



July 25, 2018

Commissioner Scott Gottlieb, MD  
c/o Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20825

Re: Regulation of Premium Cigars

**Docket No. FDA-2017-N-6107**

Dear Commissioner Gottlieb:

The Public Health Law Center is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the regulation of premium cigars. The Public Health Law Center is the coordinating center of the Tobacco Control Legal Consortium, a national network of nonprofit legal centers providing legal technical assistance to public health professionals and advocates concerning legal issues related to tobacco and public health.<sup>1</sup>

With the publication of the final deeming regulation in 2016, expanding the FDA's regulatory authority over all products made or derived from tobacco, intended for human consumption, the FDA made a decision to regulate all cigars rather than exempting so-called "premium cigars."<sup>2</sup> This was an important regulatory decision to maximize the protection of public health. There is absolutely no public health justification for the FDA to now rethink its decision barely two years later. The many health benefits of the FDA's regulation of "premium cigars" have yet to be fully realized because the agency's deeming rule is not yet fully implemented. In addition,

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<sup>1</sup> The Tobacco Control Legal Consortium's activities are coordinated by the Public Health Law Center, at Mitchell Hamline School of Law in St. Paul, Minnesota. The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at the University of Michigan, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

<sup>2</sup> Dep't. of Health and Human Servs., Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973 (May 10, 2016) (codified at 21 CFR 1100, 1140, and 1143).

exemptions in tobacco product regulation will, without fail, be exploited by the tobacco industry. Furthermore, in order to issue a new regulation that exempts premium cigars from important regulatory requirements and restrictions, the FDA must establish that its actions meet the public health standard, an impossible standard to meet for a deregulatory action.

I. There Is No Public Health Justification to Exempt Any Tobacco Product from FDA Regulation.

As the federal agency responsible for tobacco product regulation, the FDA's mission is to protect public health and reduce youth tobacco use. In the FDA's regulation of tobacco products, Congress was clear about the FDA's mission:

It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

...

The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.<sup>3</sup>

First and foremost, the FDA must protect public health from the harms caused by commercial tobacco products. Exempting any product from the agency's regulation will unquestionably harm public health. There is no public health justification to exempt "premium cigars" from FDA regulation.

A. FDA Oversight of Premium Cigars is Not a Prohibition.

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<sup>3</sup> Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387, notes 12, 44 (2012).

FDA regulation of premium cigars is not a prohibition on the products. The deeming regulation merely subjects premium cigars to requirements intended to combat industry deception, address consumer misconceptions, and ensure that more harmful products are not introduced into the market. Congress found these regulations to be necessary and proper given that the industry's history of self-regulation has not been sufficient and has resulted in deceitful business practices and devastating health consequences.

#### B. FDA Regulation is Beneficial to Cigar Users.

The FDA's current regulation of commercial tobacco products and its ability to adopt new regulations in the future benefits users of all tobacco products. There are a multitude of benefits that flow from the FDA's oversight. For example, warning labels on cigars are an important tool to help users of commercial tobacco products understand the health harms caused by the products.<sup>4</sup> The presence of warning labels on cigars increase users' knowledge of the risks of the products.<sup>5</sup> This is important because many cigar users mistakenly believe that cigars are less harmful than cigarettes.<sup>6</sup> Research demonstrates that this is a misconception and that cigar users are exposed to some toxicants and carcinogens in greater quantities than cigarettes.<sup>7</sup> Additionally, a cigar user who uses products intermittently and does not use the products to support addiction still benefits from increased knowledge of the risks of cigar use.<sup>8</sup>

Because warning labels for cigars have not yet been implemented, the health benefits of that policy have not yet been realized. Even further into the future, FDA premarket review of cigars ensures that products that enter the market are at least no more harmful than products that are already on the market. Rolling back regulation for premium cigars would destroy these future health benefits.

#### C. Regulatory Exemptions for Any Tobacco Product Incentivize Deceptive Behavior by the Tobacco Industry.

There are many examples of regulatory loopholes that have been exploited to gain favorable treatment for commercial tobacco products. Some of the clearest examples come from disparate treatment of different types of cigars.

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<sup>4</sup> Seema Mutti et al., *The Efficacy of Cigarette Warning Labels on Health Beliefs in the United States and Mexico*, 18 J. HEALTH COMM'NS 1180 (2013); David Hammond, *Health Warning Messages on Tobacco Products: A Review*, 20 TOBACCO CONTROL 327 (2011); David Hammond et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey*, 15 TOBACCO CONTROL iii19 (2006).

<sup>5</sup> *Id.*

<sup>6</sup> Baker et al., *Health Risks Associated with Cigar Smoking* 284 J. AM. MED. ASS'N. 735 (2000).

<sup>7</sup> *Id.*

<sup>8</sup> Mutti, *supra* note 4; Hammond, *supra* note 4; Hammond et al., *supra* note 4.

In 2009, Congress enacted two important tobacco control measures, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA). The Tobacco Control Act placed stringent restrictions on the manufacture and sale of cigarettes, prohibiting flavors other than menthol and tobacco,<sup>9</sup> prohibiting the use of modified risk terms including “light” and “low tar,”<sup>10</sup> and imposing significant advertising and marketing restrictions.<sup>11</sup> However, the Tobacco Control Act deferred any regulation of cigars to the future.<sup>12</sup> CHIPRA increased federal excise taxes on all tobacco products but did not increase taxes equitably, leaving the tax on cigars lower than the tax on cigarettes.<sup>13</sup> The result of these two actions was that many manufacturers of discount cigarettes slightly modified their products, by adding a nominal amount of tobacco to the paper wrappers, converting the cigarettes into cigars for regulatory and taxation purposes.<sup>14</sup> These new brands of cigars, often referred to as “little cigars,” are functionally identical to cigarettes. They are sold in a variety of flavors; they use prohibited terms for cigarettes like “low” and “mild;” and the products are subject to a lower federal tax.<sup>15</sup>

Manufacturers of roll-your-own tobacco found themselves in a similar position and simply changed the labeling on their products to “pipe tobacco,” a product not immediately subject to FDA authority and also taxed at a lower rate than roll-your-own tobacco.<sup>16</sup> Cigar manufacturers were also able to exploit CHIPRA by converting “small cigars” to “large cigars” by adding sepiolite<sup>17</sup> to increase cigar weight, moving the products into a more favorable tax category.<sup>18</sup> With this one change, cigar companies were able to avoid over \$1 billion in taxes in the first four years following

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<sup>9</sup> Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387g(a)(1)(A) (2012).

<sup>10</sup> *Id.* § 387k(b)(2)(A)(ii).

<sup>11</sup> *See, e.g.*, 21 C.F.R. § 1140.1 – 1140.34 (2018).

<sup>12</sup> Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387a(b) (2012).

<sup>13</sup> Children’s Health Insurance Program Reauthorization Act of 2009, 42 U.S.C. § 1396 (2012).

<sup>14</sup> U.S. GOV’T ACCOUNTABILITY OFF., GAO-12-475, TOBACCO TAXES: LARGE DISPARITIES IN RATES FOR SMOKING PRODUCTS TRIGGER SIGNIFICANT MARKET SHIFTS TO AVOID HIGHER TAXES (2012), <https://www.gao.gov/assets/600/590192.pdf>.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* This particular change only required manufacturers to change their packaging, *see id.* <https://www.gao.gov/assets/600/590192.pdf>

<sup>17</sup> Sepiolite is a clay substance that is also used in cat litter. Haydn H. Murray, *Traditional and New Applications for Kaolin, Smectite, and Palygorskite: A General Overview*, 17 APPLIED CLAY SCI. 207 (2000).

<sup>18</sup> Press release, Mathew L. Myers, President, Campaign for Tobacco-Free Kids, *Talk about a Scoop: Tobacco Company Puts Kitty Litter in Its Cigars* (March 1, 2013), [https://www.tobaccofreekids.org/press-releases/2013\\_03\\_01\\_kittylitter](https://www.tobaccofreekids.org/press-releases/2013_03_01_kittylitter); Anna Edny, *Tobacco Firms Save \$1 Billion With Kitty Litter in Cigars*, *Bloomberg* (Feb. 28, 2013), <https://www.bloomberg.com/news/articles/2013-03-01/tobacco-firms-save-1-billion-with-kitty-litter-in-cigars>.

CHIPRA.<sup>19</sup> The disparate regulation created an economic incentive to exploit the loophole. The result of the exploitation is that the use of the product categories that were not subject to the most stringent regulation or taxation went up, as consumers moved to less expensive and less stringently regulated products.<sup>20</sup>

D. A Comprehensive Product Standard for Nicotine Must Cover All Cigars, Including Premium Cigars.

Because many of the health harms from “premium” cigars are not significantly distinguishable from the health harms posed by other combustible products, the FDA must not deregulate premium cigars at all, and certainly not in conjunction with a comprehensive product standard reducing nicotine in commercial tobacco products. Not only would deregulation of premium cigars undermine a nicotine reduction rule by allowing combustible products to remain on the market with addiction-sustaining levels of nicotine, there are also unique harms posed to people who transition from cigarettes to cigars and such transitioning should be expected if premium cigars are allowed to retain an addiction-sustaining level of nicotine. Research demonstrates that former cigarette users that take up cigar smoking inhale more deeply, smoke more cigars per day, and had a higher tobacco smoke exposure including toxicants and carcinogens over people who had only smoked cigars.<sup>21</sup> Furthermore, exposure to some toxicants and carcinogens is actually greater for cigar users than for cigarette users.<sup>22</sup> For these reasons, the FDA must not deregulate premium cigars and must also include premium cigars in any action reducing nicotine levels in combustible tobacco products.

E. In Exempting “Premium Cigars” from its Regulation, the FDA Cannot Meet the Public Health Standard.

Even though the deeming regulation has not yet been fully implemented, the current status of the law is that all cigars are tobacco products subject to the FDA’s regulatory authority, including all of the requirements and restrictions in the Tobacco Control Act and the additional requirements established in the deeming regulation. In order for the FDA to promulgate a new regulation that undoes its previous action, the FDA must be able to demonstrate that this deregulatory action

<sup>19</sup> U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 14.

<sup>20</sup> Centers for Disease Control and Prevention, *Consumption of Cigarettes and Combustible Tobacco – United States, 2000-2011*, 61 MORBIDITY AND MORTALITY WKLY. REP. 30, 565 (2012), <https://www.cdc.gov/mmwr/pdf/wk/mm6130.pdf>.

<sup>21</sup> See Terry F. Pechacek et al., *Smoke Exposure in Pipe and Cigar Smokers*, 254 J. AM. MED. ASS’N. 3330 (1985); J.A. McM. Turner et al., *Effect of Cigar Smoking on Carboxyhaemoglobin and Plasma Nicotine Concentrations in Primary Pipe and Cigar Smokers and Ex-Cigarette Smokers*, 2 BRITISH MED. J. 1387 (1977); Judith K. Ockene et al., *Does Switching from Cigarettes to Pipes or Cigars Reduce Tobacco Smoke Exposure?*, 77 AM. J. PUB. HEALTH 1412 (1987).

<sup>22</sup> Baker et al., *Health Risks Associated with Cigar Smoking* 284 J. AM. MED. ASS’N. 735 (2000).

meets the Tobacco Control Act's public health standard. In this context, the standard represents an impossible evidentiary burden. As discussed above, FDA regulation accrues public health benefits, and the removal of those benefits inevitably jeopardizes public health. The FDA cannot demonstrate that deregulation of any product will decrease initiation, increase cessation, and benefit users and nonusers of tobacco products. In fact, the opposite is true. FDA deregulation of any tobacco product harms public health and the FDA will not be able to establish that a deregulatory action meets the statutory requirements for agency action.

There is no public health reason to deregulate some cigars. We urge the FDA to abandon all consideration of such plans and instead focus its resources on regulations that will protect the public from the devastating health consequences of tobacco use.

Respectfully,



Joelle Lester  
Director



Desmond Jenson  
Senior Staff Attorney

# Health Risks Associated With Cigar Smoking

Frank Baker, PhD

Stuart R. Ainsworth, MA

Joseph T. Dye, PhD

Corinne Crammer, MM

Michael J. Thun, MD

Dietrich Hoffmann, PhD

James L. Repace, MSc

Jack E. Henningfield, PhD

John Slade, MD

John Pinney, BA

Thomas Shanks, MPH, MS

David M. Burns, MD

Gregory N. Connolly, DMD, MPH

Donald R. Shopland

**C**IGAR SMOKING HAS INCREASED rapidly in recent years, coincident with the aggressive glamorization and promotion of cigars.<sup>1(pp195-219)</sup> The American Cancer Society convened a conference June 15 and 16, 1998, in Washington, DC, to review current knowledge of the health risks of cigar smoking. The 120 invited attendees represented governmental and private agencies, academia, health educators, and tobacco control experts. Tobacco control experts with a specific interest in cigar smoking were invited to present papers. Many of these speakers had review articles published in the recent National Cancer Institute monograph on cigar smoking<sup>1</sup> and were asked to provide an update on their research efforts. In addition, a series of panels discussed the implications of the data presented at the conference, and a final panel of all conference attendees provided a forum for summary discussion. This article summarizes the data pre-

This article summarizes principal findings from a conference convened by the American Cancer Society in June 1998 to examine the health risks of cigar smoking. State-of-the-science reports were presented and 120 attendees (representing government and private agencies, academia, health educators, and tobacco control experts) participated in panels and summary development discussions. The following conclusions were reached by consensus: (1) rates of cigar smoking are rising among both adults and adolescents; (2) smoking cigars instead of cigarettes does not reduce the risk of nicotine addiction; (3) as the number of cigars smoked and the amount of smoke inhaled increases, the risk of death related to cigar smoking approaches that of cigarette smoking; (4) cigar smoke contains higher concentrations of toxic and carcinogenic compounds than cigarettes and is a major source of fine-particle and carbon monoxide indoor air pollution; and (5) cigar smoking is known to cause cancers of the lung and upper aerodigestive tract.

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sented at the conference and the formal discussions at the concluding session.

## How Do Cigars Differ From Cigarettes?

Cigars are defined by the US Department of the Treasury as “any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco”; cigarettes are defined as a “roll of tobacco wrapped in paper or a substance not containing tobacco.”<sup>2</sup> There is no universal agreement on how to classify the many types of cigars available today (TABLE 1).

A fundamental difference between cigar and cigarette tobacco is in the processing. Cigars consist of filler (the inner part of the cigar), a binder, and a wrapper, all of which are made with air-cured and fermented tobaccos. US cigarettes contain a blend of heat-cured and air-cured tobaccos as major components and a small percentage of sun-cured (oriental) tobaccos; they do not contain fermented tobacco.

Air-curing tobacco involves hanging the whole tobacco plant or individually primed leaves (if intended for cigar use)

in barns or sheds for 30 to 40 days. In heat-curing, leaves of tobacco are hung on tiers in barns where the air is gradually warmed to a temperature of 70°C to 75°C over a period of 5 to 7 days. After curing, the leaves are typically aged for 2 or more years. Fermentation entails packing the tobacco leaves with placement in fermentation rooms for 3 to 5 weeks; they are subsequently removed, repacked, and returned to the fermentation rooms several times to achieve the desired flavor and aroma.

**Author Affiliations:** Behavioral Research Center (Dr Baker and Dye and Mr Ainsworth and Ms Crammer), Epidemiology and Surveillance Research (Dr Thun), American Cancer Society, Atlanta, Ga; American Health Foundation, Valhalla, NY (Dr Hoffmann); Repace Associates Inc, Bowie, Md (Mr Repace) and Pinney Associates, Inc (Dr Henningfield and Mr Pinney), and Smoking and Tobacco Control Program, National Cancer Institute (Mr Shopland), Bethesda, Md; Department of Medicine, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick (Dr Slade); Tobacco Control Policies Project (Mr Shanks) and University of California at San Diego School of Medicine (Dr Burns), University of California, San Diego; and Massachusetts Department of Public Health, Boston (Dr Connolly). **Corresponding Author:** Frank Baker, PhD, Behavioral Research Center, American Cancer Society, 1599 Clifton Rd NE, Atlanta, GA 30329-4251 (e-mail: fbaker@cancer.org).

**Table 1.** Cigar Types and Characteristics\*

Classification System	Cigar			
	Weight, g	Length, mm	Diameter, mm	Description
US Department of the Treasury <sup>2†</sup>	Small	≤1.36	...	...
	Large	>1.36	...	...
US Federal Trade Commission <sup>2†</sup>	Little	<1.36	...	...
	Medium	1.36-4.54	...	...
	Large	>4.54	...	...
Hoffman and Hoffman, <sup>1(pp65-104)</sup> 1998	Little	0.9-1.3	70-100	...
	Small	1.3-2.5	70-120	...
	Regular	5-17	110-150	≤17
	Premium	≤22	127-214	12-23

\*Ellipses indicate none specified.

†Converted from the US Customary System of measurement to the International System for comparability.

Cigar tobacco compared with US cigarette tobacco is rich in nitrate (1.4%-2.1% vs 0.1%-1.7%). During fermentation, which contributes greatly to the flavor and aroma of cigar tobacco, nitrate is partially reduced to the strong N-nitrosating nitrite, which reacts with amines to form nitrosamines. Cigar tobacco, compared with cigarette tobacco, is rich in the highly carcinogenic N'-nitrosornicotine (NNN) (3.0-4.5 µg/g vs 1.8-3.0 µg/g) and in 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (1.2-4.5 µg/g vs 0.1-1.0 µg/g); these tobacco-specific carcinogens are formed from nornicotine and nicotine. During fermentation, cigar tobacco is greatly reduced in protein, reducing sugars (0.9%-2.7%), phytosterols (0.14%-0.16%), and polyphenols (<0.1%), but in cigarette tobacco, sugar levels range from 5.5% to 20%, phytosterol levels range from 0.3% to 4.5%, and polyphenol levels range from 3.0% to 5.0%. Consequently, cigar smoke is rich in nitrogen oxides (150-300 µg/g of tobacco burned vs 90-150 µg/g from cigarettes), ammonia, and nitrosamines.

Furthermore, cigar smoke tends to have a higher pH than cigarette smoke, which increases the amount of free nicotine in the particulate and vapor phases of the smoke.<sup>1</sup>

### Trends in Cigar Smoking

Between the years 1993 and 1997, the consumption of all types of cigars in the United States increased by 46.4%, reversing a steady decline (66%) in cigar consumption from 1964 to 1993.<sup>1(pp21-53)</sup> Between 1993 and 1997, consumption of large cigars and cigarillos increased 69.4%.<sup>4</sup>

Premium cigars accounted for only a small part of this increased consumption. The vast majority of cigar smokers smoke other less expensive large cigars; small cigars, known as cigarillos; and little cigars, which resemble cigarettes and are packaged similarly but have a wrapper that contains tobacco (Table 1).<sup>1(55-104)</sup>

Data on cigar sales are readily available from the US Department of Agriculture, but prevalence data on current cigar smoking are sparse. Since cigar-smoking rates had remained low

for many years, questions on cigar use were omitted from many national health surveys. Surveys among California adults between 1990 and 1996 showed that the increases in cigar smoking occurred primarily among younger more educated adults.<sup>5</sup> Some data indicate that adult men are more likely to smoke cigars than adult women and that cigar smoking is increasing among adolescents in both sexes, surpassing the use of smokeless tobacco.<sup>6</sup> Data from the 1997 Youth Risk Behavior Survey<sup>7</sup> indicated that 31% of male adolescents had smoked at least 1 cigar in the past month and that cigar smoking prevalence among adolescent girls was nearly 11%. Data from the 1998 National Household Survey on Drug Abuse indicate that the rate of current cigar use among those aged 12 years or older increased from 5.9% in 1997 to 6.9% in 1998, a statistically significant increase, and that an estimated 5.6% of youths aged 12 to 17 years were current cigar users in 1998. Statistically significant increases in past-month-cigar use were also reported for (1) white, non-Hispanic males, (2) those living in the Northeast, (3) those with some college education, and (4) the unemployed.<sup>8</sup>

An additional concern relates to initial evidence suggesting that some adolescent cigar smokers may engage in a practice known as *blunting*, whereby the cigar filler tobacco is removed and replaced with marijuana and possibly other illicit drugs.<sup>9</sup>

### Marketing and Promotion of Cigars

Beginning in the mid 1980s, the cigar industry intensified its public relations efforts in the United States through strategies such as cigar dinners, product placement in movies, feature stories, sporting events, and the development of cigar-friendly lifestyle magazines (such as *Cigar Aficianado*). Electronic and print media report America's "rediscovery" of the premium cigar smoked by the affluent and successful members of society.<sup>1(pp195-219),10,11</sup> The sale of cigars has expanded from tobacco stores,



upscale restaurants, and luxury hotels to availability at gas stations, grocery stores, liquor stores, variety stores, and menswear sections in department stores. These promotional efforts resemble those undertaken in the early stages of the smokeless tobacco campaign, which ultimately became a major health problem.<sup>12,13</sup> Advertising and promotional activities for cigars, similar to those for cigarettes, routinely include sexual imagery, affluence, and celebrity endorsement (explicitly and implicitly). Unlike cigarette marketing promotions, those for cigars are not required to mention the potential health risks associated with tobacco use, which gives the impression that cigars are a “safe” product.

### The Public Perceptions of Cigars

National data indicate that 46.6% of cigar smokers surveyed believe that cigar smoking is a high-risk behavior for developing cancer.<sup>14</sup> However, they evidence an “optimistic bias” in their estimate of their own risk of developing cancer in the next 20 years: only 8.7% consider themselves to be at high risk.<sup>14-16</sup> Compared with nonsmokers, cigar smokers also underestimate the cancer risk of exposure to environmental cigar smoke.<sup>14</sup>

The glamorized image of cigar smokers presented in the media appears to be accepted both by those who smoke cigars and those who do not. A large fraction of both groups (about 40%) perceive cigar smokers as relatively well-to-do, well-educated, older managers or executives. Cigar smokers are more likely to associate athleticism with cigar smoking than are nonsmokers, which may be due in part to media imagery of sports figures smoking cigars at a victory celebration.<sup>14</sup>

### Pharmacology and Abuse Potential of Cigars

Whether cigars deliver nicotine at a level capable of producing dependence is a function of the degree of cigar smoke inhalation, the rate of nicotine absorption, the development of tolerance to

nicotine, the age of initiation, and the duration of exposure. The amount of nicotine in a cigar is approximately proportional to the amount of tobacco it contains; this may range from less than 1 g to more than 20 g of tobacco, depending on the cigar size and the amount of tobacco incorporated in its components.<sup>17</sup> Thus, the nicotine in the smoke of a single cigar can vary from an amount approximate to that in the smoke of a single cigarette to the amount generated by smoking a pack or more of cigarettes. Cigars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled.

The manner in which tobacco products are smoked and their ability to deliver nicotine is influenced by the pH of the smoke. Accurate measurement of smoke pH has eluded scientists, and measurements obtained vary depending on the method used. However, if the concept of smoke pH is defined as the pH of the smoke and aerosol particles, it is generally correct to assume that cigar smoke aerosol particles are less acidic relative to cigarette smoke aerosol particles. Furthermore, the alkalinity of cigar smoke aerosol particles relative to cigarette smoke aerosol particles tends to deter inhalation, although cigar smoke is often partially inhaled, especially by current and former cigarette smokers.<sup>1(pp181-193),7,18</sup> Studies indicate that two thirds of those who smoke both cigars and cigarettes (>40% of cigar smokers) inhale cigar smoke, compared with less than 15% of cigar smokers who never smoked cigarettes.<sup>1(pp181-193),19</sup>

Definitive studies of nicotine tolerance and withdrawal have not been conducted on cigar smokers. Some research suggests that cigars produce fewer abstinence-induced withdrawal symptoms than cigarettes, but their nicotine delivery characteristics and the daily patterns of cigar smoking by many persons suggest a distinct potential to produce dependence.<sup>1(pp181-193)</sup> The number of cigar smokers in the popu-

lation who smoke infrequently, who consume few cigars per day, and who inhale minimally suggests that cigar use beginning in adulthood may be less likely to induce dependence than that resulting from cigarette smoking.

### Chemistry and Toxicology

Most of what is known about the nature and chemistry of tobacco and tobacco smoke is derived from studies on cigarettes, with little work specifically focused on cigar smoke. Tobacco and tobacco smoke contain about 6700 compounds, of which about 4000 have been identified in tobacco smoke.<sup>20</sup> At least 63 of these compounds are known to be carcinogenic, including 11 known human carcinogens.<sup>21</sup> The chemistry of cigar smoke is believed to be qualitatively similar to that of cigarettes, except for differences caused by the aging and fermentation of cigar tobacco and by the use of additives (primarily in cigarettes). Quantitative differences are primarily due to differences in the smoke pH and lower oxygen concentrations (resulting from the poor porosity of the tobacco wrappers compared with the paper wrappers of cigarettes).

A class of highly carcinogenic compounds known as tobacco-specific, N-nitrosamines (TSNA) is present in cigar smoke at significantly higher levels than in cigarette smoke.<sup>1(pp55-104)</sup> Examination on a “per gram of tobacco smoked” basis reveals that tar, defined as the total particulate matter collected by a Cambridge filter after subtracting moisture and nicotine; carbon monoxide; and ammonia are produced in greater quantities by cigars than cigarettes. When equal doses are applied, the tar produced by cigars exerts greater tumorigenic activity in mice compared with the tar from cigarettes, because cigar tar contains higher concentrations of carcinogenic polycyclic aromatic hydrocarbons.<sup>1(pp55-104)22-24</sup>

### Environmental Tobacco Smoke

Sidestream smoke (the aerosol emitted from the burning cone of a cigar, cigarette, or pipe during the interval be-

tween puffs and the portion of the inhaled smoke that is not retained and is exhaled<sup>25</sup>) contributes significant pollutants to the environment in the form of carbon monoxide, nitrogen oxides, respirable suspended particulate matter, nicotine, polycyclic aromatic hydrocarbons, and other compounds, and sidestream smoke from cigars does so to a greater degree than the sidestream smoke of cigarettes, when equal amounts of tobacco are burned.<sup>1(pp55-104,161-179)</sup> Compared with a single cigarette (0.55 g) smoked to 70% of its mass, a large cigar smoked 70% emits about 20 times the carbon monoxide, 5 times the respirable particles, and twice the amount of polycyclic aromatic hydrocarbon.<sup>1(pp161-179)</sup>

One study of environmental pollutants from tobacco smoke found the levels of carbon monoxide at cigar banquets and in some cigar smokers' homes equal to carbon monoxide concentrations on crowded California freeways. The indoor carbon monoxide level measured at a cigar banquet averaged 10 ppm over the 3-hour-20-minute event, and peak levels were comparable to that in a busy parking garage. By comparison, the ambient outdoor carbon monoxide level at rush hour was 1 to 2 ppm.<sup>1(pp161-179),26</sup> The Environmental Protection Agency's standard for carbon monoxide places the maximum permissible level at an average of 9 ppm over an 8-hour period.<sup>27</sup>

Mathematical models designed for the analysis and interpretation of indoor air pollution measurements suggest that typical levels of respirable tar particles from cigar smoking in homes, offices, and restaurants may exceed the National Ambient Air Quality Standard for outdoor fine-particle air pollution ( $65 \mu\text{g}/\text{m}^3$  on a 24-hour average).<sup>1(161-179),27</sup> Thus, it is clear that cigar smoke can be a major source of indoor air pollution.

### Cigar Smoking and Cancer Risk

Since the 1950s, epidemiologic studies of cigar smokers have found increased risk of oral, esophageal, laryngeal, and lung cancer.<sup>1(105-158),25,28-31</sup> The

risks of cancers of the oral cavity and esophagus are similar among cigarette and cigar smokers, probably due to the similar doses of tobacco smoke delivered directly to these areas by cigars and cigarettes.<sup>1(pp105-158)</sup> Lung cancer risk is less strongly associated with cigar smoking than with cigarette smoking, but risk increases with the number of cigars smoked per day and depth of inhalation. Men who smoke 3 or more cigars per day and report moderate inhalation experience lung cancer death at about two thirds the rate of men who smoke 1 pack of cigarettes a day.<sup>1(pp105-158)</sup> A recent case-control study from Europe (where inhalation patterns and tobacco composition in cigars may differ from those in the United States) found a relative risk (RR) of 9.0 (95% confidence interval [CI], 5.8-14.1) for lung cancer among European cigar and cigarillo smokers,<sup>32</sup> substantially higher than the lung cancer risk in older studies of US cigar smokers.<sup>1</sup>

Additional estimates of the risk of cancer in cigar smokers come from an analysis of data from the Cancer Prevention Study I (CPS-I) of the American Cancer Society, a cohort study conducted between 1959 and 1972.<sup>1(pp105-158)</sup> Of the 442455 white male subjects in CPS-I, 15191 were primary cigar smokers and had never smoked cigarettes, 7404 were secondary cigar smokers and had previously smoked cigarettes, 10300 were mixed smokers and currently smoking both cigars and cigarettes; and 175000 were cigarette-only smokers. The cancer risks for these groups were compared with rates for 92300 men who never smoked based on mortality information. The analysis included consideration of a dose-response effect for all groups related to numbers of cigars smoked per day and degree of self-reported smoke inhalation.

This study provides strong support for an increased risk in cigar smokers for cancers of the lung, esophagus, larynx, oral cavity, and, probably, pancreas. The increase in risk appears to be roughly proportional to the degree of exposure to the cigar smoke. For example, the death rate from cancers of the oral cav-

ity among male cigar smokers, compared with lifelong nonsmokers, is nearly 8 times higher (RR, 7.92; 95% CI, 5.12-11.69); similarly, the death rate from cancer of the larynx is about 10-fold higher (RR, 10.02; 95% CI, 4.0-20.6). For both of these cancers, a dose-response effect is evident and is related to the frequency of cigars smoked.<sup>1(pp105-158)</sup> The death rate from esophageal cancer is 3 to 4 times higher in male cigar smokers than in lifelong male nonsmokers (RR, 3.60; 95% CI, 2.2-5.6). The increase in cancer risk associated with cigar smoking is thus greater in the oropharynx and larynx than in the more distant esophagus. The mucosa of the esophagus is exposed only to tobacco carcinogens that have been dissolved in saliva and swallowed but not to the smoke itself. Similarly, lung cancer risk is higher among cigar smokers who report inhaling the smoke than in those who report not inhaling, and higher among cigar smokers who previously smoked cigarettes than among those who only smoked cigars.<sup>1(pp105-158)</sup>

### Other Health Effects of Cigar Smoking

Several older studies suggested that cigar smoking increases the risk for coronary heart disease (CHD), chronic obstructive pulmonary disease, and aortic aneurysm, particularly among heavy cigar smokers ( $\geq 3$  cigars a day) and those who inhale smoke deeply,<sup>31</sup> but there was no clear consensus that cigar smoking causes CHD. The 1983 Surgeon General's Report, which mainly emphasized the hazards of cigarette smoking, concluded that those who smoke only cigars did not appear to experience substantially greater risks than nonsmokers.<sup>33</sup> The report notes that the category of nonsmokers also includes passive smokers so that the control group contains persons exposed to environmental tobacco smoke. However, an analysis of CPS-I data concluded that "cigar smokers who smoke several cigars per day or who inhale [the smoke] are at increased risk for CHD."<sup>1(pp105-158)</sup>

A second large cohort study, the Cancer Prevention Study II (CPS-II), was

**Table 2.** Implication for Patient Counseling

- Ask patients if they smoke cigars and advise them of the associated health risks.
- Advise patients that smoking cigars is not a safe alternative to cigarette smoking.
- Inform patients that cigar smoke contains a number of carcinogenic and noxious substances and poses risks to the smoker and persons environmentally exposed.
- Caution adolescents of the double dangers of *blunting*, removing the cigar filler tobacco and replacing it with marijuana or other drugs, exposing them to the drug as well as nicotine and carcinogens in the wrapper.

initiated by the American Cancer Society in 1982. A recent analysis of these data examined death rates due to CHD in relation to cigar smoking.<sup>34</sup> After excluding men who had ever smoked pipes or cigarettes regularly, approximately 7000 current cigar smokers, 7000 former cigar smokers, and 113 000 men who had never regularly smoked tobacco remained in the analysis. As with cigarette smoking, the association between cigar smoking and death due to CHD was strongest among younger men and current rather than former smokers. There was no apparent increase in risk for cigar smokers aged 75 years or older or among former cigar smokers. Among men younger than 75 years, current cigar smokers experienced a death rate from CHD about one third higher than those who never smoked. This relationship held over the range of cigars smoked per day and was not limited to men who reported inhaling cigar smoke (although unintentional inhalation obviously occurs).

### Policy Issues

Fewer federal and state regulations pertain to cigars than to cigarettes or smokeless tobacco.<sup>35</sup> Cigars are not included in many of the federal and state policies involving health warnings on tobacco, prohibition of sales to minors, and taxation. However, a recent Federal Trade Commission report to Congress recommended health warnings on all labeling and advertising for cigar products; prohibition on electronic advertising such as radio and television for all tobacco products, including all sizes and types of cigars; and consistency in regu-

lating youth access to tobacco products, including cigars.<sup>3</sup>

Evidence of the health hazards and an alarming increase in rates of cigar smoking underscore the pressing need for cigars to be included in a coherent national policy on tobacco use and dependence. The research on the heavy impact of secondhand cigar smoke on indoor air pollution is particularly relevant for restricting smoking in restaurants and other public places. Although smoking is usually considered an adult problem, tobacco use by children and adolescents is of a particular concern. In addition to research showing high levels of adolescent cigar use, evidence is emerging that young persons use cigars to mask illicit substance abuse.<sup>9</sup> The serious health risks associated with tobacco use, including cigars, highlights the need for a broad and inclusive national policy that addresses the constellation of tobacco products and their use by all age groups.

### Conclusions

The available scientific knowledge on the health risks of cigar smoking is more than sufficient to conclude that cigar smoking is a cause of cancer and a serious risk to the public health. The increase in cigar smoking has particular implications for both research and policy development. First, rates of cigar smoking are increasing, and not just among adults. Both male and female adolescents are using cigars, and their rates of use have met or exceeded those of adults before 1993. Second, similar to other tobacco products, cigars contain nicotine, which is highly addictive; smoking cigars instead of cigarettes does not reduce the risk of becoming addicted to nicotine. Third, as the number of cigars smoked and the amount of smoke inhaled increases, the risks of death related to cigar smoking approach those of cigarette smokers. Switching to cigars from cigarettes does not necessarily reduce the risk of death from a tobacco-caused illness. Fourth, cigar smoking does not just affect cigar smokers: environmental cigar smoke contains high concentrations of

toxic and carcinogenic compounds and can be a major contributor to indoor air pollution, in amounts greater than that produced from cigarettes. Most importantly, cigar smoking is known to cause cancer of the lung and upper aerodigestive tract.

The weight of the evidence indicates that smoking cigars is not a safe alternative to cigarette smoking. The recent increase in rates of cigar smoking and its risks to health underscore the pressing need for a comprehensive national tobacco policy and for active patient educational efforts (TABLE 2). Laws and regulations limiting the marketing of cigarettes and access to cigarettes by minors should be applied to all tobacco products.

A number of avenues for research to define further the health risks exists. Such research could include efforts to understand better the nature of tobacco addiction associated with cigar smoking; the identification of biomarkers of the uptake of carcinogens, carbon monoxide, and nicotine in active cigar smokers; and the relationship of atmospheric nicotine to body fluid cotinine in nonsmokers exposed to environmental cigar smoke. Research is necessary to establish clearly the risks of cigar smoking associated with CHD, cancers, and pulmonary disease. Future studies should focus on morbidity in susceptible groups, including younger cigar smokers; give attention to the type, size, and pattern of use of cigars; examine intermediate markers of morbidity and mortality; and address the temporal relationships between cigar smoking and the development of disease.

**Acknowledgment:** We thank Monica Cobis, BA, for her assistance in organizing the Cigar Smoking Health Risks: State-of-the-Science conference, held June 15-16, 1998, in Washington, DC.

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What smells so? Has somebody been burning a Rag,  
or is there a Dead Mule in the Back yard? No, the Man  
is Smoking a Five-Cent Cigar.  
—Eugene Field (1850-1895)

April 2012

# TOBACCO TAXES

## Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes



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## Why GAO Did This Study

In 2009, CHIPRA increased and equalized federal excise tax rates for cigarettes, roll-your-own tobacco, and small cigars. Though CHIPRA also increased federal excise tax rates for pipe tobacco and large cigars, it raised the pipe tobacco tax to a rate significantly below the equalized rate for the other products, and its large cigar excise tax can be significantly lower, depending on price. Treasury collects federal excise taxes on tobacco products.

Also passed in 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) granted FDA regulatory authority over tobacco products. This act directed GAO to report on trade in tobacco products, including the effects of differing tobacco tax rates. This report (1) reviews the market shifts in smoking tobacco products since CHIPRA; (2) examines the impact of the market shifts on federal revenue and Treasury's actions to respond; and (3) describes differences in FDA's regulation of various smoking tobacco products. GAO interviewed agency officials, industry members, and public health representatives. GAO analyzed tax and revenue data and reviewed relevant literature.

## What GAO Recommends

As Congress continues its oversight of CHIPRA and Tobacco Control Act implementation, it should consider equalizing tax rates on roll-your-own and pipe tobacco and, in consultation with Treasury, consider options for reducing tax avoidance due to tax differentials between small and large cigars. Treasury generally agreed with GAO's conclusions and observations.

View [GAO-12-475](#). View related [video clip](#). For more information, contact David Gootnick at (202) 512-3149 or [gootnickd@gao.gov](mailto:gootnickd@gao.gov).

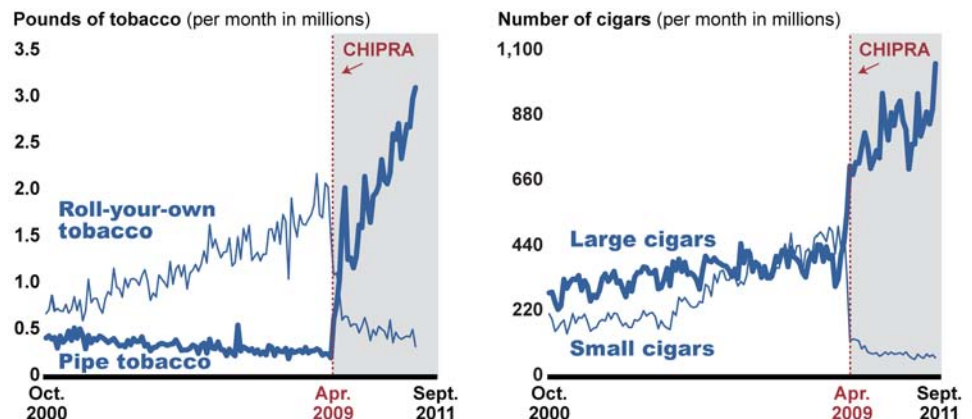
# TOBACCO TAXES

## Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes

### What GAO Found

Large federal excise tax disparities among tobacco products, which resulted from the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009, created opportunities for tax avoidance and led to significant market shifts by manufacturers and price sensitive consumers toward the lower-taxed products. Monthly sales of pipe tobacco increased from approximately 240,000 pounds in January 2009 to over 3 million pounds in September 2011, while roll-your-own tobacco dropped from about 2 million pounds to 315,000 pounds. For the same months, large cigar sales increased from 411 million to over 1 billion cigars, while small cigars dropped from about 430 million to 60 million cigars (see figure). According to government, industry, and nongovernmental organization representatives, many roll-your-own tobacco and small cigar manufacturers shifted to the lower-taxed products after CHIPRA to avoid paying higher taxes.

**FY 01-11 Monthly Sales for Roll-Your-Own and Pipe Tobacco, and for Small and Large Cigars**



Source: GAO analysis of Treasury data.

While revenue collected for all smoking tobacco products from April 2009 through fiscal year 2011 amounted to \$40 billion, GAO estimates that federal revenue losses due to market shifts from roll-your-own to pipe tobacco and from small to large cigars range from about \$615 million to \$1.1 billion for the same period. The Department of the Treasury (Treasury) has limited options to respond to these market shifts. Treasury has attempted to differentiate between roll-your-own and pipe tobacco for tax purposes but faces challenges because the definitions of the two products in the Internal Revenue Code of 1986 do not specify distinguishing physical characteristics. Treasury also has limited options to address the market shift to large cigars and faces added complexity in monitoring and enforcing tax payments due to the change in large cigar tax rates.

Unlike cigarettes and roll-your-own tobacco, pipe tobacco and cigars are not currently regulated by the Food and Drug Administration (FDA) and thus are not subject to the same restrictions on characterizing flavors, sales, or distribution. In 2011, FDA indicated its intent to issue a proposed rule that would deem products meeting the statutory definition of "tobacco product" to be subject to FDA's regulation. However, FDA had not issued the proposed rule as of March 2012. FDA officials told GAO that developing the rule was taking longer than expected.

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### Abbreviations

CHIPRA	Children's Health Insurance Program Reauthorization Act of 2009
FDA	Food and Drug Administration
IRC	Internal Revenue Code of 1986
RYO	roll-your-own tobacco
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act
Treasury	Department of the Treasury

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April 18, 2012

The Honorable Tom Harkin  
Chairman  
The Honorable Michael B. Enzi  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
United States House of Representatives

Tobacco use is the leading cause of preventable death, disease, and disability and a significant contributor to health care costs in the United States. The Centers for Disease Control and Prevention reports that smoking and exposure to secondhand smoke account for over 440,000 premature deaths per year and cost the United States an estimated \$193 billion annually in health care expenditures and productivity losses. Federal and state legislation has aimed to discourage tobacco use and raise revenues by increasing excise taxes on tobacco products. The most recent federal increase occurred in 2009 when Congress passed the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA),<sup>1</sup> which amended the Internal Revenue Code of 1986 (IRC) by raising excise tax rates on tobacco products. The Department of the Treasury (Treasury) is responsible for collecting these taxes. In addition, in order to reduce tobacco use and protect public health, in June 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act),<sup>2</sup> which granted the Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of tobacco products.

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<sup>1</sup>Pub. L. No. 111-3, 123 Stat. 8.

<sup>2</sup>Pub. L. No. 111-31, Div. A, 123 Stat. 1776.

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Title III of the Tobacco Control Act directed GAO to report on various aspects of trade in tobacco products, including the effects resulting from the differing tax rates applicable to tobacco products.<sup>3</sup> This report examines the federal revenue effects resulting from different federal excise tax rates on various smoking tobacco products and differences in FDA's regulation of these products. Specifically, we (1) review the market shifts among smoking tobacco products since CHIPRA went into effect on April 1, 2009; (2) examine the impact of these market shifts on federal revenue and Treasury's actions to respond; and (3) describe differences in FDA's regulation of various smoking tobacco products. Our review includes smoking tobacco products that are subject to federal excise tax: cigarettes and four other tobacco products—roll-your-own tobacco (sometimes called RYO), pipe tobacco, small cigars, and large cigars.<sup>4</sup> However, in analyzing the market shifts among these products, we focused solely on the four smoking tobacco products other than cigarettes.

To address the three objectives in this study, we reviewed documents and interviewed agency officials from Treasury's Alcohol and Tobacco Tax and Trade Bureau, FDA, and the Centers for Disease Control and Prevention, as well as tobacco industry members, representatives of public health and other nongovernmental organizations, and academics, to obtain information on tobacco legislation and regulations, tobacco product sales trends, and consumption patterns. We also reviewed studies analyzing the relationship between tobacco tax increases and smoking, including among youth. We analyzed Treasury removals data to identify sales trends across the different tobacco products. As used in this report, for smoking tobacco products, "removals" means the amount removed for distribution in the United States from the factory or released from customs.<sup>5</sup> In this report, we consider removals to be equivalent to sales and use the term sales. In addition, we collected and analyzed data

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<sup>3</sup>Responding to this mandate, in March 2011, we issued a first report on illicit tobacco trade and schemes. GAO, *Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees*, [GAO-11-313](#) (Washington, D.C.: Mar. 7, 2011).

<sup>4</sup>Smokeless tobacco products that are subject to federal excise taxes, such as chewing tobacco and snuff, were outside the scope of this review. "Processed tobacco" is not subject to federal excise tax and is defined in the IRC by what it is not: processed tobacco does not include the farming or growing of tobacco or the handling of tobacco solely for sale, shipment, or delivery to a manufacturer of tobacco products or processed tobacco.

<sup>5</sup>26 U.S.C. § 5702(j).

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on federal excise tax rates for these tobacco products and the revenues generated from their sale. We estimated what the effect on tax revenue collection would have been if the sales trends for roll-your-own and pipe tobacco and for small and large cigars had not been affected by substitution between the products but had been affected by the increase in price due to the tax—in other words, if the market shifts resulting from the substitution of higher-taxed products with lower-taxed products had not occurred. In this report, we refer to this estimated effect on federal tax revenue collection as revenue losses. Our analysis takes into account the expected fall in quantity demanded due to the price increases resulting from higher federal excise tax rates that CHIPRA imposed on all four of these smoking tobacco products. See appendix I for more information on our objectives, scope, and methodology.

We conducted this performance audit from March 2011 to April 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

Cigarettes continue to dominate the smoking tobacco product market, accounting for approximately 91 percent of sales in 2011. However, the use of other smoking tobacco products has increased over the past 10 years. Between 2001 and 2011, combined sales of roll-your-own tobacco, pipe tobacco, and small and large cigars grew from 3 percent of the smoking tobacco market to 9 percent. Although cigarette use in the United States is declining, it is partially offset by growing use of other smoking tobacco products. (See app. II for data on U.S. sales of smoking tobacco products from fiscal year 2001 through fiscal year 2011.)

Increasing the price of tobacco products by raising excise taxes is widely recognized as an effective policy for reducing smoking prevalence across

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socioeconomic and racial groups.<sup>6</sup> Public health and economic studies have found that adolescents are more responsive than adults to tobacco tax and price increases because they have less disposable income.<sup>7</sup> However, the impact of tax increases on reducing overall smoking prevalence is likely to be weaker if smokers can turn to tobacco products that can be used as functional equivalents of factory-made cigarettes and cost significantly less, according to public health officials and academics.

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## Tobacco Products Have Broad Definitions

Smoking tobacco products are broadly defined in the IRC.<sup>8</sup> Roll-your-own tobacco and pipe tobacco are defined by such factors as the use for which the product is suited and how they are offered for sale, as indicated by their appearance, type, packaging, and labeling. Cigars are differentiated from cigarettes by their wrapper and whether the product is, for a number of reasons, likely to be offered to, or purchased by, consumers as a cigarette. The tax rate for cigars is categorized into small and large cigars, which are differentiated by a weight threshold alone—small cigars are defined as weighing 3 pounds or less per thousand sticks.<sup>9,10</sup> The definitions found in the IRC characterize five types of

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<sup>6</sup>The World Health Organization, for example, recommends raising tobacco taxes as one of the six components of its MPOWER framework, which provides guidance to countries to implement tobacco control policies. The World Bank recommends that, to curb tobacco use, excise taxes should account for two-thirds to four-fifths of the retail price of a pack of cigarettes. In the United States, the Centers for Disease Control and Prevention, the U.S. Surgeon General, and the Institute of Medicine of the National Academy of Sciences report that tobacco excise tax increases are one of the most effective tobacco strategies for reducing tobacco use. The Centers for Disease Control and Prevention, which through its Office on Smoking and Health is the lead federal agency for tobacco control and prevention, recognizes tobacco excise tax increases as an effective population-based tobacco control and prevention intervention at the federal and state levels.

<sup>7</sup>In 1989, GAO reviewed studies available at that time; see GAO, *Teenage Smoking: Higher Excise Tax Should Significantly Reduce the Number of Smokers*, [GAO/HRD-89-119](#) (Washington, D.C.: June 30, 1989).

<sup>8</sup>26 U.S.C. § 5702.

<sup>9</sup>26 U.S.C. § 5701.

<sup>10</sup>As with small and large cigars, the IRC distinguishes between small and large cigarettes based on weight. Small cigarettes are defined as weighing 3 pounds or less per thousand sticks. When we refer to cigarettes in this report, we are discussing small cigarettes, as defined in the IRC. Treasury data show that no large cigarettes were manufactured in the United States between fiscal years 2001 and 2011.

smoking tobacco products that are relevant to our discussion, as shown in table 1.<sup>11</sup>

**Table 1: Definitions of Smoking Tobacco Products in the IRC**

Product	Definition
Cigarette	(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco or (2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in (1).
Roll-Your-Own tobacco	Any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes or cigars, or for use as wrappers thereof.
Pipe tobacco	Any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco to be smoked in a pipe.
Small cigar	Any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette) that weighs 3 pounds or less per thousand.
Large cigar	Any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette) that weighs more than 3 pounds per thousand.

Source: 26 U.S.C. §§ 5701, 5702.

Figure 1 shows a sample of different cigarette and cigar products. Several of the products closely resemble each other in size and shape. The three on the left are cigarettes. The first is a roll-your-own cigarette<sup>12</sup> made by hand with roll-your-own tobacco. The second is a roll-your-own cigarette made in a commercial roll-your-own machine<sup>13</sup> with pipe tobacco. And the third from the left is a factory-made cigarette. The three products on the right are cigars, which can vary widely in size, shape, flavor, and aroma. According to industry representatives, a nongovernmental organization, and government officials, traditionally, cigars are hand-rolled, wrapped in a tobacco leaf, large in size, and their smoke is not meant to be inhaled. However, they indicated that many small and large cigars now have filters, are wrapped in a type of paper made with tobacco, and can be similar in size and appearance to cigarettes.

<sup>11</sup>The IRC also provides definitions for smokeless tobacco products, which are not listed here.

<sup>12</sup>In this report, we define roll-your-own cigarettes as cigarettes made by consumers with loose tobacco, such as roll-your-own tobacco or pipe tobacco.

<sup>13</sup>Commercial roll-your-own machines are located in some stores that sell tobacco products. These machines allow customers to make a carton of cigarettes in less than 10 minutes. They are discussed in more detail in the next section of the report.

**Figure 1: Examples of Cigarette and Cigar Products**



Source: GAO.

## Federal Excise Taxes on Tobacco Products Most Recently Increased by CHIPRA

While the enactment of CHIPRA in 2009 represents the most recent increase in federal excise taxes on tobacco products, Congress has taxed tobacco products since its inception as a means to raise revenue.<sup>14</sup> Of the smoking tobacco products that we discuss in this report, Congress taxed only cigarettes, small cigars, and large cigars prior to 1989. Congress began taxing pipe tobacco on January 1, 1989,<sup>15</sup> and roll-your-own tobacco on January 1, 2000.<sup>16</sup> As the danger of tobacco became better known, congressional debates surrounding tobacco taxes expanded from increasing revenue to protecting the public from health risks of tobacco.

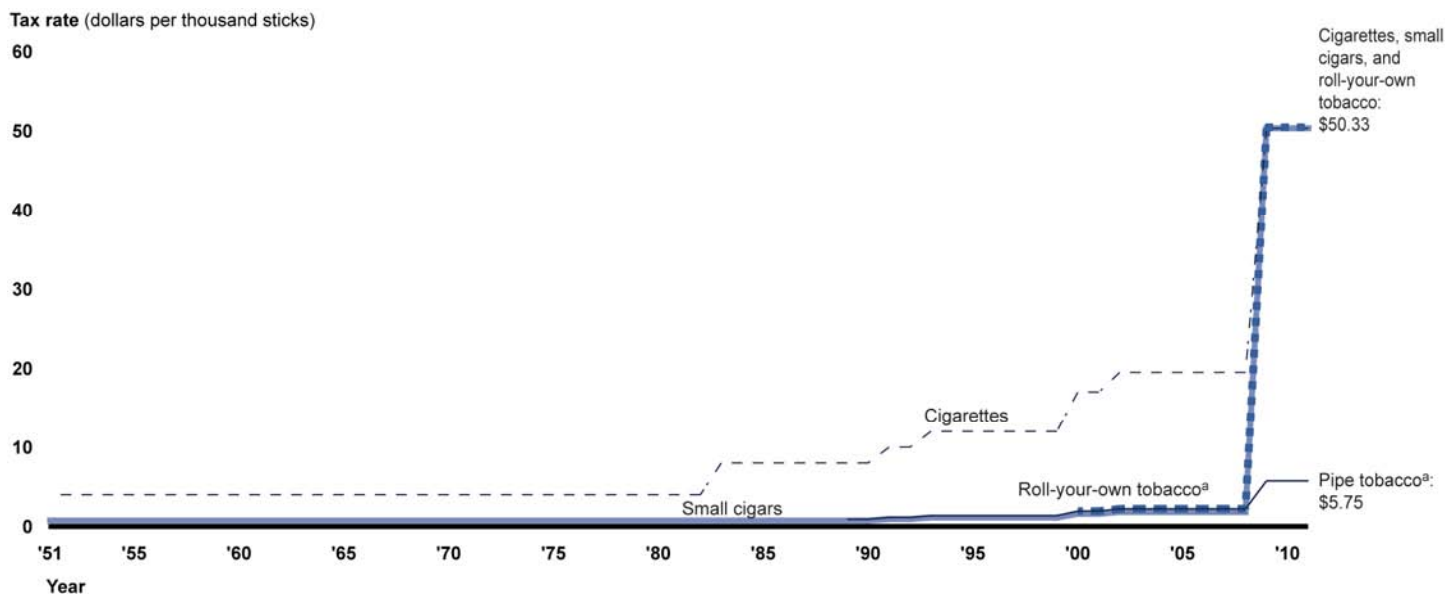
<sup>14</sup>Act of August 10, 1790, ch. 39, §§ 1-2, 1 Stat. 24 (1789).

<sup>15</sup>Technical and Miscellaneous Revenue Act of 1988, Pub. L. No. 100-647, § 5061(d), 102 Stat. 3342, 3679. This tax became effective after December 31, 1988.

<sup>16</sup>Balanced Budget Act of 1997, Pub. L. No. 105-33, § 9302(g), 111 Stat. 251, 672. This tax became effective after December 31, 1999.

Figure 2 shows the tax rates for four smoking tobacco products from 1951 to 2010.

**Figure 2: Tax Rates for Cigarettes, Roll-Your-Own Tobacco, Pipe Tobacco, and Small Cigars, 1951-2010**



Source: GAO analysis of the IRC.

Note: Large cigar tax rates are not included in this figure because they are taxed at an ad valorem rate—a percentage of the manufacturer’s or importer’s sale price—up to a maximum tax per thousand sticks, rather than a rate based on units or weight.

<sup>a</sup>Roll-your-own and pipe tobacco taxes are shown at an equivalent tax per stick rate based on the Master Settlement Agreement conversion rate for roll-your-own tobacco of 0.0325 ounces per stick. We are applying this conversion rate to pipe tobacco for the purpose of comparison because Treasury has not yet differentiated the physical characteristics of roll-your-own and pipe tobacco.

The federal excise tax rates on different tobacco products are calculated in different ways. Cigarettes and small cigars are taxed on a unit basis—number of sticks. Roll-your-own and pipe tobacco are taxed by weight. Table 2 provides information on the different federal excise tax rates for cigarettes, roll-your-own tobacco, pipe tobacco, and small cigars before and after CHIPRA.



**Table 2: Federal Excise Tax Rates for Cigarettes, Roll-Your-Own Tobacco, Pipe Tobacco, and Small Cigars, Before and After CHIPRA**

<b>Tobacco products</b>	<b>Unit of taxation</b>	<b>Before CHIPRA</b>	<b>After CHIPRA</b>	<b>Percentage increase</b>
Cigarettes <sup>a</sup>	thousand sticks	\$19.50	\$50.33	158%
Roll-Your-Own tobacco	pounds	\$1.10	\$24.78	2,159%
Pipe tobacco	pounds	\$1.10	\$2.83	158%
Small cigars	thousand sticks	\$1.83	\$50.33	2,653%

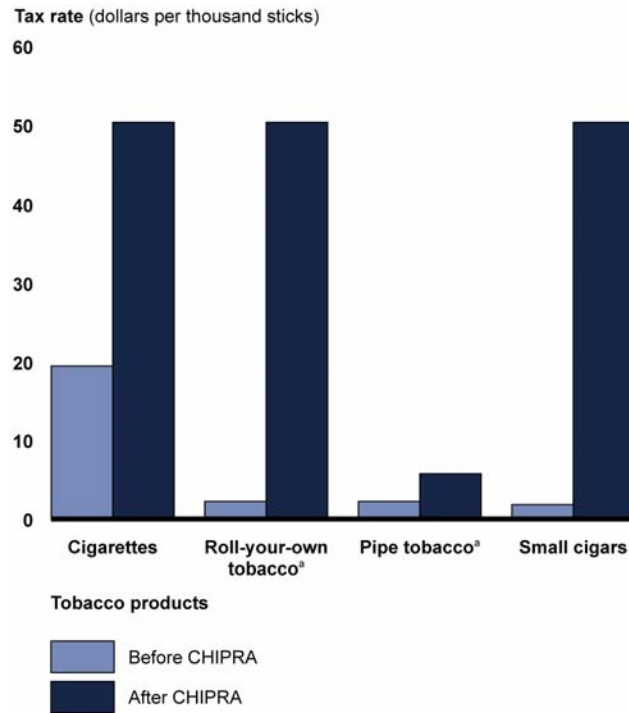
Source: GAO analysis of the IRC.

Note: Although we rounded the tax rates to the nearest cent for this table, we used the exact tax rate in our calculations.

<sup>a</sup>The federal excise tax rate for large cigarettes up to 6.5 inches long was \$40.95 per thousand sticks prior to CHIPRA and became \$105.69 per thousand sticks after CHIPRA. Large cigarettes over 6.5 inches long are taxed at the rate for small cigarettes, counting each 2.75 inches or fraction thereof of the length of each as one cigarette.

Before CHIPRA, the federal excise tax rate on cigarettes was higher than the rates on roll-your-own tobacco, pipe tobacco, and small cigars. However, CHIPRA significantly raised the tax rates on these four products and equalized the rates on cigarettes, roll-your-own tobacco, and small cigars (see fig. 3). Congress equalized the tax rates on roll-your-own tobacco and small cigars with the cigarette tax rate in part in response to concerns that smokers had been using these two products as substitutes for higher-taxed factory-made cigarettes, according to nongovernmental organizations. CHIPRA also raised the federal excise tax rate on pipe tobacco, but to a rate that is considerably lower. Prior to CHIPRA, the tax rate on roll-your-own tobacco and pipe tobacco was the same.

**Figure 3: Changes in Federal Excise Tax Rates as a Result of CHIPRA—for Cigarettes, Roll-Your-Own Tobacco, Pipe Tobacco, and Small Cigars**



Source: GAO analysis of the IRC.

<sup>a</sup>The roll-your-own tobacco and pipe tobacco cigarette stick equivalent is based on the weight of 0.0325 ounces of tobacco per cigarette stick using the Master Settlement Agreement conversion rate.

CHIPRA significantly changed the federal excise tax rate on large cigars. Large cigars are unique among tobacco products in that the tax rate is ad valorem—a percentage of the manufacturer’s or importer’s sale price per thousand sticks—up to a maximum tax per thousand sticks. Before CHIPRA, large cigars were taxed at 20.72 percent of the manufacturer’s or importer’s sale price up to a maximum tax of \$48.75 per thousand sticks. After CHIPRA, the ad valorem rate increased to 52.75 percent of the manufacturer’s or importer’s sale price, and the maximum tax per thousand sticks increased to \$402.60 (see table 3). According to an industry association, the retail prices of premium handmade large cigars range from \$3 to \$20. A public health organization noted that smaller factory-made cigars that meet the legal definition of a large cigar can cost as little as \$0.07 per cigar.

**Table 3: Federal Excise Tax Rates for Large Cigars, Before and After CHIPRA**

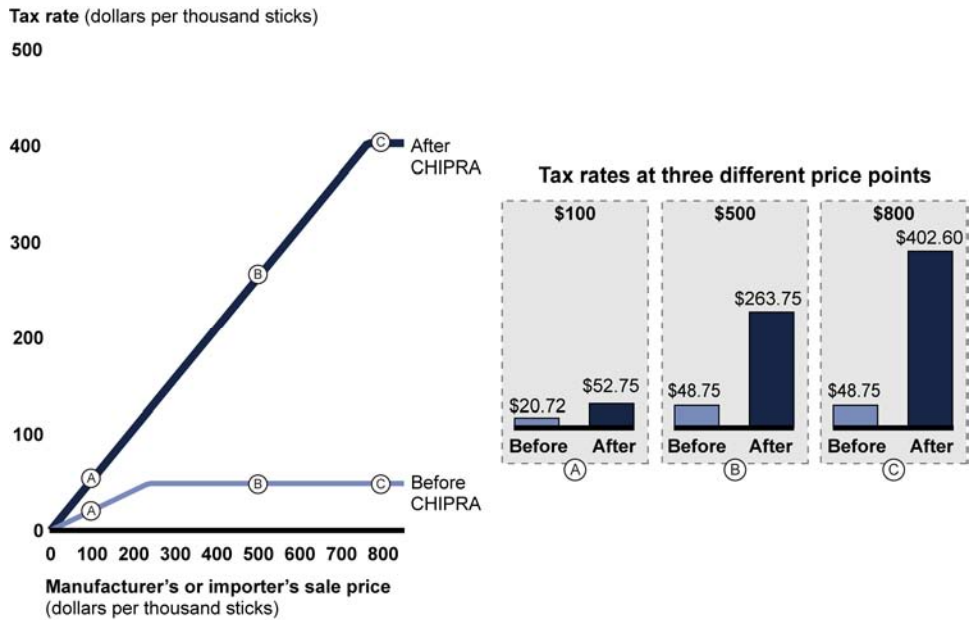
<b>Tobacco product</b>	<b>Unit of taxation</b>	<b>Before CHIPRA</b>	<b>After CHIPRA</b>	<b>Percentage increase</b>
Large cigars	Ad valorem rate based on manufacturer's or importer's sale price up to a maximum tax rate	20.72%	52.75%	155%
	Maximum tax per thousand sticks	\$48.75	\$402.60	726%

Source: GAO analysis of the IRC.

Figure 4 illustrates the tax structure for large cigars, before and after CHIPRA and includes three different scenarios. The sloped line represents the ad valorem rate, which becomes flat when it reaches the maximum tax per thousand cigars. The following are examples of the federal excise taxes manufacturers and importers would have to pay for differently priced large cigars, before and after CHIPRA (see examples corresponding with fig. 4):

- A. If the manufacturer's or importer's sale price per thousand large cigars is \$100, before CHIPRA the ad valorem tax rate was \$20.72 per thousand; after CHIPRA it became \$52.75 per thousand.
- B. If the manufacturer's or importer's sale price per thousand large cigars is \$500, before CHIPRA the tax rate was the maximum tax of \$48.75 per thousand; after CHIPRA it became \$263.75 per thousand based on the new ad valorem tax rate.
- C. If the manufacturer's or importer's sale price per thousand large cigars is \$800, before CHIPRA the tax rate was the maximum tax of \$48.75 per thousand; after CHIPRA it became \$402.60, which is the new maximum tax rate per thousand.

**Figure 4: Changes in Federal Excise Tax Rates as a Result of CHIPRA—for Large Cigars under Three Different Scenarios**



Source: GAO analysis of the IRC.

Note: The sloped lines represent the ad valorem rates for large cigars before and after CHIPRA, with the lines becoming flat when they reach the maximum rates of \$48.75 (before CHIPRA) and \$402.60 (after CHIPRA).

Treasury is responsible for administering and collecting the federal excise tax on all tobacco products, among other things.<sup>17</sup> In general, federal excise taxes are collected when tobacco products leave the domestic factory or, in the case of imports, when the products are released from

<sup>17</sup>Treasury's Alcohol and Tobacco Tax and Trade Bureau administers Chapter 52 of the IRC (26 U.S.C. Chapter 52) pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. § 531(d). The Secretary of the Treasury has delegated various authorities through Treasury Department Order 120-01 (Revised), dated January 21, 2003, to Treasury's Alcohol and Tobacco Tax and Trade Bureau Administrator to perform the functions and duties in the administration and enforcement of this law. Treasury conducts audits and investigations to enforce civil and criminal laws relating to tobacco tax collection, sometimes referring criminal cases to the U.S. Attorney's Office for prosecution. It also operates a tobacco laboratory, which conducts analyses to evaluate products for tax compliance and to support appropriate tax classification of different tobacco products.

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customs custody.<sup>18</sup> Tobacco manufacturers and importers are required to obtain a Treasury permit to operate and must comply with Treasury's recordkeeping, reporting, and other requirements.<sup>19</sup> Tobacco product wholesalers and distributors are responsible for paying state and local excise taxes, but they are not required to obtain a Treasury permit and are not subject to Treasury recordkeeping requirements. Figure 5 shows the major steps in the tobacco supply chain, including the key points at which taxes are paid.

**Figure 5: Payment of Federal, State, and Local Excise Taxes in the Supply Chain for U.S. Tobacco Products**



Source: GAO.

Note: Supply chains can differ by manufacturer/importer, and this figure does not represent all of the steps in the distribution process.

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<sup>18</sup>While Treasury collects federal excise taxes from domestic manufacturers, the U.S. Customs and Border Protection within the Department of Homeland Security collects federal excise taxes on imported tobacco products. Where tobacco products are imported for distribution in the U.S. market and first deposited into a customs warehouse or foreign trade zone, the federal excise taxes become due when they are removed from the first warehouse, even when they are removed for transfer to another warehouse (26 U.S.C. § 5703).

<sup>19</sup>CHIPRA also extended Treasury's permit requirement and related recordkeeping and reporting requirements to manufacturers and importers of processed tobacco. Treasury's temporary regulatory definitions provide that the processing of tobacco includes, but is not limited to, stemming, fermenting, threshing, cutting, or flavoring the tobacco, or otherwise combining the tobacco with nontobacco ingredients. This definition is in effect until June 22, 2012.

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## Tobacco Control Act Gave FDA Broad Authority to Regulate Tobacco Products to Protect Public Health

In the Tobacco Control Act passed in June 2009, Congress amended the Food, Drug, and Cosmetic Act by inserting a chapter governing tobacco products and granting FDA authority to regulate the manufacture, distribution, and marketing of tobacco products under that chapter.<sup>20</sup> The act aims to, among other things, reduce the use of tobacco products to decrease health risks and social costs associated with tobacco-related diseases. It recognizes that virtually all new users of tobacco products are adolescents under the age of 18. According to the law, FDA's regulation of tobacco products is based, in part, on a public health standard rather than the safety and effectiveness standard by which FDA regulates pharmaceutical drugs and medical devices. For example, FDA can issue restrictions on the sale, distribution, advertising, and promotion of a tobacco product, if the public health standard is met. This standard requires FDA to demonstrate that the proposed regulation is appropriate for the protection of public health, based on a consideration of the risks and benefits to the population as a whole, including users and nonusers of tobacco products.

The act specifies that FDA's authority over tobacco products under Chapter IX of the Food, Drug, and Cosmetic Act shall apply to cigarettes, roll-your-own tobacco, cigarette tobacco, and smokeless tobacco, as well as any other tobacco products that the agency deems by regulation to be subject to such authority.<sup>21</sup> FDA does not at present regulate pipe tobacco and small and large cigars. To implement the Tobacco Control Act, FDA has established the Center for Tobacco Products.

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<sup>20</sup>Pub. L. No. 111-31. The Tobacco Control Act amended Chapter IX of the Food, Drug, and Cosmetic Act, the main federal law that governs FDA's work. Chapter IX provides the primary authority for FDA's regulation of tobacco products.

<sup>21</sup>Pub. L. No. 111-31, § 101. The act defines cigarette tobacco as any product that consists of loose tobacco that is intended for use by consumers in a cigarette and smokeless tobacco as any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

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## Large Tax Disparities among Similar Tobacco Products Triggered Significant Market Shifts to Avoid Higher Taxes

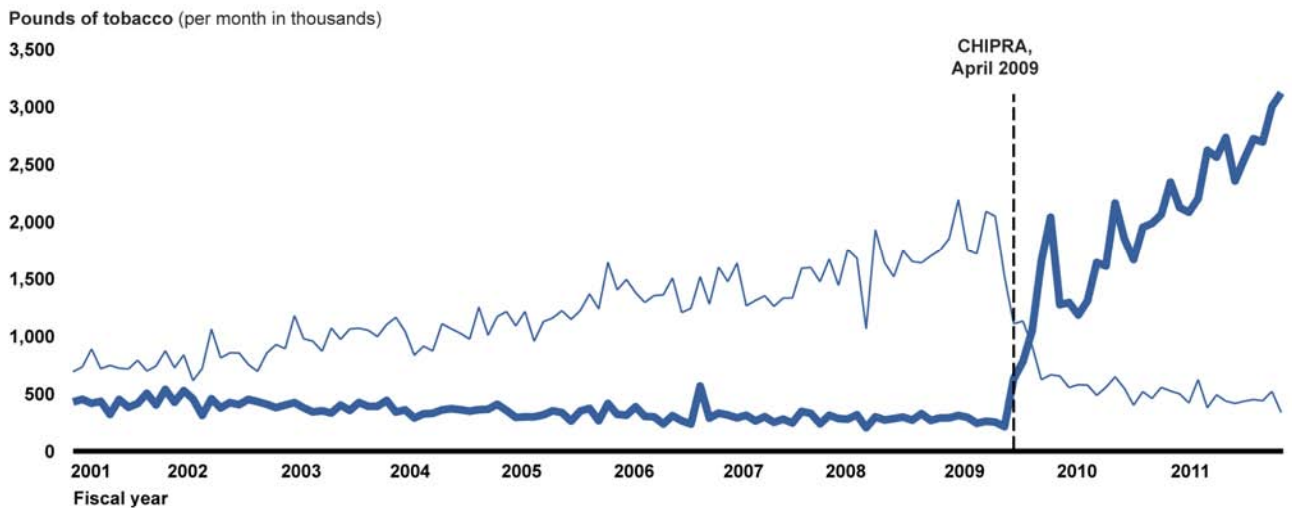
Large federal excise tax disparities among tobacco products resulting from CHIPRA caused sizable market shifts from higher to lower-taxed products. According to our analysis and interviews with knowledgeable sources, the tax disparities created incentives for price sensitive manufacturers and consumers to substitute higher-taxed products with lower-taxed products. The market for roll-your-own tobacco shifted to pipe tobacco and the growth rate of the combined market increased after CHIPRA. Roll-your-own tobacco manufacturers shifted to pipe tobacco with minimal, if any, changes to the products, and consumers substituted pipe tobacco for use in roll-your-own cigarettes. At the same time, the cigar market shifted from small to large cigars, and the combined cigar market continued to grow after CHIPRA.

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## Market Shifted from Roll-Your-Own Tobacco to Pipe Tobacco after CHIPRA

Market trends for roll-your-own and pipe tobacco changed immediately after CHIPRA, with sales of pipe tobacco rising steeply while sales of roll-your-own tobacco plummeted. According to government officials and representatives of industry and nongovernmental organizations, manufacturers and consumers switched to lower-taxed pipe tobacco to make roll-your-own cigarettes. After CHIPRA, the federal excise tax on roll-your-own tobacco was over \$20 per pound more than the tax on pipe tobacco, whereas before CHIPRA, the taxes on both products were the same. Figure 6 shows the market shift through monthly sales of roll-your-own and pipe tobacco from fiscal year 2001 through fiscal year 2011. Total annual sales of pipe tobacco grew from approximately 3.2 million pounds in fiscal year 2008, the last year before CHIPRA, to 30.5 million pounds in fiscal year 2011, representing an increase of about 869 percent. Over the same period, total annual sales of roll-your-own tobacco declined from approximately 19.7 million pounds to 5.2 million pounds, a decrease of about 74 percent. According to the representatives of industry and nongovernmental organizations we interviewed, the shift can be mostly attributed to consumers switching from using roll-your-own tobacco to pipe tobacco in roll-your-own cigarettes, rather than to a sudden increase in pipe smoking.

**Figure 6: Monthly and Annual U.S. Sales of Roll-Your-Own and Pipe Tobacco, Fiscal Years 2001-2011**



**Pounds of tobacco (per fiscal year in thousands)**

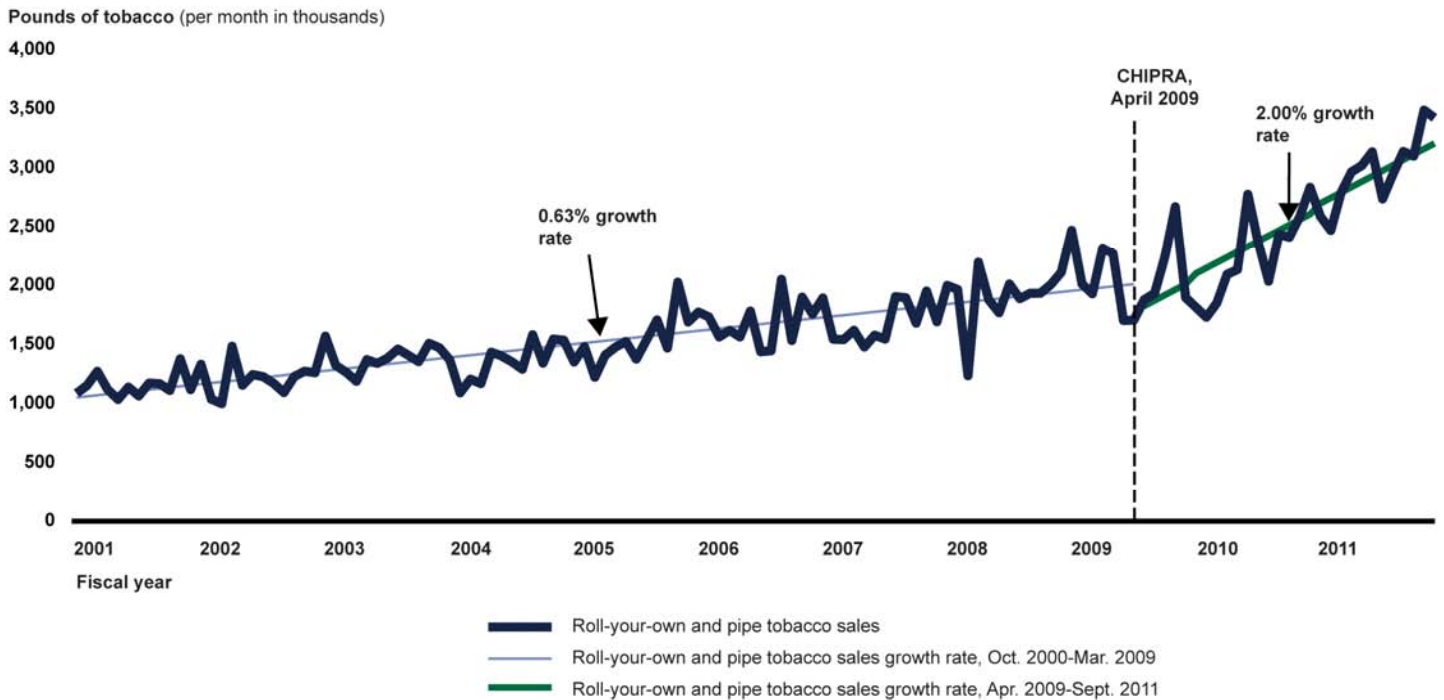
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Roll-your-own tobacco	8,793	9,626	12,221	12,230	14,536	16,451	17,010	19,673	16,167	6,152	5,195
Pipe tobacco	4,921	4,779	4,323	3,987	3,637	3,605	3,208	3,150	8,758	20,817	30,518

Source: GAO analysis of Treasury data.

CHIPRA's increase in the federal excise tax for roll-your-own tobacco did not dampen the overall sales of roll-your-own and pipe tobacco. Instead, the combined sales of roll-your-own and pipe tobacco increased because of the rapid growth in pipe tobacco sales following CHIPRA. Before CHIPRA, from October 2000 through March 2009, the combined average monthly growth rate was 0.63 percent; after CHIPRA, the combined average monthly growth rate increased to 2.00 percent. See Figure 7 for the trends in combined sales of roll-your-own and pipe tobacco from fiscal year 2001 through fiscal year 2011.



**Figure 7: Combined U.S. Sales of Roll-Your-Own and Pipe Tobacco, Fiscal Years 2001-2011**



Source: GAO analysis of Treasury data.

### Manufacturers Switched from Roll-Your-Own to Pipe Tobacco, and Consumers Began to Use Commercial Roll-Your-Own Machines

According to government officials, representatives of nongovernmental organizations, and industry, after CHIPRA many manufacturers of roll-your-own tobacco switched to producing pipe tobacco in order to avoid higher taxes. According to these representatives and government officials, the new pipe tobacco products have minimal, if any, differences from roll-your-own tobacco. Roll-your-own tobacco and pipe tobacco are defined in the IRC by such factors as the use for which the product is suited and how they are offered for sale, as indicated by their appearance, type, packaging, and labeling. To meet the definition of pipe tobacco in the IRC and Treasury's regulations,<sup>22</sup> a product must be clearly labeled as pipe tobacco and not indicate other uses. The definitions of tobacco products in the IRC do not specify physical characteristics that

<sup>22</sup>In June 2009, Treasury revised regulations on packaging and labeling roll-your-own and pipe tobacco to more clearly differentiate the two products. See table 4 for more information.

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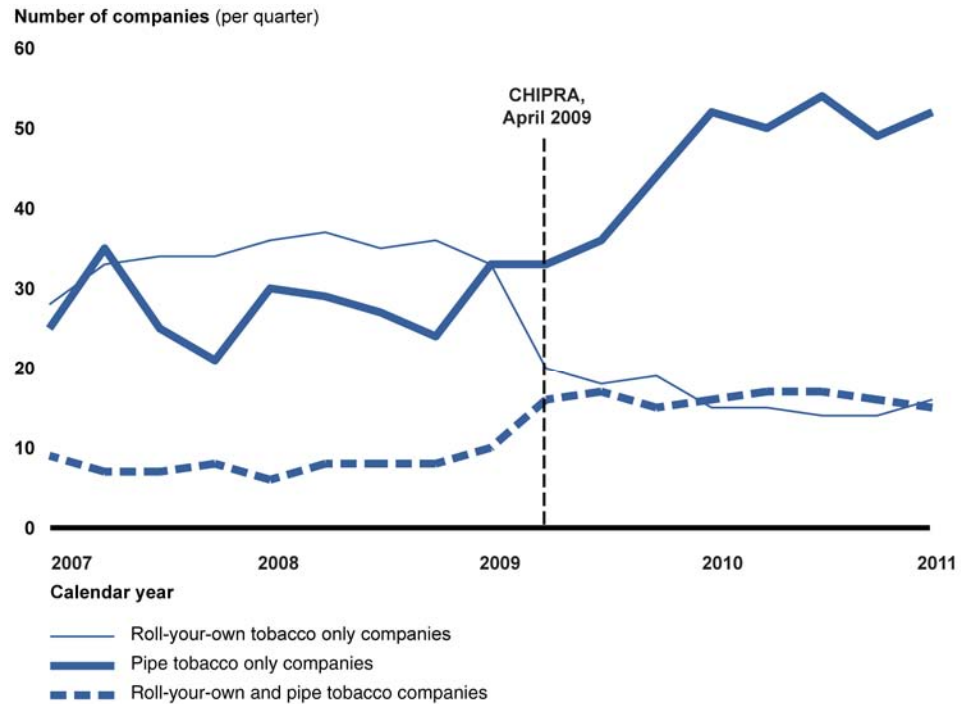
would differentiate pipe tobacco from roll-your-own tobacco.

Representatives of industry and nongovernmental organizations provided examples of current pipe tobacco brands that had been roll-your-own brands prior to CHIPRA, with minimal differences in the packaging and the appearance of the tobacco itself. We also found examples of Internet retailers signaling to customers in their marketing that pipe tobacco was suitable for smoking in roll-your-own cigarettes. One manufacturer of pipe tobacco had designed its label with three-letter markings, to indicate to customers the product's similarity to brand-name cigarettes. For example, the marking MRD indicated Marlboro Red and CML indicated Camel Light.

We approached 15 pipe tobacco manufacturers to ask about their companies' actions in response to the CHIPRA tax changes. Each of the three tobacco manufacturers that agreed to speak with us explained that their companies switched from selling higher-taxed roll-your-own tobacco to lower-taxed pipe tobacco in order to stay competitive. One company changed the cut of its roll-your-own tobacco and labeled it as pipe tobacco, although a company representative acknowledged that there was no real difference between its pipe-cut tobacco and its roll-your-own tobacco. A representative from another company that switched from selling roll-your-own tobacco to selling pipe tobacco stated that she was not aware of any difference in the two products other than the federal excise tax rate.

Data show that the total number of companies exclusively manufacturing pipe tobacco increased significantly since CHIPRA, while the number of companies exclusively manufacturing roll-your-own tobacco decreased sharply. Treasury emphasized that it is unclear whether these manufacturers modified their roll-your-own tobacco beyond reclassifying it as pipe tobacco. Data also show the number of companies producing both roll-your-own and pipe tobacco has slowly increased since 2007 (see fig. 8).

**Figure 8: Number of Companies Producing Roll-Your-Own Tobacco, Pipe Tobacco, or Both, 2007-2011**



Source: GAO analysis of U.S. Department of Agriculture data.

The rise in pipe tobacco sales coincided with the growing availability of commercial roll-your-own machines. Treasury officials stated that there has recently been significant growth in commercial roll-your-own machines. These machines enable customers to produce a carton of cigarettes using pipe tobacco and cigarette-paper tubes with filters. By using pipe tobacco instead of roll-your-own tobacco, customers are able to save almost \$9 per carton in federal excise taxes.<sup>23</sup> A common commercial roll-your-own machine can produce a carton of cigarettes in less than 10 minutes, providing a significant time saving compared with making roll-your-own cigarettes by hand.

<sup>23</sup>Treasury officials also stated that processed tobacco, which is not subject to federal excise tax, is being used in these machines to make roll-your-own cigarettes.

During our visit to a tobacco outlet store in Maryland, we used a commercial roll-your-own machine to make a carton of 200 cigarettes using pipe tobacco in about 8 minutes. We made a video showing this machine being used to make cigarettes (See [http://www.gao.gov/multimedia/video#video\\_id=589493](http://www.gao.gov/multimedia/video#video_id=589493)). The carton we made in Maryland cost about \$25, which included state and federal excise taxes. The total price of \$25 for our carton was about half the price of a carton of discount cigarettes in nearby stores that sold tobacco<sup>24</sup> (see fig. 9).

**Figure 9: Examples of Maryland Retail Prices for Cartons of Various Types of Cigarettes**

Types of cigarettes	Per carton retail price (including federal and state excise taxes) <sup>a</sup>
Premium cigarettes	\$69.50
Discount cigarettes	51.50
Roll-your-own cigarettes made with pipe tobacco <sup>b</sup>	24.95

Source: GAO.

<sup>a</sup>The retail price does not include sales tax.

<sup>b</sup>These roll-your-own cigarettes were made in a commercial roll-your-own machine.

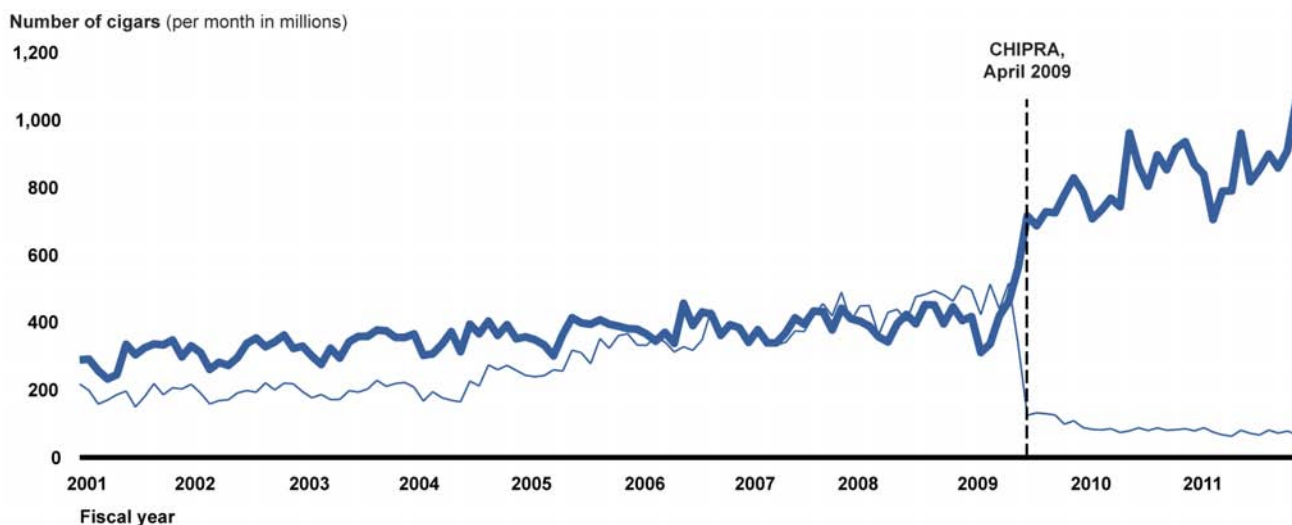
## Cigar Market Shifted from Small to Large Cigars after CHIPRA

CHIPRA's 2009 changes in federal excise tax rates on tobacco products also resulted in an immediate shift in the cigar market, with sales of lower-taxed large cigars rising sharply while sales of higher-taxed small cigars dropped. Figure 10 shows the market shift through monthly sales of small and large cigars from fiscal year 2001 through fiscal year 2011. Total annual sales of large cigars increased from approximately 4.8 billion sticks in fiscal year 2008 to about 10.3 billion sticks in fiscal year 2011, representing an increase of about 116 percent. For the same period, the total annual sales of small cigars declined from 5.3 billion sticks to 0.8

<sup>24</sup>This is not nationally representative because states have varying tobacco tax rates. According to the Campaign for Tobacco-Free Kids, state cigarette taxes vary from \$0.17 to \$4.35 per pack, and pipe tax rates vary from a tax per ounce to a percent of manufacturer's or wholesale price. Maryland's cigarette tax is \$2.00 per pack, and pipe tobacco tax is 15 percent of the wholesale price. The price shown for the roll-your-own cigarettes made in a commercial roll-your-own machine with pipe tobacco includes a \$10 fee charged by the store for the use of the machine.

billion sticks, a decrease of 85 percent. According to government officials and representatives of nongovernmental organizations, because weight is the only characteristic that distinguishes small cigars from large cigars, many cigar manufacturers made their small cigars slightly heavier to qualify for the large cigar tax rate and avoid higher taxes levied on small cigars after CHIPRA. Figure 10 shows an increase in large cigar sales in the months immediately prior to the tax change. Treasury officials stated that although they have not specifically investigated the cause of this increase, there was an incentive for retailers and wholesalers to purchase and stockpile large cigars after the date CHIPRA was signed into law (February 4, 2009) and before the tax increase went into effect (April 1, 2009). In addition, these officials noted that a floor stocks tax is typically imposed to prevent stockpiling just before a tax increase, but the floor stocks tax imposed by CHIPRA did not apply to large cigars.

**Figure 10: Monthly and Annual U.S. Sales of Small and Large Cigars, Fiscal Years 2001-2011**



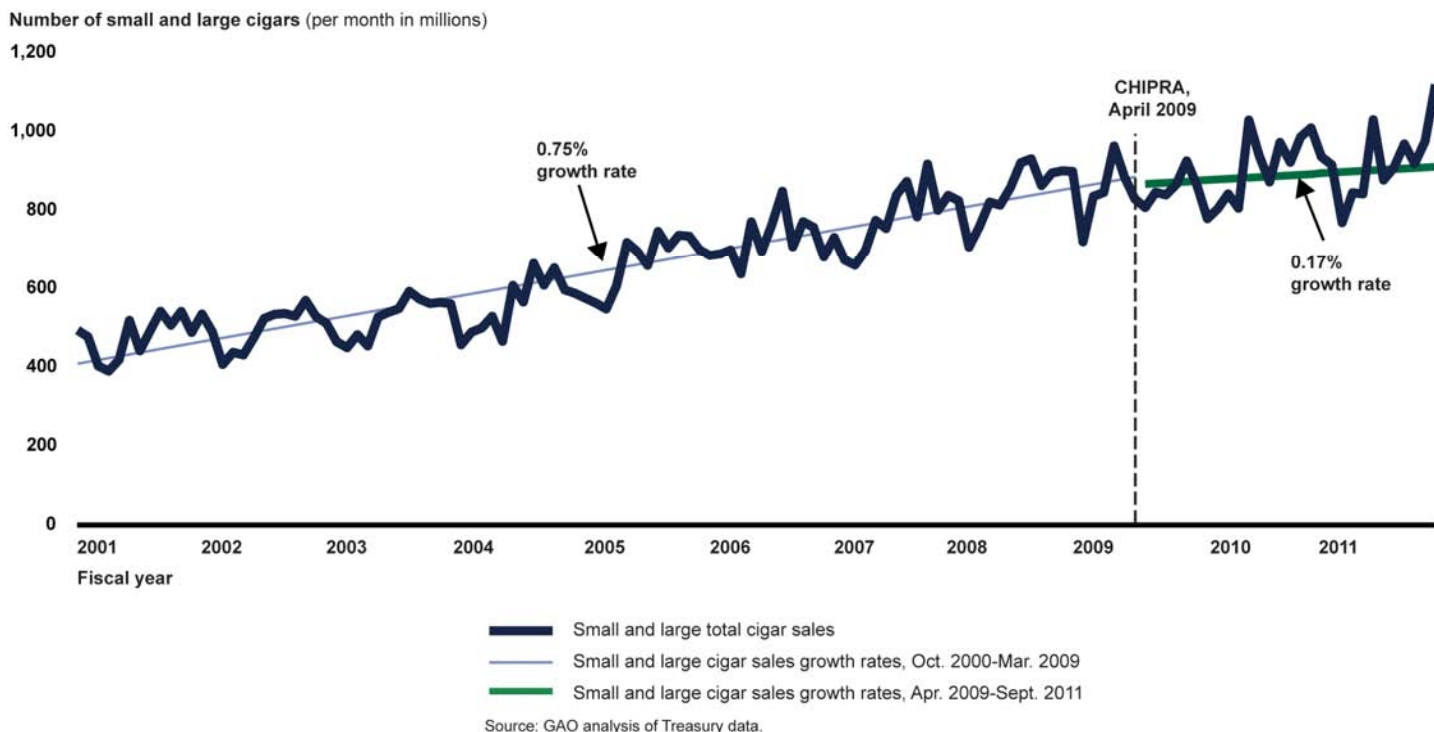
**Pounds of tobacco** (per fiscal year in thousands)

Large cigars	3,498	3,704	3,949	4,169	4,385	4,541	4,573	4,759	6,877	9,882	10,266
Small cigars	2,179	2,256	2,284	2,490	3,453	4,147	4,576	5,337	3,351	908	804

Source: GAO analysis of Treasury data.

The combined sales for small and large cigars continued to increase after CHIPRA, though at a slightly lower rate. Before CHIPRA, from October 2001 through March 2009, the combined average monthly growth rate was 0.75 percent, compared with a 0.17 percent growth rate from April 2009 through September 2011. See figure 11 for trends in overall cigar sales from fiscal year 2001 through fiscal year 2011.

**Figure 11: Combined U.S. Sales of Small and Large Cigars, Fiscal Years 2001-2011**



## Market Shifts to Avoid Taxes Have Reduced Federal Revenue, and Treasury Has Limited Options to Respond

While tax revenue collected for all smoking tobacco products from April 2009 through the end of fiscal year 2011 amounted to \$40 billion, we estimate that the market shifts from roll-your-own to pipe tobacco and from small to large cigars reduced federal revenue by a range of approximately \$615 million to \$1.1 billion for the same period. We estimated what the effect on tax revenue collection would have been if the sales trends for roll-your-own and pipe tobacco and for small and large cigars had not been affected by substitution between the products but had been affected by the increase in price due to the tax—in other words, if the market shifts resulting from the substitution of higher-taxed

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products with lower-taxed products had not occurred. In this report, we refer to this estimated effect on federal tax revenue collection as revenue losses. Although Treasury has taken steps to respond to these market shifts, it has limited options. For example, Treasury has pursued differentiating between roll-your-own and pipe tobacco for tax collection purposes but faces challenges because the definitions of the two products in the IRC do not specify distinguishing physical characteristics. Furthermore, Treasury also has limited options to address the market shift to large cigars.

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**Estimated Federal Revenue Losses from Market Shifts after CHIPRA Range from \$615 Million to \$1.1 Billion**

We estimated that federal revenue losses due to the market shifts from roll-your-own to pipe tobacco and from small to large cigars range from \$615 million to \$1.1 billion. This range includes combined tax revenue losses for the roll-your-own and pipe tobacco markets, as well as the small and large cigar markets. We conducted analyses of data from Treasury and the Bureau of Labor Statistics to estimate tax revenue losses in these markets.<sup>25,26</sup> Our methodology takes into account the expected fall in demand for a product following a price increase, holding other variables constant. To calculate the range of federal revenue losses, we included high and low estimates based on assumptions about the effect of a price increase on projected sales.<sup>27</sup> Economic studies show that, when the price of a product increases, the quantity demanded for the product will adjust downward, decreasing at an estimated rate based on the quantity demanded for the product, that is, price elasticity.<sup>28</sup> Based on our interviews with government officials and academics and our literature review, we determined that the price elasticity for the smoking tobacco

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<sup>25</sup>In the absence of this market shift due to differential tax rates, more tax revenue would have been collected because roll-your-own tobacco and small cigars had historically much higher levels of sales than pipe tobacco and large cigars, and after CHIPRA these tobacco products also had a much higher tax rate.

<sup>26</sup>Cigarettes are taxed at the same rate as roll-your-own tobacco and small cigars, but the analysis does not take into account the likely impact of a similar market shift from cigarettes to pipe tobacco and large cigars. See appendix II for information on sales of cigarettes and other smoking tobacco products.

<sup>27</sup>Using a somewhat similar approach, Treasury estimated that in 2010, over \$400 million in revenue was lost due to the shift from roll-your-own to pipe tobacco. Treasury's estimate did not take into account the expected decline in demand following a price increase.

<sup>28</sup>For example, a price elasticity of demand of -0.6 means that when prices go up by 10 percent, demand will decrease by 6 percent.

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Tax Revenue Losses in the Roll-Your-Own and Pipe Tobacco Markets

products ranges from -0.6 to -0.3 for the low and high revenue estimates, respectively. Our projections also take into account the historic sales trends for these products and the tax component of the price.<sup>29</sup> Appendix I contains more information on our methodology for developing these estimates.

Treasury collected \$573 million in tax revenue from roll-your-own and pipe tobacco from April 2009 through September 2011.<sup>30</sup> We estimate that during the same period the market shift from roll-your-own to pipe tobacco reduced federal revenues by between \$255 million and \$492 million (see fig. 12).

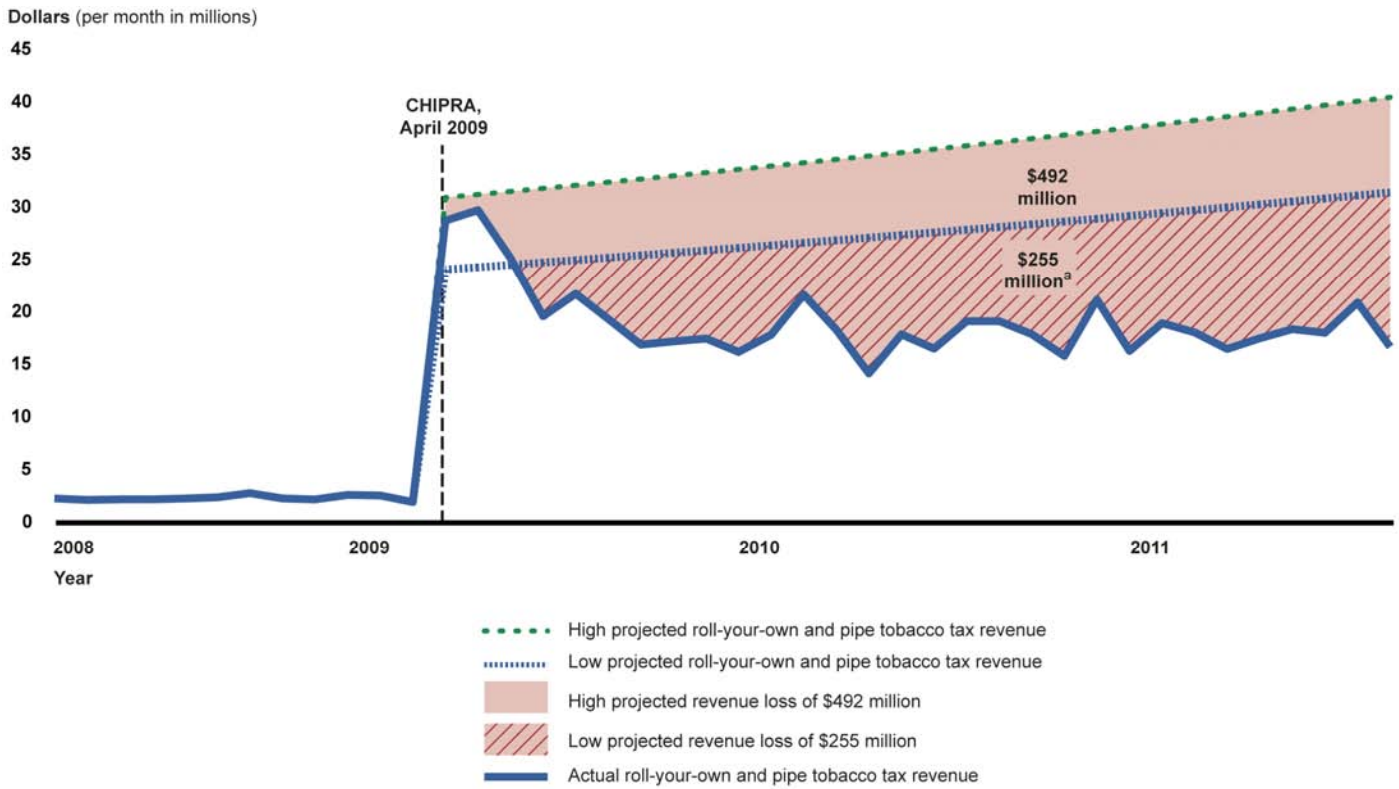
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<sup>29</sup>For a detailed explanation of this methodology, see Frank Chaloupka and Jidong Huang, "A Significant Cigarette Tax Rate Increase in Illinois Would Produce a Large, Sustained Increase in State Tobacco Tax Revenues" (Chicago, IL: University of Illinois at Chicago, Jan. 3, 2011, working paper).

<sup>30</sup>That is about \$228 million per year after CHIPRA compared with \$25.5 million for fiscal year 2008.



**Figure 12: Estimated Revenue Losses for Roll-Your-Own and Pipe Tobacco**



Sources: GAO analysis of Treasury and Bureau of Labor Statistics data.

<sup>a</sup>Low projected revenue loss is calculated as the difference between the projected revenue in the low scenario and the actual collected revenue. When the actual revenue is higher than the low projected revenue, the estimated figure of \$255 million includes the difference.

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Tax Revenue Losses in the  
Small and Large Cigar Markets

Treasury collected \$1.7 billion in tax revenue from small and large cigars from April 2009 through fiscal year 2011.<sup>31</sup> We estimate that during that same period the market shift from small to large cigars reduced federal revenue by between \$360 million to \$559 million (see fig. 13).<sup>32,33</sup>

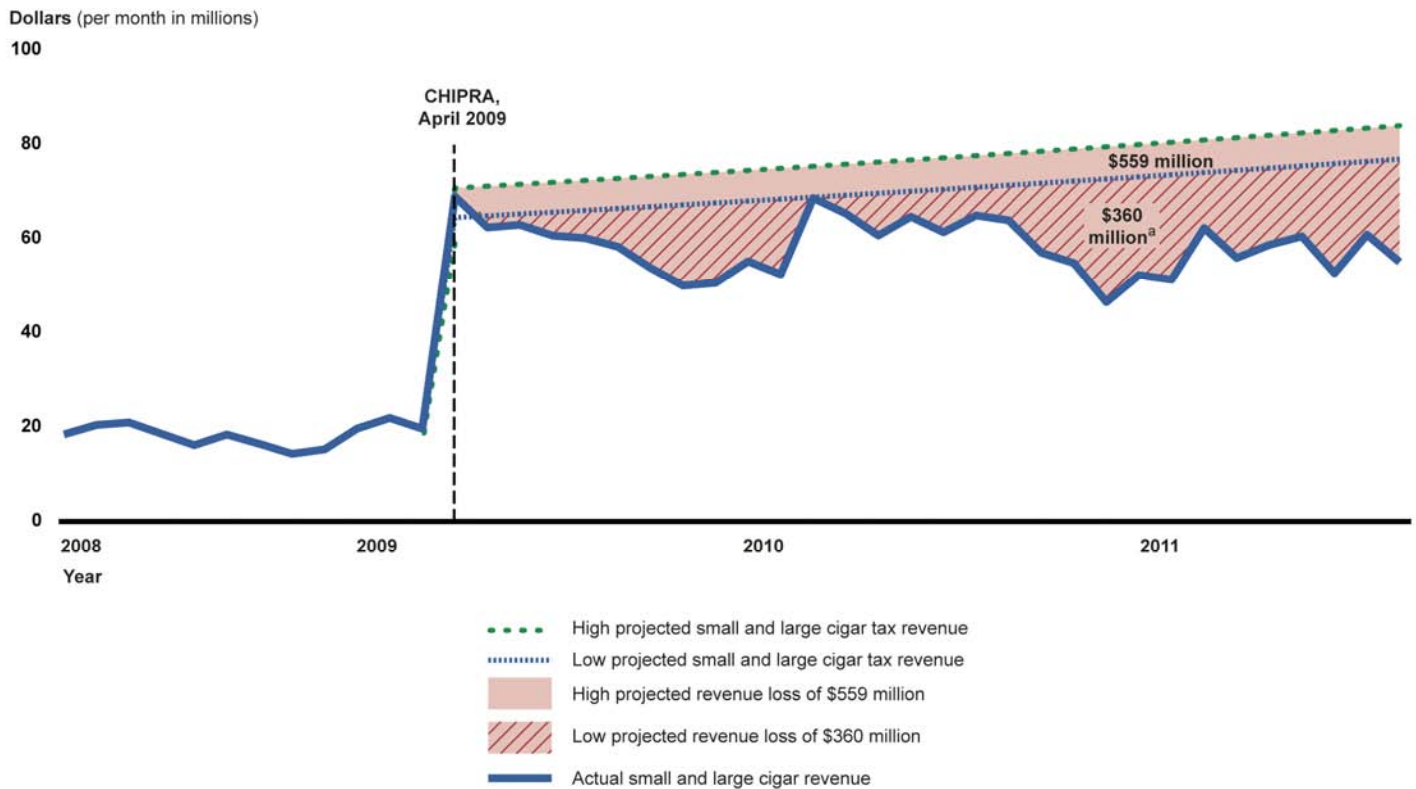
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<sup>31</sup>That is about \$680 million per year after CHIPRA compared with \$217.5 million for fiscal year 2008.

<sup>32</sup>Treasury estimates that \$723 million in revenue was lost due to the shift from small to large cigars over the 2 years after CHIPRA was enacted. Treasury did not include the price elasticity of demand in their estimate.

<sup>33</sup>As with the roll-your-own and pipe tobacco estimates, the low and high scenarios are calculated using the price elasticity of demand of -0.6 and -0.3, respectively. Because cigar taxes are based on price, our estimate included price data. Small cigar revenues were calculated by multiplying the number of unit sales in each month by the tax rate. Large cigar revenues were calculated by subtracting small cigar revenue from cigar revenue. Once the large cigar revenue was calculated, the average tax paid was estimated by dividing the large cigar revenue by the number of large cigar units. From March 2007 through March 2009, this average was 4.3 cents per stick.

**Figure 13: Estimated Revenue Losses for Small and Large Cigars**



Sources: GAO analysis of Treasury and Bureau of Labor Statistics data.

<sup>a</sup>Low projected revenue loss is calculated as the difference between the projected revenue in the low scenario and the actual collected revenue. When the actual revenue is higher than the low projected revenue, the estimated figure of \$360 million includes the difference.

### Developing Standards to Differentiate between Roll-Your-Own and Pipe Tobacco Presents Challenges to Treasury

Differentiating between roll-your-own and pipe tobacco for tax collection purposes presents challenges to Treasury because the definitions of the two products in the IRC are based on such factors as the use for which they are suited and how they are packaged and labeled for consumers and do not specify distinguishing physical characteristics. Treasury officials and representatives of nongovernmental organizations we spoke with stated that because the two products were taxed at the same rate prior to CHIPRA, there was no revenue-related reason to clarify the differences between the two products beyond the existing statutory definitions. However, according to Treasury comments in the *Federal Register*, the large differences in tax rates resulting from CHIPRA created

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#### IRC Definitions

**Roll-your-own tobacco**—Any tobacco, which because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes or cigars, or for use as wrappers thereof.

**Pipe tobacco**—Any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco to be smoked in a pipe.

an incentive for industry members to present roll-your-own tobacco as pipe tobacco products, thus enabling them to pay a lower tax rate.<sup>34</sup>

After the CHIPRA tax changes and the market shift from roll-your-own to pipe tobacco that immediately followed, Treasury took steps through rulemaking notices in an effort to more clearly differentiate the two products for tax collection purposes. However, Treasury has not yet issued a final rule to distinguish the two products based on physical characteristics. The tobacco industry members' comments on the June 2009 temporary rule and the July 2010 advance notice of proposed rulemaking highlighted the complexity and difficulties in developing objective standards that clearly differentiate the two tobacco products. Treasury also issued a ruling determining that retail establishments that make cigarette-making machines available for use by customers are manufacturers of tobacco products.<sup>35</sup> However, a U.S. District Court enjoined Treasury's enforcement of the ruling pending the outcome of a court case on this ruling, which was still pending as of March 2012. Table 4 summarizes Treasury's actions on roll-your-own and pipe tobacco following CHIPRA, the resulting tobacco industry comments, and the status of Treasury's actions.

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<sup>34</sup>74 Fed. Reg. 29,401 (June 22, 2009).

<sup>35</sup>Treasury refers to the machines as cigarette-making machines rather than roll-your-own machines. Treasury's position is that the retailers who make these machines available for use are manufacturers of cigarettes.

**Table 4: Treasury Actions on Roll-Your-Own and Pipe Tobacco following CHIPRA, Industry Comments, and Status**

Date	Treasury action	Tobacco industry comments <sup>d</sup>	Status
June 2009	<b>Temporary rule.</b> <sup>a</sup> Treasury revised regulations on packaging and labeling of roll-your-own and pipe tobacco to more clearly differentiate the two products. The temporary rule is set to expire in June 2012.	<ul style="list-style-type: none"> <li>New requirements are insufficient to prevent misclassification of roll-your-own tobacco as pipe tobacco.</li> <li>Alternative standards based on physical characteristics are suggested.</li> </ul>	<ul style="list-style-type: none"> <li>Market continued to shift from roll-your-own to pipe tobacco.</li> </ul>
July 2010	<b>Advance notice of proposed rulemaking.</b> <sup>b</sup> Treasury requested public comments on proposed standards to differentiate between roll-your-own and pipe tobacco based upon physical characteristics. Treasury reopened the notice requesting comments in August 2011. <sup>c</sup>	<ul style="list-style-type: none"> <li>Significant differences in views on proposed standards are expressed.</li> </ul>	<ul style="list-style-type: none"> <li>Treasury has not issued a subsequent rulemaking establishing standards to differentiate roll-your-own and pipe tobacco.</li> <li>Market shift from roll-your-own to pipe tobacco continued.</li> </ul>
September 2010	<b>Ruling on cigarette-making machines.</b> Treasury determined that the owner of a retail establishment who facilitates the making of cigarettes by or for others by providing the use of commercial cigarette-making machines for use on the premises is engaged in the business of a tobacco product manufacturer and must obtain a Treasury permit to engage in such business.	<ul style="list-style-type: none"> <li>A manufacturer of these machines sued Treasury, and a U.S. District Court enjoined Treasury's enforcement of the rule pending the outcome of the case.</li> <li>Use of cigarette-making machines in retail establishments is growing.</li> </ul>	<ul style="list-style-type: none"> <li>A manufacturer of these machines sued Treasury, and a U.S. District Court enjoined Treasury's enforcement of the rule pending the outcome of the case.</li> <li>Use of cigarette-making machines in retail establishments is growing.</li> </ul>

Source: GAO analysis of Treasury information.

<sup>a</sup>74 Fed. Reg. 29,401 (June 22, 2009).

<sup>b</sup>75 Fed. Reg. 42,659 (July 22, 2010).

<sup>c</sup>76 Fed. Reg. 52,913 (Aug. 24, 2011).

<sup>d</sup>Treasury received comments from a range of tobacco companies and associations, and the comments cited in this table do not reflect industry consensus. Rather, they are intended to summarize key comments made by companies or associations.

- *Temporary rule<sup>36</sup> on packaging and labeling requirements:* Following the CHIPRA tax changes that took effect in April 2009, Treasury

<sup>36</sup>A temporary rule is issued without an advance notice of proposed rulemaking, but in the publication of the rule the agency may request comments and state that it may modify the rule in response to the comments.

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published a temporary rule in June 2009, set to expire in June 2012, that outlined new labeling and packaging requirements for roll-your-own and pipe tobacco to more clearly differentiate the two products. The temporary rule required that, to be classified as pipe tobacco, the packaging must clearly indicate the product type by bearing the words “pipe tobacco” wherever the brand name appears, and that the packaging cannot suggest a use other than as pipe tobacco. Treasury also stated in the temporary rule that it was evaluating analytical methods and other standards to differentiate between roll-your-own tobacco and pipe tobacco, and it expected to publish rulemaking proposals on this subject for comment in the future. In response to this temporary rule, Treasury received comments from tobacco industry members indicating that its new labeling and packaging requirements were insufficient to prevent the misclassification of roll-your-own tobacco as pipe tobacco and that standards to further differentiate the products were urgently needed. Treasury received comments from industry members proposing alternative standards to distinguish between roll-your-own and pipe tobacco based on physical characteristics such as moisture content, cut, and variety of tobacco used. The market shift from roll-your-own to pipe tobacco continued despite Treasury’s issuance of this temporary rule.

- *Advance notice of proposed rulemaking<sup>37</sup> on standards to differentiate roll-your-own and pipe tobacco:* In July 2010, Treasury published an advance notice of proposed rulemaking issuing a request for public comments on standards and characteristics proposed by commenters to differentiate between roll-your-own and pipe tobacco, but it has not issued a subsequent rule proposing the standards it would use. In the notice, Treasury discussed the heightened need for more regulatory detail to clarify the difference between the two products and stated its primary concern that the standards be objective and enforceable. The industry members’ comments to Treasury highlighted the complexity and difficulties in developing objective standards that clearly differentiate the two tobacco products. Industry members disagreed on the standards and physical characteristics that should be implemented, with some commenters noting that the two products overlap greatly. Some industry commenters also expressed concerns that proposed standards could easily be manipulated by consumers.

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<sup>37</sup>An advance notice of proposed rulemaking can announce and explain agencies’ plans to solve problems and accomplish goals and give interested persons an opportunity to submit comments to improve the final regulation.

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For example, a proposed standard for the cut width of pipe tobacco could be compromised by a consumer using basic kitchen or hardware appliances to grind wider cut tobacco into a smaller width for use in cigarettes.

In August 2011, Treasury issued a second advance notice of proposed rulemaking, thereby reopening the period for receiving comments on the proposed standards. Treasury said it did so because it had received an additional set of proposed standards after the original comment period closed. Treasury received a number of additional comments, many by the same companies that commented on the earlier notices, and the comments continued to reflect significant differences within the industry on standards that define and distinguish roll-your-own tobacco from pipe tobacco. This second comment period closed in October 2011. As of March 2012, Treasury has not issued a subsequent rulemaking based on the comments received, and no anticipated issuance date has been communicated. Throughout this period, the market shift from roll-your-own to pipe tobacco has continued, with negative impacts on federal revenue. Appendix III contains a more detailed summary of the *Federal Register* notices issued by Treasury related to differentiating between roll-your-own and pipe tobacco and the industry comments in response to these notices.

- *Ruling on commercial cigarette-making machines:* Treasury also issued a ruling in September 2010 determining that retailers who make commercial cigarette-making machines available for use on their premises are tobacco product manufacturers and are thus subject to the permit and tax requirements of the IRC. In October 2010, RYO Machine Rental LLC, the maker of the RYO Filling Stations, sued Treasury over this ruling. In December 2010, a federal district court judge in Ohio ordered a preliminary injunction on the enforcement of the Treasury rule, and the case is currently on appeal in the U.S. Court of Appeals for the Sixth Circuit. During the period that enforcement has been delayed, several organizations told us that businesses continue to maintain these machines on their premises, and the number of machines in use has increased. These machines, which cost the retailer about \$30,000 each, have also been the focus of government regulation at the state level. A number of states are taking action against commercial roll-your-own machines, including Arkansas, Michigan, New Hampshire, and West Virginia. For

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example, Arkansas passed a law prohibiting tobacco retailers licensed, permitted, appointed, or commissioned under Arkansas tobacco tax law from possessing or using the machines.<sup>38</sup>

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### CHIPRA's Changes to Tax Rates on Large Cigars Also Present Challenges to Treasury

CHIPRA's changes to the federal excise tax rate on large cigars also present challenges to Treasury. The first challenge resulted from CHIPRA's tax rate on the most inexpensive large cigars, which was significantly lower than its rate for small cigars. This disparity in tax rates provided an incentive for some small cigar manufacturers to make minimal changes to their product to meet the legal definition of a large cigar. The second challenge came about because CHIPRA's rate for large cigar taxes resulted in more large cigar manufacturers and importers paying taxes based on the manufacturer's or importer's sale price rather than simply paying the maximum set tax rate. This added complexity to Treasury's monitoring and enforcement of large cigar tax payments and appears to have motivated some manufacturers and importers of large cigars to restructure their market transactions to lower the taxes they have to pay.

The first challenge resulted from CHIPRA's changes to the federal excise tax rate on large cigars, which created an incentive for small cigar manufacturers to switch to making large cigars when the manufacturer's or importer's sale price is less than \$95.42 per thousand cigars. Before CHIPRA, there was little incentive for small cigar manufacturers to alter their product to meet the definition of a large cigar. Because small cigars are taxed at a fixed rate, and large cigars are taxed at an ad valorem rate, when CHIPRA raised the small cigar tax from \$1.83 per thousand to \$50.33 per thousand, manufacturers of inexpensive small cigars had an incentive to change their product to fit the lower-taxed large cigar category. According to Treasury officials and other industry experts, prior to CHIPRA, many small cigars weighed close to 3 pounds per thousand sticks, which is the dividing line between small and large cigars set by the IRC.<sup>39</sup> Small cigars that weighed just under or exactly 3 pounds per thousand sticks would be able to qualify as large cigars with minimal changes. After CHIPRA, the same companies could use the same machines to add a small amount of weight to their product, turning small

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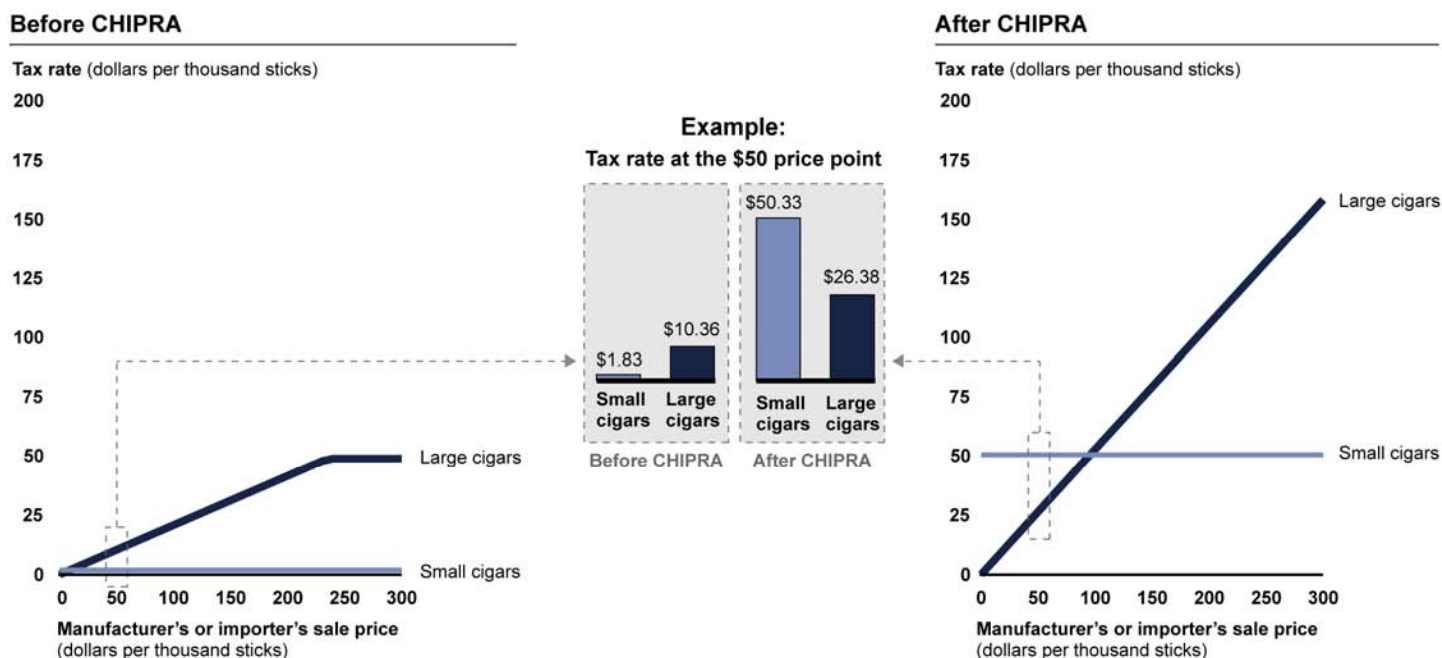
<sup>38</sup>Ark. Code Ann. § 26-57-263.

<sup>39</sup>The IRC does not distinguish small and large cigars by any characteristic other than weight.



cigars into a product legally defined and taxed as large cigars. For example, manufacturers could add weight by packing the tobacco more tightly. Some manufacturers then changed their labels from “small cigars” to “filtered cigars” or “cigars”—often with the same packaging and design. For example, if a manufacturer sold cigars for \$50 per thousand before CHIPRA, by manufacturing small cigars instead of large cigars, it would pay \$1.83 per thousand in taxes, a tax savings of \$8.53 per thousand. After CHIPRA, the same manufacturer selling cigars for \$50 per thousand would pay \$26.38 per thousand in taxes, a tax savings of \$23.95 per thousand, by manufacturing large cigars instead of small cigars (see fig. 14). Treasury officials stated that the agency lacks the authority to remedy the tax revenue losses resulting from manufacturers’ legitimate modifications of small cigars to qualify them for the lower tax rate on large cigars.

**Figure 14: Post-CHIPRA Incentives for Some Manufacturers to Switch from Small to Large Cigars**



Source: GAO analysis of the IRC.

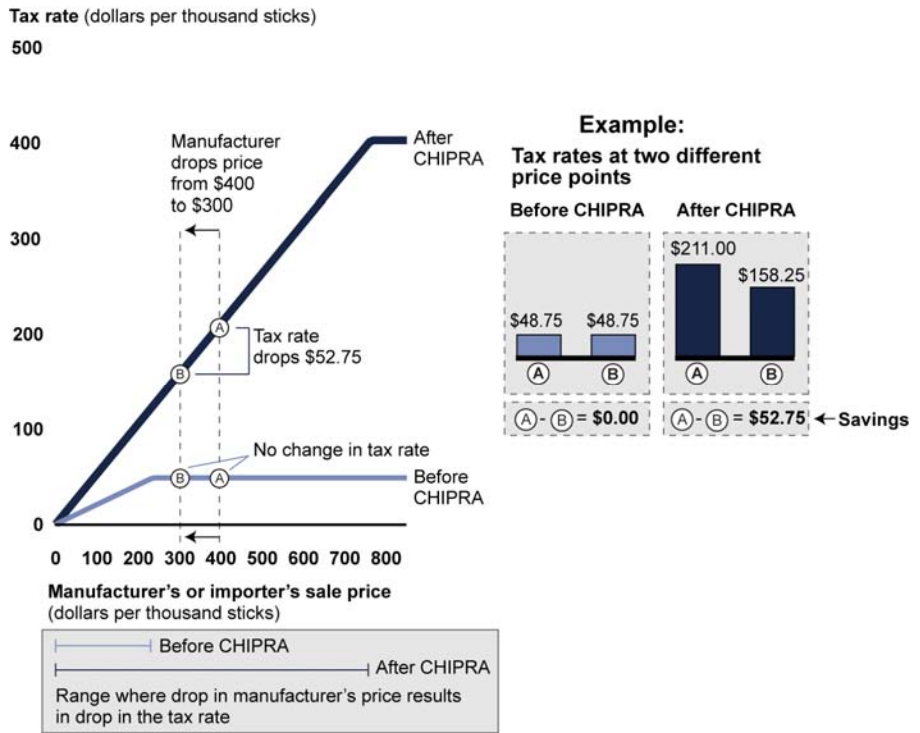
Note: The large cigar tax structure before CHIPRA is represented on the left side of the figure, with the sloped line showing the ad valorem rate and the line becoming flat upon reaching the maximum rate of \$48.75 per thousand large cigars. For space reasons, the right side of the figure does not include the maximum rate of \$402.60 per thousand large cigars.

The second challenge resulting from CHIPRA's changes to tax rates on large cigars is the complexity that has been added to Treasury's efforts to

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monitor and enforce tax payments because many more manufacturers and importers must now determine the correct tax by applying the tax rate to the manufacturer's or importer's sale price per stick (ad valorem) rather than simply paying the maximum set tax rate. According to Treasury officials, prior to CHIPRA, the majority of domestic manufacturers of large cigars paid the federal excise tax at the maximum rate of \$48.75 per thousand cigars. Specifically, manufacturers or importers that sold large cigars priced at \$235.30 per thousand and above paid the set maximum tax. The increase in the large cigar maximum tax after CHIPRA resulted in many more manufacturers and importers of large cigars paying taxes based on the ad valorem rate, according to Treasury officials. Currently, the maximum tax rate does not apply until the manufacturer's or importer's price is \$763.22 per thousand or above, and then, the maximum rate is \$402.60 per thousand. For example, if a manufacturer sold large cigars for \$400 per thousand, before CHIPRA, it would pay \$48.75—based on the maximum tax. After CHIPRA, the manufacturer's tax would increase to \$211 per thousand—based on the ad valorem rate. If the manufacturer is able to lower its price for the large cigar product from \$400 to \$300 per thousand, its tax would decrease to \$158.25 per thousand, a tax savings of \$52.75 per thousand. Before CHIPRA, if the manufacturer had lowered its price from \$400 to \$300, its tax rate would have remained at the maximum rate of \$48.75 (see fig. 15).

**Figure 15: Post-CHIPRA Incentives for Some Manufacturers and Importers to Lower the Sale Price of Large Cigars**



Source: GAO analysis of the IRC.

Note: The sloped lines represent the ad valorem rates for large cigars before and after CHIPRA, with the lines becoming flat when they reach the maximum rates of \$48.75 (before CHIPRA) and \$402.60 (after CHIPRA) per thousand large cigars.

After CHIPRA, according to Treasury officials, some large cigar manufacturers and importers began to restructure their market transactions to lower the manufacturer's or importer's sale price for large cigars in order to obtain the tax savings of a lower ad valorem rate, creating enforcement challenges. These Treasury officials stated that some manufacturers and importers are "structuring" or "layering" sales transactions by including an additional transaction at a low price before the sale to the wholesaler or distributor, and using this low initial price to calculate the tax. This transaction is conducted with an intermediary that may have a special contract arrangement with the manufacturer or importer. A large markup may then be added to the intermediary's subsequent sale to the wholesaler or distributor. This added transaction effectively lowers the manufacturer's or importer's sale price, and thus reduces the taxes collected. According to Treasury officials, these layered

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transactions have become more common after CHIPRA. Treasury officials noted that manufacturers and importers of large cigars have approached the agency for advice on different proposals to structure their sales transactions to lower their taxes and still comply with the law. They also stated that Treasury has not determined the legality of all of the proposals under consideration, and that while Treasury can investigate individual cases, its authority to enforce additional tax collection from these kinds of large cigar transactions is limited. Officials stated that Treasury is carefully examining the tobacco importer and manufacturer pricing arrangements and taking corrective actions where appropriate on a case by case basis.

The impact of the federal excise tax increases and the resulting actions by industry to mitigate the CHIPRA tax increase on large cigars are evidenced by large cigar pricing trends. Prior to CHIPRA, the average manufacturer's or importer's sale price for large cigars was \$244 per thousand, Treasury officials stated. After the CHIPRA tax increases, the average manufacturer's or importer's sale price dropped to \$189 per thousand. According to Treasury officials, since large cigar federal excise taxes increased by a minimum of 155 percent, and the federal excise tax is included in the sale price, large cigar manufacturer's and importer's sale prices were expected to increase, not decrease.

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## FDA Currently Regulates Cigarettes and Roll-Your-Own Tobacco but Not Pipe Tobacco and Cigars

When the Tobacco Control Act amended the Food, Drug, and Cosmetic Act in June 2009, it granted FDA immediate regulatory authority over four tobacco products, including cigarettes and roll-your-own tobacco, but did not specify authority over pipe tobacco and small and large cigars.<sup>40</sup>

According to the law, FDA has the authority to deem by regulation any other tobacco products, including pipe tobacco and small and large cigars, to be subject to the tobacco provisions in Chapter IX of the Food, Drug, and Cosmetic Act.<sup>41</sup> Deeming additional products to be subject to these tobacco provisions of the Food, Drug, and Cosmetic Act requires FDA to go through the process of developing and issuing a regulation (known as the rulemaking process).

Because FDA does not currently regulate pipe tobacco and small and large cigars, these products are not subject to the tobacco product provisions in Chapter IX of the Food, Drug, and Cosmetic Act or regulations that FDA has issued since June 2009 to implement the Tobacco Control Act. Some of act's provisions and key FDA regulations address, for example, (1) the use of characterizing flavors, (2) the sale and distribution of tobacco products, and (3) the requirements for new health warnings depicting negative health consequences of smoking:

- *Ban on the use of characterizing flavors:* FDA implemented a ban on cigarettes with characterizing flavors in September 2009 (with the

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<sup>40</sup>The Food, Drug, and Cosmetic Act and the IRC each maintain their own definitions of tobacco products, including the smoking tobacco products discussed in this report. The laws and implementing regulations of the Food, Drug, and Cosmetic Act utilize the definitions found at 21 U.S.C. § 387. The laws and implementing regulations of the IRC utilize the definitions found at 26 U.S.C. § 5702. These statutes have slightly different definitions for cigarettes and roll-your-own tobacco. The IRC's definition of a cigar is slightly different from the Food, Drug, and Cosmetic Act's definition of a little cigar. In addition, while the IRC defines pipe tobacco, the Food, Drug, and Cosmetic Act does not.

<sup>41</sup>Pub. L. No. 111-31, § 101(b). The law states that “[t]obacco products ... shall be regulated by the Secretary [of Health and Human Services] under this chapter ...” and that “[t]his chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.”

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exception of tobacco or menthol).<sup>42</sup> However, pipe tobacco and small and large cigars—some of which look similar to cigarettes (see fig. 1)—are available in multiple flavors because this Tobacco Control Act provision does not apply to these products. Smokers can make roll-your-own cigarettes with flavored pipe tobacco and buy cigars in candy, berry, fruit, or other flavors. According to the U.S. Surgeon General, the growing popularity of cigars among younger adults (those under the age of 30) appears to be linked to the marketing of flavored tobacco products, including cigars, that might be expected to be attractive to youth.<sup>43</sup>

- *Restrictions on the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.*<sup>44</sup> Pipe tobacco and small and large cigars are not subject to FDA’s rule containing numerous youth access and marketing restrictions that was issued in March 2010.<sup>45</sup> One restriction generally prohibits the sale and distribution of individual cigarettes or packs containing fewer than 20 cigarettes.<sup>46</sup> In contrast, cigars can be sold individually, and filtered cigars are often sold in packs containing fewer than 20. A second restriction generally

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<sup>42</sup>21 U.S.C. § 387g. The law states that “a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an 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.” On April 4, 2012, the World Trade Organization (WTO) Appellate Body issued a report finding that this restriction is inconsistent with the United States’ WTO obligations. Unless the Dispute Settlement Body rejects the report by consensus, the United States has 30 days from the time the report is adopted to state its intention regarding the implementation of the recommendations of the Appellate Body.

<sup>43</sup>U.S. Department of Health and Human Services, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* (Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012).

<sup>44</sup>75 Fed. Reg. 13,225 (Mar. 19, 2010) (codified in 21 C.F.R. pt. 1140). These restrictions apply to roll-your-own tobacco, and the rule stipulates that the definition of a cigarette “[i]ncludes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.”

<sup>45</sup>21 C.F.R. pt. 1140.

<sup>46</sup>21 C.F.R. § 1140.14.

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requires that retail sales of cigarettes and smokeless tobacco be conducted in a direct, face-to-face exchange.<sup>47</sup> This restriction does not apply to pipe tobacco and cigars, and these products are sold on the Internet. A third restriction bans brand-name sponsorship of sporting and cultural events by manufacturers, distributors, or retailers of cigarettes and smokeless tobacco<sup>48</sup> and does not currently apply to pipe tobacco and cigars. A cigar company recently signed a multiyear sponsorship deal for a major collegiate sporting event, but the deal was canceled due to public pressure, as has been reported in the press.<sup>49</sup>

- *Requirements for new health warnings depicting negative health consequences of smoking:* Pipe tobacco and cigar packs are not subject to FDA's rule that requires each cigarette pack and advertisement to bear one of nine new textual warning statements accompanied by color graphics, issued in June 2011.<sup>50</sup> According to the law, the new warnings must cover the top half of the front and back of cigarette packs and at least 20 percent of cigarette advertisements and must contain color graphics depicting the negative health consequences of smoking.<sup>51</sup> FDA selected nine color

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<sup>47</sup>21 C.F.R. § 1140.14. An exception is made for vending machines and self-service displays that are located in facilities where no person under the age of 18 is present, or permitted to enter, at any time.

<sup>48</sup>21 C.F.R. § 1140.34. The regulation does not ban a manufacturer, distributor, or retailer from sponsoring sporting and cultural events in the name of the corporation that manufactures the tobacco product, provided that, among other things, the corporate name does not include any brand name used for any brand of cigarettes or smokeless tobacco.

<sup>49</sup>In December 2011, the parent company of Camacho Cigars, according to a company press release, signed a 3-year sponsorship deal with the Orange Bowl Committee, a nonprofit organization that stages an annual football game and the supporting Orange Bowl Festival in South Florida. The press release stated that under the sponsorship agreement, Camacho Cigars intended to have a substantial presence at Sun Life Stadium in Miami Gardens, FL, with cigar lounges for football fans and a special Camacho Club Lounge at the Orange Bowl Game Day Fan Zone, the largest pregame event. News organizations reported that the Camacho Cigars logo had been featured on the official Orange Bowl website until the sponsorship agreement was canceled in response to appeals from three U.S. senators and public health groups urging the Orange Bowl Committee to call off the deal that promoted tobacco use.

<sup>50</sup>Most cigar packs and some individual cigars sold in the United States are required to display a Surgeon General warning as the result of an agreement reached in 2000 between the Federal Trade Commission and seven largest cigar companies. There are no federal requirements for pipe tobacco packages to display a Surgeon General warning.

<sup>51</sup>Pub. L. No. 111-31, § 201.

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graphic health warning messages after reviewing relevant scientific literature, 1,700 public comments, and the results of its experimental 18,000-person study to assess the effectiveness of the warnings. While the Tobacco Control Act mandates that the warnings take effect no later than 15 months after FDA issues regulations, that is, by September 2012, pending litigation may impact implementation.<sup>52</sup>

FDA indicated its interest in deeming additional tobacco products to be subject to the agency's tobacco product authorities in the four recent issues of the U.S. government's semiannual regulatory agenda.<sup>53</sup> In the spring and fall 2010 agendas, FDA announced that it planned to issue a proposed rule that would deem cigars to be subject to the provisions of the Food, Drug, and Cosmetic Act.<sup>54</sup> In the spring and fall 2011 agendas, FDA announced that it planned to broaden the proposed rule's scope to encompass all products that meet the statutory definition of "tobacco product"<sup>55</sup> under Chapter IX of the Food, Drug, and Cosmetic Act.<sup>56</sup> The fall 2011 announcement, the most recent, indicated that the proposed rule would be issued in December 2011; however, FDA had not issued the proposed rule as of March 2012, and FDA officials told us that developing the rule is taking longer than they expected.

A typical rulemaking process consists of three basic phases—initiation of rulemaking actions, development of proposed rules, and development of

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<sup>52</sup>In August 2011, several tobacco companies filed a lawsuit to stop FDA from implementing the new warning requirements. In February 2012, the U.S. District Court for the District of Columbia granted the plaintiff's motion for summary judgment and ordered a permanent injunction to halt FDA from enforcing the rule until 15 months after resolution of the plaintiff's claim on the merits. As of March 2012, the case is on appeal before the U.S. Court of Appeals for the District of Columbia Circuit.

<sup>53</sup>The semiannual agenda, also known as unified agenda, summarizes the rules and proposed rules that each federal agency expects to issue.

<sup>54</sup>75 Fed. Reg. 21,791 (Apr. 26, 2010) and 75 Fed. Reg. 79,771 (Dec. 10, 2010).

<sup>55</sup>Section 201(rr)(1) of the Food, Drug, and Cosmetic Act defines the term "tobacco product" as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). By comparison, according to the IRC, "[t]obacco products" means cigars, cigarettes, smokeless tobacco, pipe tobacco, and roll-your-own tobacco."

<sup>56</sup>76 Fed. Reg. 40,052 (July 7, 2011) and 77 Fed. Reg. 7,946 (Feb. 13, 2012).



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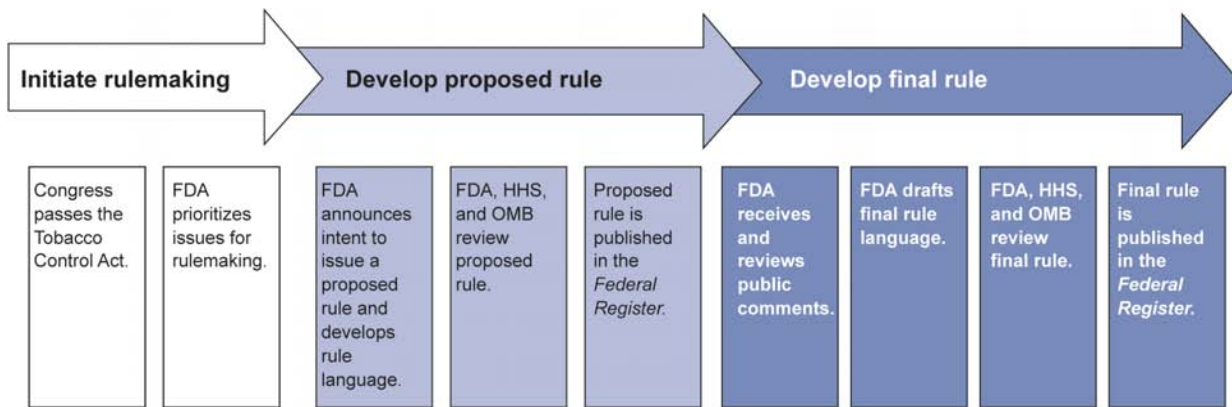
final rules—and involves internal review by the rulemaking agency, external review by the Office of Management and Budget, and public comments on proposed rules (fig. 16). In developing the proposed rule deeming additional products, including pipe tobacco and cigars, to be subject to the agency’s regulatory authority, FDA is in the second phase of the process. FDA officials told us that, as of March 2012, the proposed rule was undergoing review by the agency and the Department of Health and Human Services and that FDA had not yet submitted the proposed rule to the Office of Management and Budget. In a 2009 report on the federal rulemaking process, we found—based on an analysis of 16 rules at different federal agencies, including FDA—that the average time needed to initiate, develop, and complete a rulemaking was about 4 years, with considerable variation among agencies and rules.<sup>57</sup>

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<sup>57</sup>The time needed to complete the 16 rules ranged from 1 to 14 years. One of the recommendations we made in the report was that FDA routinely track major milestones for significant rules in its rulemaking process. See GAO, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews*, [GAO-09-205](#) (Washington, D.C.: Apr. 20, 2009).

However, FDA does not generally track rulemaking milestones during the early phases of rule development, that is, before the agency prepares proposed rules for publication in the *Federal Register*. FDA informed us that it takes several actions to track major milestones, such as maintaining the *Federal Register* Document Tracking System database to track the progress of all its *Federal Register* documents through the agency’s rule development and clearance process and holding monthly and quarterly meetings where senior agency officials discuss major milestones in the rulemaking process for potentially significant regulations.

**Figure 16: Basic Phases in FDA's Rulemaking Process**



Legend: HHS = Department of Health and Human Services; OMB = Office of Management and Budget  
 Source: GAO.

FDA will be able to exercise authority over the deemed products once the rulemaking process is completed and the final rule is published in the *Federal Register*. At that time, the deemed products will be subject to the provisions of Chapter IX the Food, Drug, and Cosmetic Act that are applicable to tobacco products in general. Examples of such provisions include a requirement for annual registration with FDA of establishments engaged in the manufacture of tobacco products, payment of user fees by manufacturers and importers of specified classes of tobacco products, as well as restrictions and penalties for misbranded products. However, if FDA decides to expand the scope of its existing regulations applicable to cigarettes and roll-your-own tobacco to encompass the deemed products, it will have to amend those regulations through the rulemaking process. For example, FDA would have to amend its rule covering the sale and distribution restrictions for cigarettes and smokeless tobacco in order to make it applicable to the deemed products.

## Conclusions

Federal legislation has aimed to discourage tobacco use and raise revenues by increasing excise taxes on tobacco products. In 2009, Congress passed CHIPRA, which increased taxation on all smoking tobacco products, but by different levels for pipe tobacco and for large cigars. Also in 2009, Congress passed the Tobacco Control Act, which gave FDA immediate regulatory authority over four tobacco products, including cigarettes and roll-your-own tobacco, but did not specify authority over pipe tobacco and small and large cigars.

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In equalizing the federal excise tax rates on small cigars and roll-your-own tobacco with the tax rate on cigarettes, CHIPRA was responding to concerns that these products were increasingly used as substitutes to factory-made cigarettes. However, by introducing large tax disparities between cigarettes, roll-your-own tobacco, and small cigars, on the one hand, and pipe tobacco and large cigars, on the other, CHIPRA has contributed to the substitution of higher-taxed tobacco products with lower-taxed products. Sales of the lower-taxed pipe tobacco and large cigars saw significant growth following CHIPRA, as manufacturers and consumers sought to take advantage of lower-taxed products. We estimate that this tax avoidance has resulted in between approximately \$615 million and \$1.1 billion in lost federal revenue since 2009.

Treasury has not succeeded in addressing the continued tax avoidance behavior reflected in the market shifts to pipe tobacco and to large cigars. In the absence of legislative changes, Treasury has limited options for effective action. First, roll-your-own and pipe tobacco are similar and, in some cases, may be substitutable products, and the IRC lacks specificity on how they should be distinguished based on physical characteristics. Treasury is currently considering and analyzing various proposals to more clearly and objectively differentiate the two products based on their physical characteristics. However, the lack of consensus on which characteristics or criteria truly define and differentiate roll-your-own from pipe tobacco reveals the complexity and difficulty in attempting to develop standards and tests to distinguish the products from each other. In addition, there is the concern that products could easily be manipulated to negate any newly established standards or tests.

Because small and large cigars are distinguished in the IRC only by weight, and because many small cigars already weighed at or close to the 3 pounds per thousand threshold for classification as large cigars, many small cigar manufacturers were able to legally shift to the lower-taxed large cigar category with minimal changes to their products. In addition, the large cigar tax structure, which consists of an ad valorem tax rate up to a maximum rate, is complex and creates an incentive to lower the manufacturer's or importer's sale price to avoid paying higher federal excise taxes.

FDA, which implements the Tobacco Control Act, currently regulates cigarettes and roll-your-own tobacco but does not regulate pipe tobacco and small and large cigars. These regulatory disparities make pipe tobacco and small and large cigars more accessible and attractive to current and potential smokers. While FDA announced its intent to issue a

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proposed rule that would subject additional products, including pipe tobacco and small and large cigars, to its regulation, it had not issued the proposed rule as of March 2012.

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## Matter for Congressional Consideration

Disparities in tax rates on smoking tobacco products have negative revenue implications because they create incentives for manufacturers and consumers to substitute higher-taxed products with lower-taxed products. In light of that fact, as Congress continues its oversight of CHIPRA and Tobacco Control Act implementation, it should consider modifying tobacco tax rates to eliminate significant tax differentials between similar products. Specifically, Congress should consider equalizing tax rates on roll-your-own and pipe tobacco and, in consultation with Treasury, also consider options for reducing tax avoidance due to tax differentials between small and large cigars.

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## Agency Comments and Our Evaluation

We provided a draft of this report to the Secretary of the Treasury and the Secretary of Health and Human Services for their review and comment. We received technical comments from Treasury and the U.S. Department of Health and Human Services, which we have incorporated in the report as appropriate. We also received written comments from Treasury, which are reprinted in appendix IV.

Treasury generally agreed with our overall conclusion that CHIPRA's introduction of large tax disparities between similar products contributed to the substitution of higher-taxed tobacco products with lower-taxed products. Treasury also agreed with our observation concerning modifying tobacco tax rates to eliminate significant tax differentials between similar products, which is consistent with our Matter for Congressional Consideration.

Treasury noted our use of the term "revenue losses" and commented that our estimates did not pertain to actual losses of revenues but rather were estimates of revenue increases that would be realized if Congress were to change the law to eliminate the tax disparities or had the market shifts due to the disparities not occurred. We state in the report that our analysis does not incorporate the hypothetical case of equal tax rates among smoking products; rather, we estimate the revenues Treasury would have collected under current law—but in the absence of the market shifts from higher-taxed products to lower-taxed products. The difference between the revenues collected under current law and our estimate of the

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higher revenues that would have been due in the absence of the market shifts is what we refer to as “revenue losses.”

In response to Treasury’s comment about the use of this term, we note that Treasury’s Alcohol and Tobacco Tax and Trade Bureau developed its own estimates of what it termed revenue losses stemming from the market shifts involving these products, and we discuss these estimates in our report. In addition, the Alcohol and Tobacco Tax and Trade Bureau’s 2011 Annual Report uses the term revenue losses when estimating the effect of the market shifts since CHIPRA. Appendix I contains a more detailed discussion of our methodology for developing our estimates.

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We are sending copies of this report to the appropriate congressional committees and to the Secretaries of Health and Human Services and Treasury, and other interested parties. This report also is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3149 or [gootnickd@gao.gov](mailto:gootnickd@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Individuals who made key contributions to this report are listed in appendix V.



David Gootnick  
Director, International Affairs and Trade

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# Appendix I: Objectives, Scope, and Methodology

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The Family Smoking Prevention and Tobacco Control Act (Pub. L. No. 111-31) directed GAO to report on various aspects of cross-border and illicit trade in tobacco products, including the effects of differing tax rates applicable to tobacco products.<sup>1</sup> In accordance with our agreement with Senate Committee on Health, Education, Labor, and Pensions and House Energy and Commerce Committee staff, this report provides information on the federal revenue effects of differing tax rates applicable to tobacco products. Our objectives for this report are to (1) review the market shifts among smoking tobacco products since the Children’s Health Insurance Program Reauthorization Act (CHIPRA) of 2009 went into effect on April 1, 2009; (2) examine the impact of these market shifts on federal revenue and the Department of the Treasury’s (Treasury) actions to respond; and (3) describe differences in regulation of various smoking tobacco products by the Food and Drug Administration (FDA). Our review includes smoking tobacco products that are subject to federal excise tax: cigarettes and four other tobacco products—roll-your-own tobacco (sometimes called RYO), pipe tobacco, small cigars, and large cigars.<sup>2</sup> However, in analyzing the market shifts among these products, we focused solely on the four smoking tobacco products other than cigarettes.

To address the three objectives in this study, we reviewed documents and interviewed agency officials from Treasury’s Alcohol and Tobacco Tax and Trade Bureau, FDA, and the Centers for Disease Control and Prevention, as well as tobacco industry members, representatives of public health and other nongovernmental organizations, and academics to obtain information on tobacco legislation and regulations, tobacco product sales trends, and consumption patterns. Tobacco industry members that we spoke with included industry associations and individual companies. We identified and contacted 15 pipe tobacco manufacturers to ask about their companies’ actions in response to the CHIPRA tax changes, and 3 of the manufacturers agreed to speak with us. We also reviewed studies analyzing the relationship between tobacco tax

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<sup>1</sup>Responding to this mandate, in March 2011, we issued a first report on illicit tobacco trade and schemes, [GAO-11-313](#).

<sup>2</sup>Smokeless tobacco products that are subject to federal excise taxes, such as chewing tobacco and snuff, were outside the scope of this review. “Processed tobacco” is not subject to federal excise tax and is defined in the Internal Revenue Code of 1986 by what it is not: processed tobacco does not include the farming or growing of tobacco or the handling of tobacco solely for sale, shipment, or delivery to a manufacturer of tobacco products or processed tobacco.

increases and smoking, including among youth. We also collected data from Treasury, the Bureau of Labor Statistics, and the Department of Agriculture and determined that they were sufficiently reliable for our purposes.

We analyzed Treasury removals data<sup>3</sup> to identify sales trends across the different tobacco products before and after CHIPRA took effect. In addition, we collected and analyzed price data and data on federal excise tax rates for roll-your-own tobacco, pipe tobacco, small cigars, and large cigars, as well as the federal tax revenue generated from their sale. We estimated what the effect on federal tax revenue collection would have been if the market shifts resulting from substitution of higher-taxed products with lower-taxed products had not occurred once CHIPRA's higher tax rates went into effect. In this report, we refer to this estimated effect on federal tax revenue collection as revenue losses. Our analysis takes into account the expected fall in quantity demanded due to the price increases resulting from the higher federal excise tax rates that CHIPRA imposed on these smoking tobacco products.

To estimate federal tax revenue losses due to market shifts after CHIPRA, we analyzed Treasury's monthly sales and revenue data from fiscal year 2001 through fiscal year 2011 for roll-your-own and pipe tobacco and for small and large cigars. Our analysis compares the actual tobacco tax revenue collected by Treasury with a counterfactual scenario. Our counterfactual model draws from one used by Dr. Frank Chaloupka, an economist who has investigated the effect of prices and taxes on tobacco consumption in numerous publications. In particular, we follow the methodology used in a paper from January 2011 in which Dr. Chaloupka calculates the effect of raising cigarette taxes in the state of Illinois.<sup>4</sup> This methodology projects the effect of a future tax increase based on the historic sales trend, the amount of the tax, and the effect of

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<sup>3</sup>As used in this report, for smoking tobacco products, "removals" means the amount removed for distribution in the United States from the factory or released from customs, as measured in pounds for roll-your-own and pipe tobacco or in the number of sticks for cigarettes and small and large cigars. 26 U.S.C § 5702(j). In this report, we consider removals to be equivalent to sales and use the term sales.

<sup>4</sup>For a detailed explanation of this methodology, see Frank Chaloupka and Jidong Huang, "A Significant Cigarette Tax Rate Increase in Illinois Would Produce a Large, Sustained Increase in State Tobacco Tax Revenues" (Chicago, IL: University of Illinois at Chicago, Jan. 3, 2011, working paper).

a price increase on projected sales (that is, price elasticity of demand).<sup>5</sup> Our counterfactual model, then, projects post-CHIPRA sales of roll-your-own and pipe tobacco and small and large cigars according to the historic sales trends for these products, adjusted downward to account for the fall in demand due to the higher post-CHIPRA tax component of the price.<sup>6</sup> To calculate the impact on demand due to the higher taxes on these products, we included high and low estimates for price elasticity. Based on our interviews with experts and a review of the relevant literature,<sup>7</sup> we assumed that the price elasticity for the smoking tobacco products in our analysis ranges from -0.6 to -0.3, which set, respectively, the low and high boundaries of the estimated revenue losses.<sup>8</sup>

Our analysis does not incorporate the hypothetical case of equal tax rates among smoking tobacco products; rather, we estimate the revenues that Treasury would have collected in the absence of the market's substitution of higher-taxed products with lower-taxed products. An analysis that projected the impact of equal tax rates across all smoking tobacco products would necessarily produce a much higher estimate of lost tax revenues. We did not attempt to develop such a model, however, because doing so was beyond the scope of our analysis. The reliability of any such model would depend on the assumptions made, particularly with regard to large cigars—the only tobacco product for which excise taxes are calculated as a percentage of price. Compared with determining the tax on all other tobacco products, according to Treasury, determining the tax on large cigars is extremely complex. Modeling hypothetical consumption trends for smoking tobacco products after equalizing tax

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<sup>5</sup>Economic theory states that when the price of a product increases, the quantity demanded for the product will decrease at a rate that is computed from the underlying demand curve.

<sup>6</sup>Hence, it is assumed that the actual change in revenue is based on the new tax differential. If changes in sales were due to other market forces, such as changes in the prices of other products or changing demand, this would cause our estimates to be over or under stated.

<sup>7</sup>For an extensive literature review of tobacco price elasticity studies, see Qiang Li, *The Effects of Cigarette Price and Tax on Smokers and Government Revenue*. Unpublished doctoral dissertation (Buffalo, NY: The State University of New York, 2007).

<sup>8</sup>In our counterfactual scenario, a lower decrease in demand results in a higher estimate of revenue losses. A price elasticity of -0.6 means that when prices go up by 10 percent, demand will decrease by 6 percent; a price elasticity of -0.3 for the same price increase means that demand will decrease by 3 percent.



rates on them would require a complex set of assumptions not necessarily grounded in reliable data.

We used data from two sources to build our counterfactual model projecting post-CHIPRA sales of roll-your-own and pipe tobacco and small and large cigars. The first source is Treasury's data from fiscal year 2001 through fiscal year 2011 on smoking tobacco product tax revenues and removals (the amount of tobacco removed for sale from the factory or released from customs). The second data source is tobacco products price data from the Bureau of Labor Statistics, which it uses to calculate the Consumer Price Index for tobacco products. The Bureau of Labor Statistics data contain retail price information collected each month throughout the country; the prices include the cost of production, markup, and excise taxes from federal, state, and local governments—shipping, handling, sales tax, and fuel surcharges have been removed from the data.<sup>9</sup>

For roll-your-own and pipe tobacco and for small and large cigars, we calculated an average taxable manufacturer's or importer's sale price for the year before CHIPRA was enacted. We then estimated the post-CHIPRA price by adding the corresponding post-CHIPRA tax to the pre-CHIPRA price.<sup>10</sup> Thus, our counterfactual model includes only the effect of CHIPRA on tax revenue.

To calculate the average taxable manufacturer's or importer's sale price for large cigars, we used Treasury's revenue data and removals data. Treasury collects revenue data for cigars but does not collect separate revenue data for small and large cigars. However, Treasury's removals data are separated by small and large cigars, reporting the number of sticks removed for sale from the factory or released from customs. After CHIPRA, small cigars are taxed at \$50.33 per thousand sticks, whereas large cigars are taxed at 52.75 percent of the manufacturer's or importer's price up to a maximum tax rate per thousand sticks. We calculated small

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<sup>9</sup>The price data for cigars, pipe tobacco, and roll-your-own tobacco are subsets of the sample used to calculate the Consumer Price Index for *Tobacco products other than cigarettes*. The Bureau of Labor Statistics cautioned that these data be interpreted with care because they do not meet its standard publication criteria.

<sup>10</sup>Using an average post-CHIPRA price from the Bureau of Labor Statistics would be misleading as it would include increases in state and local taxes and would artificially inflate the effect of CHIPRA on prices.

cigar revenue by multiplying the number of sticks reported in Treasury's removals data in each month by the tax rate. We then calculated large cigar revenues by subtracting small cigar revenues from total cigar revenues. Once we had calculated the large cigar revenues, we estimated the average tax paid by dividing the large cigar revenues by the number of large cigar sticks reported in the removals data for each month and calculating the average price. From March 2007 through March 2009, the average large cigar tax collected was 4.3 cents per stick. These figures corroborate Treasury's statement that a majority of manufacturers were paying the maximum rate. CHIPRA raised this maximum rate from 4.8 cents to 40 cents per stick. We estimated that the average taxable manufacturer's or importer's sale price before CHIPRA was 20.65 cents. Hence, the average tax paid after CHIPRA using the new tax rate should be 10.9 cents per cigar, and this is the number we used to estimate post-CHIPRA tax revenues in our counterfactual model. Treasury does not maintain records of the manufacturers' and importers' sale prices of large cigars where the manufacturer or importer paid the maximum rate, thereby making it impossible to determine the magnitude of underestimation in our model caused by the maximum rate.

To describe FDA's regulation of tobacco products under Chapter IX of the Food, Drug, and Cosmetic Act, we examined FDA's regulatory actions and announcements and interviewed officials from FDA's Center for Tobacco Products, including the Offices of Compliance and Enforcement, Policy, Regulations, and Science.

We conducted this performance audit from March 2011 to April 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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# Appendix II: Sales of Smoking Tobacco Products in the United States, Fiscal Years 2001-2011

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Treasury's data on taxable removals (sales) show that the decline in cigarette sales in the last decade has been partially offset by the combined growth in sales of roll-your-own tobacco, pipe tobacco, small cigars, and large cigars.<sup>1</sup> Table 5 provides annual sales data for cigarettes, roll-your-own tobacco, pipe tobacco, small cigars, and large cigars from fiscal year 2001 through fiscal year 2011. Figure 17 uses the same data to depict the concomitant decline in cigarette sales and growth in combined sales of the other four smoking tobacco products.

From fiscal year 2001 through fiscal year 2011, sales of the smoking tobacco products—cigarettes, roll-your-own tobacco, pipe tobacco, small cigars, and large cigars—in the United States decreased by about 26 percent. Sales of cigarettes, which continue to dominate the market, declined by 30 percent from about 414 billion sticks in fiscal year 2001 to about 289 billion sticks in 2011. However, combined sales of roll-your-own tobacco, pipe tobacco, small cigars, and large cigars increased by 131 percent during the same period from about 12 billion sticks or cigarette stick equivalents (for roll-your-own and pipe tobacco) in fiscal year 2001 to about 29 billion sticks or cigarette stick equivalents. The share of these four products grew from 3 percent of the smoking tobacco market in fiscal year 2001 to 9 percent in fiscal year 2011.

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<sup>1</sup>As used in this report, for smoking tobacco products, "removals" means the amount removed for distribution in the United States from the factory or released from customs, as measured in pounds for roll-your-own and pipe tobacco or in the number of sticks for cigarettes and small and large cigars. 26 U.S.C. (§ 5702(j)). In this report, we consider removals to be equivalent to sales and use the term sales.

**Appendix II: Sales of Smoking Tobacco  
Products in the United States, Fiscal Years  
2001-2011**

**Table 5: U.S. Sales of Cigarettes and Other Smoking Tobacco Products, Fiscal Years 2001-2011 (in Billions of Sticks)**

Fiscal year	Cigarettes	Other smoking tobacco products					Total <sup>b</sup> for cigarettes and other smoking tobacco products
		Roll-your-own tobacco <sup>a</sup>	Pipe tobacco <sup>a</sup>	Small cigars	Large cigars	Subtotal <sup>b</sup>	
2001	414.17	4.33	2.42	2.18	3.50	12.42	426.60
2002	406.59	4.74	2.35	2.26	3.70	13.05	419.61
2003	376.14	6.02	2.13	2.28	3.95	14.38	390.52
2004	372.24	6.02	1.96	2.49	4.17	14.64	386.88
2005	367.23	7.16	1.79	3.45	4.39	16.78	384.01
2006	363.01	8.10	1.77	4.15	4.54	18.56	381.58
2007	356.05	8.37	1.58	4.58	4.57	19.10	375.15
2008	337.64	9.68	1.55	5.34	4.76	21.33	358.98
2009	316.40	7.96	4.31	3.35	6.88	22.50	338.90
2010 <sup>c</sup>	296.23	3.03	10.25	0.91	9.88	24.07	320.29
2011	288.50	2.56	15.02	0.80	10.27	28.65	317.14

Source: Treasury.

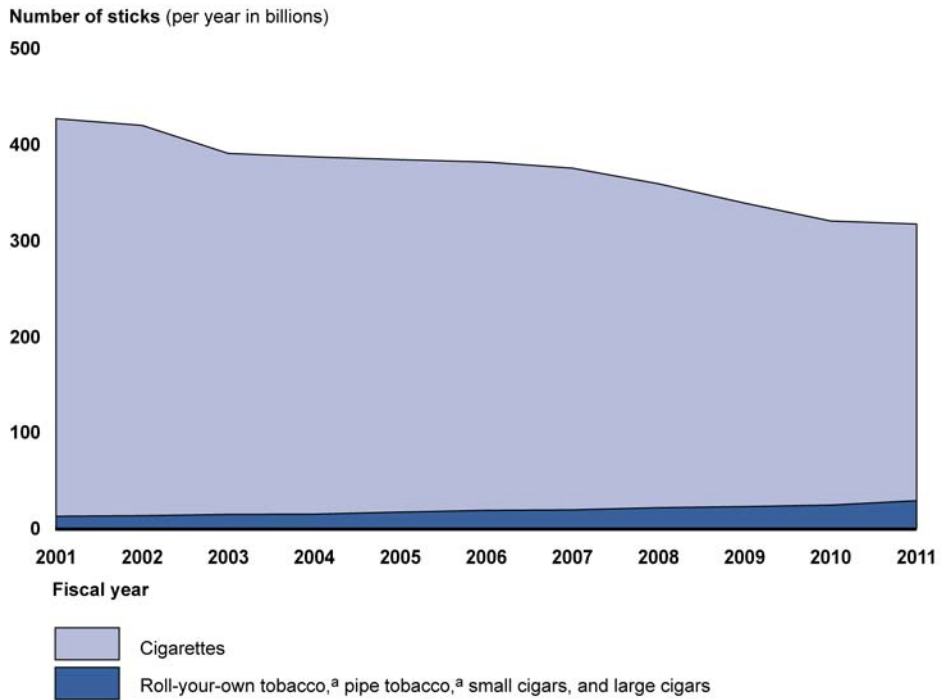
<sup>a</sup>The roll-your-own tobacco and pipe tobacco cigarette stick equivalent is based on the weight of 0.0325 ounces. of tobacco per cigarette stick using the Master Settlement Agreement conversion rate.

<sup>b</sup>The subtotal and total may not add up due to rounding.

<sup>c</sup>2010 is the first full fiscal year following April 1, 2009, when the new federal excise tax rates on tobacco products resulting from CHIPRA took effect.

Appendix II: Sales of Smoking Tobacco Products in the United States, Fiscal Years 2001-2011

Figure 17: U.S. Sales of Cigarettes and Other Smoking Tobacco Products, Fiscal Years 2001-2011



Source: GAO analysis of Treasury data.

<sup>a</sup>The roll-your-own tobacco and pipe tobacco cigarette stick equivalent is based on the weight of 0.0325 ounces of tobacco per cigarette stick using the Master Settlement Agreement conversion rate.

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# Appendix III: Summary of Treasury's Proposed Rulemaking Actions to Distinguish between Roll-Your-Own and Pipe Tobacco

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Treasury published a temporary rule and request for public comments in June 2009 that outlined new labeling and packaging requirements for roll-your-own and pipe tobacco to more clearly differentiate the two products on those bases. Treasury also noted the need for additional rulemaking on other standards and methods to differentiate the products. In response to its June 2009 rulemaking notice, industry members proposed standards to distinguish between roll-your-own and pipe tobacco based on physical characteristics. For example, Treasury received comments setting forth certain criteria for distinguishing between the products based on whether the product met a certain number of factors, including moisture content; cut width; percentage of weight consisting of reducing sugars; and percentage of weight consisting of flavoring, casing, or other nontobacco content.

In July 2010, Treasury published an advance notice of proposed rulemaking issuing a request for public comments on these and other standards proposed by commenters to differentiate between roll-your-own and pipe tobacco. The industry members' comments responding to Treasury's 2010 request highlighted the complexity and difficulties in developing objective standards based on physical characteristics that clearly differentiate the two tobacco products. Industry members disagreed on the number of criteria that should be used and the specific thresholds for differentiating between the products. For example, while some industry members generally agreed that pipe tobacco traditionally has had a thicker cut and greater moisture content than roll-your-own tobacco, they disagreed on the specific cut width or moisture content that defines pipe tobacco. Some comments noted that the physical characteristics of the two products overlap greatly, emphasizing the numerous types of roll-your-own and pipe tobacco products on the market and various manufacturing methods, all of which make it difficult to develop concrete definitions that clearly differentiate between the two products. Other comments emphasized the challenges of conducting tests to distinguish the two products as, for example, test results can be influenced by factors such as the age of the sample used and the temperature of the facility, potentially creating different results on tests of the same tobacco products. Some industry members also proposed that Treasury take into consideration the preexisting or established pipe tobacco brands prior to CHIPRA and continue to classify them as pipe tobacco through a grandfathering clause, regardless of how the tobacco might fare in any tests based on objective standards. Other industry members disagreed, however, stating that a grandfathering clause would favor existing companies, reduce competition, and give some companies

the opportunity to introduce misclassified pipe tobacco into the market without accountability.

Other industry members expressed concerns that the proposed standards could easily be manipulated by consumers. For example, the tobacco cut width standard for pipe tobacco could be compromised by a consumer using a blender or coffee grinder to obtain a smaller width for use in cigarettes. Additionally, the moisture content standard could also prove to be ineffective because end users could dry out the moister pipe tobacco for use in cigarettes.

After the initial public comment period closed in September 2010, Treasury did not issue a subsequent rulemaking on clarifying standards. Treasury said it received an additional proposal after the close of the comment period and, as a result, issued a second advance notice of proposed rulemaking in August 2011 reopening the period for receiving comments on the standards proposed by commenters, including the new proposal. Treasury received a number of additional comments, many by the same companies that commented on the earlier notices, and the comments continued to reflect significant differences within the industry on standards that define and distinguish roll-your-own tobacco from pipe tobacco. This second comment period closed in October 2011, and Treasury has not issued a subsequent rulemaking as of March 2012.

Within the 2011 notice, Treasury also published the results of the preliminary analysis conducted by its laboratory on a sample of roll-your-own and pipe tobacco products. For this analysis, Treasury purchased a sample of products labeled as roll-your-own and pipe tobacco from local retail vendors in Maryland. These samples were purchased just prior to the CHIPRA tax increases going into effect. Treasury officials emphasized that their sample was not a representative market sample and thus not generalizable. Treasury officials stated that the purpose of the preliminary analysis was to investigate what could be learned about the initial proposed standards rather than to complete a definitive test differentiating the products or attempting to determine whether the products were roll-your-own or pipe tobacco, as they were labeled. Treasury tested for several of the proposed standards, including total reducing sugars and moisture content. Treasury's results, in some cases, appeared to show a lack of a clear distinction between the roll-your-own and pipe tobacco samples.

# Appendix IV: Comments from the Department of the Treasury



Administrator

Department of the Treasury  
Alcohol and Tobacco Tax and Trade Bureau  
1310 G Street NW, Box 12, Suite 300  
Washington, DC 20005

April 10, 2012

Mr. David Gootnick  
Director, International Affairs and Trade  
U.S. Government Accountability Office  
Washington, DC 20548

Re: Draft Report GAO-12-475, "TOBACCO TAXES: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes"

Dear Mr. Gootnick:

Thank you for the opportunity to review and comment on the draft report. The U.S. Department of the Treasury (Treasury) appreciates the U.S. Government Accountability Office's (GAO) work in conducting its review of the impacts of Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 on tobacco tax revenue. We generally agree with GAO's conclusion that "by introducing large tax disparities" between similar products "CHIPRA has contributed to the substitution of higher-taxed tobacco products with lower-taxed products." We also agree with your observation that "modifying tax rates to eliminate significant tax differentials between similar products" would address the market shifts your report identifies.

In this context, it is appropriate to note that the report uses the term "revenue losses" to characterize the difference between revenues due and collected under current law, and revenues that would be collected if the tax disparities between similar products were eliminated or had the market shifts due to the disparities not occurred. These are not actual losses of revenues, but rather your estimates of the revenue increases if Congress were to change the law to eliminate the disparities.

With respect to Roll-Your-Own (RYO) and pipe tobacco, the increase in sales of pipe tobacco from 2008 to 2011 illustrates that disparate tax rates for like products influences shifts in demand. Given the tax differentials between using pipe tobacco and higher taxed RYO tobacco, Treasury expects the increased demand for pipe tobacco to continue.

While CHIPRA ended the disparate tax rates between small cigars and cigarettes, raising the tax on small cigars means the tax rate on some large cigars can be substantially less than the rate on other, slightly smaller cigars. In some cases manufacturers may reduce the tax on the tobacco used in a cigar, if they adjust the weight to avail themselves of a lower "large cigar" tax rate and select a low sales price point. (The tax on "large cigars" is based on sales price, so lower priced tobacco is taxed at a lower rate.) In fact, we have observed a notable shift in the cigar market since the passage of CHIPRA. For example, in



the year preceding the tax increase on April 1, 2009, of all cigars removed for sale in the United States by domestic manufacturers, 52 percent were small cigars (cigars weighing less than 3 pounds per thousand) and 48 percent were large cigars (cigars weighing over 3 pounds per thousand). In the 2-year period following April 1, 2009, these numbers were 8 percent for small cigars and 92 percent for large cigars.

Again, thank you for the opportunity to comment on this draft report.

  
John J. Manfreda

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

David Gootnick (202) 512-3149 or [gootnickd@gao.gov](mailto:gootnickd@gao.gov)

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## Staff Acknowledgments

In addition to the individual named above, Christine Broderick, Assistant Director; Sada Aksartova; Pedro Almoguera; David Dayton; Etana Finkler; Jeremy Latimer; Grace Lui; and Alana Miller made key contributions to this report. In addition, Barbara El Osta, Joyce Evans, Marc Molino, Theresa Perkins, Jena Sinkfield, and Cynthia S. Taylor provided technical assistance.

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## Public Affairs

Chuck Young, Managing Director, [youngc1@gao.gov](mailto:youngc1@gao.gov), (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548



## Consumption of Cigarettes and Combustible Tobacco — United States, 2000–2011

Smoking cigarettes and other combustible tobacco products causes adverse health outcomes, particularly cancer and cardiovascular and pulmonary diseases (1). A priority of the U.S. Department of Health and Human Services is to develop innovative, rapid-response surveillance systems for assessing changes in tobacco use and related health outcomes (2). The two standard approaches for measuring smoking rates and behaviors are 1) surveying a representative sample of the public and asking questions about personal smoking behaviors and 2) estimating consumption based on tobacco excise tax data (3). Whereas CDC regularly publishes findings on national and state-specific smoking rates from public surveys (4), CDC has not reported consumption estimates. The U.S. Department of Agriculture (USDA), which previously provided such estimates, stopped reporting on consumption in 2007 (5). To estimate consumption for the period 2000–2011, CDC examined excise tax data from the U.S. Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB); consumption estimates were calculated for cigarettes, roll-your-own tobacco, pipe tobacco, and small and large cigars. From 2000 to 2011, total consumption of all combustible tobacco decreased from 450.7 billion cigarette equivalents to 326.6, a 27.5% decrease; per capita consumption of all combustible tobacco products declined from 2,148 to 1,374, a 36.0% decrease. However, while consumption of cigarettes decreased 32.8% from 2000 to 2011, consumption of loose tobacco and cigars increased 123.1% over the same period. As a result, the percentage of total combustible tobacco consumption composed of loose tobacco and cigars increased from 3.4% in 2000 to 10.4% in 2011. The data suggest that certain smokers have switched from cigarettes to other combustible tobacco products, most notably since a 2009 increase in the federal tobacco excise tax that created tax disparities between product types.

USDA's previous consumption estimates were based on 1) information from TTB, including data on products that are produced domestically or imported and taxed for legal

sale in the United States; 2) tobacco industry reports; and 3) information from industry advisors. CDC developed a method to estimate consumption exclusively by using publicly available federal excise tax data available from TTB on products taxed domestically and imported into the United States (6). Using monthly tax data, CDC calculated the per unit (e.g., per cigarette or per cigar) consumption for each product. To enable comparisons with pipe tobacco and roll-your-own tobacco, CDC converted the tax data from pounds of tobacco to a per cigarette equivalent, based on the conversion formula contained in the Master Settlement Agreement (0.0325 oz [0.9 g] = one cigarette).<sup>\*</sup> Adult per capita cigarette consumption was estimated by dividing total consumption by the number of persons aged ≥18 years in the United States each year using data from the U.S. Census Bureau. When compared with USDA's previous calculations for adult per capita cigarette consumption during 2000–2006, CDC's estimates differed each year by a median of only 0.15% and a mean of 0.76%.

From 2000 to 2011, total cigarette consumption declined from 435.6 billion to 292.8 billion, a 32.8% decrease (Table 1). Per capita cigarette consumption declined from 2,076 in 2000 to 1,232 in 2011, a 40.7% decrease. Conversely, total consumption of noncigarette combustible products increased

<sup>\*</sup> Available at <http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf>.

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from 15.2 billion cigarette equivalents in 2000 to 33.8 billion in 2011, a 123.1% increase, and per capita consumption increased from 72 in 2000 to 142 in 2011, a 96.9% increase. Total consumption of all combustible tobacco decreased from 450.7 billion cigarette equivalents to 326.6, a 27.5% decrease from 2000 to 2011, and per capita consumption of all combustible tobacco products declined from 2,148 to 1,374, a 36.0% decrease.

Consumption of loose tobacco (i.e., roll-your-own cigarette tobacco and pipe tobacco) changed substantially from 2000 to 2011. Roll-your-own cigarette equivalent consumption decreased by 56.3%, whereas pipe tobacco consumption increased by 482.1% (Table 2). The largest changes occurred from 2008 to 2011, when roll-your-own consumption decreased from 10.7 billion to 2.6 billion (a 75.7% decrease), whereas pipe tobacco consumption increased from 2.6 billion to 17.5 billion (a 573.1% increase).

Substantial changes also were observed in consumption of small cigars<sup>†</sup> and large cigars (Figure 1). From 2000 to 2011, consumption of small cigars decreased 65.0%, whereas large cigar consumption increased 233.1% (Table 2). The largest changes occurred from 2008 to 2011, when small cigar consumption decreased from 5.9 billion to 0.8 billion (an 86.4% decrease), whereas large cigar consumption increased from 5.7 billion to 12.9 billion (a 126.3% increase).

<sup>†</sup> In 26 USC 5701, small cigars are defined as cigars that weigh  $\geq 3$  pounds ( $< 1.36$  kg) per 1,000 cigars, and large cigars are defined as cigars that weigh  $> 3$  pounds per 1,000.

Annual cigarette consumption declined each year during 2000–2011, including a 2.6% decrease from 2010 to 2011, but total consumption of combustible tobacco decreased only 0.8% from 2010 to 2011, in part because of the effect of continued increases in the consumption of noncigarette combustible tobacco products (Figure 2). From 2000 to 2011, the percentage of total combustible tobacco consumption composed of loose tobacco and cigars increased from 3.4% (15.2 billion cigarette equivalents out of 450.7 billion) to 10.4% (33.8 billion of 326.6 billion).

### Reported by

Michael A. Tynan, Tim McAfee, MD, Gabbi Promoff, MA, Terry Pechacek, PhD, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC.  
**Corresponding contributor:** Michael A. Tynan, [mtynan@cdc.gov](mailto:mtynan@cdc.gov), 770-488-5286.

### Editorial Note

Despite continued decreases in cigarette smoking in the United States, consumption of pipe tobacco and large cigars has increased substantially since the federal tobacco excise tax was increased in 2009, creating tax disparities that made 1) pipe tobacco less expensive than roll-your-own tobacco and manufactured cigarettes, and 2) large cigars less heavily taxed than small cigars and manufactured cigarettes (7,8). Because loose tobacco products are classified based on how they are labeled, the loose tobacco tax disparity of \$21.95 per pound

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**TABLE 1. Total consumption and adult per capita consumption\* of cigarettes, all combustible tobacco,<sup>†</sup> and noncigarette combustible tobacco products<sup>§</sup> — United States, 2000–2011**

Year	Cigarettes				All combustible tobacco				Noncigarette combustible tobacco			
	Total consumption (in millions)	% change	Adult per capita consumption	% change	Total consumption (in millions)	% change	Adult per capita consumption	% change	Total consumption (in millions)	% change	Adult per capita consumption	% change
2000	435,570	—	2,076	—	450,725	—	2,148	—	15,155	—	72	—
2001	426,720	-2.0	2,010	-3.2	440,693	-2.2	2,075	-3.4	13,973	-7.8	66	-8.9
2002	415,724	-2.6	1,936	-3.7	430,763	-2.3	2,006	-3.4	15,040	7.6	70	6.4
2003	400,327	-3.7	1,844	-4.7	415,930	-3.4	1,916	-4.5	15,603	3.8	72	2.6
2004	397,655	-0.7	1,811	-1.8	414,421	-0.4	1,888	-1.5	16,766	7.5	76	6.2
2005	381,098	-4.2	1,717	-5.2	401,187	-3.2	1,807	-4.3	20,089	19.8	90	18.5
2006	380,594	-0.1	1,695	-1.3	401,241	>-0.1	1,787	-1.1	20,648	2.8	92	1.6
2007	361,590	-5.0	1,591	-6.1	384,087	-4.3	1,690	-5.4	22,497	9.0	99	7.7
2008	346,419	-4.2	1,507	-5.3	371,264	-3.3	16,15	-4.5	24,845	10.4	108	9.1
2009	317,736	-8.3	1,367	-9.3	342,124	-7.9	1,472	-8.9	24,388	-1.8	105	-2.9
2010	300,451	-5.4	1,278	-6.5	329,239	-3.8	1,400	-4.9	28,788	18.0	122	16.7
2011	292,769	-2.6	1,232	-3.6	326,577	-0.8	1,374	-1.9	33,808	17.4	142	16.2
<b>% change, from 2000 to 2011</b>	<b>-32.8</b>	<b>—</b>	<b>-40.7</b>	<b>—</b>	<b>-27.5</b>	<b>—</b>	<b>-36.0</b>	<b>—</b>	<b>123.1</b>	<b>—</b>	<b>96.9</b>	<b>—</b>

\* Adults aged ≥18 years as reported annually by the U.S. Census Bureau.

<sup>†</sup> Includes cigarettes, small cigars and large cigars, and per-cigarette equivalents for pipe tobacco and roll-your-own tobacco based on the conversion rate in the Master Settlement Agreement: 0.0325 oz (0.9 g) of tobacco = one cigarette.<sup>§</sup> Includes all combustible products other than cigarettes.**TABLE 2. Total consumption of noncigarette combustible tobacco product, by product category and type — United States, 2000–2011**

Year	Loose tobacco				Cigars			
	Roll-your-own* (in millions)	% change	Pipe* (in millions)	% change	Small cigars (in millions)	% change	Large cigars (in millions)	% change
2000	5,995	—	2,999	—	2,279	—	3,882	—
2001	4,714	-21.4	2,915	-2.8	2,239	-1.8	4,105	5.7
2002	5,737	21.7	2,757	-5.4	2,343	4.6	4,203	2.4
2003	6,207	8.2	2,389	-13.3	2,474	5.6	4,533	7.9
2004	6,600	6.4	2,314	-3.2	2,917	17.9	4,935	8.9
2005	8,614	30.5	2,423	4.7	3,968	36.0	5,084	3.0
2006	8,594	-0.2	2,322	-4.2	4,434	11.7	5,299	4.2
2007	9,326	8.5	2,463	6.1	5,161	16.4	5,548	4.7
2008	10,721	15.0	2,586	5.0	5,881	14.0	5,657	2.0
2009	6,006	-44.0	6,256	142.0	2,343	-60.2	9,784	73.0
2010	3,168	-47.2	12,351	97.4	983	-58.1	12,287	25.6
2011	2,622	-17.2	17,459	41.4	798	-18.8	12,929	5.2
<b>% change, from 2000 to 2011</b>	<b>-56.3</b>	<b>—</b>	<b>482.1</b>	<b>—</b>	<b>-65.0</b>	<b>—</b>	<b>233.1</b>	<b>—</b>

\* These data are the per-cigarette equivalent based on the conversion rate in the Master Settlement Agreement: 0.0325 oz (0.9 g) of tobacco = one cigarette.

led manufacturers to relabel roll-your-own tobacco as pipe tobacco and then market this relabeled pipe tobacco for roll-your-own use (7–9). In addition, manufacturers were able to increase the per-unit weight of certain small cigars to take advantage of a tax benefit when classified as large cigars, which are taxed based on the product price rather than per cigar (7). As a result of relatively minor increases in per-unit weight, the new “large cigar” can appear almost identical to a “small cigar,” which resembles a typical cigarette and can cost as little as 7 cents per cigar (Figure 1) (7).

This analysis shows that cigarette consumption continues to decline in the United States, a trend that has persisted since the 1960s. However, recent changes in consumption patterns, particularly increases in large cigar and pipe tobacco use, have

resulted in a slowing of the decline in consumption of all combustible tobacco, and indicate that certain cigarette smokers have switched to using lower-taxed noncigarette combustible products. Moreover, a 2012 Surgeon General’s report found that youths and young adults had even higher rates of cigar use and simultaneous use of multiple tobacco products (10).

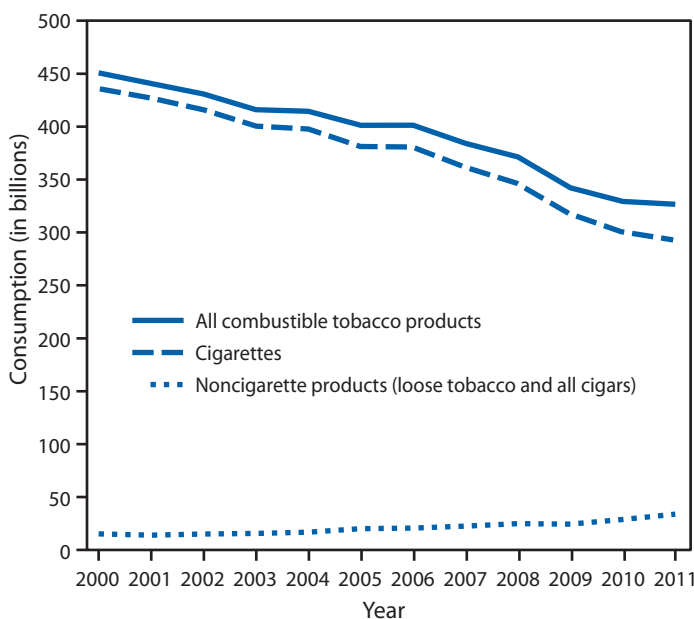
Recent analysis of excise tax data for pipe tobacco, roll-your-own cigarette tobacco, small cigars, and large cigars reveals that the tobacco industry is adapting the marketing and production of cigars and roll-your-own tobacco products to minimize federal excise tax and thus reduce these tobacco products’ prices compared with cigarettes (7–9). Reducing the effective federal and state excise tax rates on tobacco lessens the impact of cost on reducing smoking and preventing smoking

**FIGURE 1. Physical differences between combustible tobacco products — Government Accountability Office, United States**



Source: Government Accountability Office. Tobacco taxes: large disparities in rates for smoking products trigger significant market shifts to avoid higher taxes. Available at <http://www.gao.gov/products/gao-12-475>.

**FIGURE 2. Consumption of cigarettes and other combustible tobacco products — United States, 2001–2011**



initiation. The Government Accountability Office (GAO) recommends modifying federal tobacco taxes to eliminate large tax differentials between roll-your-own and pipe tobacco and small and large cigars (7). In addition, because Food and Drug Administration (FDA) regulations currently do not apply to cigars and pipe tobacco, these products can be produced with flavoring, can be labeled with misleading descriptors such as “light” or “low tar,” and can be marketed and sold with fewer restrictions than apply to cigarettes.

**What is already known on this topic?**

Cigarette use continues to decline in the United States, a trend that has persisted since the 1960s.

**What is added by this report?**

From 2000 to 2011, consumption of all combustible tobacco products decreased from 450.7 billion cigarette equivalents to 326.6 (a 27.5% decrease), and per capita consumption of all combustible tobacco products declined from 2,148 to 1,374 (a 36.0% decrease). However, whereas consumption of cigarettes decreased 32.8%, consumption of noncigarette combustible tobacco increased 123.1%. As a result, the percentage of combustible tobacco consumption composed of loose tobacco and cigars increased from 3.4% in 2000 to 10.4% in 2011.

**What are the implications for public health practice?**

The increase in cigar and pipe tobacco use is a public health concern because all combustible tobacco use causes cancer, heart disease, and other smoking-related diseases. A switch from cigarettes to other, lower-taxed, combustible tobacco products blunts the effect of increasing prices, one of the most effective ways to reduce smoking and prevent youth smoking initiation.

The findings in this report are subject to at least one limitation. CDC’s measure for cigarette and combustible tobacco consumption only accounts for products taxed for legal sale in the United States and does not account for illicit cigarette sales, such as those smuggled into or out of the country, or for untaxed cigarettes that are produced or sold on American Indian sovereign lands. Currently, no method exists for measuring or estimating illicit or untaxed tobacco trade in the United States.

Smoke from pipes and cigars contains the same toxic chemicals as cigarette smoke (1). The evidence that the increase in cigar and pipe tobacco use is the result of offering cigarette smokers a low-priced alternative product is a particular public health concern, because the morbidity and mortality effects of other forms of combustible tobacco are similar to those of cigarettes. Increasing prices has been one of the most effective ways to reduce tobacco use and prevent youth smoking initiation (10). In addition, combustible tobacco products that are similar in design but not legally considered to be cigarettes are not subject to FDA regulations related to manufacturing, flavoring, labeling, and marketing. The availability of low-priced and less regulated alternative products appears to have led certain cigarette smokers to switch to other combustible tobacco products. This group also might include persons who otherwise might have quit smoking as a result of the 2009 federal tobacco excise tax increase and FDA cigarette regulations. Diminishing the public health impact of excise tax increases and regulation can hamper efforts to prevent youth smoking initiation, reduce consumption, and prompt quitting.

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## Public Health Interventions Involving Travelers with Tuberculosis — U.S. Ports of Entry, 2007–2012

Every day, approximately 950,000 international travelers arrive in the United States (1). The Secretary of the U.S. Department of Health and Human Services is authorized to prevent the introduction, transmission, and spread of communicable diseases by travelers into and within the United States (2). The Secretary, through the CDC director, delegates this authority to CDC's Division of Global Migration and Quarantine (DGMQ). Of the communicable diseases for which federal quarantine and isolation are authorized by executive orders of the president (2), infectious tuberculosis (TB) is encountered most commonly by DGMQ's network of quarantine stations at major U.S. ports of entry (Table). Although legal immigrants and refugees undergo U.S. State Department–mandated TB screening overseas, CDC receives approximately 125 reports each year of arriving travelers with active TB, including foreign visitors, foreign students, and temporary workers (CDC, unpublished data, 2012). This report describes two cases that illustrate the TB control and prevention activities of quarantine stations. Such activities, including issuing federal isolation orders, restricting travel, arranging safe transport for patients across state lines, and conducting airline contact investigations, support CDC's mission to limit the spread of infectious disease from travelers.

### Case Reports

**Case 1.** On March 24, 2010, the Nevada State TB Program notified the CDC Los Angeles Quarantine Station about an elderly legal immigrant from Mexico with infectious TB. The patient was admitted to a Nevada hospital in October 2009. Sputum smears revealed the presence of acid-fast bacilli (AFB), and standard four-drug treatment (isoniazid, rifampin, pyrazinamide, and ethambutol) was started empirically. The local TB clinic provided outpatient treatment under directly observed therapy until December 2009, when the patient abruptly left the United States for Mexico without notifying the clinic, and before drug susceptibility tests showed isoniazid resistance. Local public health officials referred the case to Cure-TB,\* a binational TB program that facilitates continuity of care for patients with TB who travel between the United States and Mexico.

The patient returned briefly to the United States in March 2010, but made no contact with local TB control officers and departed again to Mexico. After discussions with state and local public health partners, CDC issued a federal isolation order and placed the patient on public health travel restriction

lists (Do Not Board [DNB] and lookout lists) because of the risk for infectiousness resulting from suboptimal treatment, continued nonadherence with public health recommendations, and recent history of international travel. Persons included on the DNB list are assigned a public health lookout record, which alerts Customs and Border Protection (CBP) officers if the person attempts to enter the United States through any port of entry (3).

In September 2010, the patient was detected by CBP at a border crossing in El Paso, Texas. The CDC El Paso Quarantine Station served a federal isolation order, and the patient was transported to a nearby Texas hospital under CBP custody for evaluation and treatment. After three sputum specimens tested AFB smear-negative, the patient was escorted by a CDC quarantine public health officer to Nevada. The federal isolation order was rescinded, and the patient was transferred to the custody of a local health department for court-ordered home isolation. Compliance with an effective treatment regimen, administered through directly observed therapy, permitted removal of federal travel restrictions in November 2010.

**Case 2.** On October 18, 2011, the Ohio Department of Health TB Program reported a college student from China with AFB smear-positive, cavitary TB disease to the CDC Detroit Quarantine Station. In August 2011, the student had traveled from Japan to California on a commercial flight that exceeded 8 hours, and then flew on two connecting domestic flights (California to Illinois and Illinois to Ohio, each of which was <8 hours).

When DGMQ protocol conditions for TB airline contact investigations are met, including infectiousness criteria and flight duration of ≥8 hours, the jurisdictional quarantine station obtains the flight manifest and locator information for potentially exposed passengers on the flight (4). State health departments then are notified of contacts in their jurisdictions via the Epidemic Information Exchange (Epi-X), CDC's secure electronic communications network for public health professionals.

The CDC Detroit Quarantine Station obtained the international flight manifest and identified 15 passengers as contacts based on their seat assignments (passengers in the same row, two rows in front of, and two rows behind the index case). DGMQ notified nine state health departments of 11 U.S. resident passenger-contacts and the ministries of health of two countries about four passenger-contacts who lived outside the United States. Outcomes were reported to DGMQ by U.S. health departments for five passenger-contacts. Of those, two

\*Additional information available at [http://www.sdcounty.ca.gov/hhsa/programs/phs/cure\\_tb](http://www.sdcounty.ca.gov/hhsa/programs/phs/cure_tb).

**TABLE. CDC quarantine stations and the jurisdictions in which they monitor ports of entry, 2012\***

Quarantine station	Jurisdiction
Anchorage, Alaska	Alaska
Atlanta, Georgia	Georgia, North Carolina, South Carolina, and Tennessee
Boston, Massachusetts	Massachusetts, Maine, New Hampshire, and Rhode Island
Chicago, Illinois	Illinois, Indiana, Iowa, and Wisconsin; preclearance port in Toronto, Canada
Dallas, Texas	Kansas, Missouri, Oklahoma, Arkansas, and northern Texas (Health districts 1, 2, and 3)
Detroit, Michigan	Michigan, Kentucky, and Ohio
El Paso, Texas (U.S.–Mexico unit)	Western Texas (Health districts 8, 9, 10, and 11) and New Mexico
Honolulu, Hawaii	Hawaii, Guam, and Pacific Trust Territories
Houston, Texas	Eastern Texas (Health districts 4, 5, 6, and 7) and Louisiana
Los Angeles, California	Southern California (Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, San Luis Obispo, Inyo, and Kern counties), Nevada, Utah, and Colorado
Miami, Florida	Florida, Alabama, and Mississippi; preclearance ports in the Bahamas
Minneapolis-St. Paul, Minnesota	Minnesota, Nebraska, North Dakota, and South Dakota
New York, New York	New York, Connecticut, and Vermont; preclearance ports in Montreal, Canada; Bermuda; and Shannon and Dublin, Ireland
Newark, New Jersey	New Jersey
Philadelphia, Pennsylvania	Pennsylvania and Delaware
San Diego, California (U.S.–Mexico unit)	Arizona, California (San Diego and Imperial counties)
San Francisco, California	Central and northern California (46 counties) and Wyoming
San Juan, Puerto Rico	Puerto Rico and the U.S. Virgin Islands
Seattle, Washington	Washington, Idaho, Montana, and Oregon; preclearance ports in Edmonton, Calgary, Vancouver, and Victoria, Canada
Washington, DC	District of Columbia, Maryland, Virginia, and West Virginia

\* Additional information available at <http://www.cdc.gov/quarantine/quarantinestations.html>.

were evaluated and determined not to have been infected with TB; attempts to notify the other three were unsuccessful.

### Reported by

*Curi Kim, MD, Kirsten Buckley, MPH, Karen J. Marienau, MD, William L. Jackson, MD, Miguel Escobedo, MD, Teal R. Bell, MPH, Francisco Alvarado-Ramy, MD, Nina Marano, DVM, Div of Global Migration and Quarantine, CDC. Corresponding contributor: Kirsten Buckley, [kbuckley@cdc.gov](mailto:kbuckley@cdc.gov), 404-639-7165.*

### Editorial Note

In 2011, 10,521 new TB cases were reported in the United States, with rates 12 times higher in foreign-born persons than in U.S.-born persons (5). From June 2007 to December 2011, 632 cases of active TB among travelers were reported to CDC quarantine stations (CDC, unpublished data, 2012). TB transmission during air travel has been documented (4,6), but the risk for transmission has not been determined and is believed to be low. One model estimates the risk for transmission from a highly infectious passenger on an 8.7-hour commercial flight as 1 per 1,000 for all passengers, with higher risk to those seated closer to the infectious passenger (7). Delegated authority permits DGMQ's use of public health travel restriction tools and federal isolation orders to prevent persons known or suspected of having infectious TB from traveling. These tools can facilitate the safe transport of travelers with TB to local hospitals or their home states for testing and continued treatment. Since June 2007, five federal isolation orders have been served to persons with TB (inclusive of case 1), four of whom were foreign-born; before 2007, the last federal isolation order was issued in 1963.

Domestic or international public health officials may request that a person be placed on the DNB and lookout lists, which have been managed jointly by CDC and the Department of Homeland Security since formalization of the process in June 2007 (3). If persons on the lists are identified at ports of entry, CBP notifies the jurisdictional quarantine station to facilitate public health clearance or action. From June 2007 to December 2011, 205 persons with known or suspected TB were added to the DNB and lookout lists; 173 (84%) have since been removed after meeting criteria indicating noninfectiousness (CDC, unpublished data, 2012). The first case report, involving multiple health jurisdictions and CDC quarantine stations, exemplifies the successful use of the lookout record to intercept a TB-infected traveler at a land border and return the patient to public health management. The federal isolation order had been drafted months before the patient was encountered at the port of entry, facilitating immediate medical evaluation and return of the patient to health care in his home state.

The second case report highlights CDC quarantine stations' response to notifications of travelers with infectious TB who traveled by commercial aircraft. From June 2007 to December 2011, CDC quarantine stations, in collaboration with U.S. health departments, performed airline contact investigations for 390 travelers with infectious TB, involving 508 flights with approximately 15,650 potentially exposed contacts. DGMQ also notified foreign public health authorities in more than 50 countries of at least 3,000 international contacts

**What is already known on this topic?**

The global burden of tuberculosis (TB) and the tremendous volume of travelers to the United States increase the risk for TB importation and transmission during travel. Significant resources are expended during public health responses to travelers with TB disease, including passenger contact investigations, legal measures, and implementation of federal travel restriction tools.

**What is added by this report?**

The case studies in this report illustrate the use of federal legal measures and travel restriction tools to help return noncompliant TB-infected persons to public health care, and highlight revised guidelines to optimize the cost-benefit ratio of airline TB contact investigations.

**What are the implications for public health practice?**

TB control in travelers into and within the United States can be promoted through ongoing state and local public health practitioner partnerships with their jurisdictional CDC quarantine stations and referral of immigrants with noninfectious TB conditions at ports of entry to TB clinics in their destination states.

(CDC, unpublished data, 2012). However, because outcome reporting to CDC is voluntary, contact tracing outcome reports typically are received for <20% of passenger contacts (4). In 2011, DGMQ used the results of epidemiologic and economic impact evaluations to revise its criteria for conducting airline contact investigations (Box). The policy changes conserve state and federal public health resources by assigning priority for tracing to the passenger-contacts of travelers who are most likely to transmit *Mycobacterium tuberculosis* (those with both positive sputum AFB smears and cavitation identified on chest radiograph) or who have multidrug-resistant TB. CDC quarantine stations also provide guidance to crews on ships regarding TB contact investigations when notified of travelers with infectious TB on maritime vessels.

In addition to responding to reports of infectious TB in travelers, four CDC quarantine stations meet immigrants arriving at U.S. ports of entry who have been diagnosed with admissible, noninfectious TB conditions during their pre-immigration medical screening, and provide them with a TB clinic referral in the states of their destination. Immigrants receiving referrals are four times more likely to initiate follow-up evaluation than those receiving no referral ( $p < 0.001$ ; CDC, unpublished data, 2012). Immigrants typically are not charged for these medical evaluations; the costs usually are borne by state and local health departments. Follow-up is important because newly arrived U.S. immigrants with a history of TB

**BOX. CDC criteria for initiating flight-related tuberculosis contact investigations, June 2011**

- Index case was diagnosed within 3 months of the flight AND the flight occurred within 3 months of notification to the Division of Global Migration and Quarantine.
- Flight lasted  $\geq 8$  hours gate-to-gate.\*
- Diagnosis of the index case was confirmed by sputum culture or nucleic acid amplification test for *Mycobacterium tuberculosis* AND is:
  1. Sputum smear-positive for acid-fast bacilli AND cavitation is present on a chest radiograph; OR
  2. Confirmed to have a multidrug-resistant isolate (regardless of the smear or chest radiograph results).

**Note:** A contact investigation will be considered on a case-by-case basis for situations that are unusual or not clearly addressed by the criteria. Examples include, but are not limited to, situations in which an unusually high proportion of close contacts have positive tuberculin skin test or interferon-gamma release assay test screening results, an index case has laryngeal tuberculosis, or cavitation is detected on chest computed tomography scan but no chest radiograph was performed.

\* Gate-to-gate means all time spent on the aircraft, including boarding and deplaning time or delays on the tarmac.

infection or previously treated disease have an increased risk for disease activation or reactivation during their first few years after arrival (8). DGMQ is developing a system to expand the referral program to include more CDC quarantine stations.

The network of CDC quarantine stations provides national leadership and coordination of public health responses to TB in travelers. DGMQ also communicates with foreign health authorities about TB patients or contacts who are no longer in the United States, and collaborates with U.S. health departments to work with TB patients who have left the United States but could return. Effective collaboration between CDC quarantine stations and international, state, and local public health practitioners can help reduce the spread of TB during travel by intercepting TB patients at ports of entry, returning patients to treatment, and identifying contacts for possible intervention.

**Acknowledgments**

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## Infant Lead Poisoning Associated with Use of Tiro, an Eye Cosmetic from Nigeria — Boston, Massachusetts, 2011

Lead is highly toxic and can damage the brain, kidneys, bone marrow, and other body systems; high levels can cause convulsions, coma, and death (*1*). Young children are especially susceptible to lead exposures because of their floor-hand-mouth activity, greater gut absorption, and developing central nervous systems. In June 2011, a male infant aged 6 months of Nigerian descent was referred to the Pediatric Environmental Health Specialty Unit (PEHSU) at Boston Children's Hospital because of an elevated blood lead level (BLL). An investigation found no lead exposure except for "tiro," a Nigerian cosmetic that also is used as a folk remedy to promote visual development. The tiro applied to the infant's eyelids contained 82.6% lead. Products similar to tiro, such as "surma" and "kajal" in Asia and kohl in the Middle East, also might contain lead. This case adds to the medical literature documenting nonpaint lead sources as causes of elevated BLLs in children (*2,3*) and highlights persons of certain immigrant populations as a risk group. Educational efforts are needed to inform immigrants from Africa, Asia, and the Middle East that tiro and similar products can cause lead poisoning in children. Health-care providers and public health workers should ask about eye cosmetics and folk remedies when seeking a source of exposure in children with elevated BLLs from certain immigrant populations.

In June 2011, during a well-child visit of a male infant aged 6 months born in the United States to Nigerian parents, the physician noted that an imported cosmetic had been applied to the child's eyelids. Capillary blood testing performed by the physician indicated a BLL of 13  $\mu\text{g}/\text{dL}$ , more than twice the CDC's reference value of 5  $\mu\text{g}/\text{dL}$ , based on the 97.5th percentile of the BLL distribution in U.S. children aged 1–5 years. The next day, a confirmatory venous BLL measured by graphite furnace atomic absorption spectroscopy was 12  $\mu\text{g}/\text{dL}$ . Additional laboratory evaluation revealed a normal hemoglobin level and 2+ erythrocyte microcytosis on an automated blood smear. In accordance with CDC recommendations aimed to help reduce the absorption of lead and mitigate the severe adverse health effects of lead exposure,\* the pediatrician prescribed supplemental iron, contacted the Massachusetts Department of Public Health, and referred the family to the regional PEHSU.

When the infant was brought to the PEHSU 1 week later, his venous BLL, as measured by the same laboratory, was

13  $\mu\text{g}/\text{dL}$ . His whole blood zinc protoporphyrin (30  $\mu\text{g}/\text{dL}$  whole blood [normal: 0–35  $\mu\text{g}/\text{dL}$ ]), hemoglobin (12.1 g/dL [normal: 10.4–12.5 g/dL]), erythrocyte mean cell volume (74.2 fL [normal: 68.0–83.1 fL]), plasma iron (81  $\mu\text{g}/\text{dL}$  [normal: 40–100  $\mu\text{g}/\text{dL}$ ]), and ferritin (65.0 ng/mL [normal: 10.0–75.0 ng/mL]) were in the normal range for his age. A manual blood smear showed 2+ erythrocyte microcytosis. The parents reported no health concerns for the infant, and a detailed review of systems was normal. The infant had no relevant past medical history, was growing well, and had met all developmental milestones. No other children lived in the home. Both parents had sickle cell trait; the infant had a normal hemoglobin electrophoresis. No abnormalities were noted on the physical examination.

Since 2008, the family had lived in a townhouse originally built in 2004. PEHSU staff members inspected the residence and found it to be in excellent condition, without lead hazards. Other sources of lead exposure were ruled out, including take-home exposure from parental occupations, kitchenware, family hobbies, and diet. The infant was breastfed exclusively and did not consume any imported herbs, spices, or dietary supplements. Additional questioning revealed that since age 2 weeks, a Nigerian cosmetic and folk remedy had been applied to the infant's eyelids three to four times weekly to improve attractiveness and promote visual development. A grandparent had purchased the powder, called tiro (Figure 1), from a street vendor in Ilorin, a city in Kwara State, Nigeria. The PEHSU recommended immediately discontinuing the use of tiro on the infant and continuing iron supplementation. The parents agreed to submit the suspected tiro powder for laboratory analysis.

Quantitative analysis by the PEHSU showed that the tiro consisted of 82.6% lead. A single application of 10 mg of tiro would deliver 8 mg of lead to the infant's eyelids. The most likely routes of exposure were eyelid-hand-mouth and absorption from the conjunctival surfaces of the eyes or in ingested tears. Analysis of the tiro by the U.S. Geological Survey, using scanning electron microscopy (SEM), showed that the sample was dominated by lead sulfide, known as galena (Figure 2), which has relatively low bioavailability (*1*). No other minerals were observed by SEM, although small amounts of other minerals commonly found as microscopic inclusions in lead sulfide might have escaped detection.

Three months after the family stopped applying tiro to the infant's eyelids, his venous BLL had fallen from 13  $\mu\text{g}/\text{dL}$  to 8  $\mu\text{g}/\text{dL}$ .

\*Recommendations available at [http://www.cdc.gov/nceh/lead/casemanagement/casemanage\\_chap4.htm](http://www.cdc.gov/nceh/lead/casemanagement/casemanage_chap4.htm).

**FIGURE 1.** The Nigerian tiro container and the powder that was applied to the lead-poisoned child's eyelids — Boston, Massachusetts, 2011



Photo/Pediatric Environmental Health Specialty Unit, Boston Children's Hospital

#### Reported by

*Abdulsalami Nasidi, MD, Nigeria Centre for Disease Control. Mateusz Karwowski, MD, Alan Woolf, MD, Pediatric Environmental Health Specialty Unit; Mark Kellogg, PhD, Terence Law, Dept of Laboratory Medicine, Boston Children's Hospital, Boston, Massachusetts. Marissa Scalia Sucusky, MPH, Rose M. Glass-Pue, MA, Mary Jean Brown, ScD, Div of Emergency and Environmental Health Svcs, National Center for Environmental Health; Behrooz Behbod, MChB, EIS Officer, CDC. **Corresponding contributor:** Behrooz Behbod, [bbehbod@cdc.gov](mailto:bbehbod@cdc.gov), 770-488-0788.*

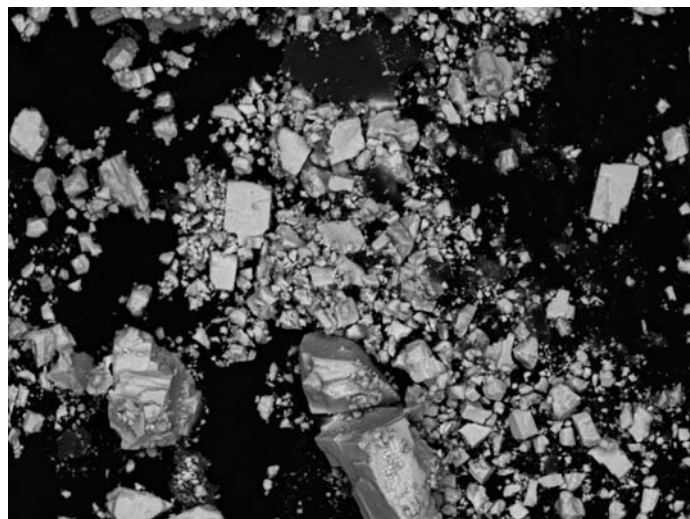
#### Editorial Note

Although the primary source of lead exposure in the United States is lead-based paint, nonpaint sources of lead increasingly are being identified in lead poisoning cases (2,3). These nonpaint exposures include recent travel to a foreign country, take-home exposure when persons exposed to lead at their workplace contaminate their homes or vehicles, and use of imported products such as spices, food, candy, cosmetics, health remedies, ceramics or pottery, and jewelry.

This report describes an eye cosmetic and folk remedy as the source of lead poisoning in a child of Nigerian descent; a similar case has been reported in the United Kingdom (4,5). Although Nigeria switched to unleaded gasoline by the end of 2003, Nigerian children might also be exposed to the lead that remains in the soil from years of use of leaded gasoline. In addition, lead contamination resulting from gold mining has caused many child deaths in Nigerian villages where artisanal gold ore processing takes place (6,7).

Tiro is the Yoruba name for this eye cosmetic implicated in the case described in this report. In another Nigerian language,

**FIGURE 2.** Scanning electron microscopy\* of the tiro eye cosmetic powder that was applied to the lead-poisoned child's eyelids, revealing the presence of cubic shapes and stair-step cleavage, both of which indicate presence of lead sulfide (also known as galena) — Boston, Massachusetts, 2011



Photo/U.S. Geological Survey, Crustal Geophysics and Geochemistry Science Center  
\* Field of view is approximately 100  $\mu\text{m}$  wide.

Hausa, it is called “tozali” or “kwalli.” Similar products intended to darken the eyes are known as kohl in English and Arabic and as “surma” or “kajal” in languages spoken in India and Pakistan. These preparations are not standardized, and not all contain lead. One alternative to lead sulfide is another toxic compound, antimony sulfide. Imported cosmetics are one of the relatively few sources of significant lead exposure for infants too young to crawl or walk; however, exposure to lead in tiro represents an additional burden to groups who might be exposed to other sources of lead. The contribution that tiro might make to the cumulative burden of lead poisoning should not be overlooked.

This fine powder is applied to the dermal surfaces of the eyelid. In addition to its use by the patient's family for improving attractiveness and promoting visual development, tiro has been used to ward off “the evil eye”; to relieve eyestrain, pain, or soreness; to prevent infection of the umbilical stump or a circumcision wound by local application; and to prevent sun glare (8,9).

This case identifies tiro as a potential lead exposure among not only Nigerians living in the United States, but also among African, Asian, and Middle Eastern populations who use similar products. Public health educational campaigns can help identify and prevent further cases (10).<sup>†</sup> Obstetricians, pediatricians, midwives, and allied health-care professionals

<sup>†</sup> Examples of such campaigns are described at <http://www.nyc.gov/html/doh/html/lead/lead-import-eyecos.shtml>.

should discuss this potential risk factor during prenatal and early childhood medical visits by families for whom these cultural practices might apply. Although CDC recommends blood lead testing for internationally adopted and refugee children,<sup>§</sup> blood lead testing in children of certain immigrant populations also might be important because of the increased risk for exposure to lead-containing foreign products.

The Nigeria Centre for Disease Control is working with the vendors of products such as tiro to find possible safer alternatives. Discussions involve the perceived benefit of tiro, and evidently, strong beliefs are attached to its use. The Nigeria Centre for Disease Control plans to launch a national public health awareness campaign.

<sup>§</sup> Guidelines available at <http://www.cdc.gov/nceh/lead/tips/populations.htm>.

### Acknowledgment

Geoffrey S. Plumlee, PhD, US Geological Survey, Crustal Geophysics and Geochemistry Science Center, Denver, Colorado.

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### What is already known on this topic?

Although the most common source of lead poisoning for young children in the United States is lead-based paint, nonpaint sources of lead are being identified increasingly in lead poisoning cases, particularly in immigrant communities.

### What is added by this report?

A male infant aged 6 months was found to have an elevated blood lead level (BLL) attributed to application of “tiro,” a Nigerian eye cosmetic, to his eyes by his parents. Tiro, also known as “tozali” and “kwalli” in Nigeria, is similar to kohl, “surma,” and “kajal” used in the Middle East, India, and Pakistan. These products often are made with lead. In this case, the lead content was 82.6%. This case adds to the medical literature documenting nonpaint lead sources as causes of elevated BLLs in children and highlights persons of certain immigrant populations as a risk group.

### What are the implications for public health practice?

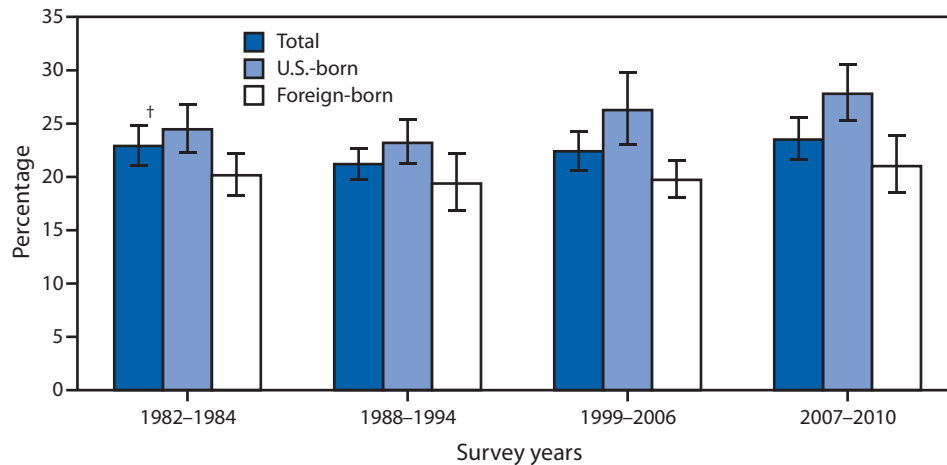
Educational and other primary prevention efforts are needed to inform immigrants from Africa, Asia, and the Middle East that tiro and similar products can cause lead poisoning in children. Health-care providers and public health workers should ask about eye cosmetics and folk remedies when seeking a source of exposure in children with elevated BLLs from certain immigrant populations.

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## QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

## Prevalence of Hypertension Among Mexican-American Adults Aged 20–74 Years, by Country of Birth — United States, 1982–1984 to 2007–2010\*



\* Age-adjusted to year 2000 U.S. Census Bureau estimates using age groups 20–39 years, 40–59 years, and 60–74 years. Hypertension is defined as a systolic blood pressure  $\geq 140$  mmHg, a diastolic blood pressure  $\geq 90$  mmHg, or currently taking medication to lower high blood pressure.

† 95% confidence interval.

Mexican-American adults who were born in the United States were more likely to have hypertension compared with those born outside of the United States. From 1982–1984 to 2007–2010, a statistically significant increase in hypertension (from 24.5% to 27.8%) was observed only among those who were born in the United States.

**Sources:** Fryar CD, Wright JD, Eberhardt MS, Dye BA. Trends in nutrient intakes and chronic health conditions among Mexican-American adults, a 25-year profile: United States, 1982–2006. *Natl Health Stat Rep* 2012(50).

CDC. Hispanic Health and Nutrition Examination Survey, data for 1982–1984.

CDC. National Health and Nutrition Examination Survey, data for 1988–1994, 1999–2006, and 2007–2010.

**Reported by:** Cheryl D. Fryar, MSPH, cfryar@cdc.gov, 301-458-4537.







## Morbidity and Mortality Weekly Report

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Clinical and laboratory data on the two groups of patients with rheumatoid arthritis and Sjögren's syndrome. Values and means and ranges are given in parentheses

	Placebo	Levamisole
No of patients	8	10
No of men	1	2
Duration of rheumatoid arthritis (years)	10.9 (3-35)	21.2 (4-55)
Duration of Sjögren's syndrome (years)	2.6 (0.5-9)	3.8 (1-10)
No with history of drug allergy	3 (2 to gold, 1 to penicillamine (11-54))	3 (1 to salicylates, 1 to gold, 1 to penicillamine) (11-65)
Articular index	26.6	23.1
Duration of morning stiffness (min)	94.5 (15-300)	130 (10-420)
Digital joint circumference (mm)		
Right	287.1 (274-302)	289.5 (251-310)
Left	284.2 (266-306)	282.0 (244-329)
Grip strength (mm Hg)		
Right	96.7 (22-160)	108.3 (39-174)
Left	79.0 (36-160)	94.4 (37-170)
Pain level	2.3 (2-3)	2.3 (2-3)
Haemoglobin (g dl)	13.02 (11.4-16.2)	12.3 (10.2-14.0)
No positive for antinuclear factor	3	3
<sup>99m</sup> Tc joint uptake (%)	3.13 (2.89-4.28)	3.66 (2.58-5.17)

withdrawn from patients who have responded well after six to nine months their condition will deteriorate. Some weeks after stopping treatment synovitis reappears with increasing pain and tenderness and loss of function ability (Dr El-Ghobarey; unpublished observations). Thus it seems more likely that levamisole is suppressing disease activity rather than removing the basic cause.

Levamisole is undoubtedly a toxic drug. Side effects seem to be more common in patients with connective tissue disease than in those without.<sup>1</sup> Our results are so striking that we felt it important to report them immediately. We have not been able to show laboratory evidence that the skin rashes were indeed immunologically mediated, although this does seem to be the most likely pathogenesis. The patients who developed an influenza like illness with muscle pains and weakness are more difficult to explain. They had not experienced a similar illness

before and the fact that the syndrome recurred on re-exposure indicates that this syndrome was probably related to levamisole. These patients did not develop a rash or proteinuria nor was their muscle weakness clinically like myasthenia. Levamisole may exert an effect on the cyclic adenosine monophosphate membrane system<sup>1</sup> and this may be relevant. Muscle enzyme concentrations (serum alanine transaminase, aspartate transaminase, creatine kinase) did not rise in these patients.

We have had the clinical impression for some time that hypersensitivity to levamisole, as with other drugs,<sup>5</sup> might be more common in patients with rheumatoid arthritis complicated by Sjögren's syndrome than in those without. Our results amply confirm that clinical impression. Although the numbers developing side effects were small, the proportion of the total treated was too large to be ignored. The results suggest that levamisole should be prescribed with considerable caution, if at all, for patients with rheumatoid arthritis complicated by Sjögren's syndrome.

<sup>1</sup> Symoens, J, and Rosenthal, M, *Journal of the Reticuloendothelial Society*, 1977, **21**, 175.

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Centre for Rheumatic Diseases, University Department of Medicine, Royal Infirmary, Glasgow, Scotland

G BALINT, MD, visiting research fellow  
A EL-GHOBAREY, MB, MRCP, Beechams research fellow  
H CAPELL, MB, MRCP, Robins research fellow  
M MADKOUR, MB, MRCP, Montedison research fellow  
W C DICK, MD, MRCP, consultant physician

Department of Oral Medicine, Dental Hospital and School, Glasgow

M M FERGUSON, MB, FDSRCP, lecturer in oral medicine and pathology

Department of Ophthalmology, Southern General Hospital, Glasgow

M ANWAR-UL-HAQ, MB, DO, registrar

## CONDENSED REPORT

# Effect of cigar smoking on carboxyhaemoglobin and plasma nicotine concentrations in primary pipe and cigar smokers and ex-cigarette smokers

J A McM TURNER, R W SILLETT, M W McNICOL

*British Medical Journal*, 1977, **2**, 1387-1389

### Summary

Five ex-cigarette smokers and five primary pipe and cigar smokers each smoked a large cigar. Carboxyhaemoglobin (COHb) and plasma nicotine levels were measured. In the ex-cigarette smokers mean COHb rose from 2.9% to 9.6% and plasma nicotine from 79.0 nmol/l to 281 nmol/l (12.8-45.6 ng/ml). This response was similar to that of cigarette smokers smoking cigarettes, which indicated that the subjects had inhaled and absorbed significant amounts of nicotine. In the primary pipe and

cigar smokers the mean COHb rose from 0.8% to 1.0% and the plasma nicotine from 21 nmol/l to 32 nmol/l (3.4-5.2 ng/ml), indicating neither significant inhalation nor significant nicotine absorption.

Since ex-cigarette smokers do not seem to lose their habit of inhaling when they change to cigars, measures aimed at persuading smokers to switch to cigars will have little effect on their health. Pipe and cigar smokers who have never smoked cigarettes do not inhale, which probably accounts for their reduced incidence of coronary heart disease and lung cancer. But they also appear not to absorb nicotine, which suggests that nicotine is absorbed largely from the lung and that the buccal mucosa is unimportant. It also raises the interesting question of why primary pipe and cigar smokers do smoke.

Department of Medicine, Middlesex Hospital, London W1

J A McM TURNER, MRCP, Sir Jules Thorn research fellow

Cardiothoracic Department, Central Middlesex Hospital, London NW10

R W SILLETT, MSCT, chief cardiological technician  
M W McNICOL, FRCP, consultant physician

### Introduction

Primary pipe and cigar smokers have only slightly greater mortality rates than non-smokers.<sup>1-3</sup> It is believed that they

smoke to obtain nicotine, but, as they do not inhale, the alkalinity of the pipe and cigar smoke allows nicotine to be absorbed via the buccal mucosa. Their lower mortality is thought to be due to the fact that they do not inhale. Changing from cigarettes to cigars would be beneficial only if the former cigarette smokers smoked cigars in the same way as primary pipe and cigar smokers—that is, without inhaling. There is, however, evidence to suggest that they continue to inhale.<sup>1-6</sup>

We carried out the present study to assess the degree of inhalation in true primary pipe and cigar smokers and compared it with that of ex-cigarette smokers when they each smoked one large cigar. We used blood carboxyhaemoglobin (COHb) concentrations as an indication of inhalation and plasma nicotine levels to estimate the amount of nicotine absorption.

### Subjects and methods

Ten men, who were members of the hospital staff (nine physicians and one cardiological technician), took part in the study. Five were ex-cigarette smokers who had stopped smoking cigarettes three to 17 years earlier; all had smoked an occasional cigar since and two were now regular pipe smokers. Five were primary pipe and cigar smokers who had never smoked cigarettes. Full details of their smoking histories are shown in table I.

The subjects were studied at the end of a normal working day. They were asked to refrain from smoking for at least six hours before the study. Light refreshments were provided before and throughout the period of smoking to create a more typical situation for the smoking of large cigars. The cigars used were petit coronas, made of Havana tobacco. They were 12.4 cm long and weighed on average 6.20 g. Pretrial investigations indicated that the average smoking time for this cigar was one hour. Venous blood samples were obtained immediately

before smoking and at 20, 40, and 60 minutes, after which the cigar was extinguished without crushing the butt. Further venous blood samples were obtained one hour after cigar smoking. Thereafter the subjects smoked freely and a final venous blood sample (for COHb determination only) was taken the next morning.<sup>7</sup> Plasma nicotine levels were analysed by gas-liquid chromatography<sup>8</sup> by Hazelton Laboratories, Europe. The length of unburnt tobacco in the cigar butt was measured.

The results were analysed statistically using Wilcoxon's rank sum test.<sup>9</sup>

### Results

The primary pipe and cigar smokers had a shorter interval since last smoking (mean 14 hours) compared with a mean of 4.7 days in the ex-cigarette smokers, but their pre-smoking COHb levels were lower (mean 0.8%) as well as their plasma nicotine levels (mean 21 nmol/l (3.4 ng/ml)), although these differences were not significant.

In the primary pipe and cigar smokers the mean COHb levels increased from a presmoking value of 0.8% to a maximum of 1.0% during smoking and fell to 0.6% by the next morning. The plasma nicotine levels showed a similar small increase from a presmoking mean of 21 nmol/l (3.4 ng/ml) to a maximum of 32 nmol/l (5.2 ng/ml), falling to 28 nmol/l (4.5 ng/ml) after stopping smoking for one hour (table II).

In the ex-cigarette smokers the mean COHb levels rose from 2.9% to a maximum of 9.6% after smoking for one hour and fell to 3.5% by the next morning. The mean plasma nicotine levels rose from 79 nmol/l (12.8 ng/ml) to a maximum of 281 nmol/l (45.6 ng/ml) at 40 minutes, falling to 153 nmol/l (24.8 ng/ml) after stopping smoking for one hour. The difference between the COHb and plasma nicotine levels in the primary pipe and cigar smokers and the ex-cigarette smokers were significant at all times during smoking (table II).

The mean butt lengths were shorter in the primary pipe and cigar

TABLE I—Smoking histories of subjects studied

Subject No	Age (years)	Past smoking history			Present smoking history		Years since last cigarette smoked	Time since last smoked
		Type	Amount	Age started (years)	Type	Amount		
<i>Ex-cigarette smokers</i>								
1	30	Cigarettes	10-15 day	15	Small cigar	2 day	3	2 days
2	30	Cigarettes	20-30 day	16	Medium cigar	2 month	6	2 weeks
3	46	Cigarettes	15 day	21	Large cigar	1 week	18	1 week
4	33	Cigarettes	20 day	17	Large cigar	3 week	14	6 hours
		Pipe tobacco	85 g week	17	Pipe	85 g week		
5	31	Cigarettes	10-15 day	22	Pipe	28 g week	5	7 hours
		Pipe tobacco	28 g week	26				
<i>Primary pipe and cigar smokers</i>								
6	50	Large cigars	1 day	41	Large cigars	1 day	Never	20 hours
		Pipe tobacco	57 g week	18	Pipe	71 g week		
7	30	Small cigars	4 day	24	Medium cigars	1 day	Never	8 hours
		Pipe tobacco	57 g week	28	Pipe	114 g week		
8	27	Small cigars	2 day	21	Small cigars	5 week	Never	9 hours
		Pipe tobacco	43 g week	21	Pipe	43 g week		
9	29	Pipe tobacco	28 g week	17	Medium cigars	1 week	Never	15 hours
		Pipe tobacco	28 g week	20	Pipe	28 g week		
10	33	Large cigars	1 month	20	Large cigars	2 month	Never	19 hours
		Pipe tobacco	28 g week	20	Pipe	28 g week		

TABLE II—Mean carboxyhaemoglobin and plasma nicotine concentrations in five ex-cigarette smokers and five primary pipe and cigar smokers before, during, and after smoking a large cigar

		Before	20 min	40 min	60 min	2 h	Next morning
<i>Plasma nicotine (nmol/l)</i>							
Ex-cigarette smokers	Mean	79.0	189.3	281.3	223.6	152.6	
	Range	18.5-207.4	35.2-411.7	64.2-728.3	82.7-327.1	42.0-224.7	
Primary pipe and cigar smokers	Mean	20.5	24.8	26.4	31.6	27.6	
	Range	15.4-27.2	15.4-39.5	20.4-42.0	28.4-38.3	21.0-37.0	
	P value	NS	<0.05	<0.01	<0.01	<0.01	
<i>COHb (%)</i>							
Ex-cigarette smokers	Mean	2.9	6.6	8.4	9.6	8.1	3.5
	Range	0.8-6.7	1.4-12.1	2.3-13.4	2.5-13.8	2.2-11.7	1.5-5.8
Primary pipe and cigar smokers	Mean	0.8	1.0	1.0	0.9	1.0	0.6
	Range	0.3-1.5	0.4-1.9	0.3-2.2	0.3-1.5	0.4-2.0	0.3-1.2
	P value	NS	<0.05	<0.01	<0.01	<0.01	<0.01

Conversion: SI to traditional units—Nicotine: 1 nmol/l ≈ 0.162 ng/ml.

group (mean 3.4 cm) than in the ex-cigarette group (mean 3.7 cm). The detailed results are shown in table A\* and the group values for COHb and plasma nicotine in fig a.

## Discussion

The rise in COHb concentrations of ex-cigarette smokers while they smoked one petit corona showed that they both inhaled significantly and absorbed nicotine. The increases were much higher than those found after smoking one medium-tar nicotine cigarette.<sup>10, 11</sup>

Although cigarette smokers have been found to continue to inhale when smoking small cigars,<sup>4, 5</sup> we were surprised that our subjects did so when smoking large cigars. Earlier studies<sup>1, 2</sup> included people who had changed from cigarettes to cigars fairly recently, whereas our subjects had stopped smoking on average nine years earlier. Despite Freedman's report of an ex-smoker who smoked large cigars and continued to inhale,<sup>6</sup> it has generally been thought that the smoke of large cigars is too irritating to inhale. Our findings and those of others<sup>1-6</sup> seem to suggest that cigarette smokers who are used to inhaling will continue to do so when they change to cigars, regardless of their size. This suggests that there would be no health benefit in trying to persuade cigarette smokers to change to cigars of any size.

The primary pipe and cigar smokers had low COHb levels throughout the study, confirming that they did not inhale. The reduced mortality in primary pipe and cigar smokers probably relates to this fact. Not only did the primary pipe and cigar smokers not inhale, they also absorbed very little nicotine. The small rise in plasma nicotine in this group was similar to that found in passive smoking<sup>12</sup> and would be expected in the environment of this study. The failure of the primary pipe and cigar smokers to absorb nicotine from the large cigar suggests that extrapulmonary routes of absorption of nicotine from smoke are unimportant.

It had been suggested that buccal absorption of nicotine from smoke is significant.<sup>1</sup> Armitage and Turner<sup>13</sup> found that nicotine in an alkaline aqueous solution could be absorbed via the buccal mucosa of a cat, and Russell *et al*<sup>14</sup> found that a nicotine-containing chewing gum that had been buffered to a pH of 8.5 allowed buccal absorption of nicotine in man. It has been assumed that these findings could be extrapolated to nicotine in smoke, but our findings suggest that, for the cigars used in this study, this extrapolation is not justified. Although there is no detailed smoke chemistry analysis available on the cigar we used, the composition of the cigar is not unusual and we see no reason why the smoke chemistry should be different from that of other cigars. Buccal absorption of nicotine from smoke would require that the nicotine from the smoke passing transiently through the mouth be absorbed in adequate quantity in saliva, and that the relatively alkaline cigar smoke (pH about 8.3-9) alkalinises

the saliva so that absorption could take place. The normal pH of saliva is 5.8-7.1.<sup>15</sup> The buffering capacity is probably such that a small quantity of alkali in cigar smoke would not alkalinise saliva.<sup>16</sup> Thus even if the quantity of nicotine dissolved in saliva were adequate, the pH most appropriate for absorption would probably not be attained. As the primary pipe and cigar smokers do not inhale and the conditions for significant nicotine absorption from the buccal mucosa are almost certainly not realised during smoking it is perhaps not surprising that they do not absorb significant amounts of nicotine, although this finding is unexpected.

Our group of primary pipe and cigar smokers were as "addicted" to their pipes and cigars as inhaling cigarette smokers are addicted to their cigarettes. In our study they tended to smoke more of the cigars than did the ex-cigarette smokers. The interval since their last smoke was shorter. Their "addiction" in the absence of evidence of nicotine absorption is a remarkable finding and clearly requires further investigation. The low pre-smoking nicotine levels in this group strengthens the view that this is a significant finding.

We conclude that cigarette smokers who change to cigar smoking do not lose their habit of inhaling even after many years. The health benefit of such a change must be uncertain. The absence of inhalation by primary pipe and cigar smokers probably accounts for their smaller risk of heart and lung disease, but the accompanying absence of nicotine absorption makes their motive for smoking an enigma.

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Copies of the unpublished table and figure are available from Dr M W McNicol, Cardiothoracic Department, Central Middlesex Hospital, Acton Lane, London NW10 7NS.

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\*Copies of table A and figure a are available from the authors.



# Health warning messages on tobacco products: a review

David Hammond

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## Correspondence to

David Hammond, Department of Health Studies and Gerontology, University of Waterloo, 200 University Avenue West, Waterloo, Ontario, N2L 3G1, Canada; [dhammond@uwaterloo.ca](mailto:dhammond@uwaterloo.ca)

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## ABSTRACT

**Objective** To review evidence on the impact of health warning messages on tobacco packages.

**Data sources** Articles were identified through electronic databases of published articles, as well as relevant 'grey' literature using the following keywords: health warning, health message, health communication, label and labelling in conjunction with at least one of the following terms: smoking, tobacco, cigarette, product, package and pack. *Study selection and data extraction:* Relevant articles available prior to January 2011 were screened for six methodological criteria. A total of 94 original original articles met inclusion criteria, including 72 quantitative studies, 16 qualitative studies, 5 studies with both qualitative and qualitative components, and 1 review paper: Canada (n=35), USA (n=29) Australia (n=16), UK (n=13), The Netherlands (n=3), France (n=3), New Zealand (n=3), Mexico (n=3), Brazil (n=2), Belgium (n=1), other European countries (n=10), Norway (n=1), Malaysia (n=1) and China (n=1).

**Results** The evidence indicates that the impact of health warnings depends upon their size and design: whereas obscure text-only warnings appear to have little impact, prominent health warnings on the face of packages serve as a prominent source of health information for smokers and non-smokers, can increase health knowledge and perceptions of risk and can promote smoking cessation. The evidence also indicates that comprehensive warnings are effective among youth and may help to prevent smoking initiation. Pictorial health warnings that elicit strong emotional reactions are significantly more effective.

**Conclusions** Health warnings on packages are among the most direct and prominent means of communicating with smokers. Larger warnings with pictures are significantly more effective than smaller, text-only messages.

## INTRODUCTION

Tobacco use is responsible for one in ten global deaths and is the second major cause of mortality in the world.<sup>1</sup> In 2009, more than 5 million people died from tobacco use, more than tuberculosis, HIV/AIDS and malaria combined.<sup>2</sup> The health burden from tobacco reflects the wide range of smoking-related diseases: causal links have been identified for 10 types of cancer as well as 18 other diseases.<sup>3</sup> Remarkably, the list of known health risks continues to grow, with cancers of the stomach and acute myeloid leukaemia among those most recently identified.

Health warnings on tobacco packages have emerged as an important medium for communicating the health risks of tobacco use to consumers. Tobacco packages provide high reach and frequency of exposure—pack-a-day smokers are potentially

exposed to the warnings over 7000 times per year—as well as an opportunity to communicate with smokers during the act of smoking.<sup>4,5</sup> Tobacco packs also serve as portable advertisements with high levels of exposure among non-smokers: unlike many other consumer products, cigarette packs are displayed each time the product is used and are often left in public view between uses.<sup>6</sup> Tobacco packages are also prominent in retail outlets, where product displays are common and typically increase in prominence as other forms of tobacco marketing are restricted.<sup>7</sup>

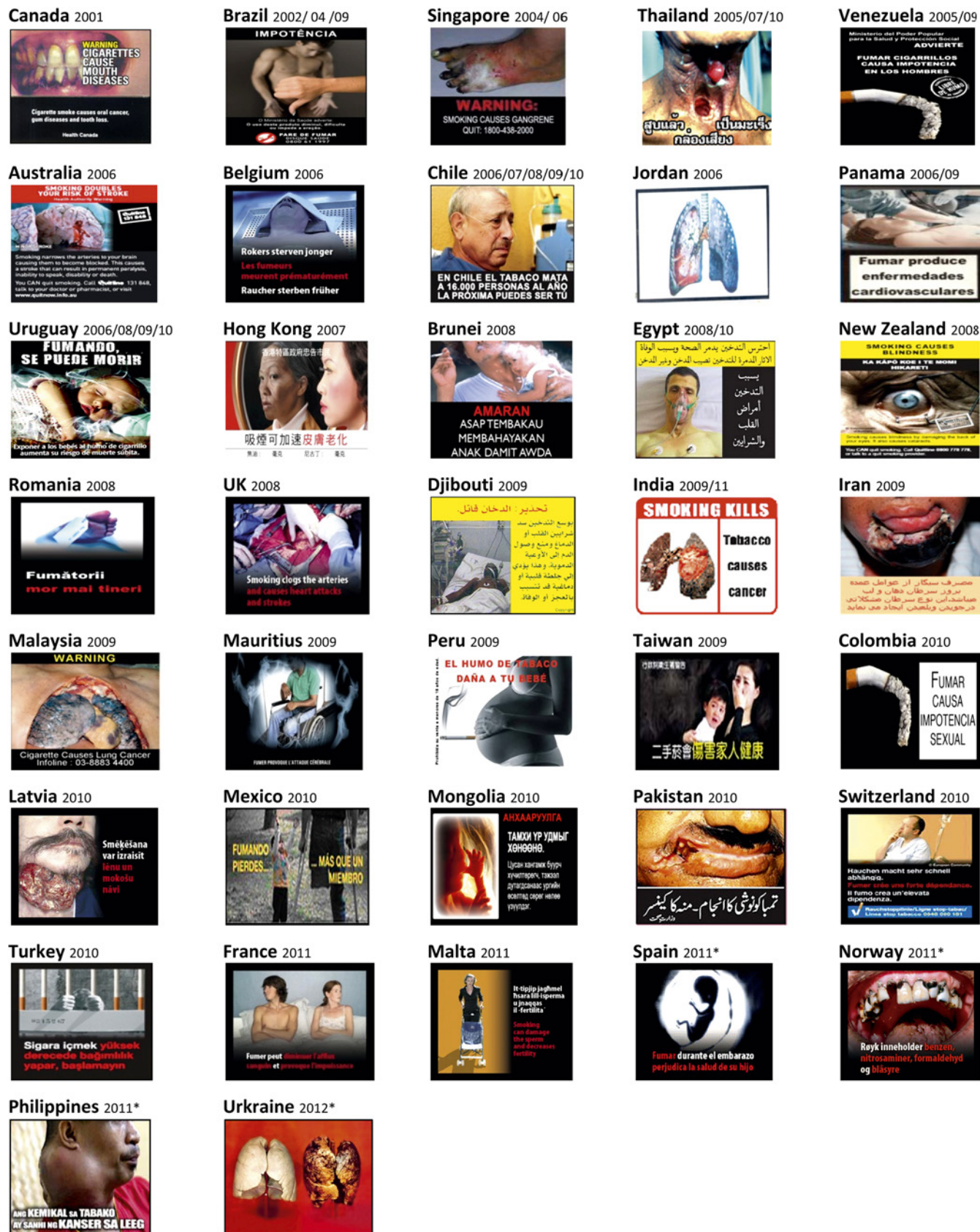
International guidelines for cigarette health warnings have been established under Article 11 of the WHO's Framework Convention on Tobacco Control (FCTC)—the first international treaty devoted to public health.<sup>8</sup> The FCTC requires rotating health warnings that cover at least 30% of the front and back of cigarette packages. Beyond these minimum requirements, the FCTC states that warnings 'should' cover 50% or more of a package's principal surfaces, and 'may' include pictures. 'Elaborated guidelines' include additional information to help guide implementation with more detailed recommendations, including general design, position and the content of warnings.<sup>9</sup> To date, more than 165 countries have ratified the treaty.

At present, cigarette packages in the vast majority of countries carry a health warning; however, the position, size and general strength of these warnings vary considerably across jurisdictions.<sup>10,11</sup> In 2001, Canada became the first country in the world to implement pictorial warnings and set new precedents in terms of the size of warnings, which covered 50% of the principal display areas (see figure 1). More than 30 countries have since adopted the FCTC recommendation for pictorial warnings that cover at least half of the package.<sup>11</sup> New precedents continue to be set in terms of the size of warnings; in Uruguay, for example, health warnings cover 80% of the front and back of packages.

Scientific literature on the impact of tobacco health warnings has grown in parallel with changes in regulatory practice. The current paper seeks to review evidence on the effectiveness of health warnings on tobacco packages. More specifically, the study sought to review evidence on the following: (1) differences between text versus pictorial warnings, (2) impact on youth and adults, (3) impact of message content and themes and (4) impact on cessation behaviour, including any potential adverse outcomes.

## METHODS

Published articles were identified through electronic searches of MEDLINE (Medical Literature Analysis



\*Proposed implementation date at time of publication.

Figure 1 Pictorial health warnings and implementation dates.

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and Retrieval System Online) and Web of Science databases. Electronic searches were also conducted to identify relevant 'grey literature', including unpublished research commissioned by governments. Additional searches using the reference lists of relevant articles were also conducted. The following keywords were used to identify relevant articles: health warning, health message, health communication, label and labelling in conjunction with at least one of the following terms: smoking, tobacco, cigarette, product, package and pack. The review was limited to articles that reported original research findings and were available for review by December 2010. Studies examining health warnings on advertisements (rather than packages) were excluded, as were studies on other aspects of packaging and labelling regulations, including labelling of ingredient and 'constituent' information as well as restrictions on deceptive marketing practices. Due to the diversity of research methods in this domain, we did not restrict studies to a particular design; however, each of the articles were reviewed for the following methodological criteria: (1) clearly stated objective/research question, (2) clear description of sample/study population, (3) consistent data collection method, (4) key measures appear to be valid, (5) main outcomes are defined and measurable and (6) analysis and summary of findings are clear and appropriate. Each article was reviewed by two independent reviewers. A total of 103 papers presenting empirical data were identified that met the general eligibility criteria. Following review of the full-text articles, seven were excluded on the basis of insufficient methodological information. The 94 original articles included in the review consisted of 72 quantitative studies, 16 qualitative studies, 5 studies with both qualitative and quantitative components, and 1 review paper. A summary of each study is available in online supplementary table 1. Research articles came from the following jurisdictions: Canada (n=35), USA (n=29) Australia (n=16), UK (n=13), The Netherlands (n=3), France (n=3), New Zealand (n=3), Mexico (n=3), Brazil (n=2), Belgium (n=1), other European countries (n=10), Norway (n=1), Malaysia (n=1) and China (n=1). Note that several articles included data collected in multiple countries: these articles were counted as a single study but recorded in multiple jurisdictions.

## RESULTS

### General awareness and prominence of health warnings

Smokers report high levels of awareness for health warnings on tobacco packages.<sup>12–25</sup> Data collected from a series of cohort studies found that more smokers reported getting information about the risks of smoking from cigarette packages than from any other source except television in a majority of countries.<sup>26</sup> For example, in countries with large pictorial warnings, such as Thailand, Australia and Uruguay, more than 85% of smokers cited packages as a source of health information.<sup>26</sup> A notable exception is the low levels of salience for more obscure warnings that appear on the side of packages, such as the health warnings implemented in the USA in 1984.<sup>27–28</sup> The findings suggest that small text warnings are associated with low levels of awareness and poor recall.<sup>29</sup>

Health warnings have also been found to be a prominent source of health information for non-smokers and the general public.<sup>14–17 21 24</sup> For example, 86% of non-smokers in Canada agreed in a national survey that the warnings on cigarette packs provide them with important health information.<sup>15</sup> Non-smokers also report high levels of recall for specific health messages on packs.<sup>17</sup> For example, more than a third of adult non-smokers in Australia could recall at least one specific

pictorial warning on cigarette packs in a 2008 survey.<sup>24</sup> In the UK, a national survey of youth conducted in 2008 found that approximately 60% of non-smokers could recall a specific warning displayed on the front of UK packs.<sup>16</sup>

The salience of health warnings depends upon the size and position of the warning message. Youth and adults are more likely to recall larger warnings, rate larger warnings as having greater impact, and often equate the size of the warning with the magnitude of the risk.<sup>18 19 24 30–34</sup> For example, a recent experimental research study conducted in Canada found that increasing the size of pictorial warnings from the current size of 50% of the principal display area to 75%, 90% and 100% enhanced their impact among adult smokers, youth smokers, as well as 'vulnerable' youth non-smokers.<sup>19 20</sup> A recent study conducted in Australia, where pictorial warnings cover 90% of the front and 30% of the back of packs, also found that the effectiveness of warnings could be improved by increasing the size of the warnings further.<sup>24</sup>

Features that distinguish the warning messages from the package design have also been found to increase the impact of health warnings. Using a box or perimeter around the outside of the message has been found to increase the salience and recall of warnings,<sup>30</sup> while contrasting colours, such as black lettering on a white background, are the easiest to read and increase comprehension.<sup>31 35</sup>

### Impact of text warning labels on health beliefs and attitudes

Several studies have shown that large text-based warnings are associated with increased perceptions of risk and health knowledge.<sup>12</sup> Cross-sectional surveys conducted in Canada during the 1990s found that the majority of smokers reported that package warning labels were an important source of health information and had increased their awareness of the risks of smoking.<sup>15 18 21 36</sup> An Australian study<sup>22</sup> found that, relative to non-smokers, smokers demonstrated an increase in their knowledge of the main constituents of tobacco smoke and identified significantly more disease groups following the introduction of new Australian warning labels in 1995.

Several studies have also evaluated the enhancement of text warnings in the European Union (EU). In 2003, EU warnings were required to be a minimum of 30% of the 'front' and 40% of the 'back' of packs. A series of 52 focus groups conducted in seven European countries in 2004 found that the enhanced text warnings in the EU were more noticeable than smaller warnings printed previously on packs, with a greater potential to help smokers to quit (figure 2).<sup>37</sup> A cohort study conducted in the UK before and after the enhanced warnings were implemented also found that the salience of the warnings increased dramatically among UK smokers, along with the frequency of thoughts regarding health effects and level of health knowledge.<sup>27</sup> These findings are consistent with a number of population-based surveys conducted after the implementation of the enhanced warnings in France,<sup>38</sup> Scotland and Ireland,<sup>39</sup> Spain<sup>40</sup> and Belgium.<sup>41</sup> Collectively, these studies indicate that smokers' awareness of the warnings increased following implementation of the new warnings and a considerable proportion of smokers reported measures consistent with increased perception of health risks as a result of more comprehensive text warnings.

### Impact of pictorial warning labels on health beliefs and attitudes

A wide variety of research has demonstrated the effectiveness of using pictures and imagery in health communications.<sup>42–50</sup> These studies suggest that health warnings with pictures are significantly more likely to draw attention, result in greater



**Figure 2** An example of EC/UK text-only warnings (2003).

information processing and improve memory for the health message.

Experimental research on cigarette warnings has also found that picture-based warnings are more likely to be rated as effective than text-only warnings on a range of outcomes, including as a deterrent for new smokers and a means to increase cessation among current smokers.<sup>51–56</sup> For example, a 2008 study conducted in China found that smokers were significantly more likely to rate pictorial warnings as more effective than text warnings for motivating smoking cessation and for preventing smoking among youth.<sup>57</sup>

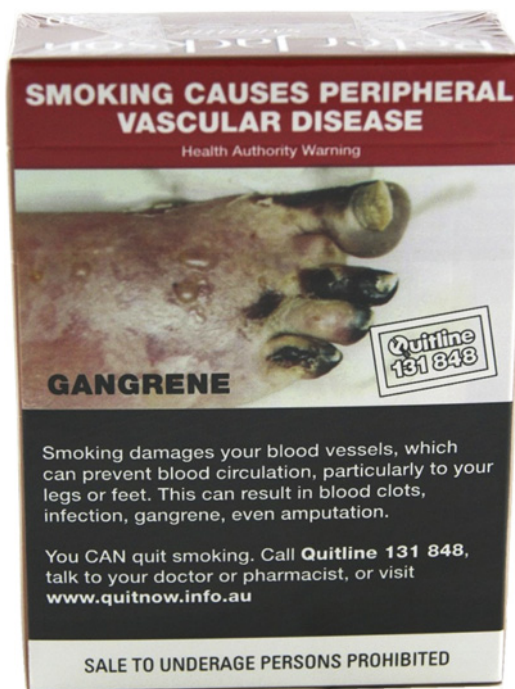
Extensive focus group testing and market research commissioned by government health agencies also support the effectiveness of pictorial health warnings on packages.<sup>50 41 53 58–67</sup> This research consistently demonstrates that health warnings with pictures are rated by smokers and non-smokers as more effective than text-only warnings. For example, a set of 40 focus groups conducted in Canada approximately 5 years after the introduction of pictorial warnings concluded that: 'The picture was generally the first thing people looked at and related to. It determined the strength of the warning's emotional impact and noticeability. For many participants, the picture played the key role in understanding the message, and tended to override the meaning conveyed by the words in the headline.' (p 26)<sup>67</sup> A series of 24 focus groups conducted in Australia approximately 2 years after the introduction of the pictorial warnings came to similar conclusions: 'Throughout the group discussions the graphic health warnings were invariably considered to have greater impact than the previous text-only health warnings... The graphic images have seemingly increased or reinforced awareness

of those consequences that were previously text only... as well as, communicated new information' (pp 12–16) (figure 3).<sup>62</sup>

Since 2001, when Canada became the first country to implement pictorial health warnings on cigarette packs, a series of population-based surveys have compared the effectiveness of text versus pictorial warnings. These findings are consistent with both experimental studies and government-commissioned research: pictorial warnings are more likely to be noticed and read by smokers, are associated with stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking.<sup>23 26 27 51 52 55 58–62 67–74</sup>

Picture warnings also appear to be effective among youth. Approximately 6 years after their introduction, more than 90% of Canadian youth agreed that picture warnings on Canadian packages had provided them with important information about the health effects of smoking cigarettes, are accurate, and made smoking seem less attractive.<sup>21</sup> Other national surveys of Canadian youth suggest similar levels of support and self-reported impact.<sup>18</sup> A recent longitudinal evaluation of pictorial warnings among Australian school children found that students were more likely to read, attend to, think about, and talk about health warnings after the pictorial warnings were implemented in 2006.<sup>71</sup> In addition, experimental and established smokers were more likely to think about quitting and to forgo smoking a cigarette, while intention to smoke was lower among those students who had talked about the warning labels and had forgone cigarettes.

Only three of the studies we identified failed to support the superiority of text over graphic warnings. An experimental study conducted with youth smokers in Germany compared the current EU text warnings with corresponding pictorial warnings, and failed to detect any significant differences between the conditions.<sup>75</sup> The second study examined the impact of briefly viewing a text versus pictorial warning on a website among 296 non-smoking secondary-school students from Canada and the USA. The study found that the picture warnings were more effective than the text-only warning at lowering intentions to



**Figure 3** A sample pictorial health warning in Australia (2010).

smoke among the Canadian students, but less effective among US students.<sup>76</sup> The third study examined the speed with which participants responded to a text statement (some of which were accompanied by an image) as an outcome, and failed to note differences.<sup>77</sup> However, as the authors note, measures of reaction time may not be an appropriate measure of the impact of a warning, particularly considering that emotional responses may increase rather than decrease reaction time.

### Health warnings and cessation behaviour

The extent to which health warnings lead to changes in smoking behaviour is difficult to ascertain within the context of population-based data.<sup>78</sup> However, significant proportions of adult and youth smokers report that large text and pictorial health warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit and increased the likelihood of remaining abstinent following a quit attempt.<sup>15 18 21–27 68 69 79–82</sup> For example, one-fifth of smokers in an EU-wide survey reported that health warnings have been effective in getting them to smoke less and in helping them try to quit.<sup>17</sup> In countries with pictorial health warnings, such as Canada and Australia, these numbers are higher: more than 40% of Canadian smokers report that the pictorial warnings have motivated them to quit smoking<sup>68</sup>; in Australia, 57% of smokers report that the labels have made them think about quitting and 34% say the warnings have helped them to try to quit.<sup>24</sup> Similar findings have been observed among youth. For example, in 2008, almost 80% of youth smokers in the UK agreed that the warnings had 'put me off smoking'.<sup>16</sup> Three longitudinal studies—two with adults and one with youth—found an association between reading and thinking about health warnings and subsequent cessation behaviour, including a cohort study conducted with nationally representative samples of smokers in Canada, Australia, the UK and the USA.<sup>23 39 71</sup>

Health warnings have also been associated with increased use of effective cessation services. Research conducted in the UK, The Netherlands, Australia and Brazil examined changes in the use of national telephone 'helplines' after the contact information was displayed within package health warnings. Each of these studies reported significant increases in call volumes following the introduction of new warnings.<sup>25 65 83–86</sup> For example, calls to the smoking cessation helpline in The Netherlands increased more than 3.5 times in the 12 months after the helpline number was printed on the back of one of 14 package warnings.<sup>84</sup> In the UK, call volume increased by as much as 4000 calls per month after the introduction of larger text warnings.<sup>83</sup>

Surveys among former smokers also suggest that health warnings promote long-term abstinence from smoking. In Australia, 62% of quitters reported in 2008 that the pictorial warnings had 'helped them to give up smoking,' while 75% reported the warnings 'had an effect on their behaviour'—a significant increase from the 25% who reported an effect from text warnings 8 years earlier.<sup>24</sup> In addition, approximately 30% of former smokers in the EU reported in 2008 that health warnings had helped prevent them from smoking again,<sup>17</sup> with similar proportions of former smokers in Canada reporting that pictorial health warnings helped them to remain abstinent.<sup>87</sup>

A single study has examined changes in prevalence due to health warnings. The study concluded that the implementation of pictorial warnings in Canada reduced daily consumption of cigarettes, but had no discernable impact on prevalence.<sup>88</sup> However, there are serious limitations to linking changes in

national prevalence and health warnings in this way. First, the study examined prevalence rates in the 6 months following the implementation date of the regulation, which did not correspond to the date when health warnings began appearing on packages. Although warnings are expected to exert their impact over time, the pictorial warnings in Canada took many months to appear in retail outlets and appeared on relatively few packs during much of the follow-up period examined by the study. In fact, the prevalence of adult smoking in Canada has declined approximately 6% since the implementation of large pictorial warnings in 2001.<sup>89</sup> However, there is no way to attribute these declines to the new health warnings given that health warnings are typically introduced against a backdrop of other tobacco control measures, including changes in price/taxation, mass media campaigns and smoke-free legislation.

### Health warnings and smoking initiation

A few studies have attempted to directly assess the impact of health warnings on smoking initiation among youth using prevalence rates. Although youth smoking rates have declined dramatically in countries such as Canada after the implementation of large pictorial health warnings,<sup>89</sup> there is no reliable way to attribute these changes specifically to the warnings rather than other tobacco control measures. However, population-based surveys indicate that significant proportions of youth non-smokers, including the most vulnerable youth populations in Canada,<sup>14 19 21</sup> the UK<sup>16</sup> and Australia<sup>71</sup> report that warnings have discouraged them from smoking. Between one-fifth and two-thirds of youth non-smokers indicated that the warnings had helped prevent them from taking up smoking in Canada<sup>21</sup> and Australia,<sup>24</sup> and approximately 90% of youth non-smokers in a national UK survey reported that the warnings 'put them off smoking'.<sup>16</sup> Longitudinal surveys in Australia also found that experimental and established smokers were more likely to think about quitting and forgo cigarettes after the implementation of large pictorial warnings, while the intention to smoke was lower among those students who had talked about the warning labels.<sup>71</sup> Finally, nationally representative surveys conducted in 2008 with over 26 000 respondents from 27 EU member states and Norway found that 3 out of 10 non-smokers in the EU reported that health warnings were effective in preventing them from smoking.<sup>17</sup> Levels were highest in Romania, where pictorial warnings were implemented shortly before the survey was conducted, with 6 in 10 non-smokers reporting that the warnings have helped to prevent them from smoking.<sup>17</sup>

Overall, while it is not possible to quantify the impact of health warnings on smoking prevalence, all of the evidence conducted to date suggests that comprehensive health warnings can promote cessation behaviour and discourage initiation, and that larger pictorial warnings are most effective in doing so.

### Message theme and content of health warnings

Health warnings vary considerably in their content and 'executorial' style. Qualitative research and pre-market focus group testing have evaluated the content of health warnings in several jurisdictions. The primary outcomes used to evaluate health warnings include their ability to attract attention, comprehension, credibility, novelty, personal identification, and emotional appeal.<sup>16 42 59 63 67</sup> Negative emotions, such as fear, may be particularly important in the effectiveness of large pictorial warnings given the importance of emotional arousal in message acceptance.<sup>90 91</sup> Negative emotional reactions to cigarette health warnings have been associated with increases in key outcomes such as intentions to quit, thinking about health risks or

engaging in cessation behaviour.<sup>55 62 69 92</sup> For example, a Canadian study found that approximately half of smokers reported at least some fear, disgust or anger in response to the pictorial health, and levels of fear and disgust were associated with an increase in cessation behaviour at follow-up.<sup>69</sup> An experimental study conducted in the USA found that pictorial warnings were associated with greater negative emotions than US style text warnings, and that these emotions were associated with more negative attitudes towards smoking.<sup>92</sup> Other negative emotions such as disgust may also play a role in message acceptance for graphic pictorial health warnings, although this has yet to be explored in the context of package warnings.<sup>93–95</sup>

Graphic depictions of disease appear to be the most reliable way to elicit negative emotional reactions to health warnings.<sup>37 42 54 59 61 62 64 65 67 69 74 96</sup> For example, research conducted in Canada with 40 focus groups to test new health warning concepts concluded that:

Participants in all groups consistently expected or wanted to be shocked by HWMs [Health Warning Messages], or emotionally affected in some way. Even if the feelings generated were unpleasant ones to tolerate, such as disgust, fear, sadness or worry, the emotional impact of a warning appeared to predict its ability to inform and/or motivate thoughts of quitting. HWMs which worked on emotions rather than on knowledge or beliefs were often acknowledged as effective and noticeable, and actually motivated thinking. When a strong emotion generated by a HWM was supported by factual information, that was the best combination possible. (p 3)<sup>67</sup>

Studies of the pictorial warnings developed in the European Union also support the effectiveness of fear-arousing health warnings. Studies in France,<sup>64</sup> Belgium,<sup>41</sup> Spain,<sup>40</sup> Bulgaria<sup>66</sup> and the UK<sup>65</sup> consistently demonstrated that warnings with shocking images (such as rotten teeth or throat cancer) were rated as most effective. Shocking images are also most likely to be recalled by smokers in population-based studies of warnings on Canadian,<sup>15 21</sup> Australian<sup>24</sup> and European<sup>41</sup> cigarette packs. For example, the top four warnings recalled by Australian smokers and nominated as most effective all depicted graphic health effects, including a picture of a lung cancer tumour, a sick baby in a hospital, a picture of mouth cancer and a gangrenous foot.<sup>24</sup> Likewise, a series of national surveys also suggest that Canadian smokers and non-smokers are most likely to recall images of rotting lungs and diseased mouths—both graphic depictions of disease—as well as a picture of a limp cigarette depicting impotence.<sup>16 21</sup> However, it is worth noting that at least one study found that recall of health warnings was lower for moderately or highly graphic pictorial warnings compared with controls and warnings with less graphic content.<sup>55</sup> As the authors of this study point out, health warning recall measured following a single exposure during a study does not replicate 'real world' conditions, in which smokers are repeatedly exposed to warnings.

Warnings that highlight negative aesthetic effects of smoking may be particularly effective among young people.<sup>37 59 62 63</sup> These messages include those that specifically target health consequences of smoking such as wrinkled skin, premature ageing and skin discolouration, as well as warnings that feature an externally visible health consequences, particularly on highly visible areas such as the face, such as rotting teeth and cancerous gums.

Warnings that depict elements of human suffering—depictions of personal experience including the social and emotional impact of tobacco use, or consequences for quality of

life—have also been found to be effective. In a study conducted among Mexican youth, warnings that depicted elements of human suffering—both to oneself and others—were rated as significantly more effective than warnings without elements of human suffering.<sup>97</sup> In contrast, warnings that relied on symbolic representations, including imagery or symbols, were significantly less likely to be effective.

The use of 'narratives' or personal testimonials that depict the images and experiences of 'real' people has been associated with increased emotional impact of warnings.<sup>98</sup> For example, a study conducted in Mexican adults and youth found that adding names and ages of the individuals portrayed in health warnings increased the perceived effectiveness of warnings.<sup>97</sup> Research also suggests that factual or 'scientific' information can enhance emotionally vivid warnings to maximise message acceptance, particularly when it is written in a clear, direct manner.<sup>59 67 99</sup> These findings underscore the importance of credibility or 'believability' with regards to message acceptance: warnings that appear to be 'staged' or 'fake' undermine a message and lead to message rejection.<sup>99</sup>

Evidence on the impact of positive health warning messages is mixed. Focus groups have consistently reported a desire among smokers for more positive health warning messages, particularly among smokers actively contemplating quitting.<sup>37 58 59 63</sup> However, positive-themed cessation messages are typically rated as having lower impact than fear-appeals or 'graphic' health warnings, and are less likely to be recalled in population-based surveys.<sup>37 58 59</sup> Experimental studies of positive messages are generally consistent with evidence from focus groups. For example, 'gain-framed' messages on packs, which focus on the benefits of quitting, were rated by youth as significantly less likely to reduce tobacco consumption and encourage quitting compared with 'loss-framed' messages.<sup>100</sup> Despite the lack of evidence supporting the effectiveness of general messages of support, smokers consistently endorse the inclusion of detailed information on the benefits of quitting, as well as concrete information on forms of cessation assistance and tips for quitting.<sup>24 67 99</sup>

Finally, focus groups have yielded mixed findings on the impact of addiction-focused messages. Many smokers view these types of messages as 'old' information and several noted that they contribute to a sense of fatalism.<sup>62</sup> Warnings on addiction may also meet with some resistance from youth and young adults, many of whom do not perceive themselves to be addicted.<sup>67</sup>

### Potential adverse outcomes from health warnings

Graphic, fear-arousing warnings have been criticised on the grounds that they may arouse 'excessive' levels of fear among smokers, leading to defensive reactions such as rejection of the message, avoidance of the warnings or even increases in smoking as an act of defiance.<sup>101–106</sup> One study conducted among US youth reported an association between increased smoking and increased knowledge of health warnings—a finding characterised by the authors as 'paradoxical' and evidence that US health warnings were ineffective.<sup>107</sup> However, because exposure to health warnings is 'tied' to exposure of cigarette packs, one might expect such an association during the period of smoking initiation among youth: as the intensity of smoking behaviour increases, so also does the familiarity with packages. Without a comparison group, the authors had no way of knowing whether the increases in smoking behaviour were greater, less or no different than would have been the case if no warnings or more comprehensive warnings had been implemented.

In contrast to the findings of this study, no significant adverse outcomes have been noted in the other quantitative or

qualitative studies included in this review. Population-based surveys have recorded significant avoidant behaviours among smokers, in terms of efforts to hide the warnings using a case or trying to avoid a particular warning at the point-of-sale; however, in the same studies, smokers who reported avoidance behaviour were just as likely as others to subsequently attempt to quit smoking and report benefits from health warnings.<sup>39</sup> In the context of the warning labels, avoidance behaviour might be more reasonably interpreted as a measure of effectiveness: if the warnings were ineffective in communicating the threatening consequences of smoking there would be no reason to avoid them.

One possible reason for the lack of adverse outcomes is that large pictorial warnings with shocking pictures are typically accompanied by supportive messages designed to increase self-efficacy for quitting smoking, as well as concrete information on quitting, such as a telephone helpline number. Health communication theories, such as the Extended Parallel Process Model, predict that messages that combine threatening information with information that increase self-efficacy for behaviour change are most likely to result in positive behaviour change.<sup>105</sup>

### Effectiveness of health warnings among subpopulations

Levels of perceived effectiveness have been found to be lower among dependent and more 'committed' smokers.<sup>57</sup> However, an EU survey found that younger respondents, less-educated respondents and 'manual' workers across all groups were slightly more likely to perceive health warnings as effective.<sup>17</sup> SES differences are likely to be most pronounced for text-only health warnings. Text-based warnings require adequate literacy skills and the literacy level of warnings in many countries is advanced.<sup>108 109</sup> This is particularly important considering that, in most countries, smokers report lower levels of education than the general public. Picture-based warnings may be particularly important in communicating health information to populations with lower literacy rates.<sup>108 110</sup> Preliminary evidence suggests that countries with pictorial warnings demonstrate fewer disparities in health knowledge across educational levels.<sup>111</sup>

### 'Wear-out' and impact of health warnings over time

Health warnings that are new or periodically updated are likely to have greater impact than 'older' warnings, even in the absence of changes in size and position. Canadian research monitored the effectiveness of the pictorial warnings among nationally representative samples over 12 waves of data collection and indicated that health warnings have their greatest impact shortly after implementation and decline in effectiveness over time.<sup>15</sup> This is consistent with national survey data from other countries, including the UK and Australia.<sup>22 59 68</sup> In particular, youth commonly report on the stale or ineffective nature of 'old' warnings that remain unchanged for more than several years.<sup>18 58 115</sup> This is consistent with the basic principles of advertising and health communications, which suggest that the salience of a communication is greatest upon initial exposure and erodes thereafter.<sup>113 114</sup> Although all warnings are subject to 'wear-out' over time, recent research suggests that larger pictorial warnings sustain their effects longer.<sup>72</sup>

### Health warnings and brand appeal

Prominent health warnings that cover a significant proportion of the package—particularly pictorial warnings—have the potential to undermine a brand's appeal and the impact of package displays at retail outlets.<sup>21 25 37 54 56 64 115 116</sup> For example, 88% of youth smokers in Canada and 90% of 'potential smokers'

reported that picture-based health warnings make smoking seem less attractive. One recent study found that including graphic pictures compared with text warnings lowered the appeal of non-combustible products, nicotine lozenges and cigarettes with modified designs.<sup>112</sup>

### Impact of 'standardised' or 'plain' packaging on health warnings

Three studies have examined the impact of removing the colour and brand imagery from packs on the effectiveness of health warnings. When shown health warnings on 'plain' white packages with a standard colour and font size, youth in Canada<sup>117</sup> and New Zealand<sup>118</sup> were significantly more likely to recall specific health warnings on packs. A survey in Ontario, Canada also found that more than half of school children rated health warnings on plain white packs as 'easier to see' and 'more serious' compared with warnings on regular branded packs, with improved recall among smokers.<sup>33</sup>

### Credibility and public support for health warnings

Research indicates that both adult and youth smokers report graphic warnings to be a credible source of information.<sup>14–16 18 21 24 119 120</sup> For example, 6 years after the implementation of pictorial warnings in Canada, 86% of adult smokers and 92% of youth smokers agreed that the warnings were accurate.<sup>15 21</sup> Similarly, more than 90% of Australian smokers reported that large pictorial health warnings were 'believable', a slight increase from the levels reported in 2000 when text warnings appeared on Australian packages.<sup>24</sup>

Several studies also report high levels of public support for graphic pictorial warnings.<sup>69 121</sup> In Brazil, a national survey indicated that 76% of those interviewed approved of the measure, including 73% of smokers.<sup>25</sup> Two years after the introduction of large pictorial warnings in Uruguay, only 8% of adult smokers reported they would prefer less health information to appear on packages, whereas 62% reported they would like more health information on packages.<sup>26</sup> Similar levels of popular support have been observed following the introduction of pictorial warnings in Canada and Thailand.<sup>23 26</sup> In Australia, the vast majority (85%) of Australians considered it 'very' or 'quite important' that the government has health warnings on packs after the introduction of pictorial health warnings, including a majority of smokers.<sup>24</sup> A significantly greater proportion of smokers and recent quitters rated health warnings as important compared with a similar survey conducted in 2000 when text warnings appeared on Australian packages.<sup>12</sup> Finally, surveys conducted in EU member states in 2008 found that more than half of EU citizens supported the effectiveness of adding a picture to text-only health warnings, while more than 87% of respondents in a nationally representative survey in Russia agreed that graphic warnings should be mandated on packages, including 80% of smokers.<sup>17 74</sup> Similar levels of support have been recorded among youth.<sup>74</sup> For example, in Canada more than 90% of youth agreed that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarettes.<sup>21</sup>

### Health warnings on 'non-cigarette' tobacco products

Labelling requirements for manufactured cigarettes are more advanced than for other tobacco products. In many jurisdictions, tobacco products such as cigars and smokeless products are subject to different regulations and often carry a different set of health warnings or no warning at all. The research literature on the effectiveness of health warnings on non-cigarette warnings is sparse. To our knowledge, only two published studies exist.

One study found that small text warnings are likely to have little impact on recall and intentions to use smokeless tobacco among US youth.<sup>115</sup> The second study was conducted among young adult cigarette smokers in Canada and found that pictorial health warnings increased the perceived risks of smokeless products and lowered intentions to try smokeless products.<sup>122</sup> There is also a need for research to examine issues such as unconventional packaging sizes, which are more common for non-cigarette products. In addition, in many jurisdictions tobacco products are sold without any manufactured packaging. This practice will inevitably reduce the impact of comprehensive labelling policies. Finally, alternative tobacco products may require unique message content to reflect differences in health effects and patterns of use.<sup>123 124</sup> Given the lack of information in this area, research on health warnings for 'alternative' tobacco products should be regarded as a priority for future work.

## DISCUSSION

Health warnings on cigarette packages have a broad population reach and represent a direct means of communicating the risks of smoking. For example, 3 out of 10 participants in an EU-wide survey—equivalent to more than 160 million individuals—recently reported that health warnings on tobacco packs are effective in informing them about the health effects of tobacco.<sup>17</sup>

The evidence also suggests that health warnings can promote smoking cessation and discourage youth uptake. Considerable proportions of smokers report that warning labels increase their motivation to quit and help them to sustain abstinence after quitting, and the use of effective cessation services increases after new health warnings have been implemented (figure 4). However, the impact of health warning labels depends upon their design: obscure text-only warnings appear to have little



**Figure 4** An example of supportive, cessation-oriented messages in the UK (2010).

impact, in contrast to larger pictorial warnings on the front and back of packages in other jurisdictions. Pictorial warnings that include vivid fear-arousing depictions of health effects appear to be particularly effective among smokers and non-smokers. This finding is consistent with research evaluating anti-tobacco television ads, which indicates that messages with 'visceral negative' themes had the strongest and most consistent effects on appraisal, recall and level of engagement.<sup>125 126</sup> Preliminary evidence also suggests that the use of narratives or 'personal testimonials', such as a first-person account of the health effects of smoking, may be an effective theme for warnings. This is consistent with the health communication literature, which suggests that narrative evidence may be less affected by 'defensive' reactions, perhaps due to greater credibility and levels of engagement.<sup>127 128</sup> Narrative evidence may also help individuals imagine health consequences, which may be particularly important for negative or loss-framed messages.<sup>129</sup> Fear-arousing information and graphic images should also be integrated with efficacy information on the benefits of quitting and concrete information on ways to quit. Inclusion of concrete quitting information is strongly supported by smokers and has been shown to increase the use of these services dramatically.

Although the research literature unequivocally demonstrates the impact of comprehensive health warnings, the evidence also highlights the importance of contextual factors. Levels of effectiveness differ across countries, even for very similar health warnings. Indeed, the same text warnings have been implemented in virtually all EU member states since 2003; yet, smokers and non-smokers in different countries report different levels of effectiveness. Social norms surrounding tobacco use, as well as the strength of other tobacco control measures, likely mediate the impact of warnings. Individual-level differences, such as level of dependence, pre-existing health beliefs, and personal experience with the health effects of smoking may also mediate the impact of health warnings. In addition, not all messages resonate equally well with all individuals or target groups.<sup>130</sup> Regulations that require a larger number of warnings to rotate on packages, such as the 16 warnings required under Canadian regulations implemented in 2001, allow for greater targeting of subgroups. Nevertheless, many messages have been found to have broad appeal and the messages found to be most effective among adults are typically rated equally well among youth and young adults.<sup>15 18 58 62 67</sup> While this evidence does not argue against the potential benefit of targeting subgroups of smokers, it does suggest that warnings do not necessarily have to be youth or adult focused to have impact.

Evidence of the benefit of using pictures and the importance of location and other design elements is consistent with evidence from other domains such as hazardous chemicals,<sup>50 131</sup> nutritional labelling<sup>132 133</sup> and alcohol labelling.<sup>134 135</sup> However, the research literature indicates greater levels of impact for cigarette health warnings compared with warnings on food and alcohol products. This is likely due to differences in the design of warnings: cigarette health warnings in many jurisdictions are considerably more prominent than food and alcohol warnings in terms of their size, position on packages and the use of pictures. Indeed, evidence on the impact of obscure text-only warnings on cigarette packages is similar to the level of effectiveness associated with alcohol warning labels, for example.

Future research on tobacco health warnings should consider effective types of *message content* for pictorial warnings to a greater extent. There is a particular need to evaluate different themes or 'executional styles', including the potential impact of

testimonials and personal narratives, as well as messages on the broader consequences of tobacco use, including the financial cost of smoking. It is also unclear whether the impact of messages varies across different cultures and geographical regions, particularly in low- and middle-income countries. Many low- and middle-income countries have implemented images designed for warnings in Canada and Australia. It is critical to ensure that these messages are culturally appropriate and are effective in much different cultural and social environments. Additional research is also required on implementation issues, including the ideal rotation period for 'revising' health warnings, as well as the extent to which regulations can be applied to tobacco packages with unorthodox shapes. Finally, research should examine other ways to increase the effectiveness of health warnings, such as the use of 'plain' or 'standardised' packaging, as well as novel uses of the pack, such as the use of inserts or 'onserts' attached to the outside of packs, which are commonly used by the industry for promotional purposes.<sup>11</sup>

### Limitations

The research included in this review consists of a wide range of study designs conducted in diverse cultural and geographic settings. As a consequence, there are constraints on subjecting this evidence to systematic inclusion criteria based on methodology. For example, focus groups and pre-market testing conducted on behalf of governments constitute a large and important source of evidence on the impact of cigarette health warnings; yet, qualitative studies present challenges to systematic reviews, particularly when placed alongside experimental and population-based research. However, we believe that the heterogeneous nature of the research literature is an asset rather than a limitation of this evidence base, particularly considering the consistent findings across methodologies. Another limitation of the current review is that, despite the relatively broad inclusion criteria, relevant studies may have been missed, particularly studies from low- and middle-income countries that may not be widely disseminated in English.

### Summary

In many ways, health warnings on tobacco packages are an ideal population-level intervention: they have broad reach, they cost little to implement and are sustainable over time. Indeed, the WHO recently identified comprehensive health warnings on packages among the six key measures required to address the global tobacco epidemic.<sup>2</sup> Research to date highlights the importance of packaging as a medium for communicating with smokers and provides strong support for two key precedents set within the last decade: the use of pictures and the increasing size of warnings on the pack. The next generation of labelling policies and research is likely to focus on message content to a greater extent. To date, content has been relatively 'static': stand-alone messages focused primarily on health effects. However, more sophisticated message campaigns are possible, including greater linkages across individual messages, building narratives over time, and using packages to link smokers with cessation services. Countries such as Australia have taken the first step towards integrating health warnings with mass media campaigns. As these regulatory developments unfold, research must keep pace to ensure that the evidence base evolves in parallel with regulatory practice.

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## RESEARCH PAPER

# Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey

D Hammond, G T Fong, A McNeill, R Borland, K M Cummings

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See end of article for authors' affiliations

Correspondence to:  
Dr David Hammond,  
Department of Health  
Studies and Gerontology,  
University of Waterloo,  
200 University Avenue  
West, Waterloo, Ontario,  
N2L 3G1, Canada;  
dhammond@uwaterloo.ca

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**Background:** Health warnings on cigarette packages are among the most common means of communicating the health risks of smoking. However, few studies have evaluated the impact of package warnings on consumer knowledge about tobacco risks.

**Objective:** The aim of the current study was to use nationally representative samples of adult smokers from the United States (USA), the United Kingdom (UK), Canada (CAN), and Australia (AUS) from the International Tobacco Control Four Country Survey (ITC-4) to examine variations in smokers' knowledge about tobacco risks and the impact of package warnings.

**Methods:** A telephone survey was conducted with 9058 adult smokers from the following countries: USA (n = 2138), UK (n = 2401), CAN (n = 2214) and AUS (n = 2305). Respondents were asked to state whether they believed smoking caused heart disease, stroke, impotence, lung cancer in smokers, and lung cancer in non-smokers. Respondents were also asked whether the following chemicals are found in cigarette smoke: cyanide, arsenic and carbon monoxide.

**Findings:** Smokers in the four countries exhibited significant gaps in their knowledge of the risks of smoking. Smokers who noticed the warnings were significantly more likely to endorse health risks, including lung cancer and heart disease. In each instance where labelling policies differed between countries, smokers living in countries with government mandated warnings reported greater health knowledge. For example, in Canada, where package warnings include information about the risks of impotence, smokers were 2.68 (2.41–2.97) times more likely to agree that smoking causes impotence compared to smokers from the other three countries.

**Conclusion:** Smokers are not fully informed about the risks of smoking. Warnings that are graphic, larger, and more comprehensive in content are more effective in communicating the health risks of smoking.

Tobacco use has been identified by the World Health Organization as the leading cause of death and disability in the world.<sup>1</sup> To date, more than 24 different smoking-related diseases have been identified, including cardiovascular disease, respiratory disease, and 10 different forms of cancer.<sup>2</sup>

The extent to which smokers understand the magnitude of these health risks has a strong influence on their smoking behaviour.<sup>3–5</sup> Smokers who perceive greater health risk from smoking are more likely to intend to quit and to quit smoking successfully.<sup>6–7</sup> The health risks of smoking are also the most common motivation to quit cited by current and former smokers, as well as the best predictor of long-term abstinence among reasons for quitting.<sup>8–10</sup>

At present, most smokers concede that tobacco use is a health risk; however, important gaps remain in their understanding of these risks.<sup>11–14</sup> Many smokers are unable to recall specific health effects and most tend to underestimate the scope of these effects.<sup>11–19</sup> Even in countries such as Canada, with among the most progressive tobacco control policies in the world, a significant proportion of smokers continue to underestimate the most serious risks of smoking, including heart disease, stroke, and respiratory disease, as well as the risks of environmental tobacco smoke.<sup>11–20</sup>

In addition to the fact that smokers are not fully informed, there are biases in how smokers perceive these risks. In a review of the research literature, Weinstein<sup>21</sup> found that, although most smokers acknowledge the risk of smoking, they tend to “minimize that risk and show a clear tendency to

believe that the risk applies more to other smokers than to themselves” (page 139). Considerably less is known about smokers' knowledge of the constituents of tobacco smoke, including well-known toxicants such as carbon monoxide and cyanide. What little evidence exists suggests a very low level of awareness,<sup>22–23</sup> although the impact of this knowledge remains largely unexplored.

Communicating the health effects of smoking remains a primary goal of tobacco control policy.<sup>24</sup> Indeed, the World Health Organization's Framework Convention on Tobacco Control (FCTC) states as its first guiding principle that: “Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke” (Article 4.1). Cigarette warning labels are among the most widespread policy initiatives implemented to educate smokers. Recent research indicates that graphic warning labels on cigarette packages can increase cessation behaviour among smokers<sup>25–27</sup>; however, despite their prominence among tobacco control policies, only a handful of studies have evaluated the impact of different product warning policies on consumer knowledge about tobacco risks.

A study commissioned by Imperial Tobacco reported an increase in the proportion of smokers who agreed that smoking is dangerous following the introduction of Canada's

**Abbreviations:** CATI, computer assisted telephone interviewing; FCTC, Framework Convention on Tobacco Control; ITC-4, International Tobacco Control Four Country Survey



**Figure 1** Cigarette package warning labels of the four countries (Canada, Australia, United Kingdom, United States) participating in the International Tobacco Four Country Survey (as of 2002).

first warning labels in 1972.<sup>28</sup> Cross-sectional surveys conducted in Canada during the 1990s found that the majority of smokers reported that package warning labels are an important source of health information and have increased their awareness of the risks of smoking.<sup>11-29</sup> In Australia, Borland<sup>30</sup> found that, relative to non-smokers, smokers demonstrated an increase in their knowledge of the main constituents of tobacco smoke and identified significantly more disease groups following the introduction of new Australian warning labels in 1995. However, considering the importance of health warnings among tobacco control policies, there is a need for additional research. In particular, there is a need for research that can help policymakers to choose the size and general strength of health warnings from within the general recommendations outlined in the FCTC.

At present, cigarette packages in virtually every country carry warning labels,<sup>31</sup> yet the size, number, and the way the health information is presented differs notably between countries. Labelling policies range from vague statements of risk (for example, “Smoking can be harmful to your health”), to graphic pictorial depictions of disease. Because of the variation between countries in package warning labels, an opportunity now exists to explore the impact of different warning policies on consumer knowledge. The International Tobacco Control Four Country Survey (ITC-4) is a cohort survey of adult smokers conducted in four countries—the United States (USA), the United Kingdom (UK), Canada (CAN), and Australia (AUS)—that was designed to examine the impact of national-level tobacco control policies, including warning labels. Figure 1 depicts health warnings in the four countries participating in the ITC-4 Survey as of Wave 1 of the survey, conducted in 2002.\*

The aim of the current study was to use nationally representative samples of adult smokers from the USA, UK, CAN, and AUS to: (1) examine smokers’ knowledge that smoking causes heart disease, stroke, impotence, and lung cancer; (2) to assess smokers’ knowledge of the constituents of tobacco smoke, including carbon monoxide, cyanide, and arsenic; and (3) to examine the relationship between health knowledge in each country and that country’s tobacco labelling policy.

**METHODS**  
**Sample**

Participants in the ITC-4 Survey were 9058 adult smokers (18 years or older, smoked more than 100 cigarettes in their life, and smoked at least once in the past 30 days) in four countries: CAN (n = 2114), USA (n = 2138), UK

(n = 2401), and AUS (n = 2305). Table 1 provides the sample characteristics for each country.

**Procedure**

The ITC-4 cohort was constructed from probability sampling methods with telephone numbers selected at random from the population of each country, within strata defined by geographic region and community size. Eligible households were identified by asking a household informant the number of adult smokers. The Next Birthday Method<sup>32</sup> was used to select the respondent in households with more than one eligible adult smoker.

The survey was conducted using computer assisted telephone interviewing (CATI) software and was completed in two calls: a 10-minute recruitment call was followed one week later by a 40-minute main survey. In order to increase recruitment rates,<sup>33</sup> participants were mailed compensation equivalent to US\$10 before completing the main survey. Interviews were conducted by two survey firms: Roy Morgan Research (Melbourne, Australia) surveyed Australian and UK respondents, and Environics Research Group (Toronto, Canada) surveyed Canadian and US respondents. All aspects of the interviewer training and calling protocol were standardised across the two survey firms and closely supervised by the ITC-4 team. The present analysis is limited to respondents from Wave 1, conducted between October and December 2002. A full description of the ITC-4 methodology, sample profile, and survey rates, including comparisons with national benchmarks, is available at <http://www.itcproject.org>.

**Measures**

The ITC-4 Survey was standardised across the four countries: respondents in each country were asked the same questions, with only minor variations for colloquial speech.

**Demographics and smoking behaviour**

The survey included validated measures of smoking behaviour and quit history. Intention to quit was assessed by asking: “Are you planning to quit in the next month, 6 months, beyond 6 months, or not at all?” Level of education consisted of three categories: high school diploma or lower; technical, trade school, community college, or some university; and university degree. Annual income was categorised into “under \$30 000”, “\$30 000–\$59 999”, and “\$60 000 and over” for the US, Canadian, and Australian samples. For the UK sample, we used the following categories: “£15 000 or under”, “£15 001–£30 000,” and “£30 001 and over”. Ethnicity was measured using the relevant census question for each country and then analysed as a dichotomous variable to allow for comparisons across countries (“white” v “non-white and mixed race”), except

\* Note that new UK package warnings (one of 16 text warnings covering 30% of the package) were implemented in January 2003, following Wave 1 of the ITC-4 survey.

**Table 1** Characteristics of International Tobacco Four Country Survey (ITC-4) sample by country (n = 9058)

	Unweighted				Weighted			
	CAN	AUS	USA	UK	CAN	AUS	USA	UK
Sex								
Female	54.3%	52.7%	55.2%	56.6%	45.8%	44.5%	46.4%	49.8%
Male	45.7%	47.3%	44.8%	43.4%	54.2%	55.5%	53.6%	50.2%
Age								
18–24	15.6%	16.8%	15.7%	8.5%	14.3%	17.2%	15.3%	14.2%
25–39	31.8%	36.8%	30.9%	32.4%	33.7%	35.5%	31.3%	33.2%
40–54	34.5%	32.8%	33.9%	33.9%	34.7%	32.2%	35.8%	28.7%
55+	18.1%	13.5%	19.6%	25.2%	17.3%	15.1%	17.6%	24.0%
Education								
12 years or less	46.9%	66.8%	44.1%	64.5%	47.7%	67.8%	45.2%	63.4%
More than 12 years	53.1%	33.2%	55.9%	35.5%	52.3%	32.2%	54.8%	36.6%
Ethnicity/language								
White/English only	87.5%	86.2%	76.4%	94.7%	88.1%	86.5%	74.7%	94.6%
Other/mixed	12.5%	13.8%	23.6%	5.3%	11.9%	13.5%	25.3%	5.4%
CPD* (SD)	16.0 (9.6)	17.9 (12.7)	17.9 (11.7)	16.7 (10.6)	16.6 (9.7)	18.7 (13.6)	18.6 (11.8)	17.0 (11.0)

\*CPD, cigarettes per day.

Australia. Language was used as a proxy for Australian ethnicity (“English-speaking” = white, “non-English speaking” = non-white), as is consistent with the Australian census.

### Knowledge of health effects

Respondents were asked to state whether they believed smoking causes heart disease, stroke, impotence, lung cancer in smokers, and lung cancer in non-smokers. Respondents were also asked to state whether they believed any of the following chemicals were included in cigarette smoke: cyanide, arsenic, and carbon monoxide. Response categories were “Yes”, “No,” or “Don’t know.”

### Exposure to anti-smoking media and warning labels

Exposure to anti-smoking media was measured by asking: “In the past 6 months, how often, if at all, have you noticed advertising or information that talks about the dangers of smoking, or encourages quitting?” Responses were given on a five-point Likert scale where 1 = “Never” and 5 = “Very often”. Respondents were then asked whether they had noticed such information in each of nine specific locations (“Yes” or “No”). Exposure to warning labels was measured by asking: “In the last month, how often, if at all, have you noticed the warning labels on cigarette packages?” using the same five-point scale as for anti-smoking media.

### Analysis

SPSS (version 12.0) was used for all statistical analyses. Logistic regression analyses were conducted to predict knowledge of health effects and intentions to quit. Knowledge of health effects were coded as 0 (“Not caused by smoking”/“Don’t know”) and 1 (“Caused by smoking”); intentions to quit were coded as 0 (“No plan to quit”) and 1 (“Plans to quit sometime in the future”). Analyses were conducted on both weighted and unweighted data. There were no significant differences between analyses of weighted and unweighted data; unless otherwise noted, weighted results are presented below.

## RESULTS

### Sample characteristics

Table 1 presents the weighted and unweighted sample characteristics for each country.

### Knowledge of health effects and smoke constituents

Table 2 presents smokers’ knowledge of health effects by country. Most smokers reported that smoking causes lung cancer and heart disease, fewer believed that smoking causes stroke and lung cancer among non-smokers, whereas less than half agreed that smoking causes impotence. There was a significant difference between countries in the total number of diseases endorsed by respondents ( $F [3, 9024] = 75.5$ ,

**Table 2** Knowledge of health effects from smoking (n = 9058)

Health effect	Proportion who agree					Odds of planning to quit† (95% CI)
	CAN	AUS	USA	UK	Overall	
Smoking causes lung cancer in smokers	<b>94.8%</b>	<b>94.3%</b>	<b>94.3%</b>	<b>93.7%</b>	94.3%	2.88 (2.34 to 3.54)
Smoking causes heart disease	<b>90.8%</b>	<b>88.7%</b>	<b>85.8%</b>	<b>89.5%</b>	88.7%*	2.51 (2.16 to 2.91)
Smoking causes stroke	<b>82.7%</b>	80.8%	73.3%	70.3%	73.0%*	1.91 (1.70 to 2.15)
Smoking causes lung cancer in non-smokers	<b>79.6%</b>	69.0%	68.1%	75.2%	70.1%*	1.62 (1.45 to 1.81)
Smoking causes impotence	<b>59.5%</b>	35.8%	34.3%	36.1%	41.3%*	1.56 (1.42 to 1.77)
Total number of health effects reported*						
0	2.8%	3.3%	3.5%	2.7%	3.1%	Reference
1	2.3%	3.7%	4.5%	3.5%	3.5%	1.84 (1.27 to 2.67)
2	5.0%	7.9%	9.4%	8.4%	7.7%	2.51 (1.81 to 3.47)
3	13.7%	18.3%	22.1%	21.6%	18.9%	3.78 (2.80 to 5.09)
4	27.2%	39.7%	36.2%	39.1%	35.7%	4.58 (3.42 to 6.12)
5	49.1%	27.1%	24.3%	24.7%	31.2%	5.73 (2.25 to 7.71)

\*Significant differences between countries ( $p < 0.001$ ).

†Odds of planning to quit smoking (0: No plan, 1: Plan) are adjusted for age, sex, income, ethnicity, and cigarettes smoked per day.

Bolded values indicate diseases that are listed in health warnings on packages in each country.

CI, confidence interval.

**Table 3** Knowledge of tobacco constituents (n = 9058)

Smoke contains...	Proportion who agree					Odds of planning to quit† (95% CI)
	CAN	AUS	USA	UK	Overall	
Carbon monoxide	<b>90.7%</b>	<b>82.6%</b>	<b>85.1%</b>	64.6%	80.3%*	1.72 (1.51 to 1.94)
Arsenic	<b>57.7%</b>	41.1%	42.1%	16.9%	38.9%*	1.59 (1.41 to 1.75)
Cyanide	<b>71.7%</b>	44.4%	51.6%	25.1%	47.6%*	1.66 (1.49 to 1.84)
Total constituents reported						Reference
0	5.9%	12.4%	11.7%	30.5%	15.5%*	
1	19.3%	36.2%	32.3%	43.7%	33.1%*	1.44 (1.24 to 1.67)
2	23.8%	22.1%	21.4%	14.4%	20.3%*	1.90 (1.60 to 2.25)
3	51.1%	29.2%	34.6%	11.3%	31.1%*	2.41 (2.05 to 2.83)

\*Significant differences between countries (p<0.001).  
 †Odds of planning to quit smoking (0=No plan, 1=Plan) are adjusted for age, sex, income, ethnicity, and cigarettes smoked per day.  
 Bolded values indicate constituents that are listed on packages in each country.  
 CI, confidence interval.

p < 0.001). Canadian smokers endorsed a greater number of diseases than smokers from the other three countries (p < 0.001), while Australian respondents were more likely to endorse diseases than US respondents (p = 0.005). Between-country differences were also observed for all individual diseases, with the exception of lung cancer among smokers. Most notably, almost twice as many Canadian respondents reported that smoking causes impotence relative to respondents from the USA, UK, and Australia. Table 2 also indicates the diseases that are included on health warnings within each country (see bolded values).

Table 2 also indicates that planning to quit smoking was positively associated with health knowledge. The odds of planning to quit were greater among smokers who endorsed each of the five diseases, and increased in a linear fashion with the total number of health effects reported. This pattern was observed within respondents of each country, as well as across countries, with no significant health effect by country interactions.

Table 3 provides smokers' knowledge of tobacco smoke constituents. Smokers were most likely to agree that tobacco smoke contains carbon monoxide and least likely to agree that arsenic is contained in tobacco smoke. Similar to the results for health knowledge, Canadian smokers were more likely to agree that tobacco smoke contains each of the three smoke constituents relative to US, UK, and Australian smokers. Note that the proportions in table 3 are in bold for countries in which the constituents were printed on cigarette packages at the time of the survey.

**Health knowledge and labelling policy**

A majority of respondents reported noticing information about the dangers of smoking "often" or "very often" in the last six months: CAN 59.4%, USA 60.4%, UK 55.6%, AUS 61.0%. Table 4 indicates the sources of anti-smoking information for each country. "Cigarette packages" were a

**Table 4** Sources of information on the dangers of smoking and anti-smoking media (n = 9058)

Source	CAN	AUS	UK	USA	Overall
TV	88.2%	90.4%	83.9%	86.2%	87.7%
Cigarette packages	84.3%	69.3%	56.1%	46.7%	64.6%
Magazine/newspaper	66.1%	34.4%	62.6%	62.8%	64.1%
Poster	57.4%	43.2%	51.3%	58.6%	56.2%
Radio	40.7%	42.7%	26.1%	45.2%	38.9%
Leaflets	35.3%	32.6%	37.7%	24.6%	33.2%
Shops/stores	25.7%	39.0%	14.0%	18.5%	24.5%
Movie theatre	8.5%	12.7%	11.1%	10.1%	11.1%
Internet	10.4%	6.4%	4.1%	12.4%	8.4%

prominent source of health information in all four countries, particularly within Canada.

Smokers were also asked how often, if at all, they noticed cigarette warning labels in the last month. A logistic regression was conducted to examine the extent to which noticing cigarette warning labels was associated with health knowledge (table 5). The results indicate between-country differences in health knowledge: as with the bivariate analyses reported in table 2, Canadian respondents demonstrated an overall greater knowledge of the health effects of smoking. The findings also indicate that noticing the health warnings on cigarette packages was positively associated with health knowledge, after adjusting for noticing anti-smoking media in general. In other words, smokers who noticed the health warnings were more likely to agree that smoking causes each of the five diseases listed in table 5, adjusting for demographic variables and smoking behaviour.

Finally, analyses were conducted to compare health knowledge between smokers with and without health warnings on their cigarette packages. Countries were coded either as "0" (No health warning) or "1" (Health warning) for each disease and constituent listed in tables 2 and 3. Levels of health knowledge were then compared between respondents in countries with and without health warnings using logistic regression analysis. (Note that analyses were only run for diseases and constituents for which there were differences in labelling between the four countries). As fig 2 indicates, health knowledge was significantly greater among respondents in countries with health warnings, even after controlling for the number of other information sources cited by respondents. For example, smokers were 3.13 times more likely to say that tobacco smoke contains carbon monoxide when this information was printed on cigarette packages.\*

**DISCUSSION**

It is commonly assumed and often argued by the tobacco industry that smokers are adequately informed about the health risks of smoking.<sup>18 34 35</sup> This study clearly demonstrates that this assumption is false. The findings indicate significant gaps in smokers' understanding of the risks of smoking: most, but not all, smokers reported that smoking causes heart disease and lung cancer in smokers—health consequences that have been established for over 25 years; more than a quarter of smokers did not believe that smoking caused stroke; and fewer than half of smokers believed that smoking causes impotence. Smokers' knowledge of toxic constituents in tobacco smoke was also unacceptably low.

\* Note that carbon monoxide yields are listed on Canadian and Australian package, while one of the four US warning messages mentions carbon monoxide.

**Table 5** Predictors of health knowledge (n = 9058)

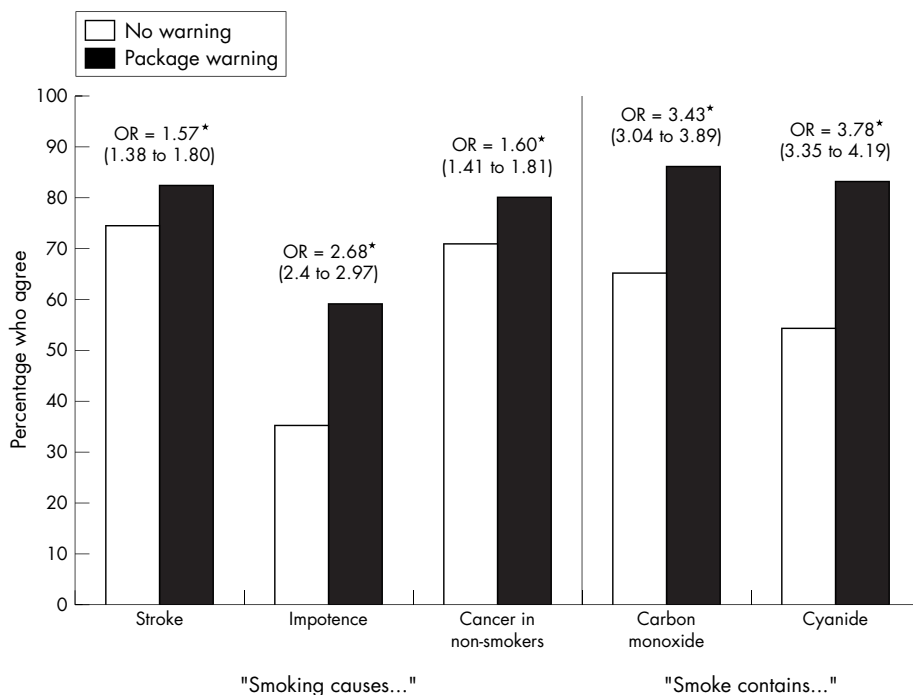
	Adjusted odds* (95% CI) of believing smoking causes....				
	Heart disease	Stroke	Impotence	Lung cancer (smokers)	Lung cancer (non-smokers)
Country					
CAN (reference)	1.00	1.00	1.00	1.00	1.00
USA	0.72 (0.59 to 0.89)	0.64 (0.55 to 0.75)	0.35 (0.31 to 0.40)	1.09 (0.81 to 1.48)	0.60 (0.52 to 0.70)
UK	0.95 (0.77 to 1.18)	0.51 (0.44 to 0.59)	0.41 (0.36 to 0.47)	0.98 (0.74 to 1.31)	0.84 (0.72 to 0.98)
AUS	0.82 (0.66 to 1.01)	0.90 (0.77 to 1.06)	0.37 (0.33 to 0.42)	0.90 (0.68 to 1.19)	0.55 (0.47 to 0.64)
Noticing anti-smoking information	1.20 (1.04 to 1.39)	1.16 (1.04 to 1.36)	1.05 (0.96 to 1.15)	1.10 (0.90 to 1.34)	1.11 (1.15 to 1.41)
Noticing warning labels	1.20 (1.04 to 1.38)	1.23 (1.11 to 1.26)	1.14 (1.05 to 1.24)	1.31 (1.08 to 1.61)	1.27 (1.15 to 1.41)

\* Odds of believing smoking causes disease (0: No/Don't know, 1: Yes).  
 Odds ratios are adjusted for age, sex, income, ethnicity, and cigarettes smoked per day.  
 CI, confidence interval.

It is important to note that these results derive from smokers in among the most affluent, most highly educated countries in the world and in countries with among the most comprehensive tobacco control policies. We would expect health knowledge to be substantially lower among the majority of the world's smokers, particularly those living in lower and middle income countries where resources for tobacco control are non-existent or lower by orders of magnitude.

The findings also indicate that health warnings on cigarette packages are a prominent source of health information. Approximately two-thirds of smokers cited cigarette packages as a source of health information, with a significant association between the strength of package health warnings (as depicted in fig 1) and the likelihood of citing packages as a source of health information. In short, larger, more comprehensive warnings were more likely to be cited as a source of health information. For example, over 84% of smokers living in Canada—the country with the strongest health warnings—cited packages as a source of health information, compared with only 47% of those in the USA, the country with the weakest health warnings.

Not only were health warnings self-identified as an important source of health information about smoking, but also an effective means of communicating health information. The results provide evidence at both the individual and country-level that health warnings on cigarette packages are strongly associated with health knowledge. First, noticing labels was strongly associated with endorsing each of the five health effects, after controlling for smoking behaviour, demographic variables, and the frequency of noticing anti-media in general. Smokers who reported noticing warnings were between 1.5–3.0 times more likely to believe in each health effect. Second, in all five cases where labelling policies differed between countries, smokers living in countries with government mandated warnings reported greater health knowledge. This pattern is best illustrated in the case of smokers' knowledge of impotence. Canada was the only country where packages carry warnings about impotence, and accordingly, Canadian smokers were almost three times more likely than smokers from the other three countries to believe that smoking causes impotence. This finding provides a measure of specificity for the effect of warning labels; we are unaware of any media source or educational initiative in



**Figure 2** Health knowledge as a function of tobacco labelling policy (n = 9058). \*Odds ratios (ORs) are adjusted for age, sex, income, ethnicity, cigarettes smoked per day, and the number of information sources cited, other than cigarette packages.

Canada, other than the package warnings, to have highlighted the risks of impotence. Clearly, smokers in the other four countries may have been exposed to information on impotence and other health risks not listed on the pack; however, this only strengthens the findings on the effectiveness of the warnings. For example, in 1998 and 1999, the state of California conducted a \$22 million mass media campaign that included messages linking smoking and impotence.<sup>36</sup> As might be expected, California smokers in the current study were more likely to endorse impotence as a cause of smoking than other US respondents, yet they were no more likely to endorse impotence than Canadian respondents. This example underscores the cost-effectiveness of package warnings: California spent several millions of dollars to attain levels of awareness that were achieved in Canada via warning labels that were introduced at little or no cost to the government.

Finally, health knowledge was strongly associated with intentions to quit among smokers in all four countries. This finding supports previous evidence that, although awareness and acceptance of the health risks of smoking may not be a sufficient condition for quitting, it is likely a necessary one for most smokers and serves an important source of motivation.

### Limitations

Health knowledge can be assessed several ways. The measures used in the current study constitute a relatively low threshold for knowledge or risk perception. Indeed, respondents were not asked to recall smoking-related diseases unprompted, nor were they asked to estimate the likelihood or severity of smoking-related disease. Had these measures been used, the findings would inevitably have yielded relatively lower levels of “health knowledge” than those reported here. In addition, the cross-sectional nature of these data cannot address the directionality of the associations between health knowledge, warnings, and other variables. For example, it may be that smokers with greater health knowledge were more likely to attend to health warnings. Finally, the between-country differences in health knowledge may partly reflect concomitant efforts to inform the public of the health risks of smoking through other channels, such as mass media campaigns. However, this limitation is tempered by the fact that noticing the labels predicted health knowledge even after controlling for other sources of information, as well as by the specificity provided by the Canadian warnings in the case of impotence. Nonetheless, longitudinal data would help to clarify the causal nature of these associations.

### Implications

Tobacco products remain the most lethal consumer product in every country in which they are sold. The US Surgeon

#### What this paper adds

Health warnings on tobacco products are a primary means of communicating with smokers; however, few studies have evaluated the impact of health warnings on consumer knowledge about tobacco risks. The current findings from adult smokers in four countries demonstrate that health warnings on cigarette packages are a prominent source of health information and an effective means of communicating specific disease risks. The findings also indicate that more comprehensive warnings—such as the graphic warnings on Canadian packages—are associated with greater health knowledge.

General recently reported a causal link between smoking and 28 individual diseases, including the leading causes of death in the western world.<sup>2</sup> Remarkably, the list of known health risks continues to grow, with cancers of the stomach and acute myeloid leukemia among those most recently identified. Given this list, it would be folly to assume that smokers are currently, or likely ever will be, fully informed of the risks of smoking. Nevertheless, tobacco companies and governments are responsible for making every effort to ensure the highest levels of health knowledge possible. At present, however, tobacco consumers receive little information regarding the ingredients, additives, and chemical composition of their products. In countries such as the USA, chocolate bars carry more information about ingredients than cigarette packages.

The current findings indicate that large, graphic warnings on cigarette packages are an effective means of increasing health knowledge among smokers. Previous research also suggests that Canadian-style warnings provide substantial cessation benefits and enjoy widespread support among smokers.<sup>9 25 26</sup> The effectiveness of warning labels in communicating health effects suggests that warnings could also be used to address knowledge deficits in other areas, such as filter ventilation, the risks of “light” or “low-tar” cigarettes, and the effects of behavioural compensation.<sup>37–40</sup> Given their universal reach, health warnings may also help to reduce the disparities in health knowledge by providing low-income smokers with regular access to health information.<sup>41 42</sup> Yet, despite growing evidence of their effectiveness, most governments remain reluctant to mandate comprehensive health warnings, while the tobacco industry continues to fight their introduction.<sup>43</sup> The industry’s opposition is understandable: they fear that strong warning labels will shrink their market and erode profits; the reluctance among governments and regulators is more puzzling.

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### Authors’ affiliations

**D Hammond**, Department of Health Studies and Gerontology, University of Waterloo, Waterloo, Ontario, Canada

**G T Fong**, Department of Psychology, University of Waterloo

**A McNeill**, Division of Public Health & Epidemiology, University College London, London, UK

**R Borland**, The Cancer Council, Victoria, Melbourne, Australia

**K M Cummings**, Department of Health Behavior Roswell Park Cancer Institute, Buffalo, New York, USA

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## The Efficacy of Cigarette Warning Labels on Health Beliefs in the United States and Mexico

**SEEMA MUTTI,**

School of Public Health and Health Systems, University of Waterloo, Waterloo, Ontario, Canada

**DAVID HAMMOND,**

School of Public Health and Health Systems, University of Waterloo, Waterloo, Ontario, Canada

**JESSICA L. REID,** and

PropeI Centre for Population Health Impact, University of Waterloo, Waterloo, Ontario, Canada

**JAMES F. THRASHER**

Department of Health Promotion, Education and Behavior, Arnold School of Public Health, University of South Carolina, Columbia, South Carolina, USA, and Departamento de Investigaciones sobre Tabaco, Centro de Investigación en Salud Poblacional, Instituto Nacional de Salud Publica (INSP), Cuernavaca, México

### Abstract

Concern over health risks is the most common motivation for quitting smoking. Health warnings on tobacco packages are among the most prominent interventions to convey the health risks of smoking. Face-to-face surveys were conducted in Mexico ( $n=1,072$ ), and a web-based survey was conducted in the US ( $n=1,449$ ) to examine the efficacy of health warning labels on health beliefs. Respondents were randomly assigned to view two sets of health warnings (each with one text-only warning and 5–6 pictorial warnings) for two different health effects. Respondents were asked whether they believed smoking caused 12 different health effects. Overall, the findings indicate high levels of health knowledge in both countries for some health effects, although significant knowledge gaps remained; for example: less than half of respondents agreed that smoking causes impotence and less than one third agreed that smoking causes gangrene. Mexican respondents endorsed a greater number of correct beliefs about the health impact of smoking than the US sample. In both countries, viewing related health warning labels increased beliefs about the health risks of smoking, particularly for less well-known health effects, such as gangrene, impotence, and stroke.

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Worldwide, tobacco use remains the leading preventable cause of death (WHO, 2008a). Smoking-related diseases, including respiratory diseases, various forms of cancer, and cardiovascular disease, account for more than 5 million deaths per year. It is estimated that this number will rise to 8 million by 2030, if current patterns remain unchanged.

Concern about the health risks of smoking is among the most common motivations to quit among current and former smokers (Curry, Grothaus, & McBride, 1997; Hammond, McDonald, Fong, Brown, & Cameron, 2004; Hyland, Li, Bauer, Giovino, Steger, & Cummings, 2004). Previous studies have demonstrated that smokers with greater knowledge of the health risks of smoking were more likely to intend to quit and were more successful in their quit attempts (Nourjah, Wagener, Eberhardt, & Horowitz, 1994; Romer & Jamieson,

2001). Although it is generally assumed that smokers are well aware of the health risks associated with smoking and tobacco use, significant gaps in health knowledge remain, even in high-income countries such as Canada and the United States (US) (Health Canada, 2000; Hammond, Fong, McNeill, Borland, & Cummings, 2006). Risk perceptions are lower in most low-or middle-income countries (LMICs), which are characterized by limited access to health information, less exposure to mass media campaigns, and lower literacy levels (WHO, 2008b).

Communicating the health effects of smoking remains a primary objective for tobacco control. Health warnings on cigarette packages are an excellent medium for communicating health information given their reach and frequency of exposure, both at the point of purchase and at the time of smoking behaviour. Findings from both experimental and population-based studies have demonstrated that pictorial health warnings are more likely to be noticed and read by smokers than text-only warnings, and they are associated with greater motivation to quit smoking (Hammond, 2011).

Despite the evidence demonstrating a consistent association between health knowledge and smoking cessation, few studies have examined the influence of pictorial health warning labels directly on health knowledge. Further, most of this research has been conducted in high-income countries and it is unknown whether these findings would apply to LMICs. For example, graphic pictures of disease may violate cultural norms or simply prove to be too offensive in populations with little or no exposure to strong health communications. Cultural groups also vary in their focus on different organ systems as responsible for illness, as well as in the anxiety that they associate with different kinds of bodily symptoms (Good & Good, 1981; McElroy & Jezewski, 2003). For example, graphic pictures of disease may violate cultural norms or simply prove to be too offensive in populations with little or no exposure to strong health communications. As a result, the effectiveness of pictorial health warnings may differ with respect to the type of health effect they communicate.

The current study examined the efficacy of health warning labels on health beliefs among samples of adults and youth in the US and Mexico. At the time this study was conducted, text-only warnings appeared on cigarette packages in both countries. In Mexico, text-only warnings covered 50% of the back of cigarette packages, and included the following three messages that have remained the same since 2004: 1) "Smoking causes cancer and emphysema", 2) "Quitting smoking reduces significant health risks", and 3) "Smoking during pregnancy increases risk of premature birth and low birth weight babies". US labelling policy requires that text-only warnings cover one side panel of cigarette packages, and include the following four messages that have remained the same since 1984: 1) "Surgeon General's warning: Smoking causes lung cancer, heart disease, emphysema, and may complicate pregnancy", 2) "Quitting smoking now greatly reduces serious risks to your health", 3) "Smoking by pregnant women may result in fetal injury, premature birth, and low birth weight", and 4) "Cigarette smoke contains carbon monoxide". The study sought to: 1) assess knowledge that smoking causes death, lung cancer, throat cancer, emphysema, mouth cancer, heart disease, harm to unborn babies, wrinkling and aging of skin, stroke, lung cancer from second-hand smoke exposure, impotence in male smokers, and gangrene; 2) determine whether health warnings increase health knowledge that is specific to warning label content; 3) determine the extent to which health beliefs differ by socioeconomic and individual-level factors, such as gender, age, education, and ethnicity; and 4) examine potential country-level differences in health knowledge and effects of warnings between the US and Mexico.

## METHODS

In Mexico, face-to-face surveys were conducted between June and August 2010 using computer-assisted personal interviewing. Respondents were recruited using a standardized “intercept” technique (Sudman, 1980), whereby people were counted as they passed a geographical landmark and every 3rd individual was approached by a trained interviewer. Study sites included two public parks, a bus terminal, and outside five WalMart stores in Mexico City. Respondents were given a 50-peso phone card (equivalent to ~\$4 USD) as a token of appreciation.

In the US, a web-based survey was conducted in December 2010. Respondents were recruited via email from a consumer panel maintained by Global Market Institute (GMI), with a panel reach of more than 2.8 million individuals. Respondents received points from GMI (equivalent to ~\$3 USD) in appreciation of their time. Additional panel details can be found at: <http://www.gmi-mr.com/>.

All respondents were at least 16 years of age. Two groups of people were recruited for the study: 1) adult (age 19 and older) smokers, and 2) youth (age 16–18), including both smokers and non-smokers. Prior to beginning the interview, all respondents were provided with information about the study and asked to provide verbal consent (in Mexico), or by clicking a box on-screen (in the US). No personal information identifiers were collected; respondents remained anonymous. The study was reviewed by and received ethics clearance from the Office of Research Ethics at the University of Waterloo.

### Protocol

After completing questions on socio-demographics and smoking behaviour, participants viewed a series of health warnings. Each respondent was randomly assigned to view two of 15 “sets” of health warnings, each for a different health effect of smoking (note that the Mexico study included an additional two sets of warnings on tobacco smoke constituents that are not reported in the current paper). Each “set” included 5–7 warnings on the same health effect, in a variety of executional styles. These included a text-only warning, as well as a variety of approaches to pictorial warnings, including graphic health effects (i.e., physical impact on the body), “lived experience” (i.e., individual suffering the consequences of smoking), symbolic (i.e., metaphorical representation of risk), or other popular approaches used in other countries. The text used in the warnings was the same for each warning within a particular set, with the exception of the testimonials. Testimonials featured the same picture as one of the “lived experience” warnings, but with a brief narrative describing a personal aspect of the same content, written as a quote from a person in the image, whose name and age were also included.

After viewing health warnings, respondents were asked whether they believed that smoking causes the following 12 health effects: lung cancer, heart disease, stroke, mouth cancer, throat cancer, emphysema, gangrene, impotence in male smokers, wrinkling and aging of the skin, death, harm to unborn babies, lung cancer in non-smokers from breathing cigarette smoke. Warnings were kept as similar as possible across countries, but were adapted for local use. Adaptation of the warnings included: 1) translation into the local language, 2) use of racially appropriate models in images, where relevant and possible, and 3) locally-appropriate names for the testimonials. All local versions of the warnings were checked by the local research team for appropriateness. All warnings included in the study can be viewed at <http://www.tobaccolabels.ca/study>.

## MEASURES

**Demographics**—Demographic variables included gender, age, education level, income level, and ethnicity. In Mexico, adult education level was categorized as ‘Low’ (Primary, Middle, Technical/vocational school, or less), ‘Moderate’ (Highschool or some university), or ‘High’ (University degree or higher). In the US, adult education level was categorized as ‘Low’ (Highschool or less), ‘Moderate’ (Technical/trade school or community college, or some university), and ‘High’ (University degree or higher). Income, collected only for US respondents, was categorized as ‘Low’ (under \$30,000), ‘Moderate’ (\$30,000 to \$59,999), or ‘High’ (\$60,000 and over). Ethnicity also collected only for US respondents, was categorized as ‘Minority’ (included Black or African-American, Hispanic or Latino, Asian or Pacific-Islander, Native American Indian, Mixed race, and Other) or ‘Non-minority’ (White).

**Smoking behaviour**—Respondents were asked about their smoking behaviour, including smoking frequency and quit intentions. To assess smoking frequency, respondents were asked “In the last 30 days, how often did you smoke cigarettes?” Those who responded ‘Every day’ were categorized as ‘daily smokers’, those who responded with ‘At least once a week’ or ‘At least once in the last month’ were categorized as ‘non-daily smokers’, and ‘non-smokers’ were those who responded with ‘Not at all’. Adult samples in both the US and Mexico did not include ‘non-smokers’. To assess quit intentions, adult and youth smokers were asked “Are you planning to quit... 1) ‘Within the next month’, 2) ‘Within the next 6 months’, 3) ‘Sometime in the future, beyond 6 months’, or 4) ‘Not planning to quit’”. Response options were dichotomized into 0= ‘Not planning to quit’ and 1= ‘Planning to quit’ (which included the first three options).

**Health beliefs**—After presentation of the health warnings, respondents were prompted with the following in Mexico “I am going to read you a list of health effects and diseases that may or may not be caused by smoking cigarettes. Based on what you know or believe, does smoking cause... [lung cancer, heart disease, stroke, mouth cancer, throat cancer, emphysema, gangrene, impotence in male smokers, wrinkling and aging of the skin, death, harm to unborn babies, lung cancer in non-smokers from breathing cigarette smoke]”. This was worded differently in the US because of the self-complete web-based survey design “You will now be presented with a list of ...” Response options included ‘Yes’, ‘No’, ‘Don’t Know’, and were dichotomized as follows: 0=‘No’ and ‘Don’t Know’; 1=‘Yes’.

A Health Belief Index (HBI) was created to measure respondents’ level of health knowledge. The index was calculated based on the number of correct health beliefs each participant endorsed for the 12 health effects presented in the study (range =0 to 12). Higher values correspond to higher levels of health knowledge. Lastly, a variable was created to capture whether respondents had viewed the set of health warnings specific to one of the twelve health effects presented in the study (coded as 1) or not (coded as 0).

## Analysis

Statistical analyses were conducted using SPSS version 19.0. Logistic regression models were conducted to examine correlates of health belief outcomes for each of the twelve health effects caused by smoking: lung cancer, heart disease, stroke, mouth cancer, throat cancer, emphysema, gangrene, impotence in male smokers, wrinkling and aging of skin, death, harm to unborn babies, and lung cancer in non-smokers from breathing cigarette smoke. A standard set of covariates was included in the regression models for adults: age (continuous), gender, smoking status (daily vs. non-daily), education, income (US only), and ethnicity (US only). Covariates in the youth regression model(s) included age (continuous), gender, and smoking status (non-smoker, daily smoker, non-daily smoker). Linear regression models

were conducted to examine the influence of potential predictors of health knowledge using the Health Belief Index scale as the outcome.

## RESULTS

### Sample characteristics

Table 1 presents the sample characteristics of adults and youth from the US and Mexico included in the current analysis. The total sample consisted of 544 adult smokers and 528 youth in Mexico City, and 772 adult smokers and 677 youth from the US.

### Levels of health knowledge after viewing non-targeted health warning labels

Table 2 presents the proportion of respondents who believe smoking causes each of 12 health effects only among those who had not viewed the health warnings to the health effect in question. In both the US and Mexico, beliefs about the risks of lung cancer were high (86% to 99%); however, less than half agreed that smoking causes male impotence, and less than one third that smoking causes gangrene.

**Differences between adults and youth**—Chi-square tests were conducted for Mexico and the US to examine age group (Adult vs. Youth) as a predictor for each of the 12 health belief outcomes. In the US, youth reported significantly higher levels of health knowledge than adults for 7 of the 12 health effects listed in Table 2: lung cancer, mouth cancer, throat cancer, gangrene, death, harm to unborn babies, and lung cancer in non-smokers from breathing cigarette smoke. Adults were more likely than youth to believe that smoking causes just one of the health effects: emphysema. In contrast, adults in Mexico were more likely than youth to endorse 7 of the 12 health effects of smoking: heart disease, stroke, throat cancer, emphysema, impotence in male smokers, wrinkling and aging of the skin, and lung cancer in non-smokers from breathing cigarette smoke.

**Differences between the US and Mexico**—A chi-square analysis including youth and adults from Mexico and the US was conducted to examine country differences for each of the 12 health belief outcomes. Significant differences between the US and Mexico were observed for 10 of the 12 health beliefs. Mexican respondents were significantly more likely to endorse 7 of the 10 health effects, including: lung cancer, emphysema, gangrene, impotence in male smokers, death, harm to unborn babies, and lung cancer in non-smokers from breathing cigarette smoke. US respondents were more likely to believe that smoking causes: stroke, mouth cancer, and wrinkling and aging of the skin.

### Levels of health knowledge after viewing targeted health warning labels

Chi-square tests were conducted for each health effect, separately by country, to examine whether health beliefs differed between respondents who had viewed the health warning labels targeted to that health effect, and those who had not (Figure 1).

In the US, those who viewed the relevant warning set were more likely to endorse 7 of the 12 health effects relative to those who had not viewed the relevant warning set: death (OR 1.70, 95%CI 1.02–2.83), mouth cancer (OR 2.09, 95%CI 1.28–3.43), heart disease (OR 1.97, 95%CI 1.26–3.09), wrinkling and aging of skin (OR 1.53, 95%CI 1.03–2.27), stroke (OR 2.02, 95%CI 1.41–2.88), impotence in male smokers (OR 2.92, 95%CI 2.14–3.98), and gangrene (OR 5.27, 95%CI 3.83–7.25).

In Mexico, respondents who viewed the health warning labels specific to the health effect were also more likely to endorse 7 of the 12 health beliefs: throat cancer (OR 2.72, 95% CI 1.08–6.83), mouth cancer (OR 2.09, 95%CI 1.19–3.66), heart disease (OR 3.14, 95% CI

1.56–6.32), wrinkling and aging of skin (OR 4.12, 95% CI 2.27–7.43), stroke (OR 3.93, 95% CI 2.61–5.92), impotence in male smokers (OR 3.70, 95% CI 2.37–5.79), and gangrene (OR 4.09, 95% CI 2.75–6.07).

A second set of logistic regression models, which pooled the US and Mexico samples, were conducted for each health effect. Step one of the models included only the 'Health warnings viewed' variable. Step two of the models adjusted for the following covariates: age, gender, smoking status, quit intentions, and country. The interaction term between 'Health warnings viewed' and country was also tested in this model. Between-country differences were observed for two of the twelve health effects: after viewing health warnings specific to the health effect, respondents in Mexico were more likely than US respondents to endorse the belief that smoking causes wrinkling and aging of the skin (OR 2.72, 95% CI 1.33–5.56) and that smoking causes stroke (OR 1.91, 95% CI 1.10–3.30), compared to respondents in the US. No other significant associations were observed.

### Predictors of Health Knowledge

The HBI indicates the number of correct health beliefs (0 to 12) endorsed by respondents. In the US, average HBI score for adults was 8.0 (SD 3.1), significantly lower than the youth mean HBI score of 9.0 (SD 2.6),  $p < .001$ . Conversely, in Mexico, mean HBI score was significantly higher for adults compared to youth, at 9.4 (SD 1.8) and 8.8 (SD 1.8), respectively ( $p < .001$ ).

Linear regression models were conducted, separately by country and age group, to examine the influence of various covariates on level of health knowledge (as measured by the HBI). The youth models included the following covariates: age, gender, and smoking status. The adult models included age, gender, smoking status, quit intentions, education, income, and ethnicity.

**Predictors of health knowledge among youth in Mexico and the US**—Among youth in Mexico, age emerged as a predictor of health knowledge: older respondents reported higher levels of health knowledge relative to younger respondents ( $\beta = 0.29$ ,  $p = .001$ ). Non-smokers also reported lower levels of health knowledge than both daily and non-daily smokers ( $\beta = -0.75$ ,  $p = .001$  and  $\beta = -0.35$ ,  $p = .033$ , respectively). Among youth in the US, females reported higher levels of health knowledge ( $\beta = 0.42$ ,  $p = .034$ ). In contrast to Mexican youth, non-smoking youth in the US reported higher levels of health knowledge than both daily and non-daily smokers ( $\beta = 0.96$ ,  $p = .002$  and  $\beta = 1.40$ ,  $p < .001$ , respectively).

**Predictors of health knowledge among adults in Mexico and the US**—Education was the only significant predictor of health knowledge among adult smokers in Mexico. Those with high levels of education (University degree or higher) reported greater levels of health knowledge compared to those with low (Primary, middle, or technical/vocational school) or moderate (Highschool or some university) levels of education ( $\beta = 0.63$ ,  $p = .009$ ;  $\beta = 0.62$ ,  $p = .001$ , respectively).

Among adults in the US, age, gender, quit intentions, and income were significant predictors of health knowledge. Older individuals reported lower levels of health knowledge than younger individuals ( $\beta = -0.03$ ,  $p < .001$ ). Females reported higher levels of health knowledge than males ( $\beta = 0.54$ ,  $p = .018$ ). Respondents who were planning to quit were more likely to report higher levels of health knowledge than were those who were not planning to quit ( $\beta = 1.00$ ,  $p < .001$ ). Finally, high-income respondents were more likely than both low- and moderate-income respondents to report higher levels of health knowledge ( $\beta = 1.12$ ,  $p < .001$  and  $\beta = 0.82$ ,  $p = .003$ ).

## DISCUSSION

It is generally assumed that smokers are well aware of the health risks of smoking. Despite widespread endorsement of some more prominent health risks of smoking, such as lung cancer, findings from the current study highlight significant gaps in health knowledge. Most notably, less than half of adult smokers in either country agreed that smoking can cause stroke, one of the leading causes of death from smoking, and only half of US adult smokers agreed that second-hand smoke can cause lung cancer. In addition, less than half of respondents in Mexico and the US believed that smoking causes impotence in male smokers and less than one third believed that smoking causes gangrene.

Mexican respondents reported significantly higher overall levels of health knowledge compared to US respondents. It is noteworthy that the health effects (lung cancer, emphysema, and health risks to unborn babies) with higher levels of endorsement in Mexico were those which appeared on cigarette packages at the time this study was conducted.

The less prominent placement of the text-only US health warnings, coupled with the fact that the same four messages have been in rotation for the last 27 years, may help account for the lower levels of health knowledge found in the US. Pictorial health warning labels were implemented after this study was conducted in Mexico (September 2010) and were scheduled to be implemented in the US in September 2012, pending legal challenges. The new pictorial warnings in Mexico cover 30% of the front and 100% of the back and one side of cigarette packages ([www.tobaccolabels.org](http://www.tobaccolabels.org)), and they appear to have increased knowledge about health effects and toxic tobacco constituents addressed in the new warnings (Thrasher, Arillo-Santillán, Pérez-Hernández, Sansores, Regalado-Piñeda, 2011). In the US, the new graphic health warnings will be placed on the top 50% of the front and back of cigarette packages (US FDA, 2011).

Socio-demographic factors were associated with health knowledge in both Mexico and the US. Education emerged as a predictor in the Mexican sample (income was not measured); in the US income, but not education, was associated with health knowledge. Income and education are typically correlated with each other and positively associated with health knowledge. Overall, despite slightly different patterns of socio-demographic predictors in the US and Mexican sample, the current findings are consistent with previous research demonstrating the socio-economic gradient in health knowledge.

In the US, youth reported higher levels of health knowledge than adults, whereas the opposite pattern was observed in Mexico. In the US, non-smokers (youth) held higher levels of health knowledge than both daily and nondaily smokers. In contrast, Mexican non-smokers (youth) held lower levels of health knowledge than both daily and non-daily smokers. Previous research in the US and other countries has generally found that non-smokers endorse a greater number of health effects, mostly likely due to higher levels of education among non-smokers and cognitive dissonance among smokers (Hammond et al., 2006). The opposite pattern in Mexico could potentially be a result of its shorter history of tobacco education campaigns, in addition to the warning labels themselves, which smokers were more likely to have seen.

After viewing the relevant health warnings, respondents in both the US and Mexico were more likely to endorse related health beliefs. Increases were greatest for health effects with lower levels of belief, such as gangrene and stroke. These findings are consistent with previous research in which a strong association was found between pictorial health warning labels and health knowledge (O'Hegarty, Pederson, Nelson, Mowery, Gable et al., 2006; Liefeld, 1999).

## Limitations

The studies in Mexico and the US were conducted via different survey modes. The face-to-face surveys in Mexico may have encouraged more socially desirable responses among Mexican respondents and may account, in part, for the higher levels of health knowledge, both for targeted and non-targeted health warnings. In addition, the surveys were not conducted with representative samples of smokers, although a heterogeneous cross-section of respondents was recruited in each country.

All respondents in the study viewed two sets of health warnings prior to answering the health knowledge questions. As a result, the levels of health knowledge when respondents viewed non-targeted health warnings are likely to be an over-estimate of health knowledge in the general population given that viewing health warnings for other health effects may increase health beliefs in a non-specific manner. Research conducted after the implementation of pictorial warnings should confirm whether naturalistic exposures to pictorial warnings in each country will produce results that are consistent with those found here. Cross-country research suggests that this will be the case (Hammond et al., 2006; Thrasher, Hammond, Fong, Arillo-Santillán, 2007).

## Implications

Overall, the findings suggest that both consumers and the general public are far from fully informed regarding the health effects of tobacco use. Recently, five major tobacco companies have filed a lawsuit against the United States Food and Drug Administration (US FDA) challenging the nine new graphic warning label images to be implemented on cigarette packages in 2012 (R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, Common Wealth Brands, Liggett Group, and Santa Fe Natural Tobacco Company vs. US FDA, 2011). The Motion argues that US smokers and the general public are fully informed of the health risks of smoking and new warnings, therefore, would have no impact. The current study highlights the effectiveness of health warning labels in increasing health knowledge, particularly for less well-known health effects, such as gangrene, impotence in male smokers, and stroke.

Finally, although some differences were observed between the samples in Mexico and the US, the general pattern of the results—including the effect of viewing health warnings—was generally similar across the two countries. These findings add to the evidence base on the potential impact of health warnings.

## Acknowledgments

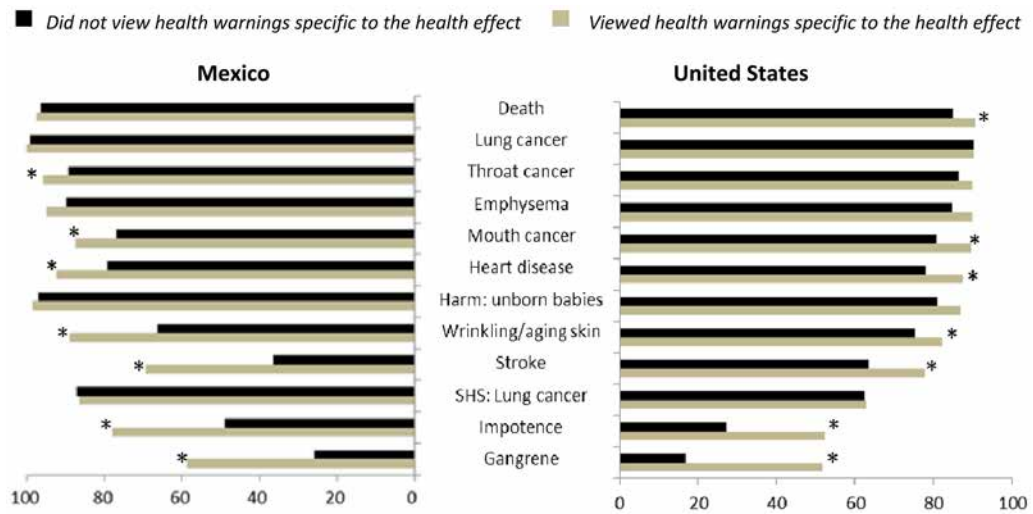
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**Figure 1.** Percentage of respondents who believe smoking causes various health effects, by health warnings viewed. \*Significant differences ( $p < .05$ ) between those who did vs. did not the health warnings specific to the health effect

Table 1

## Sample Characteristics

CHARACTERISTICS	MEXICO % (n)			UNITED STATES % (n)		
	ADULTS (n=544)	YOUTH (n=528)	OVERALL (n=1,072)	ADULTS (n=772)	YOUTH (n=677)	OVERALL (n=1,449)
<b>Gender</b>						
Male	51.7 (281)	50.0 (264)	50.8 (545)	47.3 (365)	53.3 (361)	50.1 (726)
Female	48.3 (263)	50.0 (264)	49.2 (527)	52.7 (407)	46.7 (316)	49.9 (723)
<b>Age (mean)</b>	29.3 (SD=11.6)	16.9 (SD=0.9)	23.2 (SD=10.3)	47.2 (SD=12.5)	16.7 (SD=0.7)	32.9 (SD=17.7)
<b>Education level<sup>a</sup></b>						
Low	18.2 (99)	--	18.2 (99)	28.0 (216)	--	28.0 (216)
Moderate	51.9 (262)	--	51.9 (262)	41.3 (319)	--	41.3 (319)
High	29.8 (162)	--	29.8 (162)	30.7 (237)	--	30.7 (237)
<b>Income (annual net household)</b>						
Low (less than \$30,000)	--	--	--	26.6 (203)	--	26.6 (203)
Moderate (\$30,000 to \$59,999)	--	--	--	36.2 (276)	--	36.2 (276)
High (\$60,000 and over)	--	--	--	37.1 (283)	--	37.1 (283)
<b>Smoking frequency</b>						
Daily	51.7 (281)	12.9 (68)	32.6 (349)	88.1 (680)	12.1 (82)	52.6 (762)
Non-daily	48.3 (263)	36.0 (190)	42.3 (453)	11.9 (92)	19.4 (131)	15.4 (223)
Non-smoker	0	51.1 (270)	25.2 (270)	0	68.5 (464)	32.0 (464)
<b>Quit Intentions</b>						
Not planning to quit	45.4 (247)	35.3 (91)	42.1 (338)	20.9 (156)	20.0 (41)	20.7 (197)
Planning to quit	54.6 (297)	64.7 (167)	57.9 (464)	79.1 (589)	80.0 (164)	79.3 (753)
<b>Ethnicity</b>						
Non-minority	--	--	--	83.4 (644)	75.5 (511)	79.7 (1,155)
Minority <sup>b</sup>	--	--	--	16.5 (127)	24.4 (165)	20.2 (292)

<sup>a</sup>Low=Highschool or less (US), Primary, Middle, or Technical/vocational school or less (Mexico); Moderate= Technical/trade school or community college or some university (US), Highschool or some university (Mexico); High=University or Post graduate degree (US, Mexico)

<sup>b</sup>Minority includes: Black or African-American, Hispanic or Latino, Asian or Pacific-Islander, Native American Indian, Mixed race, and Other

--No data

Table 2

Percentage of respondents who believe smoking causes various health effects<sup>a</sup>

Based on what you know or believe, does smoking cause...	MEXICO			UNITED STATES		
	Adults (n=443)	Youth <sup>†</sup> (n=450)	Overall (n=893)	Adults (n=667)	Youth <sup>†</sup> (n=590)	Overall* (n=1,257)
Lung cancer?	99.3%	98.9%	99.1%	86.1%	94.7% <sup>‡</sup>	90.1%*
Heart disease?	85.1%	73.2% <sup>‡</sup>	79.1%	76.8%	79.4%	79.4%
Stroke?	43.2%	30.1% <sup>‡</sup>	36.6%	61.7%	65.3%	63.4%*
Mouth cancer?	79.2%	74.2%	76.7%	78.1%	84.1% <sup>‡</sup>	80.9%*
Throat cancer?	92.8%	85.7% <sup>‡</sup>	89.2%	83.7%	89.6% <sup>‡</sup>	86.5%
Emphysema?	93.5%	85.9% <sup>‡</sup>	89.7%	88.5%	80.5% <sup>‡</sup>	84.8%*
Gangrene?	27.1%	24.7%	25.9%	13.7%	20.3% <sup>‡</sup>	16.8%*
Impotence in male smokers?	56.9%	41.2% <sup>‡</sup>	49.0%	25.9%	29.1%	27.4%*
Wrinkling and aging of the skin?	71.2%	61.5% <sup>‡</sup>	66.3%	73.8%	76.6%	75.1%*
Death?	96.4%	96.2%	96.3%	79.9%	91.1% <sup>‡</sup>	85.1%*
Harm to unborn babies?	97.1%	96.7%	96.9%	75.5%	87.4% <sup>‡</sup>	81.0%*
Lung cancer in non-smokers from breathing cigarette smoke?	89.4%	84.7% <sup>‡</sup>	87.1%	51.1%	75.1% <sup>‡</sup>	62.4%*

Data are shown only from respondents who did not view the health warnings specific to the health effect listed. Within this population, logistic regression models were conducted for each health effect to examine whether beliefs differed by age group (youth vs. adults) and by country (Mexico vs. US).

<sup>a</sup> % responding 'Yes'; remainder include 'No' and 'Don't Know' responses.

<sup>‡</sup> Significant differences between adults and youth within each country, where  $p < .05$

\* Significant differences "overall" between Mexico and the United States, where  $p < .05$

# Does Switching from Cigarettes to Pipes or Cigars Reduce Tobacco Smoke Exposure?

JUDITH K. OCKENE, PHD, TERRY F. PECHACEK, PHD, THOMAS VOGT, MD, AND KEN SVENDSEN, MS

(For the MRFIT Research Group)

**Abstract:** Cigarette smoking histories, reported depth of inhalation, number of pipe and cigars (PC) smoked, serum thiocyanate (SCN) and expired air carbon monoxide (CO) levels were examined in PC male smokers enrolled in the Multiple Risk Factor Intervention Trial (MRFIT). Serum SCN levels for all PC smokers were higher than for non-smokers and lower than for current cigarette smokers. Levels were related to the amount of product smoke. Prior cigarette smokers had higher SCN levels when compared to PC users who had

never smoked cigarettes, smoked a larger number of tobacco products per day, and reported inhaling into the chest more often. Prospective data on baseline cigarette smokers demonstrated that smokers who stopped all tobacco products had a greater drop in SCN and CO than those who switched to PC. The findings strongly suggest that cessation of all tobacco products is the best strategy for decreasing exposure to tobacco smoke. (*Am J Public Health* 1987; 77:1412-1416.)

## Introduction

There are over 30 million adult former cigarette smokers in the United States<sup>1</sup> However, not all ex-cigarette smokers, especially males, have stopped tobacco use completely. Some have switched to pipes and/or cigars, perhaps in part because of the belief that pipe and/or cigar (PC) smoking is less harmful and thus more acceptable than cigarettes. Several studies examining exposure to tobacco smoke have suggested that certain characteristics of PC smoking behavior can produce exposure levels similar to those seen in cigarette smokers although the results are far from conclusive.<sup>2-10</sup> Thus, pipes and cigars may not be safe alternatives to cigarettes.

Prospective epidemiologic studies which have examined the relationship of smoking various tobacco products to chronic disease mortality have generally concluded that the use of PC results in cardiopulmonary mortality rates which are slightly elevated when compared to nonsmokers but considerably lower than those of current cigarette smokers.<sup>11-15</sup> Prospective studies which have specifically looked at the relationship of smoking various tobacco products to the subsequent development of coronary heart disease (CHD) have produced conflicting findings.<sup>16-19</sup> Incidence rates of acute myocardial infarction (MI), angina pectoris, and possible MI have been found to be similar among PC smokers to those seen in cigarette smokers and considerably higher than those for nonsmokers.<sup>16</sup> PC use following unstable angina or MI was also related to as poor a survival rate as continued cigarette smoking.<sup>16</sup> In other studies,<sup>17,18</sup> the incidence of CHD in PC smokers was intermediate between the rates of nonsmokers and cigarette smokers or showed no increase in CHD deaths, MI, or angina in pipe smokers relative to the rates of nonsmokers.<sup>19</sup> In early prospective studies, the harmful effects of PC smoking on cancer rates have been thought to be limited primarily to sites exposed to PC smoke, that is, the oral cavity, larynx, pharynx, and esophagus.<sup>11</sup>

Only small increases in lung cancer rates have been noted in PC smokers.<sup>11</sup> Unfortunately, few studies have examined the relationship of lung cancer to prior smoking status<sup>19</sup> or to other smoking characteristics which are possibly related to smoke exposure.

Investigators have used carboxyhemoglobin (COHb), plasma nicotine, saliva and serum cotinine or serum thiocyanate (SCN) measurements—all objective indicators of exposure to tobacco smoke—to examine exposure to tobacco smoke by PC smokers.<sup>2-10</sup> The PC smoker who had previously smoked cigarettes (secondary PC smoker) has been found in both types of studies to have higher smoke exposure than the PC smoker who had not previously smoked cigarettes (primary PC smoker). Reported inhalation<sup>6</sup> and amount of pipe or cigar tobacco smoked<sup>8</sup> have also been found to be related to smoke exposure. All of the noted studies have used relatively small samples of PC smokers (range of N is 10-306), and only cross-sectional data.

The present study used serum SCN levels and expired air CO measurements to investigate the cross-sectional relationship of cigarette smoking history, number of pipe-bowls or cigars smoked per day, and reported level of inhalation of pipe and cigar smoke to exposure to tobacco smoke among pipe and/or cigar smokers and to prospectively follow cohorts of smokers who change their tobacco use over a six year follow-up period.

## Methods

The subjects in this study were participants in the Multiple Risk Factor Intervention Trial (MRFIT), a six-year collaborative, randomized clinical trial investigating the prevention of coronary heart disease (CHD) through risk factor modification.<sup>20</sup> Each participant was followed for a minimum of six years. Participants were randomized into either a special intervention (SI) or a usual care (UC) group at baseline. SI participants were involved in an intervention program which included educational and behavioral techniques to help them stop smoking cigarettes. Pipe and cigar smoking were not targets for intervention, and persons who switched from cigarettes to pipes or cigars were considered successful ex-smokers.

All participants, both SI and UC, had a baseline examination and yearly physical examinations which included serum thiocyanate (SCN) determinations, self-reports of tobacco use, and CO measurement (at years three and six).<sup>20</sup> Questions used to determine smoking status included items

Address reprint requests to Judith K. Ockene, PhD, Division of Preventive and Behavioral Medicine, Department of Medicine, University of Massachusetts Medical School, Worcester, MA 01605. Dr. Pechacek is with the Office of the Director, Division of Cancer Prevention and Control, National Cancer Institute, Bethesda, MD; Dr. Vogt is with the Center for Health Services, Portland, OR 97215; Mr. Svendsen is with the Coordinating Centers for Biometric Research, University of Minnesota, Minneapolis. This paper, submitted to the *Journal* April 2, 1987, was revised and accepted for publication June 4, 1987.

TABLE 1—Mean Serum Thiocyanate Levels\* by Smoking Status at Baseline among MRFIT Participants

Type of smoker	N	Mean $\pm$ SD	95% CI	% >100 $\mu$ mole/l
Never smoked tobacco products	1,356	54.4 $\pm$ 30.1*	(52.8, 56.0)	7.4
Ex-cigarette smokers	2,142	56.4 $\pm$ 29.8	(55.1, 57.6)	8.2
Primary PC smokers†	414	90.2 $\pm$ 51.4	(85.3, 95.2)	33.3
Secondary PC smokers‡	497	111.6 $\pm$ 66.3	(105.8, 117.4)	48.7
Cigarette only smokers	5,090	173.8 $\pm$ 55.4	(172.3, 175.3)	91.4
Cigarette & PC smokers	1,784	170.6 $\pm$ 54.1	(168.1, 173.1)	89.6
Other§	1,192	132.6 $\pm$ 67.9	(128.8, 136.5)	63.8
Total	12,475	131.0 $\pm$ 72.5	(129.8, 132.3)	61.5

\* = Micromoles per liter

CI = Confidence interval

† = Primary PC smokers of pipes, cigars or both who never smoked cigarettes

‡ = Secondary PC smokers are smokers of pipes, cigars or both who were former cigarette smokers

§ = Includes those who quit between 1st and 3rd screen and cigarillo smokers

assessing cigar, pipe, and cigarette smoking status as well as depth of inhalation. Serum SCN was analyzed using an AutoAnalyzer II by a colorimetric method developed by Butts and his colleagues.<sup>21</sup> In addition to yearly follow-up, SI participants were also monitored every four months at which time they reported their smoking status.

Baseline analyses are reported for SI and UC groups combined. Cohort data are presented for only the SI participants because of the availability of smoking data for this group every four months rather than just annually as is the case for the UC group. Mean levels of SCN and CO were adjusted in some analyses using analysis of variance (ANOVA) methods.

### Results

The means of serum SCN levels for participants at entry indicate that PC users (primary and secondary) had SCN levels intermediate between nonsmokers and cigarette smokers (Table 1). The mean SCN level for secondary PC users was 21.4  $\mu$ mole/l higher than that for primary PC users; both were lower than the mean level of cigarette smokers but substantially higher than non-users of any tobacco.

In the MRFIT, a cut-point of 100  $\mu$ mole/l was used as a crude assessment of whether or not an individual was truthful in his/her reporting of cessation of cigarette smoking. This cut-point would produce 7.4 per cent false positives in baseline never smokers and 8.2 per cent false positives in baseline ex-cigarette smokers. Approximately 33 per cent of the primary PC users and 49 per cent of the secondary PC users had SCN levels above this cut-point.

A comparison of the mean serum SCN levels for primary and secondary users of pipes only, cigars only, and combined PC at baseline reveals that secondary users had higher levels than primary users. Primary pipe smokers had higher SCN levels than primary cigar smokers with a difference of 13.0  $\mu$ mole/l. Secondary pipe smokers had higher levels than secondary cigar smokers (with a difference of 30.6  $\mu$ mole/l).

Figure 1 illustrates serum SCN levels for pipes-only smokers by previous cigarette smoking status and for number of pipes smoked per day. Within each stratum of pipe smoking, SCN levels were greater for secondary as compared to primary users suggesting they may indeed inhale more. This occurred similarly for cigar smokers except in the five-to-seven cigars daily stratum.

Secondary pipe and cigar smokers used a larger number of pipes or cigars per day than did primary pipe and cigar smokers and reported inhaling into the chest more often (Table 2).

For pipe only smokers, after adjusting for number of pipes smoked per day and depth of inhalation, the mean levels of SCN

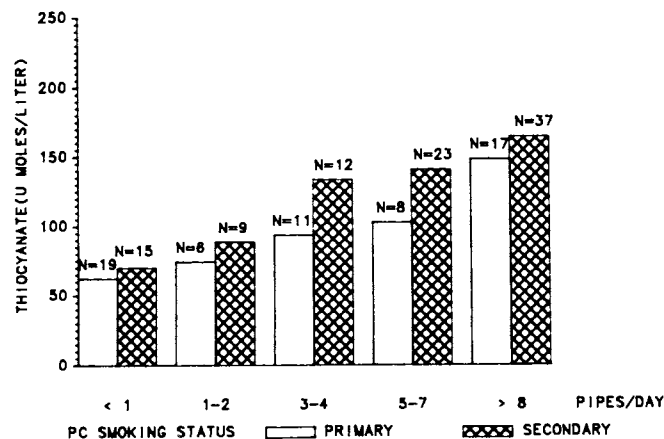


FIGURE 1—Mean Baseline Serum Thiocyanate Levels for Pipe Only Smokers by Numbers of Pipes Smoked per Day

were 107.6 and 127.7 for primary and secondary pipe smokers, respectively (Difference, 20.1; 95% CI, 6.2, 33.9).

For cigar smokers, after adjusting for number of cigars smoked per day and depth of inhalation, the mean levels of SCN are 91.4 and 97.9 for primary and secondary cigar smokers, respectively (Difference, 6.5; 95% CI, -2.3, 15.2).

To further demonstrate the joint effect on baseline SCN of previous cigarette smoking status, number of pipe-bowls or cigars smoked per day, and inhalation into the chest, a multiple regression analysis was performed for pipe only smokers and for cigar only smokers (Table 3). The coefficients for pipe only smokers indicated that being an ex-cigarette smoker and the number of pipes smoked per day were each strongly related to increased SCN but self-report of inhalation into the chest was substantially less important. Among cigar smokers, being a former cigarette smoker was not as strong a predictor as was number of cigars smoked per day or reported inhalation into the chest.

The MRFIT afforded the opportunity to follow cohorts of baseline cigarette smokers from the beginning of the trial through at least six years of follow-up. The analyses included only SI baseline cigarette smokers. Cigarette quitters at six years were defined as baseline cigarette smokers who reported not smoking for at least one year prior to the sixth annual visit. The cohorts of baseline cigarette smokers used in the analyses are the following: continued to smoke cigarettes only (n=1,137); quit cigarettes, started PC (n=75); quit cigarettes, did not start PC (n=747).

Those smokers who stopped all tobacco products had

**TABLE 2—Amount Smoked per Day and Per Cent Participants Who Report Inhaling Smoke into the Chest by Pipe and Cigar Smoking Status for Primary and Secondary PC Smokers**

Smoking Status	Primary		Secondary		Difference in Means (95% CI)	
	Mean	SD	Mean	SD		
<b>Pipes Only</b>						
Number of pipes smoked per day	4.2	3.5	5.6	3.3	-1.3	(-2.4, -0.2)
% Who reported inhaling smoke into chest	6.6	—	19.8	—	-13.2	(-24.2, -2.2)
N	61		96			
<b>Cigars Only</b>						
Number of cigars smoked per day	1.8	2.1	2.5	2.6	-0.6	(-1.0, -0.2)
% Who reported inhaling smoke into chest	3.3	0.00	11.0	—	-7.7	(-12.2, -3.3)
N	243		290			

the greatest drop in SCN; smokers who continued with cigarettes had very little change; and smokers who stopped cigarettes and started PC had a decrease in SCN between the two former cohorts but closer to that of continuing cigarette smokers (Table 4). Although baseline carbon monoxide (CO) measures were not taken, the relationship of CO to smoking status at 6 years for the three cohorts is similar to that observed for SCN (Table 5).

*Discussion*

As in the data reported from the Minnesota surveys by Pechacek and his colleagues,<sup>8</sup> the number of PCs smoked per day was a predictor of SCN levels in PC smokers although, contrary to that study, previous smoking status also remained a predictor of SCN level for pipe smokers. Reported inhalation into the chest was not strongly related to exposure, suggesting that pipe smokers who inhale may not be aware of how much they are inhaling. For cigar smokers, history is a less powerful predictor of exposure than is number of cigars smoked. Data in the present investigation also suggest that both primary and secondary pipe smokers experience greater exposure to tobacco than do cigar smokers.

The MRFIT provided prospective data which demonstrate that switching from cigarettes to pipes or cigars produces a decrease in smoke exposure, although the amount of change is substantially less than for cigarette smokers who stop the use of all tobacco products. Smokers who switch to PC are more likely to smoke a greater amount and report deeper inhalation than PC smokers who have never smoked cigarettes. This lends support to the nicotine titration hy-

pothesis suggested by Benowitz and his colleagues,<sup>22</sup> which suggests that smokers who change to lower nicotine level cigarettes change their inhalation patterns and increase the number of cigarettes smoked so that they can continue to obtain the same level of nicotine as with their original cigarette brand.<sup>23</sup> Smokers who stop smoking cigarettes but take up PC smoking may adopt inhalation and dose patterns which allow them to continue to obtain a level of nicotine similar to what was obtained with their prior cigarette use. That secondary PC users had SCN levels which remain elevated even after they had not been smoking cigarettes for at least one year reflects the likelihood that once an individual is a cigarette smoker he continues to inhale other tobacco products and experiences almost as much exposure to noxious materials as when he/she was smoking cigarettes.

Although risks of pipe and cigar smoking without inhalation are primarily limited to excess oral cancers, smokers who take up pipes and cigars after quitting cigarettes are more likely to inhale them and to achieve tobacco exposure levels nearly as high as they received from cigarettes. In addition, the more PC smoked per day the higher the exposure level achieved. Since pipe and cigar smoke is much higher in tar than is cigarette smoke, the risks of pulmonary cancers may actually be increased.

Although serum SCN levels are only a marker for exposure to gas and possibly particulate phases of tobacco smoke, these data are consistent with the elevated risk for lung cancer previously noted for heavier PC smokers.<sup>2</sup> This increased lung cancer risk may be largely limited to secondary PC smokers who are more likely to inhale the smoke. Estimates of the relative risk of coronary heart disease for heavier PC smokers have varied and have commonly been only slightly higher than for nonsmokers.<sup>2</sup> However, number of PC used per day usually has not been reported, biochemical measures of exposure have been collected only recently, and the prevalence of PC smoking has been too low in most study populations to permit risk estimates by level of product use. Similarly, most epidemiologic studies have not had sufficient numbers of PC users to analyze data for primary and secondary PC smokers separately. Due to increased cigarette smoking cessation in recent years, the prevalence of secondary PC users likely has increased since early epidemiologic studies. Since secondary users are more likely to be heavy users of PC, the prevalence of heavy PC use may also be increasing. Morbidity and mortality follow-up data which relate disease risk to PC use may need to separate persons by previous smoking status and amount smoked in order to assess risk more accurately. Reported depth of inhalation would also have some value but it is unlikely that this would be easily obtainable. Data from a Finnish study<sup>24</sup> strongly

**TABLE 3—Estimated Regression Coefficients and Their Standard Errors for the Multiple Regression of Baseline Thiocyanate for Pipe only Smokers and Cigar only Smokers**

Independent Variable	Coefficient	SE
<b>Pipe Only</b>		
Ex-cigarette smoker		
Indicator (1 = yes, 0 = no)	20.08	7.078
Pipes per day	9.68	1.04
Inhale into chest	14.46	9.99
Constant	56.65	
R <sup>2</sup> = 0.4562		
<b>Cigar Only</b>		
Ex-cigarette smoker		
Indicator (1 = yes, 0 = no)	6.46	4.46
Cigars per day	14.05	0.97
Inhale into chest	22.85	8.73
Constant	59.40	
R <sup>2</sup> = .3413		

**TABLE 4—Thiocyanate at Baseline and 72 Months for Special Intervention Participants Who Were Cigarette Only Smokers at Entry by Number of Cigarettes Smoked Per Day at Entry and Smoking Status at 72 Months**

Baseline Cigs/day	Continued to Smoke Cigarettes Only				Quit Cigarettes, Started PC				Quit Cigarettes, Did Not Start PC			
	N	Base-line SCN	72-Month SCN	Change	N	Base-line SCN	72-Month SCN	Change	N	Base-line SCN	72-Month SCN	Change
1-19	91	135.2	144.9	9.7	9	142.1	107.4	-34.1	161	113.1	67.0	-46.1
20-39	554	178.7	173.2	-5.5	36	166.8	145.0	-21.8	344	158.3	65.7	-92.6
GE 40	492	194.4	186.5	-7.9	30	186.5	170.0	-16.5	242	185.4	58.9	-126.5
Total	1137	182.0	176.7	-5.3	75	171.7	150.5	-21.2	747	157.3	63.8	-93.5
Total (adjusted change)*				(-3.6)*				(-22.6)*				(-96.0)*

\*Adjusted for baseline cigarettes per day.  
PC = Pipes and or cigars.

**TABLE 5—Expired Carbon Monoxide at 72 Months for Special Intervention Participants Who Were Cigarette Only Smokers at Entry by Number of Cigarettes Smoked per Day at Entry and Smoking Status at 72 Months**

Baseline Cigs/day	Continued to Smoke Cigarettes Only		Quit Cigarettes, Started PC		Quit Cigarettes, Did Not Start PC	
	N	72-Month CO**	N	72-Month CO	N	72-Month CO
1-19	85	19.3	8	10.5	158	6.7
20-39	546	25.5	37	14.1	337	7.0
GE 40	489	29.1	28	22.5	240	6.9
Total	1120	26.6	73	16.9	735	6.9
Total adjusted CO*		(26.3)		(17.2)		(7.4)

\*Adjusted for baseline cigarettes per day  
\*\*Parts per million (ppm)

suggest that elevated SCN levels reflect risk. Continued follow-up of the MRFIT population may clarify the risk ratios of both primary and secondary PC use.

In summary, the present investigation indicates that cessation of all tobacco products is the best strategy for reducing exposure to tobacco smoke; switching to pipes or cigars or using a large number of pipe or cigar tobacco products increases the probability of continued high exposure to tobacco smoke and should not be recommended. For the individual who is unable to stop his/her use of pipes or cigars, recommendations should be made to reduce the amount smoked and to become aware of possible inhalation. The efficacy of such recommendations, however, remains to be tested.

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**MRFIT Credit Roster**

The principal investigators and senior staff of the clinical, coordinating, and support centers, the National Heart, Lung and Blood Institute, and members of the MRFIT Policy Advisory Board and Mortality Review Committee are:

- American Health Foundation, New York:* C. B. Arnold, MD, MPH—Principal Investigator, R. Mandriota, MS, MEd, R. Ames, MD.
- Boston University, Boston:* H. E. Thomas, Jr., MD—Principal Investigator, W. B. Kannel, MD—Co-Principal Investigator, R. Rotondo, MA.
- Cox Heart Institute, Kettering, Ohio:* P. Kezdi, MD—Principal Investigator, E. L. Stanley, MD—Co-Principal Investigator.
- Dade County Department of Public Health, Miami:* G. Christakis, MD,

- MPH—Principal Investigator, J. M. Burr, MD—Co-Principal Investigator, T. A. Gerace, PhD—Co-Principal Investigator.*
- Dalhousie University, Halifax, Nova Scotia:* (MRFIT ECG Center): P. M. Rautaharju, MD, PhD—Principal Investigator, H. Wolf, PhD.
- Harvard University, Boston:* R. C. Benfari, PhD—Principal Investigator, K. M. McIntyre, MD, JD—Co-Principal Investigator, O. Paul, MD—Co-Principal Investigator, Judith Ockene, PhD.
- Kaiser Foundation Research Institute, Portland, Oregon:* J. B. Wild, MD—Principal Investigator, M. Greenlick, PhD—Co-Principal Investigator, J. Grover, MD—Co-Principal Investigator.
- Lankenau Hospital, Philadelphia:* W. Holmes, PhD—Principal Investigator, J. Allaire, MEd.
- National Center for Disease Control, Atlanta:* G. R. Cooper, PhD, MD—Principal Investigator, A. Hainline, Jr., C. L. Winn, B. L. Botero, J. B. Gill, Jr.
- New Jersey Medical School, Newark:* N. L. Lasser, MD, PhD—Principal Investigator, N. Hymowitz, PhD—Co-Principal Investigator.
- University of Chicago, Chicago:* L. Cohen, MD—Principal Investigator, J. Morgan, PhD—Co-Principal Investigator.
- St. Joseph's Hospital, Chicago:* D. M. Berkson, MD—Principal Investigator, G. Lauger, MS.
- Institutes of Medical Sciences—University of California, San Francisco and Berkeley:* J. Billings, PhD, MPH—Principal Investigator, S. B. Hulley, MD, MPH—Co-Principal Investigator, W. M. Smith, MD, MPH—Co-Principal Investigator.
- Institutes of Medical Sciences, San Francisco Central Laboratory:* G. M. Widdowson, PhD—Co-Principal Investigator.
- Rush Presbyterian-St. Luke's Medical Center, Chicago:* J. A. Schoenberger, MD—Principal Investigator, J. C. Schoenenberger, PhD, R. B. Shekelle, PhD.
- Rutgers Medical School, Piscataway, New Jersey:* N. H. Wright, MD, MPH—Principal Investigator, S. A. Kopel, PhD—Co-Principal Investigator, K. R. Suckerman, PhD.
- St. Louis Heart Association, St. Louis:* N. Simon, MD—Principal Investigator, J. D. Cohen, MD—Co-Principal Investigator.
- University of Alabama in Birmingham:* H. W. Schnaper, MD—Principal Investigator, G. H. Hughes, PhD—Co-Principal Investigator.
- University of California, Davis:* N. O. Borhani, MD—Principal Investigator, C. Sugars, RD, K. Kirkpatrick, BA.
- University of Maryland, Baltimore:* R. W. Sherwin, MB, BChir—Principal Investigator, M. S. Sexton, PhD, MPH—Co-Principal Investigator.
- University of Minnesota, Minneapolis:* R. H. Grimm, Jr., MD, MPH—Principal Investigator, M. Mittlemark, PhD—Co-Principal Investigator, R. S. Crow, MD—Co-Principal Investigator, H. Blackburn, MD—Co-Principal Investigator, D. Jacobs, PhD—Co-Principal Investigator, T. Pechacek, PhD.
- University of Minnesota ECG Coding Center, Minneapolis:* R. J. Prineas, MB, BS, PhD—Director, R. C. Crow, MD—Associate Director.
- University of Minnesota Nutrition Coordinating Center, Minneapolis:* M. O. Kjelsberg, PhD—Principal Investigator, G. E. Bartsch, ScD—Co-Principal Investigator, J. D. Neaton, PhD, S. K. Broste, MS.
- University of Pittsburgh, Pittsburgh:* L. H. Kuller, MD, DrPH—Principal Investigator, E. Meilahn, MPH, B. Conniiff, BA, MSW.
- University of South Carolina, Columbia:* W. K. Giese, PhD—Principal Investigator, J. F. Martin, MD—Co-Principal Investigator, J. A. Keith, PhD
- University of Southern California, Los Angeles:* E. Fishman, MD—Principal Investigator, L. Wampler, PhD.
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- National Heart, Lung and Blood Institute Staff, Bethesda, Maryland:* W. T. Friedewald, MD (Program Director), C. D. Furberg, MD (Project Office



Director), J. A. Cutler, MD (Scientific Project Officer), E. R. Passamani, MD (former Scientific Project Officer), C. T. Kaelber, MD (former Scientific Project Officer).

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## To the Dickens with Them

**T**hey were ruined when they were required to send labouring children to school; they were ruined when inspectors were appointed to look into their works; they were ruined when such inspectors considered it doubtful whether they were quite justified in chopping people up with their machinery; they were utterly undone when it was hinted that perhaps they need not make quite so much smoke. Whenever . . . (it was) proposed to (hold) them accountable for their acts they were sure to come out with the awful menace that they would "sooner pitch their property into the Atlantic." This had terrified the Home Secretary within an inch of his life on several occasions.

However, (they) were so patriotic after all, that they never pitched their property into the Atlantic yet, but, on the contrary had been kind enough to take mighty good care of it. So there it was, in the haze yonder, and it increased and multiplied.

——Dickens C: *Hard Times* (1854)

# Smoke Exposure in Pipe and Cigar Smokers

## Serum Thiocyanate Measures

Terry F. Pechacek, PhD; Aaron R. Folsom, MD; Regis de Gaudermaris, MD; David R. Jacobs, Jr, PhD; Russell V. Luepker, MD; Richard F. Gillum, MD; Henry Blackburn, MD

• Pipe or cigar smoking traditionally has been considered a less risky alternative to cigarette smoking. Some surveys and experimental studies have suggested, however, that former cigarette smokers who switch to cigars and/or pipe (CP) are more likely to inhale than CP users who never smoked cigarettes; but this relationship has not been consistently noted. To clarify smoke-exposure levels from CP smoking, smoking histories and serum thiocyanate (SCN) levels were studied in 9,106 adults aged 25 to 74 years in population-based surveys of seven upper Midwestern communities. Analyses of the 306 male CP smokers indicated a significantly higher SCN level in the ex-cigarette-smoking CP users vs the CP users who never smoked cigarettes. Serum thiocyanate levels of both CP groups were significantly higher than those of nonsmokers and lower than cigarette-only smokers. However, the number of pipe bowls or cigars smoked per day was also significantly related to SCN levels, and this could account for much of the association between SCN and previous cigarette smoking status. Individuals currently smoking four or more pipe bowls or four or more cigars per day had an elevated smoke exposure equivalent to about ten cigarettes per day, whether or not they previously smoked cigarettes. Because of these findings and because former cigarette smokers were more likely to report heavy CP usage, cigarette smokers should be advised to quit rather than to switch to a pipe or cigar.

(*JAMA* 1985;254:3330-3332)

THE MAJOR prospective studies of smoking have found that smokers of cigars and/or pipes (CP), as a group, have mortality rates that average only 20% to 40% higher than those of nonsmokers, but 50% to 60% lower than those of cigarette smokers.<sup>1</sup> The 1979 US Surgeon General's Report<sup>1</sup> concluded that the harmful effects of CP smoking are largely limited to sites most exposed to CP smoke, namely, the oral cavity, larynx, pharynx, and esophagus, but that CP smoking is not associated with excess cardiopulmonary diseases. According to that report, lower cardiopulmonary disease risks for CP smokers than for cigarette smokers may be due to less inhalation (because of the alkalinity and irritation of CP smoke) and less frequent smoking. Epidemiologic

studies suggested a dose-response relationship between the number of pipes or cigars smoked and overall mortality, but few have examined CP smoking risk in relation to prior cigarette smoking status.<sup>1</sup>

Several surveys and experimental studies<sup>2-7</sup> have cautioned that ex-cigarette smokers who switch to a pipe and/or cigars (secondary CP smokers) are more likely to inhale than those who never smoked cigarettes (primary CP smokers) as indicated by significantly higher carboxyhemoglobin (COHb%) and serum nicotine levels in the ex-cigarette smokers. However, one survey measuring COHb% and cotinine levels found this difference for cigar smokers only and not for pipe smokers.<sup>8</sup> Another examined serum thiocyanate (SCN) levels in CP users and found no relation to previous cigarette smoking status.<sup>9</sup> Furthermore, a test of plasma nicotine levels of primary and secondary pipe smokers shortly after pipe smoking showed no difference between the groups, and little indication of inhalation in either group.<sup>10</sup>

The current study seeks to delineate the exposure to CP smoke as

reflected by serum SCN levels, a chemical marker for inhaled tobacco smoke.<sup>11</sup> Serum thiocyanate levels may be a better survey measure of inhaled pipe and cigar smoke than nicotine and COHb%. Nicotine in CP smoke can be absorbed by the oral mucosa<sup>12</sup> and COHb% smoke has a relatively short half-life (four to six hours).<sup>13</sup> On the other hand, hydrogen cyanide and cyanogen, the gases that elevate SCN levels,<sup>14</sup> are primarily absorbed in the lungs, and SCN has an estimated half-life of 12 to 14 days.<sup>11</sup> However, since SCN levels primarily measure gas-phase exposures, particulate phase retention can only be inferred from SCN assessments.

### SUBJECTS AND METHODS

The subjects were participants in cardiovascular disease risk factor surveys conducted in 1980 to 1982 on 9,106 adults aged 25 to 74 years in seven Midwestern US communities. The surveys were part of two larger projects, the Minnesota Heart Survey,<sup>15,16</sup> an ongoing surveillance study, and the Minnesota Heart Health Program, a community trial in primary prevention of cardiovascular diseases.<sup>17</sup> All were population-based surveys, using a two-stage cluster design and similar data collection protocols involving a home interview and survey clinic visit.<sup>18</sup> Response rates for the home interview ranged from 85% to 95%, and overall completion rates for both visits ranged from 69% to 80% across the communities. Smoking and CP status were determined during standardized interviews performed during the clinic visits. In some surveys, participants were asked the number of cigars, cigarillos, and/or pipe bowls smoked per day. Levels of SCN were analyzed using a spectrophotometer (Technicon AutoAnalyzer II) by a colorimetric method based on the procedure of Butts et al.<sup>18</sup>

The present analysis combined data for smokers from all seven communities. Only seven women were CP smokers, so data are presented for men only. Among men, 11.4% (n=482) smoked some CP product; 3.7% (n=155) also smoked cigarettes. For the analyses presented here, CP smokers who also smoked cigarettes and those with missing serum SCN measurements (n=21) were excluded. Of the remaining 306, 192 were secondary CP users (former cigarette smokers) and 114 were primary CP users (never smoked cigarettes). For comparison, SCN data are also presented for all male nonsmokers who never smoked ciga-

From the Division of Epidemiology, School of Public Health, University of Minnesota, Minneapolis. Dr de Gaudermaris was a visiting scholar in the Division of Epidemiology and currently is at the Service Medicine Interne et Cardiologie, Grenoble Cedex, France.

Reprint requests to University of Minnesota School of Public Health, Division of Epidemiology, Stadium Gate 27, 611 Beacon St SE, Minneapolis, MN 55455 (Dr Pechacek).

Table 1.—Mean ± SD and 95% CI\* of Serum Thiocyanate Level (Micromoles per Liter) by Smoking Status Among Men

Type of Smoker	n	Mean±SD	95% CI	% >70 μmole/L†
Never smoked	1,197	43.3±27.6	41.7-44.9	11.4
Primary CP‡	114	72.7±44.0	64.6-80.9	46.5
Secondary CP‡	192	96.9±61.2	88.2-105.7	58.9
Cigarette smoker	1,196	145.3±52.2	142.4-148.3	91.9

\*CI indicates confidence interval.

†Optimal cut point to discriminate between complete nonsmokers and cigarette smokers (see text).

‡CP indicates cigar and pipe smokers; Primary CP, CP smokers who have never smoked cigarettes; Secondary CP, CP smokers who have formerly smoked cigarettes.

Table 2.—Mean Serum Thiocyanate Levels for Primary\* and Secondary\* Pipe and Cigar Smokers

Type of Tobacco Product Smoked	Primary Smokers		Secondary Smokers		Student's <i>t</i> Test for Difference	P Value
	n	Mean, μmole/L (SEM)	n	Mean, μmole/L (SEM)		
Pipe only	41	73.4 (6.9)	83	118.4 (6.0)	4.58	<.0001
Cigar only	49	67.0 (5.3)	79	78.3 (7.1)	1.14	>.255
Cigarillo only	4	72.3 (18.8)	1	128.0 (..)	...	...
Combination†	20	85.6 (13.1)	29	84.9 (10.8)	0.04	>.965
Total	114	72.7 (4.1)	192	96.9 (4.4)	3.69	<.0003

\*Primary pipe and cigar smokers never smoked cigarettes; secondary smokers formerly smoked cigarettes.

†Combination users smoke more than one product.

Table 3.—Mean Serum Thiocyanate Levels by Number of Cigars or Pipes Smoked per Day\* †

Type of CP Smoker	No. of Pipe Bowls Smoked per Day				No. of Cigars Smoked per Day			
	<1	2-3	4+	Total	<1	2-3	4+	Total
Primary smokers‡								
Mean SCN, § μmole/L	45.9	73.8	115.6	79.2	66.3	80.8	133.7	74.4
(SEM)	(5.2)	(11.6)	(11.4)	(9.1)	(5.6)	(15.4)	(23.8)	(6.0)
Mean No. CP/day	1.0	2.3	11.4	5.3	1.0	2.5	5.3	1.6
(SEM)	...	(0.3)	(0.2)	(1.3)	...	(0.2)	(0.9)	(0.2)
No.	7	4	7	18	27	6	3	36
Secondary smokers								
Mean SCN, § μmole/L	52.8	88.3	133.3	110.6	65.7	83.1	128.3	80.2
(SEM)	(9.4)	(16.8)	(10.7)	(9.3)	(7.2)	(15.9)	(21.8)	(7.4)
Mean No. CP/day	1.0	2.5	8.7	6.0	1.0	2.6	6.7	2.3
(SEM)	...	(0.2)	(0.9)	(0.7)	...	(0.1)	(0.7)	(0.3)
No.	4	11	21	36	51	7	15	73

\*Cases may appear more than once due to combination cigar and pipe (CP) usage.

†One cigar or pipe bowl per day was the minimum value coded even for cases reporting infrequent smoking.

‡Primary smokers indicates CP smokers who have never smoked cigarettes.

§SCN indicates serum thiocyanate levels.

||Secondary smokers indicates CP smokers who have formerly smoked cigarettes.

rettes and currently use no other tobacco product, including snuff or chewing tobacco (n=1,197), and for all current male cigarette smokers (n=1,196).  $\chi^2$  Analyses, Student's *t* tests, and analyses of variance were performed using statistical software (Biomedical Computer Programs)<sup>9</sup> to test differences in distributions or means.

## RESULTS

Table 1 compares the means and distributions of serum SCN levels for male CP smokers, nonsmokers, and current cigarette-only smokers. The CP users had SCN levels that were intermediate between nonsmokers

and cigarette smokers. The mean thiocyanate level was 96.9 μmole/L for secondary CP users and 72.7 μmole/L for primary CP users ( $t=3.69$ ,  $P<.0003$ ). Among men in our population, an SCN level of 70 μmole/L is the optimal cut point for minimizing misclassifications of nonsmokers and current cigarette smokers. In men, this cut point produced 7.7% false-positives in persons who have never smoked and 9.1% false-negatives in current cigarette smokers. Almost 59% of secondary CP users had an SCN level greater than

70 μmole/L, vs slightly over 46% of primary CP users. This is consistent with the hypothesis that secondary CP users have higher exposure to inhaled tobacco smoke than primary users.

Table 2 shows serum SCN levels by type of product and previous cigarette use for pipe-only, cigarillo-only, and CP combination smokers. Mean thiocyanate levels for all of the groups were significantly higher than for nonsmokers ( $P<.0001$ ) and lower than cigarette smokers ( $P<.0001$ ). The SCN difference between primary vs secondary CP smokers was apparent for pipe smokers ( $P<.0001$ ) but not for cigar smokers ( $P<.25$ ) nor for combined CP smokers ( $P<.96$ ).

To clarify differences between primary and secondary CP smokers, number of cigars or pipe bowls smoked per day was used to stratify the population (Table 3). Within each stratum of pipe smoking, the secondary pipe smokers had higher SCN levels than primary pipe smokers, suggesting they may indeed inhale more. However, SCN levels were strongly related to number of pipes smoked per day, and secondary pipe smokers used a larger number per day than primary pipe smokers. In a two-way analysis of variance, number of pipes was significantly related to serum SCN level ( $F_{2/48}=11.3$ ,  $P<.0001$ ) whereas previous cigarette smoking status was not ( $F_{1/48}=0.9$ ,  $P$  value not significant). Smoking one or fewer bowls a day elevated serum SCN above nonsmoker levels only slightly, but smoking four or more bowls per day yielded SCN levels equivalent to smokers using about ten cigarettes per day. Ninety-three percent of those smoking four or more bowls per day had SCN levels greater than 70 μmole/L.

There was very little difference in mean SCN levels by previous cigarette smoking history for cigar smokers ( $F_{1/103}=0.01$ ,  $P$  value not significant), but SCN was significantly related to number of cigars per day in a graded fashion ( $F_{2/103}=7.1$ ,  $P<.001$ ). As with pipes, secondary cigar smokers were more likely than primary cigar smokers to smoke four or more cigars per day. The group smoking four or more cigars per day had quite high levels of SCN: 77.8% had SCN levels greater than 70 μmole/L, and mean SCN levels again were equivalent to cigarette smokers using about ten cigarettes per day.

## COMMENT

Smoking and health concerns have focused primarily on cigarette smok-

ing because far more people smoke cigarettes and epidemiologic investigations generally have shown lower disease risks for CP smokers.<sup>1</sup> Several studies have reported that secondary CP smokers, who switched from cigarettes, are more likely than primary CP smokers to inhale the smoke.<sup>3,6,7</sup> Others have found this effect stronger for cigars<sup>8</sup> or not present at all for pipes.<sup>10</sup> However, number of CP smoked per day may be a major confounding factor in past studies. Although our data confirm more smoke exposure among secondary pipe smokers, this was found to be due almost entirely to the fact that ex-cigarette smokers are heavier CP users. Our data suggest that *heavy* CP smokers (four or more cigars and/or pipe bowls per day) may be at elevated risk regardless of whether they previously smoked cigarettes. Differences may indeed exist in the inhalation patterns of secondary vs primary CP smokers, but it is clear that even primary CP smokers who use tobacco products heavily have significantly elevated exposure to inhaled tobacco smoke.

This elevated exposure has generally been assumed to be due to increased direct inhalation of pipe and/or cigar smoke<sup>3,6,7</sup>; however, it is possible that increased exposure to side stream (second-hand smoke) created by the CP products may also contribute to elevated biochemical levels. Unfortunately, the SCN, COHb%, and nicotine-cotinine measures are unable to distinguish between exposures from direct inhalation and side-stream smoke from the CP products.<sup>11</sup> While experimental

studies suggest that elevated exposures are due primarily to direct inhalation (possibly through a two-stage process of exhaling most of the bolus of CP smoke from the mouth and then inhaling a diluted smoke into the lungs),<sup>2,7</sup> the SCN measure primarily estimates gas-phase exposure and can only imply retention of particulates. If a significant portion of the elevated SCN exposure were due to the smoky environment caused by the CP products, the lower deposition rate of particulates from this side-stream exposure could lower the validity of estimated risk from the SCN measure.

Although serum SCN levels are only a marker for exposure to gas and possibly particulate phases of tobacco smoke, these data are consistent with the significantly elevated risk for lung cancer previously noted for heavier CP smokers.<sup>1</sup> Hickey et al<sup>20</sup> reported that CP smoking following unstable angina or myocardial infarction was related to as poor survival as continued cigarette smoking. However, the relative risk of initial coronary events for CP smokers is still at issue, as Wald et al<sup>6</sup> have noted. Estimates of the relative risk of coronary heart disease for heavier CP smokers have varied and have commonly been only slightly higher than for nonsmokers.<sup>1</sup> But, number of CP used per day usually has not been reported, biochemical measures of exposure have been collected only recently, and the prevalence of CP smoking has been too low in most study populations to permit risk estimates by level of product use. Similarly, most epidemiologic studies have

not had sufficient numbers of CP users to analyze data for primary and secondary CP smokers separately. The prevalence of secondary CP users probably has increased since early epidemiologic studies due to increased cigarette smoking cessation in recent years, while the overall prevalence of CP use and primary CP smoking has decreased.<sup>1</sup> Since secondary users are more likely to be heavy users of CP, the prevalence of heavy CP use may be increasing.

In conclusion, assuming a dose-response relationship between SCN values and risk of cardiopulmonary disease, then current CP smokers, especially individuals who have switched from cigarettes or who smoke four or more cigars or pipe bowls per day, should be warned about their possible high levels of smoke exposure and the potential risks associated with CP smoking. Heavy CP users should be advised to reduce consumption or quit CP smoking. Cigarette smokers contemplating switching to CP should be advised that they are likely to inhale CP smoke and may not significantly reduce their risk. Hence, quitting completely is the best and safest strategy.

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This article is dedicated to George Pechacek, the senior author's uncle, a pipe smoker who died of bronchial carcinoma.

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