps seized under this law.

In addition, the penalties listed in entry 102 may apply.

93. TOBACCO RETAILER LICENSE

California Business and Professions Code Sections 22971–22971.5, 22972–22973.1, 22980.2, 22981

Scope: Tobacco retailers must be licensed by the state Board of Equalization (BOE) for each tobacco retail location. For the purposes of this law, a retailer is someone who sells tobacco products from a building or a vending machine. Each retailer must pay a onetime license fee of $100 for each retail location, and an additional fee of $100 to reinstate an expired license. The license is not assignable or transferable, and it must be renewed annually for no fee. A retailer may not obtain a license if the retailer has been issued a license that is currently suspended or revoked. Licenses will not be issued for any location where a license has been revoked in the last five years, unless a new owner obtained the property in an arms-length transaction.

The state licensing law does not preempt or supersede any local tobacco control law other than those related to the collection of state taxes. Local tobacco retailer licensing laws may provide for the suspension or revocation of the local license for any violation of a state tobacco control law.

> **Note:** The state licensing law focuses on protecting state revenue by targeting tax evasion. Local jurisdictions can pass tobacco retailer licensing laws that focus on protecting the public's health by, for example, providing for the suspension of tobacco retailer licenses for illegal sales to minors.
>
> **Note:** In 2012, the BOE implemented a new policy based on a legal opinion that determined that catering trucks, lunch wagons, and other mobile facilities cannot be licensed as retail locations. Tobacco products cannot be sold from a mobile location. *Mobile Sellers of Cigarettes and Tobacco Products* (undated), **www.boe.ca.gov/pdf/Mobile_Seller_Letter.pdf.**

Enforcement: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Unlicensed retailers are guilty of a misdemeanor and subject to a fine not to exceed $5,000 and/or imprisonment not to exceed one year. Each day of continued sales or gifting without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation. Continued sales or gifting after notification by the BOE that a license has been suspended or revoked shall result in the seizure and forfeiture of all tobacco products in the possession of the person making such sales.

In addition, the penalties listed in entry 102 may apply.

94. RETAILER LICENSE DISPLAY

California Business and Professions Code Sections 22980.5, 22972, 22974.5

Scope: A retailer shall conspicuously display the license at each retail location in a manner visible to the public. A retailer whose license has been suspended or revoked by the state Board of Equalization (BOE) must conspicuously post a notice of that suspension or revocation at each public entrance to the retail location and at each cash register and other point of sale. The notice must be posted for the duration of the suspension or for 30 days following the effective date of a revocation.

Enforcement: The BOE is authorized to enforce this law.

Penalty: A retailer who fails to display the license is liable for a $500 fine. A retailer who removes, alters, or fails to post required notices of suspension or revocation shall be subject to a civil penalty of $1,000 for each offense.

In addition, the penalties listed in entry 102 may apply.

95. PROVISIONAL LICENSING PENALTIES FOR SALES-TO-MINORS VIOLATIONS

California Business and Professions Code Sections 22958, 22974.8

Scope: Retailers convicted of either a STAKE Act violation (see entries 23, 26, 28–30, 36, and 54) or a Penal Code Section 308 violation (see entries 22 and 28) shall be subject to license-related penalties, but only if the most recent official statewide youth purchase survey finds that 13 percent or more of youth were able to purchase cigarettes (see entry 25 for a summary of the youth purchase survey requirement).

Enforcement: The state Board of Equalization (BOE) is charged with enforcing this law.

Penalty: The following penalties apply:

- Upon a first conviction, the retailer shall be fined $400-$600.
- Upon a second conviction within a five-year period, the retailer shall be fined $900-$1,000.
- Upon a third conviction within a five-year period, the retailer shall be fined $1,200-$1,800. The California Department of Public Health is required to notify the BOE. The retailer shall be assessed an additional $250 penalty by the BOE, and the BOE shall suspend the retailer's license for 45 days.
- Upon a fourth conviction within a five-year period, the retailer shall be fined $3,000-$4,000. The California Department of Public Health is required to notify the BOE. The retailer shall be assessed an additional $250 penalty by the BOE, and the BOE shall suspend the retailer's license for 90 days.

- Upon a fifth conviction within a five-year period, the retailer shall be fined $5,000-$6,000. The California Department of Public Health is required to notify the BOE. The retailer shall be assessed an additional $250 penalty by the BOE, and the BOE shall revoke the retailer's license.

The BOE must give a retailer at least 10 days' written notice of a pending suspension or revocation and an opportunity to appeal the suspension, revocation, and/or civil penalty, but only for the purpose of correcting a mistake or clerical error.

Convictions by a retailer at one retail location are not accumulated against other locations owned by that retailer. Convictions accumulated against a prior retail owner of a franchise location are not accumulated against a new retail owner of the same franchise location.

In addition, the penalties listed in entry 102 may apply.

96. DISTRIBUTOR AND WHOLESALER LICENSES

California Business and Professions Code Sections 22971, 22975–22978.8, 22980.2, 22981

Scope: Tobacco distributors and wholesalers must be licensed by the state Board of Equalization (BOE) and must pay an annual license fee of $1,000. This license requirement is in addition to the California Revenue and Taxation Code license requirements described below in this entry.

Enforcement: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Unlicensed distributors and wholesalers are guilty of a misdemeanor and subject to a fine not to exceed $5,000 and/or imprisonment not to exceed one year. Each day of continued sales or gifting without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation. Continued sales or gifting after notification by the BOE that a license has been suspended or revoked shall result in the seizure and forfeiture of all tobacco products in the possession of the person making such sales. The BOE shall include on its website the name of any distributor or wholesaler whose license has been suspended or revoked.

In addition, the penalties listed in entry 102 may apply.

California Revenue and Taxation Code Sections 30140–30149

Scope: Tobacco distributors must be licensed by the state Board of Equalization (BOE) for each place of business. This license requirement is in addition to the California Business and Professions Code license requirements described above in this entry. License applicants must submit a security deposit (minimum of $1,000) to the BOE. The security is conditioned upon the lawful performance of all tobacco tax related requirements.

Enforcement: The BOE is authorized to enforce this law.

Penalty: The license may be revoked for failure to comply with applicable rules and regulations. Distributing without a license is a misdemeanor.

In addition, the penalties listed in entry 102 may apply.

California Revenue and Taxation Code Sections 30155–30159

Scope: Tobacco wholesalers must be licensed at no cost separately for each place of business. This license requirement is in addition to the California Business and Professions Code license requirements described above in this entry. This license must be prominently displayed at each place of business.

Enforcement: The state Board of Equalization is authorized to enforce this law.

Penalty: The license may be suspended or revoked for failure to comply with applicable rules and regulations. Engaging in wholesaling without a license is a misdemeanor.

In addition, the penalties listed in entry 102 may apply.

97. DISTRIBUTOR AND WHOLESALER REPORTING

California Business and Professions Code Sections 22954, 22957 (STAKE Act)

Scope: Tobacco distributors, tobacco wholesalers, and cigarette vending machine operators shall report annually to the California Department of Public Health (CDPH) the names and addresses of those persons to whom they provide tobacco products. The data provided shall be deemed confidential by CDPH and shall be exempt from disclosure under the California Public Records Act. California Government Code Sections 6250–6276.48.

Enforcement: Primary enforcement responsibility rests with CDPH. However, this requirement may also be enforced by any "enforcing agency" authorized to enforce the STAKE Act, including the California Attorney General's office and local law enforcement agencies.

Penalty: Not specified.

98. MANUFACTURER AND IMPORTER LICENSE AND REPORTING

California Business and Professions Code Sections 22971, 22979, 22979.21–22979.24, 22979.7, 22980.2

Scope: Tobacco manufacturers and importers must be licensed by the state Board of Equalization (BOE). In order to obtain and maintain a license, the manufacturer or importer must supply the BOE with specified lists, certifications, and consents.

Every manufacturer or importer of chewing tobacco or snuff must pay a onetime license fee of $10,000, and every manufacturer or importer of other tobacco products must pay a onetime license fee of $2,000.

Every tobacco manufacturer and importer must file a monthly report to the BOE that includes a list of all licensed distributors to which the manufacturer or importer shipped its products and the total wholesale cost of the products. The data provided shall be deemed confidential by the Department and shall be exempt from disclosure under the California Public Records Act. California Government Code Sections 6258-6276.48.

In order to be eligible to obtain a license, every tobacco manufacturer or importer must do either of the following: (1) waive any sovereign immunity defense that may apply to any enforcement action brought by the Attorney General or the BOE to enforce state manufacturer and importer licensing requirements, the manufacturer requirements relating to the Master Settlement Agreement (MSA), or state tobacco tax laws; or (2) file a surety bond with the Attorney General in favor of the State of California that is conditioned on the manufacturer's performance of its duties and obligations.

Enforcement: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Every tobacco manufacturer or importer must consent to the jurisdiction of the California courts for enforcement of the MSA and the Cigarette and Tobacco Products Tax Law, must appoint a registered agent for service of process in California, and must identify the registered agent to the BOE and the state Attorney General.

Penalty: Unlicensed manufacturers and importers are guilty of a misdemeanor and subject to a fine not to exceed $5,000 and/or imprisonment not to exceed one year. For a first offense, the BOE may revoke or suspend the license or licenses of the manufacturer or importer pursuant to the procedures applicable to the revocation of a license, which include written notice and opportunity for a hearing. The procedures for revocation are set forth in Section 30148 of the Revenue and Taxation Code.

Each day of continued sales or gifting without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation. Continued sales or gifting must result in the seizure and forfeiture of all tobacco products in the possession of the person making such sales. *Gifting* is defined as any transfer of title or possession without consideration, exchange, or barter.

In addition, the penalties listed in entry 102 may apply.

99. RECORD RETENTION BY STATE LICENSEES

California Business and Professions Code Sections 22974, 22978.1, 22979.4, 22979.5, 22981

Scope: Each retailer, distributor, wholesaler, manufacturer, and importer must retain purchase and sale invoices for all tobacco products for a period of four years. Such records shall be kept at the location identified in the license for a period of one year and shall be made available for inspection upon request of the state Board of Equalization (BOE) or by a law enforcement agency.

Enforcement: The BOE is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of a misdemeanor punishable by a fine not to exceed $5,000 and/or imprisonment not to exceed one year.

In addition, the penalties listed in entry 102 may apply.

100. INSPECTIONS

California Business and Professions Code Sections 22980, 22981

Scope: Any peace officer or authorized state Board of Equalization (BOE) employee may enter and inspect any place where tobacco products are sold, produced, or stored; any site where evidence of activities involving evasion of tobacco product taxes may be discovered; or any site where there is evidence of a violation of Section 30165.1 of the California Revenue and Taxation Code, which prohibits the sale of tobacco products that are not included on the state Attorney General's directory of tobacco product manufacturers and brands.

Enforcement: State and local law enforcement agencies and the BOE are authorized to enforce this law.

Penalty: Anyone who fails to permit an inspection is guilty of a misdemeanor punishable by a fine not to exceed $5,000 and/or imprisonment not to exceed one year.

In addition, the penalties listed in entry 102 may apply.

California Revenue and Taxation Code Sections 30435, 30471

Scope: State Board of Equalization (BOE) employees may enter and inspect any place where tobacco products are sold, produced, or stored, or any site where there is evidence of activities involving tobacco tax evasion or Master Settlement Agreement violations.

Enforcement: The BOE is authorized to enforce this law.

Penalty: Refusal to allow an inspection is a misdemeanor punishable by a fine not to exceed $1,000 for each offense.

In addition, the penalties listed in entry 102 may apply.

101. TRANSACTIONS WITH UNLICENSED ENTITIES

California Business and Professions Code Sections 22980.1, 22981

Scope: No entity shall sell or purchase tobacco products to or from an entity that is unlawfully operating without a license or that has a suspended or revoked license. No entity shall acquire any package of cigarettes to which the required tax stamp or meter impression may not be properly affixed or that fails to comply with federal ingredient reporting provisions. *See* 15 United States Code Section 1335a.

Enforcement: The state Board of Equalization is authorized to enforce this law. Local law enforcement agencies have the general authority to enforce this law under California Penal Code Section 830.1.

Penalty: Violators are guilty of a misdemeanor punishable by a fine not to exceed $5,000 and/or imprisonment not to exceed one year.

In addition, the penalties listed in entry 102 may apply.

102. ADMINISTRATIVE PENALTIES APPLICABLE TO ALL LICENSEES

California Business and Professions Code Sections 22974.7, 22978.7, 22979.7

Scope: In addition to any other penalties, violators of the California Cigarette and Tobacco Products Licensing Act of 2003, California Business and Professions Code Sections 22970–22991, are subject to administrative penalties (see entries 93-96, and 99–101 for summaries of relevant provisions of the California Cigarette and Tobacco Products Licensing Act).

Enforcement: The state Board of Equalization (BOE) is authorized to enforce this law.

Penalty: The BOE may for a first offense, revoke or suspend a license; and for a second or subsequent offense, revoke or suspend a license, and impose a civil penalty not to exceed the greater of five times the retail value of the seized tobacco products or $5,000.

Note: These provisions apply to retailers, distributors, wholesalers, manufacturers and importers.

California Business and Professions Code Section 22980.3

Scope: In addition to any other fines or penalties, violators of the tobacco tax laws or the California Cigarette and Tobacco Products Licensing Act of 2003, California Business and Professions Code Sections 22970–22991, may have their licenses suspended or revoked. After having received notice of suspension or revocation, violators may not sell, gift, or display for sale cigarettes or other tobacco products for sale (see entries 87–88, 90–94, 96, and 98–101 for summaries of relevant provisions of the tobacco tax laws and the California Cigarette and Tobacco Products Licensing Act).

Enforcement: The state Board of Equalization (BOE) is authorized to enforce this law.

Penalty: For a first conviction, the penalty is a written notice from the BOE detailing the suspension and revocation provisions of this law, and the BOE at its discretion may suspend the license for up to 30 days. For a second conviction within four years, the license shall be revoked, but a previously licensed applicant may apply for a new license six months after a revocation. Violations at one location are not counted against other locations of that same licensee or against a new owner at the same licensed location. Each day of continued sales without a valid license after notification by a law enforcement agency that a valid license is required constitutes a separate violation.

California Business and Professions Code Sections 22974.4, 22978.6

Scope: The license of a retailer, distributor, or wholesaler shall be revoked if (1) the license holder has been convicted of a felony pursuant to California Revenue and Taxation Code Sections 30473 (see entry 91) or 30480 (see entry 87); or (2) the license holder has had any permit or license revoked under any provision of the California Revenue and Taxation Code.

Enforcement: The state Board of Equalization is authorized to enforce this law.

Penalty: Revocation of the license.

103. BOARD OF EQUALIZATION LICENSING DATABASE

California Business and Professions Code Sections 22973.2, 22978, 22979.3

Scope: Upon request, the state Board of Equalization shall provide its database of licenses issued to retailers, distributors, wholesalers, manufacturers, and importers to the California Department of Public Health, the state Attorney General, a law enforcement agency, or any agency authorized to enforce local tobacco control laws. The database may be used only for the purposes of enforcing tobacco control laws, and its use must adhere to all state laws, policies, and regulations governing the use of personal information and privacy.

Enforcement: Not applicable.

Penalty: Not applicable.

104. MANUFACTURER CERTIFICATION

California Revenue and Taxation Code Sections 30165.1(b), 30165.1(c)(5), 30165.1(m)

Scope: A manufacturer must make an annual certification to the state Attorney General (AG) that it has signed the Master Settlement Agreement or has complied with California law regarding nonparticipating manufacturers. The certification must include a complete list of brand families.

For each manufacturer that has submitted the required certification, the AG shall provide a written acknowledgment of receipt within seven business days. In turn, each manufacturer shall provide to each distributor to whom it sells or ships cigarettes a copy of the AG's receipt.

Enforcement: The state Board of Equalization and the AG are authorized to enforce this law.

Penalty: False certifications knowingly made are a misdemeanor punishable by a fine of not more than $1,000 and/or imprisonment for up to one year.

In addition, the penalties listed in entry 102 may apply.

California Revenue and Taxation Code Sections 30165.1(b), 30165.1(m)

Scope: Manufacturers located outside the U.S. must provide the state Attorney General (AG) with current contact information for all importers that sell their cigarettes in California,

and must require these importers to provide the AG with copies of a valid importer permit issued by the U.S. Treasury and a valid importer license issued by the state Board of Equalization (BOE). Nonparticipating manufacturers who are newly qualified or whom the AG deems to pose an elevated risk for noncompliance must file a surety bond with the AG in favor of the state, in an amount equal to the greater of $50,000 or the amount of escrow the manufacturer was required to deposit as a result of the largest of its most recent five calendar years' sales in California.

Enforcement: The BOE and the AG are authorized to enforce this law.

Penalty: Any person who makes a certification pursuant to this subdivision that asserts the truth of any material matter that he or she knows to be false is guilty of a misdemeanor punishable by imprisonment of up to one year in the county jail, or a fine of not more than $1,000, or both the imprisonment and the fine.

California Revenue and Taxation Code Sections 30165.1(c)–(l)

Scope: The state Attorney General (AG) shall publish and maintain a website directory listing manufacturers that have complied with the required certification and listing all certified brand families of the manufacturer. No one shall affix a tax stamp or meter impression to any package of cigarettes unless the brand family is included in the AG's directory. No one shall sell, offer, possess for sale, or import for personal consumption cigarettes of a brand family not included in the AG's directory. No one shall acquire, hold, own, possess, transport, or import cigarettes that the person knows or should know are intended to be distributed in violation of the requirement that tax stamps and meter impressions may only be affixed to packages of cigarettes whose brand families are included on the AG's directory.

Enforcement: The state Board of Equalization (BOE) and the AG are authorized to enforce this law.

Penalty: A violation constitutes a misdemeanor. In addition, distributors who violate this law are subject to a license revocation or suspension for a first offense. For a second or subsequent offense, the BOE may revoke or suspend the distributor's license and may impose a civil penalty not to exceed the greater of five times the retail value of the seized cigarettes or $5,000.

In addition, the penalties listed in entry 102 may apply.

105. RECORD-KEEPING: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387t

Scope: The U.S. Department of Health and Human Services (HHS) must issue regulations regarding how any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products should establish and maintain records. Some records must be furnished for inspection upon request by the government to aid an investigation about illicit trade, smuggling, or a counterfeit product.

Exception: Retailers do not have to maintain records for individual purchasers who purchase tobacco products for personal consumption. HHS must have the express written consent of an Indian tribe before inspecting records located in Indian country.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments. The HHS Secretary may also consult with the U.S. Attorney General and the Secretary of the Treasury. Manufacturers and distributors of a tobacco product must notify the Attorney General and the Secretary of the Treasury if they have knowledge of illegal transactions.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

106. REGISTRATION OF TOBACCO ESTABLISHMENTS: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387e

Scope: Owners and operators engaged in the manufacture, preparation, compounding, or processing of a tobacco product sold or distributed must register their establishments, both foreign and domestic, with the U.S. Department of Health and Human Services (HHS). Registration information shall be made available to the public.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

107. USER FEES: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387s

Scope: Tobacco manufacturers and importers must pay a quarterly fee that will be earmarked for tobacco regulation activities. The annual fee varies by fiscal year and class of tobacco products.

Enforcement: The U.S. Department of Health and Human Services is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

108. REQUIRED DISCLOSURES TO THE FDA: THE TOBACCO CONTROL ACT

21 United States Code Sections 333, 372, 387d, 387i, 387o
15 United States Code Section 1333

Scope: Tobacco manufacturers and importers or their agents must provide the U.S. Food and Drug Administration (FDA) with:

1. A list of the ingredients used in each product;
2. A description of content, delivery, and form of nicotine;
3. A list of smoke constituents that are harmful or potentially harmful to health and reports of required testing; and
4. All documents related to health, toxicological, behavioral, or physiological effects.

Exception: Small tobacco product manufacturers shall be exempt from testing and reporting requirements regarding tobacco product constituents, ingredients, and additives either for two years after final regulations are issued or when a compliance date is set by HHS for all other tobacco product manufacturers, whichever is later.

Note: At the request of HHS, tobacco manufacturers and importers must furnish any or all documents relating to particular research activities. In addition, tobacco product manufacturers or importers must maintain records and provide information to HHS upon request to assure that a tobacco product is not adulterated or misbranded, and to otherwise protect public health.

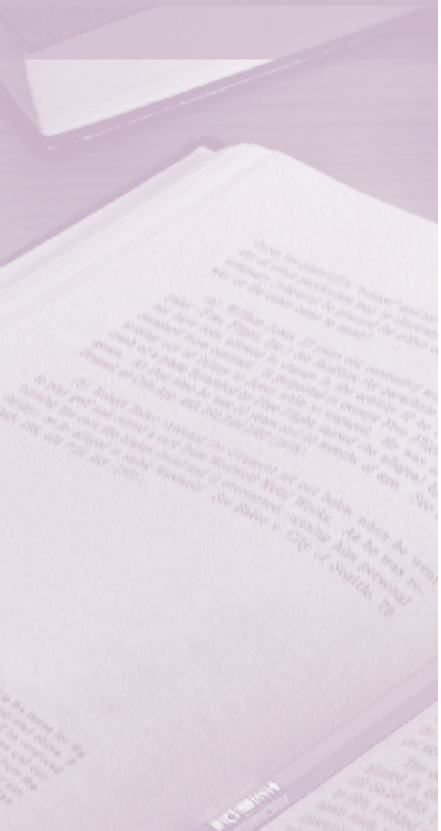
Note: This provision requires each tobacco product manufacturer or importer to begin reporting to the FDA on June 22, 2012. In April 2012, the FDA issued a notice establishing a list of tobacco product constituents that the agency believes are harmful or potentially harmful to health. The notice includes the criteria the FDA used to develop the list and the reasons the FDA may add or remove constituents from the list. 77 Fed. Reg. 20,034 (Apr. 3, 2012). At the time of publication, the FDA was gradually phasing in enforcement. The FDA has identified an abbreviated list of harmful or potentially harmful constituents that tobacco product manufacturers and importers must report. Draft Guidance for Industry: *Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act* (Apr. 2012), **www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297828.pdf**.

This guidance likely will be changed and/or withdrawn as the FDA begins to more fully enforce this provision.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Any person who violates this provision shall be subject to a civil penalty of up to $15,000 for each violation and up to $1 million for multiple violations ruled on in a single proceeding.

Any person who intentionally violates this provision shall be subject to a civil monetary penalty of up to $250,000 per violation and up to $1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice, the violator is subject to a penalty of $250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to $1 million in any 30-day period or $10 million for all such violations ruled on in a single proceeding.



MASTER SETTLEMENT AGREEMENT (MSA) FUNDS

109. MSA PAYMENTS

Master Settlement Agreement Sections IX, XI, VII(c); Exhibit A,VII

Scope: Under the Master Settlement Agreement (MSA) between the major tobacco companies and the attorneys general of 46 states, the settling companies are responsible for making annual payments to the settling states in perpetuity. These payments are distributed to the states based on formulas agreed to in the MSA.

Note: In recent years, California has received between $700-$750 million per year. Half of that money is allocated to the state and half to local governments within the state.

Enforcement: The state Attorney General (AG) may enforce these provisions.

Penalty: The AG may seek a court order to enforce the provisions or stop a violation of the provisions. If such an order is violated, the AG may pursue monetary compensation, civil contempt charges, or criminal sanctions. The parties must first attempt to resolve alleged violations through discussion.

110. MSA BONDS

California Government Code Sections 63049–63049.55

Scope: California law allows state and local governments to generate revenue by selling tobacco bonds that are backed by the future flow of payments to the state by tobacco companies as required by the Master Settlement Agreement (MSA) (see entry 109 for a summary of the MSA payments).

Note: State and local agencies can use the proceeds to fund capital improvement projects and health care programs/facilities. There is no limit on the amount of tobacco securitization bonds that can be issued. From 2001 to 2007, state and local governments in California issued bonds totaling $16.8 billion. See Cal. Debt and Investment Advisory Commission, Issue Brief: *Tobacco Securitization Bond Issuance in California* (June 2009), **www.treasurer.ca.gov/cdiac/reports/tobacco.pdf**. Some local governments have elected to borrow against expected future payments but haven't guaranteed to cover their debt with general fund revenue.

Exception: The sale of state tobacco bonds does not affect MSA funding received by California local governments.

Enforcement: Not applicable.

Penalty: Not applicable.

111. APPEAL BONDS

California Health and Safety Code Section 104558

Scope: In a civil lawsuit involving a tobacco company that has signed the Master Settlement Agreement (MSA) or that involves a successor or affiliate of such a company, the amount of the bond to be furnished during the course of an appeal shall not exceed 100 percent of the verdict or $150 million, whichever is less. The stated purpose of the appeal bond cap is to secure the funds owed to the state by tobacco companies as required by the MSA.

Exception: If the opposing party proves by a preponderance of the evidence that a tobacco company is intentionally dissipating or diverting assets outside the ordinary course of its business for the purpose of avoiding ultimate payment of the judgment, the cap may be lifted and the court may order any actions necessary to prevent dissipation or diversion of the assets.

Enforcement: The court shall set the amount of the appeal bond.

Penalty: Not applicable.

RELATED LAWS

112. PRESERVATION OF STATE AND LOCAL AUTHORITY: THE TOBACCO CONTROL ACT

21 United States Code Section 387p

Scope: State and local governments are permitted to enact more stringent restrictions related to the sale, distribution, possession, use, availability, or advertising and promotion of tobacco products. The Tobacco Control Act also does not limit the existing ability of state and local governments to regulate the reporting of information to the state, fire safety standards for tobacco products, and taxation of tobacco products.

Exception: State and local governments cannot enact restrictions that are different from or in addition to the provisions in the Tobacco Control Act regarding tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

Enforcement: Not applicable.

Penalty: Not applicable.

113. ADDITIONAL REGULATIONS: THE TOBACCO CONTROL ACT

21 United States Code Sections 372, 387f

Scope: The U.S. Department of Health and Human Services (HHS) may issue additional regulations restricting the sale and distribution of tobacco products, including restrictions on advertising and promotion. Regulations must be appropriate for the protection of the public health, which should be determined with respect to the risks and benefits to the population as a whole, taking into account whether individuals will likely either stop or start using tobacco products.

Exception: Federal regulations may not limit the sale or distribution of a tobacco product to prescription by licensed medical professionals; prohibit the sale of a tobacco product in face-to-face transactions by a specific category of retail outlets; or raise the minimum age for the sale of tobacco products above the age of 18.

> **Note:** Restrictions on the advertising or promotion of a tobacco product must be consistent with the First Amendment to the U.S. Constitution.

Enforcement: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

Penalty: Not applicable.

114. ADVISORY COMMITTEE: THE TOBACCO CONTROL ACT

21 United States Code Section 387q

Scope: The U.S. Department of Health and Human Services shall appoint 12 people to a Tobacco Products Scientific Advisory Committee (Advisory Committee) to provide advice, information, and recommendations. The members will include seven individuals from the medical, dental, scientific, and health care industries; one government employee; one member of the general public; and three nonvoting members representing the tobacco manufacturing industry, the small business tobacco manufacturing industry, and tobacco growers.

Exception: Full-time employees of the U.S. Food and Drug Administration (FDA) or any agency responsible for enforcing the Tobacco Control Act may not be appointed to this Advisory Committee.

Enforcement: Not applicable.

Penalty: Not applicable.

At the time of publication, two tobacco companies, Lorillard and R.J. Reynolds, had challenged the make-up of the Advisory Committee, claiming that several members are biased against the tobacco industry and should not be allowed to continue to serve in this capacity. *Lorillard, Inc. v. U.S. Food and Drug Administration,* No. 11-CV-00440 (D.D.C. argued Feb. 14, 2012). The FDA's motion to dismiss the case was denied on August 1, 2012, and the case was pending at the time of publication.

115. FEDERAL AMERICANS WITH DISABILITIES ACT (ADA)

42 United States Code Sections 12101–12213

Scope: The federal Americans with Disabilities Act (ADA) prohibits discrimination against a person with a disability. 42 United States Code Section 12112(a). The law applies to public entities, including schools and public transportation, employers with at least 15 employees, and to those who operate places where the public is invited, such as restaurants, hotels, and theaters. 42 United States Code Sections 12111(5), 12181-12182.

Note: The ADA does not apply to private housing, which is covered by the federal Fair Housing Act (entry 116).

The ADA defines a *disability* as: (1) a physical or mental impairment that substantially limits one or more of a person's major life activities; (2) a record of having such an impairment; or (3) being regarded as having such an impairment. Breathing is specifically listed as one of the major life activities covered by the ADA and a major life activity is also defined as the operation of a major bodily function, including respiratory functions.

An impairment that is episodic or in remission is a disability if it would substantially limit a *major life activity* when active. Even if the person's breathing is substantially improved through the use of oxygen therapy equipment, he or she would still be considered disabled under the ADA. 42 United States Code Section 12102.

Note: For example, a person may be disabled under the ADA if he or she has Chronic Obstructive Pulmonary Disease (COPD) or severe asthma which substantially limits breathing. *EEOC v. Supervalu, Inc.,* 674 F. Supp. 2d 1007, (N.D. Ill. 2009).

Under the ADA, employers must provide reasonable accommodation to the known physical or mental limitations of an otherwise qualified individual with a disability who is an applicant or employee unless that accommodation causes an undue hardship. 42 United States Code Sections 12112(b)(5)(A), 12111(8)–(10). In addition, places of public accommodation may not deny patrons with disabilities an equal opportunity to enjoy the goods, services, facilities, privileges, advantages, or accommodations of such a place. 42 United States Code Section 12182.

Note: The ADA may be used by a person with a respiratory disability to enforce existing laws against smoking. For example, a California restaurant owner who knowingly allows smoking in the restaurant in the presence of an employee or patron with severe asthma may be violating the ADA, in addition to other laws.

Enforcement: Employees and tenants may file a complaint with the Equal Employment Opportunity Commission (EEOC) or with the California Department of Fair Employment and Housing (DFEH). 42 United States Code Section 2000e-5. The EEOC and DFEH are obligated to investigate the complaint. A private lawsuit may be filed if the EEOC and DFEH do not file an action based on the complaint. Patrons who believe a business has violated the ADA may also file a private lawsuit.

Penalty: Available penalties include financial penalties (limited based on the number of employees), injunctive relief (a court order to stop the violation of the ADA), and attorneys' fees. 42 United States Code Sections 1981a & 2000e-5).

116. FEDERAL FAIR HOUSING ACT (FHA)

42 United States Code Sections 3601–3619
24 Code of Federal Regulations Sections 100.200–100.205

Scope: The federal Fair Housing Act (FHA) prohibits discrimination based on handicap, which is defined as: (1) a physical or mental impairment that substantially limits a person's major life activities; (2) a record of having such an impairment; or (3) being regarded as having such an impairment. 42 United States Code Sections 3602, 3604(f)–3606).

Note: The U.S. Department of Housing and Urban Development (HUD) has ruled that multiple chemical sensitivity disorder and environmental illness could qualify as a *handicap* under the FHA. HUD Memorandum, Multiple Chemical Sensitivity Disorder and Environmental Illness as Handicaps, doc. no. GME-0009 (Mar. 5, 1992), **www.hud.gov/offices/adm/hudclips/lops/GME-0009LOPS.doc**. A person may have a handicap under the FHA if he or she is hypersensitive to tobacco smoke. *Vickers v. Veterans Administration,* 549 F. Supp. 85, 86-87 (W.D. Wash. 1982).

If a resident has a disability under the law, the FHA requires landlords and condominium associations to make reasonable accommodations in rules, practices, policies, and

services that provide the resident with a disability an equal opportunity to use and enjoy the housing. 24 Code of Federal Regulations Section 100.204.

Note: Examples of reasonable accommodations that a tenant with a respiratory disability might request include: allowing the tenant to move to a vacant apartment to avoid exposure to drifting smoke; allowing the tenant to break a lease without penalty; or implementing a no-smoking policy for common areas or units.

The FHA applies to most private and federal government housing, including Section 8 housing. 42 United States Code Section 3603.

Note: Section 8 housing refers to federal programs offering low-income housing assistance through payments to private landlords. 42 United States Code Section 1437f.

Exception: The law may not apply to buildings with four or fewer units if the owner lives on-site or to single-family homes sold or rented by the owner. 42 United States Code Section 3603(b).

Enforcement: Individuals may file a complaint with HUD or a state agency which is its substantial equivalent (California Department of Fair Employment and Housing) within one year of the discrimination and/or file a lawsuit in federal district court within two years of the discrimination.

Penalty: Available relief includes actual damages, injunctive relief (a court order to stop the violation of the law), attorneys' fees, civil penalties, and other relief as appropriate.

117. CALIFORNIA FAIR EMPLOYMENT AND HOUSING ACT (FEHA)

California Government Code Sections 12900–12996

Scope: The state Fair Employment and Housing Act (FEHA) prohibits discrimination based on physical disability, mental disability, or medical condition. Under the law, a physical disability includes physiological and anatomical conditions that limit a person's ability to participate in major life activities. California Government Code Section 12926(k).

Note: FEHA's definition of physical disability is broader than the definition in the federal Americans with Disabilities Act (ADA), which requires a disability to substantially limit a major life activity (see entry 115 for a summary of the ADA).

Note: A person may be disabled under FEHA if he or she is hypersensitive to tobacco and tobacco exposure interferes with a major life activity, such as breathing. *See County of Fresno v. Fair Employment & Housing Comm'n*, 226 Cal. App. 3d 1541, 1548-1550 (1991).

Under FEHA, both private and public employers with five or more employees must engage in an interactive process to determine what accommodation is reasonable and must provide reasonable accommodation for the known physical or mental disability of an applicant or employee unless that accommodation causes an undue hardship. California Government Code Section 12940.

Note: FEHA may be used by an employee with a respiratory disability to enforce existing laws against smoking. For example, a California restaurant owner who knowingly allows smoking in the restaurant in the presence of an employee with severe asthma may be violating FEHA, in addition to other laws.

FEHA also applies to most *housing accommodations*, which are defined as any building, structure, or portion of a structure occupied or intended for occupancy as a residence by one or more families, and any vacant land that is offered for sale or lease for the construction of such buildings. California Government Code Sections 12927(d) & 12955. FEHA requires landlords and condominium associations to make reasonable accommodations and/or modifications of policies for residents with disabilities in order to ensure equal access to and enjoyment of their housing. California Government Code Section 12927(c).

Note: Examples of reasonable accommodations that a tenant with a respiratory disability might request include: allowing the tenant to move to a vacant apartment to avoid exposure to drifting smoke; allowing the tenant to break a lease without penalty; or implementing a no smoking policy for common areas and/or units.

Enforcement: Individuals may file a complaint with the California Department of Fair Employment and Housing (DFEH) and/or file a lawsuit in state court; however, before filing a lawsuit in state court individuals must exhaust administrative remedies by filing a complaint with DFEH and obtaining a right-to-sue notice.

Penalty: Available relief includes actual damages, injunctive relief (a court order to stop the violation of the law), prospective relief (ongoing remedies to correct past unlawful practices), attorneys' fees, and other relief as appropriate.

118. CALIFORNIA UNRUH CIVIL RIGHTS ACT

California Civil Code Sections 51–51.3

Scope: The state Unruh Civil Rights Act (Unruh Act) applies to all business establishments in California, including housing and public accommodations, and prohibits discrimination based on physical disability, mental disability, or medical condition, among other protected statuses. The Unruh Act's definitions of physical disability, mental disability, and medical condition mirror the definitions in the state Fair Employment and Housing Act (FEHA) (see entry 117 for more information about FEHA's definition of physical disability). California Civil Code Sections 51(e)(1) & 51(e)(3).

Note: While FEHA covers discrimination in employment and housing, the Unruh Act covers discrimination in housing and public accommodations. The Unruh Act requires full and equal accommodations, advantages, facilities, privileges, and services in all business establishments. California Civil Code Section 51(b).

Enforcement: Individuals may file a complaint with the California Department of Fair Employment and Housing (DFEH) and/or file a lawsuit in state court. The Unruh Act is different from FEHA in that it is not necessary for individuals to exhaust administrative remedies prior to filing a lawsuit in state court. Individuals do not need to obtain a right-to-sue notice from DFEH before filing a lawsuit.

Penalty: Available relief includes actual damages, injunctive relief (a court order to stop the violation of the law), attorneys' fees, and other relief as appropriate.

119. PROPOSITION 65

California Health and Safety Code Sections 25249.6–25249.13

Scope: The state Safe Drinking Water and Toxic Enforcement Act of 1986 requires notification to the public about exposure to chemicals known to the State of California to cause cancer or reproductive toxicity. This law applies to exposure to tobacco smoke. Warnings need not be made to each exposed individual. Instead, warnings may be provided by general methods such as posting clear and reasonable notices or labels on consumer products. The law requires businesses with at least ten employees to post warnings when they knowingly or intentionally expose an individual to a chemical on the list.

Exception: The law applies only to exposures that are made knowingly and intentionally.

Enforcement: Actions may be brought by the state Attorney General, a district attorney, a city attorney of a city with a population larger than 750,000, a city prosecutor in any city having a full-time city prosecutor (with the consent of the district attorney), or an individual acting in the public interest.

Penalty: Violators may be subject to an injunction to stop the violation and are liable for a civil penalty not to exceed $2,500 per day for each violation.

120. UNFAIR COMPETITION LAW

California Business and Professions Code Sections 17200–17209

Scope: It is illegal to engage or propose to engage in an unfair, unlawful, or fraudulent business act or practice.

> **Note:** This general law can be used as a mechanism to enforce many tobacco control laws that affect businesses, since a business that violates a tobacco control law is presumed to be in violation of the unfair competition law. For example, the law has been used against retailers who sell tobacco to minors in violation of California Penal Code Section 308 (see entry 22 for a summary of California Penal Code Section 308).

Enforcement: Actions may be brought by the state Attorney General, a district attorney, or, with the consent of the district attorney in certain cases, by a county counsel, city attorney, or city prosecutor. Actions also may be brought by anyone who has suffered injury in fact and has lost money or property as a result of the unfair competition.

Penalty: Violators are subject to an injunction to stop the behavior and a civil penalty of up to $2,500 for each violation.

121. PATIENT PROTECTION AND AFFORDABLE CARE ACT

42 United States Code Sections 300u-11, 300gg, 1396d, 1396o, 1397e, 1397r-8

Scope: The federal Patient Protection and Affordable Care Act (PPACA) expands Medicaid coverage to include tobacco cessation therapy for pregnant women, effective October 1,

2010. Beginning January 1, 2014, states are prohibited from excluding tobacco cessation coverage from the Medicaid program. Under the PPACA, health insurers are permitted to vary their premium rates on the basis of tobacco use; however, California allows insurers in the individual and small group markets to use only age, geographic region, and family size for purposes of establishing premium rates. California Insurance Code Sections 10753.14 & 10965.9. As a result, in California, these insurers cannot charge an individual a higher premium based on the individual's tobacco use. The prohibition on differential premiums does not apply to certain "grandfathered" health care plans that were in effect on March 23, 2010.

The PPACA establishes a Prevention and Public Health Fund to be administered by the U.S. Department of Health and Human Services (HHS), which is made available to individual communities for tobacco prevention and other public health programs on a competitive basis. Information about funding distribution is available at **www.hhs.gov/open/recordsandreports/prevention/**.

Enforcement: Each state must establish one or more rating areas in order to apply the requirements of this title. The HHS Secretary reviews the rating areas to ensure they are adequate to carry out the requirements. If the Secretary determines a state's rating areas are not adequate, or that a state has not established such areas, the Secretary may establish rating areas for that state.

At least once every two years each state must audit its expenditures from funds received under this division. These audits must be conducted by an entity independent of any agency administering activities funded under this division. Within 30 days of each audit, the state must submit a copy of that audit to its state legislature and to the HHS Secretary.

Penalty: Each state must repay to the U.S. any amount found not to have been expended in accordance with this division, or the HHS Secretary may offset these amounts against any other funds to which the state is entitled under this division.

122. TRICARE SMOKING CESSATION PROGRAM

32 Code of Federal Regulations Section 199.4(e)(30)

Scope: On February 27, 2013, the U.S. Department of Defense issued regulations regarding a smoking cessation program under TRICARE, which provides health benefits for military personnel, military retirees, and their dependents. The regulations state that smoking cessation medications are available through TRICARE at no cost to the beneficiary, and that TRICARE covers individual and group cessation counseling. Beneficiaries also have access to a toll-free quit line and web-based resources. Beneficiaries are entitled to two quit attempts per 12-month period. A third quit attempt may be covered with physician authorization.

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