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Division of Dockets Management (HFA305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. FDA-2010-N-0568

To Whom It May Concern:

The Campaign for Tobacco-Free Kids, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, and the American Academy of Pediatrics submit these comments in support of the proposed regulation issued by the FDA in the above-designated docket. With minor exceptions, the proposed regulation is consistent with statutory requirements, factually based and consistent with the scientific consensus on the effects of cigarette smoking, consistent with the overwhelming weight of scientific evidence on the effective use of cigarette warning labels, consistent with an international consensus on the standards for warning labels, and consistent with actual experience on what is required to make warning labels effective. These comments also propose several specific changes in the regulation and in the accompanying Notice to address unintended problems that might be created if the proposed language is not amended.

Our comments are supported by extensive citations from authoritative sources, including reports by the Surgeon General, the Institute of Medicine, the World Health Organization, and the International Tobacco Control Policy Evaluation Project, which has conducted in-depth studies of the effectiveness of tobacco warning labels in many countries. The scientific literature supporting the proposed regulation is rich and diverse.

Our comments cover the following subject areas:

- Current warning labels fail to convey information effectively.
- Congress had an ample factual and scientific basis to support its warning label requirements. The validity of the statutory provisions mandating the warning labels promulgated in this regulation has already been upheld on judicial review.
- The proposed warning labels have a solid scientific basis and are consistent with international standards.

- Experience in other countries that have adopted pictorial warning labels shows that they are effective. The evidence is clear: larger, graphic warning labels are more effective than text-only warnings and smaller warnings.
- Warning labels are necessary to inform smokers and potential smokers about the dangers of smoking.
- Independent of providing factual information to smokers, warning labels should be designed to discourage smoking.
- Inclusion on warning labels of a reference to a telephone quitline for science-based assistance for quitting enhances the effectiveness of warning labels; addition of a reference to a web-based source as well could further increase the effectiveness of the warning labels.
- Warning labels by themselves are effective, but they are even more effective when accompanied by a public education campaign. A public education campaign should accompany the introduction of the new warning labels.
- The FDA should institute procedures to ensure that new warning labels will be introduced on a schedule that will ensure that the warnings will not become stale.
- Provisions should be adopted to clarify the manufacturers' grace period for the sale of existing inventories manufactured or imported before the effective date.
- Clarifying changes should be made to the proposed regulation to ensure that it accomplishes its purpose.
- Although the economic analysis included in the Notice provides strong support for the regulation, the analysis understates the benefits of the regulation and overstates the costs.
- Consumer testing demonstrates that some of the potential images are more effective than others.

## **Importance of Warning Labels on Cigarette Packs**

It has long been recognized that cigarette packs and advertisements are appropriate vehicles for conveying factual information concerning the dangers of smoking and discouraging usage of cigarettes. Smokers encounter warning labels at critical times: both at the time they buy cigarettes and at the time they take out a pack to smoke a cigarette. In addition, smokers are repeatedly exposed to the warning label. A pack-a-day smoker would encounter the warning label more than 7,000 times in a year. In recognition of these facts, the Congress has required warning labels to be placed on cigarette packs since 1965. However, warning labels fulfill their function only if (1) they are noticed by smokers and potential smokers; and (2) convey information effectively.

The warning labels on cigarette packs in the United States have not changed in more than 25 years. When it enacted the Family Smoking Prevention and Tobacco Control Act (“the Act”), the Congress determined that the existing warning labels were no longer effective to accomplish their intended purpose and it gave specific instructions to the FDA regarding (1) the size of warning labels; (2) the placement of warning labels on the pack; (3) the text of the warning labels; and (4) the inclusion of pictorial images in the warning labels. The Congressional findings fully support the conclusion that new warning labels are needed and that the warning labels must be larger, must contain graphic images and must more effectively convey the harms of tobacco use and the benefits of quitting.

The proposed regulation that is the subject of this Notice of Proposed Rulemaking (“Notice”) responds to these specific Congressional mandates. The undersigned organizations strongly support the warning labels proposed by the FDA but suggest several changes to the Notice that accompanies the warning labels to ensure that the warning labels function most effectively to convey information regarding the danger of smoking, to discourage smoking initiation, and to encourage smoking cessation.

### **I. Current warning labels fail to convey information effectively.**

FDA’s Notice demonstrates persuasively that the existing warning labels, which have not been changed for twenty-five years, fail to convey information about the dangers of smoking effectively and are largely ignored.<sup>1</sup> (75 F.R. at 69529-31) In order to be effective, a warning label must first be noticed. As long ago as 1994, the Report of the Surgeon General concluded that the then-current warning labels had already become ineffective because of their size, shape and familiarity. Unfortunately, those same warning labels that were already stale in 1994 are still in use.<sup>2</sup> In the same year, an Institute of Medicine study concluded that “the current warnings are inadequate even when measured against an informed choice standard [and] woefully deficient when evaluated in terms of proper public health criteria.”<sup>3</sup> In 2007, a comprehensive report issued

by the Institute of Medicine concluded that the warnings—unchanged since 1984—had become “unnoticed and stale” and “failed to convey relevant information in an effective way.”<sup>4</sup>

At least four factors contribute to the ineffectiveness of current warning labels to serve their intended function: the lack of change in the message over a long period of time, the small size of the warning labels, the text of the message and the lack of graphic images.

#### **A. Lack of change**

Research indicates that the frequency with which smokers notice, read and think about health warnings lessens over time as smokers become desensitized to the warnings.<sup>5</sup> Studies show that the salience of health warnings decreases with repeated exposure and diminishes over time.<sup>6</sup> In a Canadian study conducted in 1999, researchers found that a majority of those surveyed believed that Canadian warning labels that had been in use for only 5 years were already stale and had lost much of their impact.<sup>7</sup> In the U.S., a 1999 study found that smokers had become habituated to the style of labels, to the point that the labels were seldom noticed.<sup>8</sup> This conclusion was corroborated by the 2007 Institute of Medicine study, which also collected an extensive body of research on the subject.<sup>9</sup> The Institute of Medicine concluded that “the currently mandated federal health warnings are inadequate and should be strengthened to promote greater understanding of the health risks of tobacco use and to discourage consumption.”<sup>10</sup>

The 2007 Institute of Medicine study quoted extensively from the 1994 Institute of Medicine study and then went on to recommend a series of changes in the required warning labels. The study stated:

Although federal law has remained unchanged for more than 20 years, evidence regarding the ineffectiveness of the prescribed warnings has continued to accumulate. U.S. package warnings have served the tobacco industry well by reducing their liability exposure while communicating ineffectively with smokers and potential smokers. The basic problems with the US warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way. In contrast to the messages used in other countries, the United States requires one of four text messages in black and white that occupy only 50 percent of the side of a pack. These messages have not changed in 20 years. They therefore have little effect on decision making or behavior.<sup>11</sup>

Accordingly, the Committee specifically recommended that

Congress should strengthen the federally mandated warning labels for tobacco products immediately and should delegate authority to the FDA to update and revise these warnings on a regular basis upon finding that doing so would promote greater public understanding of the risks of using tobacco products or reduce tobacco consumption. Congress should

require or authorize the FDA to require rotating color graphic warnings covering 50 percent of the package equivalent to those required in Canada.<sup>12</sup>

### **B. Size and placement of the warning**

Current cigarette pack warnings are small and are placed on the side of packs. As stated in the Notice (75 F.R. at 69531), smokers are more likely to recall larger warnings, as well as warnings that appear on the front of packages as opposed to on the sides.<sup>13</sup>

Several studies have concluded that the U.S. text warnings on the side of packages have low levels of salience among smokers.<sup>14</sup> In a comparative study of students in Canada and the United States carried out in 1995, at a time when Canadian packages carried text warnings on the front of packages but prior to the time when Canadian packages were required to carry pictorial images, 83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages, compared to only 7 percent of U.S. students.<sup>15</sup>

Moreover, small warnings such as those currently required on packs in the United States can easily be overwhelmed by the sophisticated packaging used by tobacco manufacturers to attract customers. Cigarette manufacturers have recognized the importance of pack design as a marketing tool and continually improved pack designs to communicate brand image more successfully.<sup>16</sup> The small and unchanging warnings currently required on cigarette packs in the United States cannot successfully compete for attention with the state-of-the-art pack designs of the major cigarette manufacturers.

### **C. Text of the message**

The intended target populations for the warning labels include all potential tobacco users, current users and former tobacco users. Virtually all new tobacco users are children and increasingly tobacco use in the United States is becoming concentrated among those with less education and from poorer socio-economic backgrounds. Smokers have lower educational attainment than non-smokers. Warnings must be effective with all populations, but it is critical to recognize that the need is even greater with youth and those most at risk. For both adult and adolescent populations, messages must be tailored to be read easily by the target population. There is evidence that smokers with less education are less likely to recall health information in text-based messages.<sup>17</sup> Thirty million adults in the U.S. lack basic literacy skills.<sup>18</sup> The current U.S. warning labels require a college reading level—a level which is too sophisticated for youth and adults with poor reading abilities.<sup>19</sup> Furthermore, according to the U.S. Census, in 2000, nearly 47 million people -- about 1-in-5 U.S. residents age 5 and older, reported regularly speaking a language other than English at home, indicating that their English language skills may be limited.<sup>20</sup> Moreover, the wording of current warning labels lacks specificity. Specific, unambiguous warnings, (e.g., “cigarettes cause lung cancer”) are also more likely to be noticed and less likely to be discounted than vague, equivocal warnings (e.g., “cigarettes are hazardous to your health”).<sup>21</sup>

#### **D. Lack of graphic images**

Since the United States last revised cigarette warning labels more than 25 years ago, many countries have adopted warning labels that include graphic images about the dangers of smoking. There is now an international consensus, reflected in the practice of more than 30 countries, including most industrialized countries, that warning labels with graphic images should be required. Moreover, the evidence from studies in countries that have required graphic images suggests that such images communicate the dangers of smoking more effectively, are more likely to be remembered, and are more likely to induce cessation compared to text-only warnings. After surveying policies regarding warning labels worldwide, the World Health Organization endorsed use of pictorial images on tobacco packs. WHO concluded that “health warnings on tobacco packages increase smoker’s awareness of their risk. Use of pictures with graphic depictions of disease and other negative images has greater impact than words alone[.]”<sup>22</sup> The WHO study also found that pictorial warnings are an important information source for younger smokers and that pictures are effective in conveying messages to children. During the past ten years, adoption of pictorial warning labels has become an internationally recognized “best practice.”

#### **II. The validity of the statutory requirements mandating the warning labels promulgated in this regulation has already been upheld on judicial review.**

As noted above, the validity of the statutory requirements for warning labels on cigarette packs and advertising (as well as that for other tobacco products) has already been upheld on judicial review.<sup>23</sup> In reaching its conclusion, the District Court for the Western District of Kentucky rejected an argument that the new warnings were too large and too prominent. The court noted that the Congress had relied on the international consensus reflected in the World Health Organization’s Framework Convention on Tobacco Control. The court also noted that the text of the warnings was factual, objective, and not controversial.<sup>24</sup>

The major part of the subject matter covered by these regulations is specifically mandated by the statute. This includes the size of the warning labels themselves, their placement on the pack or advertisement, the print size, and the text of the message. With respect to these matters, the Congress has already made its own findings based on the substantial record before it. The Notice cites voluminous additional authority in support of these conclusions. Moreover, the authority cited is not only extensive but also authoritative. The conclusions reached by both the Congress and the agency are supported by reports over a period of decades by the Surgeon General, three extensive studies by the Institute of Medicine, authoritative reports by the World Health Organization, scores of studies by respected researchers worldwide, and a developing worldwide consensus demonstrated by policies adopted by numerous countries.

Moreover, even with regard to those matters where the statute granted discretion to the agency, such as the choice of specific pictorial images and the inclusion of a reference to

cessation resources, the Congress based its grant of discretion on an extensive factual record and made clear its approval of such measures. There can be no doubt that the proposed regulation is well within the boundaries of the discretion the statute has granted to the agency.

**III. The proposed warning labels are consistent with international standards.**

A large body of research and real-world experience has established several elements that enhance a warning label’s effectiveness.<sup>25</sup> According to the World Health Organization guidelines for the Framework Convention on Tobacco Control, the components of an effective warning label are as follows:<sup>26</sup>

<u>COMPONENT</u>	<u>DESCRIPTION</u>	<u>IMPACT</u>
<i>Location</i>	Labels should appear on the top of the principal display areas (front and back—the largest panels of the package).	If the message is in a prominent location, it is more likely to be noticed.
<i>Size</i>	Should cover at least 50% of the package’s principal display areas.	Large messages are more likely to be noticed. Label effectiveness increases with size. Large labels provoke emotional responses and increase motivation to quit.
<i>Pictorials</i>	Pictures and/or pictograms should illustrate the ill-effects of tobacco use.	Photos and strong graphics help smokers visualize the nature of a tobacco-caused disease better than words alone. Pictures are more likely to draw attention and are more likely to be remembered when an individual makes decisions about whether or not to smoke or cut back on smoking. Pictures are especially important in regions with low literacy or where research shows smokers are ignoring text-only warning labels. Pictorial warnings are likely to reach children and adolescents, especially the children of smokers, who are particularly vulnerable.

<i>Color, Background, and Font</i>	Use full color. Contrast colors with the background and the text.	Maximizes visibility and ease of comprehension.
<i>Rotation</i>	Multiple health warnings and messages can appear on all tobacco products concurrently or be rotated periodically.	Prevents overexposure.
<i>Text</i>	<p>List risk factors by highlighting harmful effects and impact of exposure to tobacco. Include the magnitude of specific risks.</p> <p>Provide cessation advice and local quit line information.</p> <p>Identify the addictive nature of tobacco.</p> <p>Elicit unfavorable emotional association with tobacco use.</p>	<p>Messages highlight the harmful effects of tobacco and provide important public health information to the public which may not be otherwise accessible.</p> <p>Messages eliciting unfavorable emotional associations about tobacco use are more believable and convincing.</p>
<i>Language</i>	Label should be in the country's principal language(s).	Messages in all principal languages ensures a broader reach.

Additional research on the characteristics of effective warning labels is summarized below.

- Warning labels should be large enough to be easily noticed and read. Smokers are more likely to recall larger warnings and equate the size of the warning with the size of the risk.<sup>27</sup> In addition, studies have also found that the largest warnings are most likely to be rated as effective by both adults and youth.<sup>28</sup>
- Warning labels should be positioned on the front of packs. Smokers report greater recall for warnings that appear on the front, compared to the side, of packages.<sup>29</sup>

- Warning labels should contain a clear, direct and comprehensible message about the dangers of tobacco use, including messages about specific health effects or diseases. Messages should be worded simply and speak directly to the reader.<sup>30</sup>
- Warning labels should include pictures. Focus group testing and market research has demonstrated that compared to text-only warnings, picture-based warnings are more likely to be rated as effective, are more likely to be noticed and read and are associated with greater awareness of health risks. To increase effectiveness, pictures should be in color and the largest size possible.<sup>31</sup> Pictures also increase the message's accessibility to people with low levels of literacy.<sup>32</sup> Research demonstrates that just as the use of pictures is a common and effective feature in advertisements and packaging of a wide variety of consumer products, so the use of pictures in cigarette health warnings effectively communicates the dangers of smoking.<sup>33</sup>
- Warning labels should include graphic images that elicit an emotional response. Strong, emotional responses are associated with increases in the warning's effectiveness. Studies suggest that factually-based health warnings that include graphic, fear-arousing depictions of smoking's effect on the body are the most effective because they are associated with increased motivation to quit smoking, increased consideration of health risks and increased attempts at cessation.<sup>34</sup> An extensive review by the UK Department of Health found that the warnings that included the hardest-hitting messages and graphics were rated the highest.<sup>35</sup> These findings are consistent with the health communications literature, which indicates that warnings with emotionally arousing content are more likely to be noticed and processed by smokers.<sup>36</sup>
- Warning labels must be rotated regularly to avoid overexposure.<sup>37</sup>

The warning labels mandated by the statute and proposed by FDA meet these standards. Requiring the warning label to be placed at the top of the front and back of cigarette packs places it in a more prominent position on the pack and makes it far more likely that the warning will be noticed. This placement is consistent with the international standard.

The size of the label is increased to fifty percent of the front and back panels of a cigarette pack and twenty percent of the area of a cigarette advertisement. As noted above, research shows that larger warning labels are more likely to be noticed and more likely to be remembered. Adult and youth smokers report that large comprehensive warning labels increase motivation to quit and increase the likelihood that they will remain abstinent following a quit attempt.<sup>38</sup> The size of the warning required by the proposed regulation is consistent with the international standard.

The regulation will require the warnings to be rotated regularly. FDA should monitor rotation of the labels to ensure compliance. Increasing the number of warnings from four to nine

and requiring regular rotation will help prevent the warnings from becoming stale in a short time. Although rotation of warning labels has long been required by statute and regulation, the failure to change the language and format of the warnings since 1984 has greatly reduced the effectiveness of the warnings. Increasing the number of warnings, requiring regular rotation, and preparing new warnings to be implemented before these warnings become stale will increase the effectiveness of the warnings.

The new texts of the warning labels are consistent with international standards. The new texts are shorter and more direct than the texts of the existing regulations. They are written in simpler language to make them easily comprehensible to those with limited education and to underage potential smokers.

The inclusion of pictorial images is consistent with international standards. More than 30 countries have required warning labels to include pictorial images depicting the dangers of smoking. As indicated below, research shows that inclusion of pictorial images makes the warning more effective, promotes memory, and discourages smoking.<sup>39</sup> A comparative evaluation of the specific images proposed in the Notice is included in part XIII of these comments.

#### **IV. Experience in other countries that have adopted pictorial warning labels shows that such labels are effective.**

Since the adoption of pictorial warning labels in Canada in 2000, many countries have required warning labels to include graphic depictions of the dangers of smoking. In December 2010, Canada announced that it plans to require companies to increase the size of tobacco health warnings to cover 75 percent of the surface of cigarette packs.<sup>40</sup> The warnings will remain highly graphic and include individuals' stories and will be changed regularly.

As of October 2010, 39 countries and jurisdictions in the Americas, Eastern Mediterranean, Europe, South-East Asia and Western Pacific regions had enacted legislation to require pictures or images on cigarette packs.<sup>41</sup> A European Union directive gives its 27 member countries the option of adding pictures to warnings as a way to educate smokers about the risks of continuing to smoke. These actions reflect the growing consensus that warning labels are effective at communicating health messages and discouraging tobacco use and that pictorial warnings enhance that effectiveness.

The International Tobacco Control Policy Evaluation Project ("ITC") is the first-ever international cohort study, with an emphasis on national-level tobacco control policy evaluation. The ITC Project consists of cohort surveys of adult smokers in nineteen countries. Research done by the principal scientists in the ITC Project constitutes the most searching and authoritative

analysis to date of the effects of warning labels. The ITC study of tobacco warning labels reaches the following conclusion:

A vast body of health communication research has clearly shown that the use of pictures and vivid imagery results in messages that are more easily noticed and remembered. An understanding of both the health risks and the severity of smoking are important factors in motivating smokers to quit. Consumer research, experimental studies, and population-based surveys consistently demonstrate the importance of using pictures in package health warnings. ITC Four Country Survey demonstrated that larger pictorial warnings, such as those implemented in Canada and other countries, are likely the most effective means of communicating the full range and severity of health risks to smokers.<sup>42</sup>

Numerous studies done by ITC researchers and others demonstrate that labels with pictorial warnings are more effective in discouraging smoking than text-only labels.<sup>43</sup> Evidence from several countries suggests that large warnings with photographs are particularly effective in discouraging smoking and increasing public awareness of the health effects of smoking.<sup>44</sup> Moreover, research summarized in the Tobacco Labeling and Packaging Toolkit and the National Cancer Institute's Workshop on Cigarette Warning labels meeting summary conclude that larger, picture-based warnings are more effective in increasing knowledge of the risks of tobacco use, discouraging smoking initiation, and encouraging cessation.<sup>45</sup> These conclusions reflect a growing consensus worldwide for picture-based warning labels and support for FDA's proposal. Additional research regarding the effectiveness of graphic warning labels is summarized below.

- A 2004 study of Canadian smokers found that approximately one-fifth of participants in the study were smoking less as a result of the introduction of graphic warning labels, while only 1% were smoking more.<sup>46</sup> Canadian surveys found that the majority of Canadian smokers cited tobacco package warning labels as an important source of health information and that the labels increased their awareness of the risks of smoking.<sup>47</sup> This finding is important because smokers who perceive greater health risk from smoking are more likely to intend to quit and quit smoking successfully.<sup>48</sup> A more recent Canadian survey found that "more than 90% of Canadian youth agreed that picture warnings have provided them with important information about the health effects of smoking cigarettes, are accurate, and make smoking seem less attractive."<sup>49</sup>
- The introduction of new pictorial warning labels in 2006 in Australia made 57% of smokers report thinking about quitting, helped 36% of smokers smoke less, helped 34% of smokers try to quit, and helped 55% of recent quitters remain abstinent.<sup>50</sup>
- After Brazil introduced new pictorial warnings in 2002, 73% of smokers said they approved of them, 54% said they had changed their opinion about the health consequences of smoking, and 67% said the new warnings made them want to quit. The impact was particularly strong among less educated, lower income people.<sup>51</sup> Brazil introduced a second set of warning labels in 2004. In a study evaluating both sets of warning labels,

researchers found the most graphic and threatening fact-based warning labels increased intentions to avoid smoking.<sup>52</sup>

- After Singapore introduced pictorial warning labels in 2004, a Health Promotion Board survey found that 28% of the smokers surveyed reported smoking fewer cigarettes because of the warnings; 14% of the smokers surveyed said that they made it a point to avoid smoking in front of children; 12% said that they avoided smoking in front of pregnant women; and 8% said that they smoked less at home.<sup>53</sup>
- Since Thailand introduced its second set of pictorial labels in 2006, 53% of smokers said the pictorial warning labels made them think "a lot" about the health risks, and 44% of smokers said the warnings made them "a lot" more likely to quit over the next month.<sup>54</sup>
- An investigation of the impact of the text-only Chinese labels compared to other text and pictorial labels from around the world found that larger pictorial labels were perceived to be more effective at informing about the dangers of smoking, convincing youth not to start and motivating smokers to quit.<sup>55</sup> Furthermore, a survey of Chinese smokers found that while half of smokers report that they notice the text-only labels "often" or "very often", only eight percent indicated that the warning labels made them think about health risks "a lot".<sup>56</sup>
- A randomized trial of adult male smokers in Malaysia found that exposure to pictorial warnings increased knowledge about the health impacts of smoking and also increased interest in quitting.<sup>57</sup>

## **V. There is a continuing need for warning labels to provide accurate information about the danger of cigarette smoking.**

Tobacco manufacturers have argued that larger and more prominent warning labels are unnecessary because the dangers of smoking are already well known.<sup>58</sup> Despite the impression that "everyone knows smoking is bad for you," there are still important areas of consumer ignorance or misunderstandings that tobacco product warning labels and informational signs at retail outlets could directly address. Despite the numerous public reports on the risks of smoking, studies show that a large number of smokers have inadequate knowledge of the health effects of smoking.<sup>59</sup> Research indicates that most people only know one or two of the many diseases caused by smoking. One survey found that while a majority of people knew that smoking caused life-threatening illnesses, no smoking-caused illness besides lung cancer could be named by more than half of the respondents.<sup>60</sup> Furthermore, while some smokers generally know that tobacco use is harmful, they underestimate the severity and magnitude of the health risks.<sup>61</sup> A 2007 study found that two in three smokers underestimate the chance of developing lung cancer compared to a non-smoker, and four in ten incorrectly believe that developing lung cancer depends more on genes than anything else. In addition, the survey found that up to a third of smokers think that certain activities such as exercise and taking vitamins could "undo" most of the effects of

smoking.<sup>62</sup> An earlier study found that 65 percent of smokers either incorrectly thought that low tar and filter cigarettes are less dangerous than full-flavored cigarettes or did not know whether these features made cigarettes less dangerous. In the same study, when asked about health risks of smoking, 39 percent of respondents either answered incorrectly or said they did not know.<sup>63</sup>

Knowledge of the health risks of smoking is even lower among people with low incomes and fewer years of education because of limited access to information and lower literacy rates.<sup>64</sup> A 2005 study of smokers in the United States, the United Kingdom, Canada and Australia found that there were significant gaps in smokers' knowledge about the risks of smoking and that smokers living in countries where warning labels referred to specific disease consequences of smoking were much more likely to be aware of the consequences referred to in the warnings.<sup>65</sup> The study concluded that smokers are not fully informed about the risks of smoking and that warnings that are graphic, larger, and more comprehensive in content are more effective in communicating the health risks of smoking.

In addition, many smokers continue to believe that cigarettes labeled or marketed as light, low or mild are safer or less risky, when they are actually at least as dangerous as other cigarettes; and studies have found that correcting this mistaken belief will prompt more smokers to try to quit.<sup>66</sup> While the law now prohibits the use of misleading terms such as "light," "low" or "mild," "effective June 22, 2010, new research shows that other kinds of words, colors, such as silver, or images can also mislead many smokers into thinking a particular brand is safer or less risky, as can brands sold with lighter colors or with pictures of filters.<sup>67</sup>

There are many other examples of consumer ignorance or misunderstandings about tobacco products that help to keep tobacco use rates higher than they would otherwise be. For example, the vast majority of Americans are not aware of the many dangerous chemicals in cigarettes and cigarette smoke.<sup>68</sup> Most youth do not understand how powerfully addictive cigarettes are, with one survey finding that fewer than five percent of daily smokers in high school thinking that they will still be smoking at all in five years but more than 60 percent of high school smokers are still regular daily smokers seven to nine years later.<sup>69</sup> Another survey found that only 7.4 percent of adult smokers and 4.8% of young smokers expected to smoke longer than five years when they started, but 87 percent of these adults and 76 percent of these youth reported that they had been smoking for more than five years.<sup>70</sup> Many smokers also inaccurately believe that smoking reduces stress and worry that quitting smoking will increase stress levels.<sup>71</sup> Many smokers are confused about the relative risks of different types of tobacco and nicotine products.<sup>72</sup>

Similarly, many smokers grossly underestimate their own risks of harm and death from smoking, with one study even finding that substantial numbers inaccurately believe that they can offset most of the risks and harms from smoking by exercising, taking vitamins, or simply having good genes.<sup>73</sup> Youth are especially prone to underestimating or misunderstanding the health risks

to themselves and others from tobacco use, with a recent survey finding that more than thirty percent of kids aged 12 to 17 (more than in past years) think that it is not a great health risk to smoke one or more full packs of cigarettes each and every day.<sup>74</sup>

Furthermore, Americans lack knowledge about and grossly underestimate the health effects of secondhand smoke. Although secondhand smoke triggers childhood asthma,<sup>75</sup> and passive smoke exposure has been associated with both heart disease and cancer,<sup>76,77</sup> Americans continue to underestimate the hazards of secondhand smoke exposure. A 2009 study of smokers in the United States, the United Kingdom, Canada, and Australia found that nearly one-fifth of individuals surveyed in the United States do not believe that secondhand smoke is dangerous to non-smokers.<sup>78</sup> Additionally, most parents believe that smoke exposure has little or no negative impact on children's asthma.<sup>79</sup> Increased public awareness about the consequences of exposure to secondhand smoke is important, as studies have demonstrated that a negative perception of secondhand smoke can reduce smoking initiation. One such study found that when negative perceptions of personal or parental secondhand smoke exist, adolescents are deterred from initiating smoking.<sup>80</sup> Warning labels demonstrating the dangers of secondhand smoke would further enhance consumer awareness of the adverse effects of smoking.

The new warning labels are designed to communicate specific factually based information about the health risks of smoking in simple, straightforward, and understandable language. Even if consumers already know that cigarette smoking is dangerous, the kinds of information provided by these labels will enhance consumer awareness of factual information about the specific dangers of cigarette smoking.

## **VI. Warning labels serve an independent purpose of discouraging smoking.**

In addition to the valid and important function of providing information to smokers and potential smokers about the dangers of smoking, warning labels are designed to be a part of a public health strategy to prevent non-smokers from initiating and to encourage existing users to quit. The Institute of Medicine drew this distinction in its 1994 report when it called for warning labels that would be a part of a public health campaign explicitly designed to reduce smoking.

Even though tobacco products are legally available to adults, the paramount public health aim is to reduce the number of people who use and become addicted to these products, through a focus on children and youths. The warnings must be designed to promote this objective.<sup>81</sup>

The warning labels mandated by the statute are designed to serve this function. Thus, pictorial warnings are designed not only to be factually accurate in their depiction of the consequences of smoking but also to create the kinds of strong emotional responses necessary to prevent young people from initiating smoking and to persuade established smokers to break an

addiction. Such strategies must be designed to be effective in the face of advertising campaigns and a host of promotional strategies mounted by the tobacco industry.

Use of cigarette warning labels to discourage smoking initiation and to encourage cessation is entirely consistent with the findings and purposes of the Tobacco Control Act.

**VII. Inclusion on warning labels of a reference to a telephone source of science-based assistance for quitting enhances the effectiveness of warning labels and addition of an online source as well may further enhance their effectiveness.**

**A. Inclusion of a quitline number enhances the positive effect of the warning label.**

We support the proposal in the regulation to include on warning labels a telephone number that would provide smokers with science-based assistance for quitting. This requirement would enhance the effectiveness of warning labels in promoting smoking cessation. Research has shown that a large majority of existing smokers would like to quit. The evidence demonstrates that smokers who use the services of science-based telephone quitlines have a significantly higher rate of success in quitting than those who make unassisted quit attempts.<sup>82</sup> The scientific literature demonstrates that inclusion in warning labels of a reference to a quitline number substantially increases the number of smokers who contact the quitline and the number of smokers who make a quit attempt.<sup>83</sup>

Effective communication about the risk of tobacco use requires not only accurate information about health effects and their severity but also messages about the benefits of quitting and information about how to quit.<sup>84</sup> According to international experts, cessation should be one critical theme of health warnings and warnings should include information on cessation services, such as telephone quitline numbers and web-based cessation interventions.<sup>85</sup> Increased awareness of quitlines and other cessation services will encourage tobacco users to think about quitting and link those who want to quit with effective services.

Telephone quitlines are a proven intervention that greatly increase the chances that a smoker will quit.<sup>86</sup> An exhaustive review of the research literature in the U.S. Public Health Service's updated *Treating Tobacco Use and Dependence: 2008 Update—Clinical Practice Guideline* (PHS Guideline) found strong evidence to support the use of quitline counseling to help people quit. Smokers who use quitlines are at least two to three times more likely to succeed in quitting than those who try to quit on their own. With expanded counseling sessions and medications, they can be up to five times as likely to quit.<sup>87</sup>

Graphic warnings in Canada, Australia, Brazil as well as other countries include information on health risks in addition to general messages of support for quitting and concrete

information on ways to quit such as quitline numbers and website addresses. Experience from these countries indicates that graphic warnings that include specific ways to get help in quitting are an effective way to encourage tobacco users to quit.

- After Australia introduced pictorial labels with quitline information in 2006, the number of calls to the quitline doubled from each of the previous two years.<sup>88</sup> The rise in calls to the Australian quitline service was substantial and sustained and researchers concluded that this was the result of the introduction of the new graphic cigarette pack warnings that included the quitline number.
- More recent data from Australia show that there is high awareness of the quitline phone number on tobacco packs, particularly among smokers who are contemplating quitting. One in three smokers thought they would call the quitline in the future. In addition, current smokers were significantly more likely to be aware of the Quitnow website address on tobacco packs than non-smokers and those who were contemplating quitting were much more likely to access the website.<sup>89</sup>
- After New Zealand introduced pictorial labels with quitline information in 2008, the average number of new monthly calls increased and more first-time callers reported obtaining the quitline number from tobacco product packaging.<sup>90</sup> Another New Zealand study found that identifying the quitline number on the tobacco package as a “Quitline” or as part of a specific smoking cessation message such as “You CAN quit smoking” was associated with a 24 percentage point increase in quitline number recognition (from 36.8% to 60.9%).<sup>91</sup>
- Tobacco pack warnings that included a quitline number were reported as the second largest driver of calls to the UK National Health Service Stop Smoking Helpline, according to the United Kingdom Department of Health. Survey respondents also indicated that tobacco warnings are more likely to be effective if they are coupled with information on where to get help to quit and suggested that the warning labels in the UK include reference to the NHS Stop Smoking Helpline or Website on all packs.<sup>92</sup>
- A study of 7 EU countries found significant increases in quitline call volume in the two years after the quitline number appeared on cigarette packs independent of factors such as tobacco price increases and media campaigns. The introduction of the numbers on packs in some countries led to increases in call volumes of over 100%. In addition, researchers found that mentioning the quitline number in media campaigns also had a significant impact on quitline call volume.<sup>93</sup>
- In 2002, the Netherlands experienced a 3.5 fold increase in calls to its national quitline after a smoking cessation message and quitline phone number were included on cigarette packs.<sup>94</sup>

- Calls to the quit smoking hotline in Brazil increased following placement of the hotline phone number on tobacco product packs.<sup>95</sup>

This experience indicates that warning labels are not only an important source of consumer health information but can also be a worthwhile cessation intervention, particularly if information about how to access cessation services is provided. In addition, quitlines are a relatively low-cost intervention strategy.

**B. Labels listing 1-800-QUIT-NOW would provide access to a comprehensive network of quitlines.**

Since 2004, the federal government has provided support to publicly-sponsored quitlines in each State. Each such State quitline can be reached by dialing a single number, 1-800-QUIT-NOW. The National Cancer Institute oversees the 1-800-QUIT-NOW telephone portal and determines where calls are transferred to through the 1-800-QUIT-NOW portal number. The Centers for Disease Control and Prevention (CDC) provides funding that supplements state support for all state quitlines. As part of the funding requirements, CDC has set out performance measures and reporting criteria for the states. Through performance measures and reporting criteria, CDC is positioned to assure the quality of quitline services. By mandating that the 1-800-QUIT NOW number be imprinted on each pack of cigarettes, FDA would thereby provide smokers with a reference to the most comprehensive network of quitlines available. In addition, designation of a single national quitline number would avoid the difficulty that would arise if manufacturers were required to imprint different dialing information on packs depending on where they would ultimately be sold. In most cases, the ultimate destination of cigarettes is not determined at the time the manufacturer ships the cigarettes, but is only determined when a distributor affixes state excise stamps to a pack. Use of a uniform national number would avoid the practical difficulties that could arise if the required number differed according to the ultimate destination of the cigarettes.

**C. The proposed regulations would unreasonably restrict the operations of the quitline.**

The proposed regulations seek to impose a set of detailed criteria on quitlines reachable by the listed number. (75 F.R. at 69540) While most of these criteria are unobjectionable and mirror the criteria established by CDC, the inclusion of such new criteria could inhibit the effective operation of quitlines that have long been operating successfully because such criteria would create a set of requirements outside those administered by CDC. Rather than create a second set of criteria for such quitlines, FDA regulations should simply mandate the listing of the 1-800-QUIT-NOW number and rely on CDC to continue its role of monitoring and supporting the state quitlines. It was not the intention of the statute for FDA to supplant the role of the CDC simply because the quitline number was being printed on the cigarette pack.

A valid concern exists that one or more quitlines could be subjected to challenge because of allegations that they had not complied with one or more of the criteria listed in the regulation. Rather than subjecting quitlines to two potentially different sets of requirements, the regulation should simply specify that quitlines authorized by CDC for connection to the 1-800-QUIT-NOW number are qualified.

However, should FDA choose to include a set of detailed criteria for smoking cessation assistance resources in its final rule, these criteria should include the provision of secondhand smoke prevention and cessation advice. Two of the nine warning labels specifically address the dangers of secondhand smoke, and quitlines should be prepared to counsel smokers who seek assistance after seeing these messages. Preventing harm to children from secondhand smoke can be a powerful incentive for an adult to quit smoking or to change smoking behaviors to reduce smoke exposure to children. If FDA retains detailed criteria for quitlines in the final rule, section 1141.16(b) should be amended to recommend that quitlines “provide evidence-based advice regarding the protection of children and other nonsmokers from secondhand smoke.”

**D. The Notice references vague and unreasonable conditions not required by or consistent with the statutory mandate on the referenced quitlines and websites that would greatly reduce the value and effectiveness of the services they offer.**

One of the criteria for quitlines discussed in the Notice could seriously impede the ability of quitlines to perform their intended function. The provision stating that advice given by a quitline “cannot include derogatory statements regarding cigarette manufacturers, importers, distributors or retailers or advocate public policy changes” (75 F.R. 69540) is vague and is likely to lead to efforts by the tobacco industry to challenge entirely legitimate cessation programs. Such a provision is neither required by nor consistent with the statute. Inclusion of such a condition could cripple the effectiveness of the very services the warning is designed to promote.

The prohibition of “derogatory statements” regarding cigarette manufacturers is extremely vague. Is it a derogatory statement about cigarette manufacturers to suggest that they manufacture products that cause death and disease? Is it a derogatory statement to suggest that manufacturers have increased the nicotine content of cigarettes during the past decade? Is it a derogatory statement to suggest that cigarette packaging and advertising is designed to counter governmental efforts to reduce cigarette usage? Is it a derogatory statement to point out how the tobacco companies have deceived the public with regard to “light” and “low tar” products or produced advertisements that appeal to youth? With a product that causes addiction, disease and death, and an industry found by the courts to have engaged in decades of deceptive and wrongful behavior, there is a legitimate concern that factually true statements that have been shown to be highly effective in encouraging people to quit smoking could be attacked by the tobacco industry as “derogatory.”

The problem with so vague a restriction on speech is that it inevitably chills permissible speech. In this case, such a chilling effect could curtail the effectiveness of quitline services that are highly professional, evidence-based and effective and deny smokers trying to quit appropriate treatment.

Moreover, this kind of vague prohibition on speech is especially dangerous given the tobacco industry's history of using litigation to intimidate, impede and delay legitimate efforts to reduce tobacco use. A vague provision such as the one at issue here would encourage unnecessary litigation and facilitate the efforts of the tobacco industry to disrupt evidence-based, legitimate tobacco control programs. The history of the tobacco industry's challenges to such effective tobacco control efforts as the Legacy Foundation's Truth® campaign demonstrates that this uncalled for condition should be deleted.

The Master Settlement Agreement of 1998 established a foundation, the American Legacy Foundation ("Legacy"), to engage in counter-advertising and public education designed to reduce smoking. Section VI of the MSA prohibited funds under the Public Education Fund to be used for "vilification" or "personal attack." Lorillard Tobacco Company alleged in litigation that one of Legacy's advertisements constituted "vilification" and/or "personal attack."<sup>96</sup> Although Lorillard's claim was ultimately unsuccessful, Legacy was forced to spend millions of dollars that could have been used for counter-advertising mounting a legal defense. Vague prohibitions such as this invite such unproductive attacks by the tobacco industry. At a time when resources available to support state tobacco control activities have shrunk to their lowest level in more than a decade, the vulnerability of state-sponsored counseling resources to harassing litigation is acute.<sup>97</sup>

Similar attacks by the tobacco industry have been launched against other public education efforts. For example, R.J. Reynolds Tobacco Corp. and Lorillard Tobacco Company unsuccessfully attacked California's Proposition 99, which used the proceeds from a fee on cigarettes to fund a tobacco prevention program.<sup>98</sup> The fact that quitlines and cessation-focused websites are effective only makes them more likely targets for such attacks.

Furthermore, there is nothing in the statute providing FDA jurisdiction over tobacco that mandates the proposed limitation and there is no legitimate reason for its inclusion. It should be deleted.

#### **VIII. A public education campaign should accompany introduction of the new warning labels.**

As with many tobacco control strategies, the impact of the introduction of new warning labels will be enhanced if this initiative is combined with other tobacco control measures. As noted by the CDC, the most effective tobacco control programs are those that combine

educational, clinical, regulatory, economic and social strategies.<sup>99</sup> Extensive discussion at the National Cancer Institute's 2009 Workshop on Cigarette Warning Labels supported the implementation of new warning labels as part of a larger communication effort that includes mass media and other educational efforts to inform smokers about the health risks of smoking.<sup>100</sup>

In this case, a public education campaign should be planned to coincide with the introduction of new health warnings. A coordinated media campaign will reinforce the information found in the warnings as well as information about the benefits of quitting and provided information about where to get quitting assistance. Australia has used the messages and themes from the health warnings in public education campaigns on television and on buses. Linking the warnings with a broader education campaign helped to constantly remind smokers of the health effects of smoking and helped make the information in the health warnings more vivid.<sup>101</sup> Similarly, New Zealand used a mass media campaign to support the introduction of graphic warning labels and to encourage calls to the national smoking cessation service. New Zealand's campaign featured individuals who had personally suffered harm from smoking. The campaign engendered powerful emotional responses and generated a great deal of unearned media coverage. As a result, calls to the New Zealand quitline increased. Researchers concluded that coordinated implementation of graphic warning labels with a strong media campaign produced a successful outcome.<sup>102</sup>

#### **IX. The new warning labels do not prevent cigarette manufacturers from using the pack to communicate their message.**

Neither the proposed regulation nor the statute limits cigarette manufacturers from using the cigarette pack or other advertising materials to communicate their message to consumers. In enacting the statute the Congress found that the existing warning labels were ineffective and that strengthening of the warnings was necessary to more effectively communicate the dangers of cigarette smoking.<sup>103</sup> Moreover, as shown above, the FDA relied on an overwhelming body of research that reached the same conclusion. The proposed regulation does no more than implement the express requirements of the statute that the size of warning labels be expanded to make them more noticeable and more effective.

Contentions by cigarette manufacturers that expansion of the warning labels prevents them from communicating their message are unfounded. Although the proposed regulation would increase the size of the warning label, the proposed regulation would leave the remainder of the surface area of the pack—half the front and back and the entire top, bottom, and sides of the pack—open for the manufacturer to communicate its message. And 80 percent of the surface area of advertisement remains available for communication of the manufacturer's message. Moreover, the proposed regulation does not prescribe the design of the pack—its color, its markings or the

content of any message outside the warning label. Nor does the regulation limit the design of advertisements. In establishing clear and detailed standards for the size of the warning labels, the Congress struck a balance between effective communication of the warning and effective communication of the manufacturer's message. The regulation does no more than follow the requirements of the statute—a statute that has been upheld on judicial review.<sup>104</sup>

**X. The FDA should ensure that warning labels are replaced often enough to remain fresh and effective.**

Science demonstrates that the effect of specific warnings is likely to deteriorate over time.<sup>105</sup> The statute provides for substitution of new warning labels. In order to ensure that warning labels remain as effective as possible, FDA should establish a target schedule for reconsideration and revision of the warnings in the light of evidence developed from evaluation of the warnings promulgated pursuant to this regulation. Such a schedule should call for ongoing consumer research and re-examination of the adequacy of existing warning labels at no more than a one-year interval. There should be a presumption that new labels will be required at no more than a two-year interval.

Introduction of new labels may also be required to convey newly available information about the dangers of smoking or as a result of additional research indicating that certain warnings are particularly effective. Moreover, in considering introduction of new warning labels, FDA should consider warning labels that refer to other diseases caused by smoking that are not specifically mentioned in the set of warning labels currently proposed.

**XI. Provisions should be adopted to clarify the manufacturers' grace period for the sale of existing inventory manufactured or imported before the effective date of the regulation.**

Although the proposed regulation would not take effect until fifteen months after a final rule is adopted, the regulation gives manufacturers an additional grace period to permit them to sell cigarettes that do not comply with the new warning label requirements provided such cigarettes were manufactured before the effective date of the regulation. The Notice requests comments regarding mechanisms for enforcing this rule and its effective date, such as ways to differentiate cigarette packages sold from existing inventory from those that were manufactured after the effective date.

The Act makes it clear that no cigarettes manufactured after the effective date may be introduced into commerce unless they comply with the new labeling requirements. FDA has no discretion to extend this date. Given that the statute provides a fifteen-month interval between issuance of the final regulation and the effective date, there can be no argument that manufacturers had insufficient time to make appropriate plans to comply with their obligations.

FDA should make it clear that under no circumstances will cigarettes manufactured after the effective date be permitted to be introduced into commerce unless they comply with the new regulation. Moreover, the Act makes it clear that manufacturers have only a 30-day grace period after the effective date of the regulation in which they can introduce cigarettes that do not comply with the new regulation but were manufactured before the effective date. FDA has no discretion to extend this 30-day period. FDA should make it clear that under no circumstances will this period be extended.

Experience has demonstrated that market distortions in the cigarette market often occur immediately prior to the effective date of regulatory changes. For example, there is often a disproportionate increase in cigarette sales immediately prior to an increase in federal or state excise taxes. It is likely that manufacturers will seek to sell a disproportionate number of non-complying cigarettes immediately prior to the expiration of the grace period. Accordingly, it is appropriate to ensure that all such sales are fully documented. We recommend that the right of a manufacturer to sell non-complying cigarettes during the 30-day period following the effective date be conditioned on the following;

In order to be introduced into commerce after the effective date of the regulation, any cigarette pack must be marked with the legend “Manufactured before September 22, 2012” or with a readily identifiable symbol common to all manufacturers. The legend or marking must be placed on the pack underneath any cellophane covering and must not be removable. Each manufacturer should be required to certify, under penalty of perjury, that all cigarettes so marked were in fact manufactured before that date. Each manufacturer should be required to submit an accounting to FDA stating (1) the number of packs manufactured before September 22, 2012 on hand as of the effective date of the regulation; (2) the number of packs introduced into commerce during the 30-day period following the effective date; and (3) the number of packs on hand as of the expiration of the 30-day period and the disposition of such cigarettes. The disposition of packs introduced into commerce during the 30-day period should be required to be supported by records to be made available for audit upon request. Each manufacturer should be required to account for the disposition of all packs remaining on hand as of the expiration of the 30-day period and such disposition should be required to be supported by records to be made available for audit upon request.

In addition, regardless of the size of their inventory on the effective date of the regulation, no manufacturer should be permitted to introduce into commerce in any calendar month a number of non-complying packs that exceeds ten percent of the average total number of packs introduced per month during the preceding year. Such a provision would discourage manufacturers from stockpiling non-compliant packs immediately before the effective date.

All requirements applicable to manufacturers should be made applicable to importers. Importers should be prohibited from introducing non-complying cigarettes imported after the effective date and should be required to meet all the same requirements as manufacturers with respect to cigarettes on hand as of the effective date.

The regulations should also be amended to make it clear that manufacturers are not prohibited from introducing into commerce packs that comply with the regulation before the effective date of the regulation.

## **XII. Clarifying changes should be made in the language of the regulation to ensure that the regulation accomplishes its intended purposes.**

We believe that several clarifying changes should be made in the language of the regulation to ensure that it accomplishes its intended purposes. For the agency's convenience, we are including a red-lined version of the language of the proposed regulation that shows these changes. This section describes the suggested changes.

Under the FDCA as amended by the Act, cigarettes can be deemed to be "misbranded" unless they meet a number of criteria, only one of which relates to compliance with the warning label requirements. Failure to meet any one of such criteria is sufficient to constitute misbranding. The intention of the proposed regulation is to deem all cigarettes as "misbranded" under the FDCA if the warning labels required under this regulation are not affixed. The language of sections 1141.14(a) and (b) should make it clear that a pack that complies with the warning label requirement but violates another provision of the Act can still be held to be "misbranded".

In order to avoid displaying the graphic images on cigarette packs in retail displays, in the absence of an express provision in the regulation both manufacturers (who supply most retail display devices) and retailers may seek to install retail display appliances that obscure the graphic images required by the regulation and display those portions of the pack that do not contain such graphic images or the text of the warning. The regulation should be amended to prohibit the use of appliances that obscure the graphic images or warning text but leave visible those portions of the pack that do not contain such images or text. In addition, manufacturers and retailers should be prohibited from taking any action to obscure the warning label either on packs or on advertisements. The definition of "retailer" in the proposed rule appears to be broad enough to include internet sellers, but to avoid any argument to the contrary the definition should be clarified to make such inclusion explicit. Moreover, the rule should explicitly require images of cigarette packs for sale on the internet, by catalogs, or by email to include the warning labels. In addition, the requirement that all images, depictions, advertisements, or photographs of cigarette packs must include the warning labels should explicitly include depiction of packs in any materials prepared by or for cigarette manufacturers, retailers, or distributors.

The regulation should be amended to prohibit distributors from obscuring any portion of the warning label with revenue stamps.

The definition of “importer” should be expanded to include persons who introduce into commerce cigarettes manufactured in the United States, exported therefrom, and subsequently imported. Although legislation in 2000 substantially curtailed this practice, it is still possible for cigarettes manufactured in the United States and exported therefrom to be imported for sale in the United States; in such a case, the importer should be obligated to comply with the warning label requirements.

The requirements for telephone quitlines or websites devoted to provision of cessation advice contained in section 1141.16 should be clarified as recommended in the attached red-line version of the regulations.

## **XII. The economic impact analysis greatly understates the likely benefits from the proposed regulation and greatly overstates the likely costs .**

Although the economic impact analysis contained in the Notice (75 F.R. at 69541-62) concludes that the likely benefits of the proposed regulation greatly exceed the likely costs, the analysis omits or understates many significant likely economic benefits and overstates the likely economic costs. Consequently, the net economic benefits of the proposed regulation are likely to be far higher than those estimated in the Notice and any possibility that the costs of adopting the regulation would approach or exceed the benefits of such adoption is so remote as to be inconsequential. Although the critique in these comments is far from exhaustive, we believe it is sufficient to support this conclusion.

### **A. The methodology of the analysis**

The methodology of the analysis is, first, to attempt to estimate the societal costs of smoking; second, to estimate the likely reduction in smoking that would occur as a result of the regulation; third, to quantify the “benefit” flowing from the regulation as the incremental reduction in societal cost resulting from the likely reduction; and, fourth, to compare the likely benefit with societal costs that would be incurred to achieve this objective. In each of these steps, the analysis has adopted positions that result in a substantial understatement of the net benefits of the regulation.

### **B. The economic analysis fails to take account of many smoking-related costs.**

Although it is difficult, if not impossible, to describe and quantify, all of the many costs and other economic damage caused by smoking, FDA could use available research, data and analysis to provide a clearer and more comprehensive picture.

FDA’s analysis of the economic benefits of reduced smoker mortality are probably too low since, as FDA states, the methodology it used found smaller increases in life expectancy attributable to smoking avoidance than other studies. (75 F.R. at 69544) The economic analysis does not even attempt to quantify the potential impact on its results of ignoring the results of studies other than the one upon which it chose to rely.

Moreover, while admitting that cigarette smoking is major risk factor for diseases that are “less immediately fatal” than lung cancer or cardiovascular disease, the economic analysis attempts to quantify only the effect on reduction in the incidence of emphysema. (75 F.R. 69544-45) The analysis thus ignores any effect of chronic obstructive pulmonary disease or any of the host of other diseases that fit this description.<sup>106</sup> The analysis concedes that ignoring such effect makes the estimates a “lower bound” on the value of morbidity reductions, but in fact the methodology employed simply ignores effects that would likely increase the probable benefits of the rule by substantial amounts. Although it is beyond the scope of these comments to quantify such benefits, their omission from the economic analysis must be noted. In addition, the economic analysis makes several other methodological errors that understate the likely benefits of the proposed rule. For example, the analysis does not reveal that the cited estimates of smoking-caused healthcare costs and productivity losses are in 2004 dollars unadjusted for the inflation in medical care costs that has occurred since that date. Nor does the text mention that healthcare costs caused just by exposure to secondhand smoke has been found to total close to \$5 billion per year (2004 dollars).<sup>107</sup> In addition, much more could be said about the impact of smoking on increasing overall pregnancy and birth costs and the overall costs associated with other specific healthcare problems, such as heart attacks and strokes.<sup>108</sup>

The economic analysis fails to include numerous losses in productivity that result from smoking. While the text properly explains that the estimate of \$96.8 billion in productivity losses caused by smoking each year refers only to a fraction of all smoking-caused productivity losses, it provides no insights into what the total of all smoking-caused productivity losses might be. Yet existing research and data indicates that the additional productivity losses just from smokers and former smokers taking more sick days than non-smoking employees likely totals an *additional* more than \$100 billion in smoking-caused productivity losses each year.<sup>109</sup> Beyond these additional smoking-caused productivity losses from higher smoker work absences because of sick days, available research and data also shows that:

- Smoking employees are less healthy and less productive when on the job, and more prone to accidents and injuries;<sup>110</sup> and there is a direct link between smoking and increased occupational disability.<sup>111</sup>
- Workers Compensation payments for smoking employees over a four-year period averaged \$1,420, compared to only \$120 for non-smoking workers –

with smoking employees taking, on average, 5.1 related days away from work versus less than a half a day of lost work for the nonsmoking workers receiving workers comp.<sup>112</sup>

- Depending on the type of workplace and its break policies, time wasted per smoking worker from cigarette breaks has been found to range between 4 to 30 minutes per day (above and beyond normal break times), the equivalent of losing two to fifteen full days of work per year per smoking employee, just from cigarette breaks.<sup>113</sup> In a study of more than 2500 nurses at 34 different hospitals, nurses who smoked were much more likely to take normal work breaks than non-smoking nurses.<sup>114</sup>

Several U.S. military studies provide additional insight into the problem of lost productivity and related excess employer costs caused by smoking:

Among young healthy men and women in the Army followed for 2.4 years, those that smoked had more lost workdays and more hospitalizations than those who did not.<sup>115</sup>

Female Navy recruits who smoked had poorer job performance reviews than nonsmokers, more demotions and desertions, and more misconduct and dishonorable discharges, and were less likely to re-enlist.<sup>116</sup>

Among Air Force recruits tracked for one year, smokers had a higher rate of premature discharge, producing training cost losses to the Air Force of an estimated \$18 million per year, which translated to a lost of \$130 million per year for all the U.S. military services just for training recruits who wash out because of smoking.<sup>117</sup>

Nor does the economic analysis properly take into account how smoking increases the healthcare expenditures of both governments and the private sector. For example, existing studies and federal government reports find that smoking-caused Medicaid program costs total \$30.9 billion per year (2004 dollars), with smoking-caused Medicare program expenditures annually totaling \$27.4 billion (2004 dollars).<sup>118</sup> The federal government has estimated that smoking-caused healthcare expenditures by other federal programs, such as the Department of Veterans Affairs healthcare system, totaled close to \$10 billion per year (1999 dollars).<sup>119</sup> In addition, research has found that annual Social Security Survivors Insurance payments to the more than 300,000 kids who have lost at least one parent from a smoking-caused death total another \$2.6 billion per year (2004 dollars).<sup>120</sup> Available data and research also indicates that the private sector's excess healthcare costs caused by smoking total more than \$25 billion per year<sup>121</sup> and that the private sector incurs more than half of all smoking-caused productivity losses.<sup>122</sup> Other

research indicates that the healthcare costs to employers for smoking employees are more than \$1,000 more per year than for non-smoking employees.<sup>123</sup>

There are also additional non-health-care business costs and losses caused by smoking that the introductory section of the proposed rule fails to mention, such as excess employer cleaning and maintenance costs from smoking that total roughly \$3 billion per year;<sup>124</sup> and the property losses and damage, as well as loss of life and physical harms, caused by smoking-caused fires, which the proposed rule mentions in its cost-benefit analysis but not in its discussion of current costs caused by smoking.<sup>125</sup>

It is also worth noting that the many expenditures to address smoking-caused harms – as well as the more than \$80 billion consumers spend each year on cigarettes and other tobacco products and the tobacco industry's annual expenditures of more than \$12.5 billion to market their deadly products – takes resources away from much more productive purposes.<sup>126</sup> For example, research shows that expenditures on cigarettes and other tobacco products reduces overall employment and reducing smoking has a positive impact on overall employment.<sup>127</sup>

**C. The economic analysis fails to discuss or quantify significant economic benefits from the smoking declines resulting from the new warning labels.**

Just as the proposed rule does not adequately describe the wide range of costs and economic damage caused in the United States each year by smoking, it does not properly consider the full range of savings and economic benefits secured by smoking declines in its cost-benefit analysis of the implementation of the new warning labels.

One of the most critical omissions is the failure of the analysis to estimate declines in mortality, disease or suffering caused by exposure to secondhand smoke and the decrease in costs associated with such exposure that would result from implementation of the regulation. The text justifies this omission by stating that "recent public smoking restrictions and educational campaigns have reduced external smoking exposure to well below historical levels, though not to zero." But this explanation completely ignores two key facts. First, existing smoke-free laws that restrict smoking in public places are nowhere close to being in place nationwide, nor are all such smoke-free laws comprehensive. Second, much of the most harmful secondhand smoke exposure occurs in the home, and existing smoke-free laws do not prohibit smoking in homes. Similarly, while some jurisdictions do prohibit smoking in cars when small children are present, smoking in personal vehicles remains a major source of damaging secondhand smoke exposure, not just for children but for adults.

Moreover, the analysis does not take account the productivity gains from the estimated smoking declines. When smoking employees quit, sick days decline and on-the-job productivity increases.<sup>128</sup> More specifically, the 2006 *Journal of Occupational and Environmental Medicine*

study indicates that for each smoking employee shifting to nonsmoker status the productivity savings from fewer sick days and fewer days on the job while sick would, on average, total \$1,084.<sup>129</sup> The savings from increased productivity on the job because of fewer smoker work breaks would add to that total. In addition, smoking declines reduce the number of years that productive work lives are cut short by smoking-caused disability, disease or death, thereby producing additional productivity gains.

As mentioned above, studies have also found that smoking declines are also linked to modest increases in overall employment as expenditures on cigarettes are shifted to more constructive and more labor-intensive products and services.<sup>130</sup> Along the same lines, households of smokers who quit will enjoy a substantial increase in disposable income as they no longer spend large amounts on cigarettes or various other smoking-caused costs. A pack-a-day smokers who quits, for example, would save about \$1,950 per year just by not buying cigarettes anymore.<sup>131</sup> Similarly, the smoking declines will help to reduce government, private sector and household smoking-caused cleaning and maintenance costs. The proposed rule's cost-benefit analysis should at least mention the full range of these types of smoking decline benefits.

**D. The analysis improperly reduces the net benefit of the regulation by “lost consumer surplus associated with the activity of smoking.”**

The analysis reduces the estimated benefits resulting from declines in smoking to account for something called "lost consumer surplus associated with the activity of smoking." (75 F.R. 69546) Such an adjustment is wholly improper and inappropriate. The adjustment, for which no citation whatsoever is provided, inaccurately assumes that smokers enjoy smoking, want to smoke, and benefit from it; and that they are somehow being deprived of a benefit or good when they freely decide to try to quit because of the new warning labels and are able to do so successfully. It also rests on the even more erroneous assumption that youth who are prevented from smoking by the warning labels are somehow being deprived of a benefit or good as well. Among the many reasons with this kind of analysis is wrong, cigarette smoking is highly addictive; the vast majority of smokers begin to smoke when they are minors, often at young ages where their actions and choices cannot be considered mature or fully rational or responsible; smoking kills when cigarettes are used as intended; the vast majority of smokers want to quit; smoking is inescapably linked to direct harms to the user; and those who quit because of the new warning labels will do so out of choice not out of compulsion. More generally, it makes no sense to evaluate the cost-effectiveness of a law or any of its related rules that are all directed explicitly and intentionally at minimizing tobacco use and its harms by assuming that a large consumer surplus or benefit results from the very activity that is being discouraged. There is no “lost consumer surplus” when the law and rules do exactly what they were designed to do. It would be far more appropriate for the analysis to have increased the estimated benefits to take account of the enhanced “consumer surplus” associated with accomplishing a liberation from addiction, an

increase in physical well-being, and a new-found ability to devote time, resources, and energy to more productive pursuits.

**E. The analysis overstates the costs associated with implementing the new warning labels.**

The analysis overstates the costs cigarette manufacturers will incur in order to implement the new warning labels. For example, the analysis properly assumes that cigarette manufacturers and retailers will have to replace existing cigarette advertisements with new ones that include the new warning labels, but fails to take into account the fact that cigarette manufacturers and retailers frequently change their advertisements and produce new ones anyway. The cost attributable to the new warning labels is not the total cost of such replacements, but only the incremental cost of such replacement over the cost of replacements that would have been done regardless of the adoption of the regulation. That increment is negligible.

In addition, the analysis inflates the cigarette companies' design costs to accommodate the new warning labels on their packs and advertising by ten percent to account for "rush charges" associated with a compliance period shorter than 24 months," despite the fact that the companies have actually known that these new warning label requirements were coming (and how much of each pack and advertisement they would cover) at least since Congress enacted the legislation in early 2009 and final compliance is not required until late in 2012.

The analysis includes consideration of costs expected to be incurred by the larger cigarette companies to conduct expensive quantitative studies and focus group testing regarding the new warning labels "to study how they might best be able to mitigate their effects." But it simply cannot be appropriate or legitimate to include in a cost-benefit analysis of warning labels directed at improving the public health by reducing smoking any costs incurred by the tobacco industry's efforts to mitigate the effect of that rule by minimizing its impact. Moreover, such costs are not societal costs at all: the costs to the companies are benefits to the employees and contractors who perform the work.

The analysis also overstates the likely revenue loss to the federal government and state governments as a result of the regulation. The analysis erroneously assumes that the loss of tax revenue should be measured by multiplying the number of packs associated with the reduction in smoking as a result of the regulation by the per-pack federal and state excise taxes. But this methodology ignores the fact that tax revenues will increase as expenditures are shifted away from cigarettes to the purchase of other products and services. For example, the federal Joint Committee on Taxation regularly assumes that the revenue increases from federal excise tax increases will reduce other federal revenues by twenty-five percent of the excise tax revenue increase; and the reverse should hold true, as well, with reductions in cigarette excise tax receipts

increasing other tax revenues by an amount equal to twenty-five percent of the excise tax revenue decline.<sup>132</sup>

In its discussion of the employment impact of the smoking declines in those states with high levels of both cigarette manufacturing and tobacco farming, the analysis should provide and consider the available data regarding how the substantial decline in the importance of such manufacturing and farming to those state's economies during the past several decades (when the related economic studies were done) and even in just the past several years.<sup>133</sup> The diminished economic role of tobacco in regional economies makes it highly unlikely that states would experience any employment declines at all, even if smoking rates dropped sharply, and would likely enjoy net increases in overall employment along with the rest of the states. In fact, research about the impact of proposed cigarette tax increases in tobacco states has found that overall employment in those states would increase because of the related smoking declines.<sup>134</sup>

### **XIII. Consumer testing demonstrates that some of the potential images for the warning labels are likely to be more effective than others.**

The FDA has produced a set of proposed images to accompany each of the nine warning statements specified in the legislation. The number of images proposed for each statement varied from 2 to 6, with a total of 36 images. The statements and images were tested with consumers to evaluate reaction to the warning labels across a number of criteria – emotional reaction, cognitive reaction, difficult to look at, immediate recall of statement, follow-up recall of statement, immediate recall of image, follow-up recall of image, beliefs about health risks to smokers, beliefs about health risks of secondhand smoke, and quit intention (intention to not smoke for youth). The pack warning labels were evaluated across all these criteria for three groups – adult smokers 25 years old and older, young adult smokers, youth 13-17 who are current smokers or susceptible to smoking. In addition, because the warning labels will also appear on advertisements, the images were also tested among adults as part of advertisements.

Based upon both this research and the published literature about warning labels that provides an independent science base to evaluate the proposed warnings, it is possible to conclude that the proposed warnings are likely to be effective and that some are likely to be more effective than others. It is important to note that this research was not designed by itself and in isolation from the independent published research on warning labels to evaluate the overall effectiveness of the warning labels but to evaluate effectiveness relative to one another. Furthermore, the subjects in the research encountered each image only once. This limitation made it unrealistic to base any conclusion about the actual effect of the image on the likelihood that a subject would be persuaded to quit solely on this research. Rather, the studies were intended to measure the kinds of impacts each image produced. When this research is combined with research that indicates that some kinds of impacts can be associated with eventual attempts at cessation, it is possible to draw meaningful evidence based conclusions.

For example, the literature on warning labels, as described elsewhere in these comments, suggests that warning labels that include graphic images that elicit a strong emotional response are most likely to result in smokers making quit attempts. Studies show that graphic depictions of smoking's adverse effects on the body arouse reasonable fears and are associated with increases in motivation to quit smoking, greater consideration of health risks and, ultimately, attempts at cessation.<sup>135</sup> Thus, even if a study does not directly measure cessation attempts, it can measure whether a pictorial image induces the kind of responses that are eventually associated with cessation attempts.

Findings from the extant literature on warning labels indicate that the most relevant criteria for determining which images are most likely promote cessation are the strength of the emotional reaction evoked by the image and the difficulty subjects had in looking at it. There was significant variation in the degree to which the warning labels tested in the consumer research met these criteria.

With multiple images evaluated on numerous criteria with four groups of respondents, there is a judgment that still has to be made on which graphic images perform best overall. However, we believe that for most of the warning statements, one or two images emerge as the best choice(s), taking into account the existing research on warning label effectiveness. Our conclusions of the findings from the FDA's consumer research are summarized below:

**Cigarettes Are Addictive:** Hole in Throat tested significantly better than the control and higher than any of the other images on the emotional reaction scale and difficult to look at scale among all four groups. It also tested well on cognitive reaction and was first or second to cigarette injection across the four groups. While Hole in Throat did not do as well on recall as some of the other images, it still performed significantly better than the control for 3 of the 4 groups. Cigarette injection performed best on recall of image. When looking across criteria, especially the most important ones, Hole in Throat is the preferred image. Woman in Rain clearly performed the worst and should not be considered for inclusion in the final warning labels.

**Tobacco Smoke Can Harm Your Children:** While the results from this set are not as consistent across criteria and groups, some of the images do perform better, and others do not do well at all. Warning in Child Lettering is consistently less effective across dimensions and groups and should not be considered. Smoke at Baby (cartoon image), while somewhat effective with some groups, appears slightly less effective on the emotional reaction scale and difficult to look at scale than the remaining four. Girl Crying, Girl in Oxygen Mask, and Smoke at Toddler appear to perform slightly better

than Smoke Approaching Baby on the emotional reaction and difficult to look at scale, although not on the cognitive scale.

**Cigarettes Cause Fatal Lung Disease:** The Healthy/Diseased Lung performs significantly better than the control and better than the other 3 images on the most important criteria across all four groups of consumers. This is the warning label for which the choice of image seems most clear.

**Cigarettes Cause Cancer:** The Cancerous Lesion on Lip and Deathly Ill Woman test best with virtually all the groups on the most important dimensions. Cancerous Lesion on Lip appears somewhat more effective, but both of these are clearly more effective than either Cigarette Burning image. This conclusion is consistent with the literature on warning labels, which indicates that depictions of the health effects of smoking on the body are most effective.

**Cigarettes Cause Stroke and Heart Disease:** On the emotional and difficult to look at dimensions, Oxygen Mask on Man's Face tests significantly better than the control and much better than the other images with all the groups. It does not do quite as well as Hand with Oxygen Mask on the cognitive dimension but still tests significantly better than the control and appears to be the most effective among this group.

**Smoking During Pregnancy Can Harm Your Baby:** Just two images were tested for this statement. Baby in Incubator outperforms the Pacifier & Ashtray image and is significantly better than the control on the key criteria that have proven most discriminating in the research.

**Smoking Can Kill You:** While Man in Casket does well on some criteria with some groups, the Man with Chest Staples stands out against control and against the other images for all groups on the emotional and difficult to look at scales. The human figures appear more compelling, with Man with Chest Staple performing most consistently well and standing out on some criteria.

**Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers:** The Woman Crying Image performs better than control and slightly better than other images on the emotional reactions scale for all groups. It stands out even more on being difficult to look at and seems to be a cut above the other images, also standing out on image recall.

**Quitting Smoking Now Greatly Reduces Serious Risks to Your Health:** The results are much less compelling overall for this set and likely the result of this message being less amenable to producing emotional reactions. Performance by the Man I Quit T-Shirt and Cigarettes in Toilet Bowl ad are somewhat mixed across dimensions and groups, with Toilet Bowl marginally better on emotional and cognitive scales but T-Shirt much better on image recall. The Woman Blowing Bubbles Image does consistently worst and should likely be eliminated from consideration. These results point to the need to provide quitting resources such as 1-800-QUITNOW on the warning label.

The undersigned organizations believe that requiring the use of warning labels selected from among the 36 proposed by FDA will have a significant positive effect. The principal goal of the agency should be to ensure that a regulation requiring new pictorial warning labels is implemented in accordance with the timetable established in the Act. However, it is conceivable that even stronger pictorial images, tested by appropriate survey evidence and used in other countries, might be even more effective. If the agency has the ability to identify such images and still ensure that a valid final regulation becomes effective on the timetable established by the Act, the undersigned organizations would not oppose such action.



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- <sup>124</sup> Mudarri, D., U.S. Environmental Protection Agency, *Costs and Benefits of Smoking Restrictions: An Assessment of the Smoke-Free Environment Act of 1993*, submitted to Subcommittee on Health and the Environment, Committee on Energy & Commerce, U.S. House of Representatives, April 1994 [finding that cleaning and maintenance costs would decline by \$4 to \$8 billion if all non-residential buildings with more than 10 persons went smoke free]. While some of these costs have likely been reduced as more and more businesses have adopted smoke-free policies since the 1994 analysis, more and more states and localities have implemented smoke-free laws, and overall smoking rates have declined, the study did not include the smoking-caused cleaning and maintenance costs in commercial buildings with fewer than 10 people and, more importantly, the \$4 to \$8 billion of smoking-caused cleaning and maintenance costs in 1994 dollars amounts to \$5.9 to \$11.9 billion in current dollars. Full report at: <http://legacy.library.ucsf.edu/tid/rdu76d00/pdf?search=%22epa%20mudarri%20cost%20benefits%22>.
- <sup>125</sup> J. R. Hall, Jr., National Fire Protection Association, *The Smoking-Material Fire Problem*, November 2007, <http://www.nfpa.org/assets/files/PDF/OS.SmokingMaterials.pdf>. See, also, Kristein, Marvin M., "How Much Can Business Expect to Profit from Smoking Cessation," *Preventive Medicine*, 12(2):358-81, March 1983. For more on the non-health costs caused by smoking, see U.S. Dept. of the Treasury, *Economic Costs of Smoking in the U.S. and the Benefits of Comprehensive Tobacco Legislation*, 1998; Chaloupka, FJ & Warner, KE, "The Economics of Smoking," in Culyer, A & Newhouse, J, (eds), *The Handbook of Health Economics*, 2000; CDC, *MMWR* 46(44), November 7, 1997.
- <sup>126</sup> According to data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), cigarette pack sales in the United States totaled more than 15 billion packs in fiscal year 2009-2010; and the average retail price of a pack of cigarettes (not including sales tax) was approximately \$5.32. [Orzechowski & Walker, *Tax Burden on Tobacco 2009, 2010.*] \$5.32 X 15 billion = \$79.8 billion (and does not include sales of cigars, smokeless tobacco, etc.). For tobacco industry marketing expenditures, see U.S. Federal

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Trade Commission (FTC), *Cigarette Report for 2006*, 2009, <http://ftc.gov/os/2009/08/090812cigarettereport.pdf>; and FTC, *Smokeless Tobacco Report for the Years 2006*, 2009, <http://ftc.gov/os/2009/08/090812smokelesstobaccoreport.pdf> (data for top 5 manufacturers only).

<sup>127</sup> See, e.g., Warner KE, et al., "Employment implications of declining tobacco product sales for the regional economies of the United States," *JAMA* 275(16):1241-6, April 24, 1996; Warner, KE & Fulton, GA, "The economic implications of tobacco product sales in a nontobacco state," *JAMA* 271(10):771-6, March 9, 1994; Warner, KE, "Implications of a nicotine-free society," *Journal of Substance Abuse* 1(3):359-68, 1989; Gottlob, B, *The Fiscal and Economic Impacts of Increasing the Cigarette Tax in New Hampshire*, PolEcon Research, March 2003; Gottlob, B, *The Fiscal and Economic Impacts of Increasing the Cigarette Tax in Virginia*, PolEcon Research, April 15, 2004, <http://tobaccofreekids.org/pressoffice/VACigTaxReport.pdf>.

<sup>128</sup> See, e.g., Halpern, MT, et al., *Tobacco Control* 10(3):233-238, September 2001. Javitz, HS, et al, *Clinics in Occupational & Environmental Medicine* 5(1):9-29, 2006.

<sup>129</sup> Bunn, W., et al., "Effect of Smoking Status on Productivity Loss," *Journal of Occupational and Environmental Medicine* 48(10): 1099-1108, October 2006 [on the job productivity loss per average smoker \$4,430 compared to \$3,246 per average former smoker].

<sup>130</sup> See, e.g., Warner KE, et al., "Employment implications of declining tobacco product sales for the regional economies of the United States," *JAMA* 275(16):1241-6, April 24, 1996; Warner, KE & Fulton, GA, "The economic implications of tobacco product sales in a nontobacco state," *JAMA* 271(10):771-6, March 9, 1994; Warner, KE, "Implications of a nicotine-free society," *Journal of Substance Abuse* 1(3):359-68, 1989; Gottlob, B, *The Fiscal and Economic Impacts of Increasing the Cigarette Tax in New Hampshire*, PolEcon Research, March 2003; Gottlob, B, *The Fiscal and Economic Impacts of Increasing the Cigarette Tax in Virginia*, PolEcon Research, April 15, 2004, <http://tobaccofreekids.org/pressoffice/VACigTaxReport.pdf>.

<sup>131</sup> The average retail price of a pack of cigarettes (not including sales tax) in November 2009 was approximately \$5.32. [Orzechowski & Walker, *Tax Burden on Tobacco 2009*, 2010.] 365 X \$5.32 = \$1,941. But the average cigarette price has gone up since then because of state cigarette tax increases and cigarette company price increases. For a descriptive accounting of other individual costs from smoking and savings from quitting, see Smith, H., "The High Cost of Smoking," *msm.com, Money: The Basics*, updated September 3, 2008, <http://articles.moneycentral.msn.com/Insurance/InsureYourHealth/HighCostOfSmoking.aspx>.

<sup>132</sup> Joint Committee on Taxation, *Overview of Revenue Estimating Procedures and Methodologies Used by the Staff of the Joint Committee on Taxation*, (JCX-1-05), February 2, 2005.

<sup>133</sup> See, e.g., the Campaign for Tobacco-Free Kids factsheets on the shrinking role of tobacco farming and manufacturing in the so-called "tobacco states" [and the sources cited therein], available at <http://www.tobaccofreekids.org/research/factsheets/index.php?CategoryID=20>.

<sup>134</sup> Gottlob, B, *The Fiscal and Economic Impacts of Increasing the Cigarette Tax in Virginia*, PolEcon Research, April 15, 2004, <http://tobaccofreekids.org/pressoffice/VACigTaxReport.pdf>.

<sup>135</sup> D. Hammond, G.T. Fong, et al. Graphic Canadian warning labels and adverse outcomes: evidence from Canadian smokers," *American Journal of Public Health* 94 (8), 2004. Hammond, D. Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11, February 2009. See also, Environics Research Group. Testing New Health Warning Messages for Cigarette packages: A Summary of Three Phases of Focus Group Research: Final Report, Prepared for Health Canada, 2000; Les Etudes de Marche Createc. Final Report: Qualitative testing of health warnings messages. Prepared for the Tobacco Control Programme Health Canada, June 2006; Goodall C, Appiah O, "Adolescents' perceptions of Canadian cigarette package warning labels: Investigating the effects of message framing," *Health Communication* 23, 2008; Sobani Z, et al., "Graphic tobacco health warnings: which genre to choose?" *Int J Tuberc Lung Dis* 14(3), 2010; Kees, J, et al., "Understanding How Graphic Pictorial Warnings work on Cigarette Packaging," *Journal of Public Policy & Marketing*, Vol. 29(2), Fall 2010; Hammond, D. et al., "Impact of the graphic Canadian warning labels on adult smoking behaviour," *Tobacco Control* 12, 391-395, 2003.