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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Docket No. Docket No. FDA–2014–N–0189

RE: Economic model used in Regulatory Impact Analysis underestimates benefits by ignoring short term effects of stopping and starting tobacco use

The Regulatory Impact Analysis for the proposed rule bases its assessment of benefits on the old 2004 book, *The Price of Smoking*, by Sloan, et al (Ref 68). The analysis in this book, while reasonable at the time it was published, is badly out of date because it does not account for the rapid changes in risk of several diseases (most notably heart and lung diseases and well as complications of pregnancy) that happen when people stop or start smoking. Even cancer risks begin to fall much more quickly than reflected in Sloan, et al. Because of the (appropriate) use of time discounting, the FDA's failure to account for these short-term effects leads the RIA to substantially underestimate benefits and so substantially overestimate the break-even point in terms of years of life saved.

Because we provided a detailed critique of using this book as the key reference in our public comment submitted to FDA in response to its Notice of Proposed Rulemaking on Cigarette Warning Labels (Docket No. FDA–2010–N–0568, 75 Fed. Reg. 69524 et seq., November 12, 2010) on January 10, 2011, I am resubmitting that comment to the current docket.

There is also a discussion of the FDA's overestimate of the costs of complying with warning label requirements which are relevant to the current rule (although the details are different).

This comment also outlines reasons that it is inappropriate to include a consumer surplus discount in estimating net benefits of the proposed deeming rule. We will also be submitting an additional more detailed critique of the use of consumer surplus before the comment period closes.

Stanton A. Glantz, PhD
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COMMENT ON FDA COST-BENEFIT ANALYSIS OF PROPOSED CIGARETTE WARNING LABELS

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January 10, 2011

It is very important that the cost-benefit analysis for the proposed labeling rule be done using the best available current science, not only to ensure the highest quality decision-making for this rule, but because the approach taken and models used to do this analysis will set the precedent for future analyses and rule making.

The approach outlined by the FDA in its Notice Proposed Rulemaking (Docket No. FDA–2010–N–0568, 75 Fed. Reg. 69524 *et seq*., November 12, 2010) severely underestimates the benefits through a combination of not considering the fact that the warning labels will have a continuing effect on smokers every year, failing to consider the short-term health benefits of smoking cessation, failing to consider most of the non-mortality benefits, using an unreasonably long discounting period for benefits, and assuming, without any evidence to justify doing so, that there will be a massive loss of consumer surplus, presumably because of the loss of the "pleasure" of smoking. The cumulative effects of these errors mean that the FDA is likely underestimating the benefits by a factor of 30-40 or more.

Likewise, the costs of the rule are substantially overestimated by not considering several practicalities of cigarette packaging (such as the presence of brand families) and modeling total costs rather than marginal costs. The cumulative effect of these errors is to overestimate the costs by nearly an order of magnitude.

The combined effects of these errors mean that the FDA's analysis underestimates the cost-benefit ratio by 2 or 3 orders of magnitude. This underestimate goes well beyond being "conservative" in the economic analysis and amounts to serious systematic bias in the analysis that severely understates the value of the proposed rule. It is imperative that a more realistic model be developed not only to ensure that the Proposed Rule is based on solid analysis, but because this analysis could become the precedent for similar analyses in future rule making.

(P. 69541) "FDA's estimate of the benefits of the proposed rule is determined by the predicted reduction in the number of U.S. smokers and the consequent reduction in the number of people who will ultimately become ill or die from causes related to smoking. FDA estimates that this proposed rule will reduce the number of smokers by 537,000 in 2013, with small additional reductions over the following 20 years."

COMMENT: As discussed in detail in response to a similar statement on P. 69543, the estimate of the reduction in the number of smokers underestimates the impact of the proposed warning labels on the number of smokers by an order of magnitude.

(P. 69542) The benefits of the proposed rule "including … reduced non-fatal emphysema …"

COMMENT: While it is appropriate to include the economic benefits of cases of non-fatal emphysema avoided, the analysis should include the morbidity effects due to all the major causes of smoking-induced disability and death, including heart and vascular disease and cancer. According to an analysis in the *MMWR* based on data from the year 2000, emphysema was not even the major cause of morbidity and only accounted for 24% of smoking-induced morbidity.[1]

This extremely limited focus on the analysis is particularly surprising, given the existence of a large literature on the costs of smoking, both in terms of premature death and disability, much of it produced by other authoritative agencies such as the Centers for Disease Control and Prevention. A good starting place would be the *MMWR* article, "Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses --- United States, 2000—2004" cited above.[2]

The fact that the FDA states (later on the same page) that, "The estimated totals may understate the full public health benefits of the proposed rule because they fail to quantify reductions in smokers' nonfatal illnesses other than emphysema, the reduction in external effects attributable to passive smoking, and the reduction in infant and child fatalities caused by mothers' smoking during pregnancy." does not excuse this gross understatement of the health benefits of increased smoking cessation and prevention.

If the FDA insists in hanging the whole morbidity analysis on emphysema (although see comments on severe problems with how the agency estimated the effects of emphysema later in these comments), one crude way to come up with a closer estimate of the actual costs avoided would be to inflate the emphysema estimates by a factor of 32 (1/0.031) to 83 (1/0.012). This reviewer is not recommending this procedure, but it points to the magnitude of the gross underestimate of benefits that the FDA analysis has.

(P. 69542) "Most of the public health benefits from the proposed rule would be realized in the future; perhaps several decades after the rule took effect. In other words, the benefits estimated here for the typical dissuaded smoker consist of health gains to be realized decades in the future."

COMMENT: While the FDA is correct that the benefits of the proposed rule will accrue for decades into the future, it is also true that some of the health benefits will accrue almost immediately, particularly those due to the almost immediate benefits of smoking cessation in terms of reduced risk of acute myocardial infarctions[3] and low birth weight infants.[4] In addition, within 5 years of quitting, the risk of cancers of the mouth, esophagus, and bladder is cut in half.[5]

The rapid benefits in terms of heart disease are particularly important for evaluating an educational/policy intervention such as warning labels. Another educational campaign, the California Tobacco Control Program, led to almost immediate and rapid drops in age-adjusted heart disease mortality.[6] (While this study did not address morbidity costs, there are about 2 nonfatal heart attacks for every fatal heart attack,[7] so the short-term economic impacts of smoking cessation will be much larger because of the morbidity costs avoided.) Similar, albeit slower (but over a period of a few years, not "decades") were observed for lung cancer and bladder cancer.[8]

These effects, combined with other effects of increased cessation and reduced initiation, led the fact that the California Tobacco Control Program was associated with reduced direct healthcare expenditures that began in one year and grew over time, reaching 7.3% of total healthcare costs after just 15 years. The direct healthcare cost savings associated with the California Tobacco Control Program over its first 15 years amounted to 50 times what it cost.[9] Likewise, the less aggressive Arizona Tobacco Control Program was associated with direct health care cost savings of 10 times what it cost over the first 9 years.[10]

Moreover, there are is now strong, widely-accepted evidence that 100% smokefree policies produce immediate and reductions in hospitalizations for acute myocardial infarction that increase with time[11-13] (with more recent evidence showing rapid reductions in hospitalization for pulmonary conditions[14, 15]) because of a combination of reduced secondhand smoke exposure and, probably, primary smoking. In addition, there was a rapid and accelerating decline in hospitalizations for acute myocardial infarctions immediately after the county implemented a tobacco education program focused on promoting smoking cessation.[16] These data are important because they provide more evidence that heart disease risk changes rapidly in response to reductions in tobacco smoke exposure in general and point to the need for the FDA to take into account the effect that the proposed warning labels will directly and indirectly have on both active smoking and secondhand smoke exposure.

A 2010 study[15] reported not only the effects of the Arizona smokefree law on heart attacks, angina, stroke and asthma, but also reported effects on hospitalization costs. During the first 13 months after the law took effect, AMIs were reduced by 13% with a corresponding reduction in hospital charges of $7.2 million. Therefore, the total hospital charges for AMIs for that period would have been $55.1 million ($7.2/0.13). The total hospitalization cost savings over just these four conditions amounted to $16.8 million out of a total of $110.2 million, thus the law accounted for a 15% ($16.8/$110.2) reduction in hospitalization costs over just 13 months.

Note that these estimates do not include costs of lost lives or morbidity costs, which the FDA should fully consider in its cost-benefit analysis.

The fact that these health benefits accrue so quickly is particularly important in light of the fact that the FDA discounts future benefits. While there is nothing wrong with doing proper discounting, ignoring these almost immediate benefits and only considering benefits "decades" into the future will lead to severe underestimates of the benefits of the proposed rule because of the effect of discounting benefits in the distant future.

(P. 69543) "FDA estimates that the average unexplained difference between the United States and Canada in national smoking rates is 0.212 percentage points higher for the 2001–2008 period than for 1999–2000. Applying this estimate to population projections (Ref. 65) and summing over all age groups yields an estimate that the rule would reduce (either through cessation or avoided initiation) the United States' smoking population by approximately 537,000 in 2013, with the total decrease rising to approximately 619,000 in 2031 due to population growth."

COMMENT: It is not clear how this calculation was done, particularly how the FDA handled cohort effects. Given that there are 46.6 million smokers[17] it is hard to believe that there would only be 82,000 (619,000 minus 537,000) additional nonsmokers generated in the 18 years between 2013 and 2031.

To investigate the magnitude of the FDA underestimate, we developed a simple model to estimate the impact of cigarette warning label on the number of smokers and the number that would quit because of the labels from 2010 to 2028. We used this time period rather than the 2013 to 2031 period the FDA used because we could only find US Census population projections through 2030. While the numbers will be slightly different for the 2013 to 2031 period, the difference from what we find will be small.

<u>We made the following assumptions:</u>

As the FDA, we obtained the total and adult population (age 15 and older) in year 2010, 2020 and 2030 from US Census Bureau and estimated populations from other years using geometric interpolation (columns B and C in the table below).

We begin with 46.6 million adult smokers, the number reported for 2009,[17] as the number of smokers in 2010 (column E).

About 1,000 teens become daily smokers every year in US[18] or 0.365 million in 2010. To estimate the number of new smokers every year, we assume that that the ratio of the new smokers to nonsmoking adults (adult population - smokers) is fixed as 0.18% (0.365/(246.637-46.6) based on the 2010 numbers) every year (column F).

We assumed that the warning label did not affect the number of new smokers. Because the warning labels will almost certainly reduce smoking initiation, this assumption will lead us to underestimate the effect of the warning labels. (The FDA should not make such an assumption.)

The U.S. Centers for Disease Control and Prevention reported that approximately 17% of all deaths annually are attributed to smoking.[2]In addition, a national report showed that there are about 760.2 deaths per 100,000 US standard population.[19] Based on these data, we estimated that the number of deaths from smoking in 2010 was about 0.399 million (308.936 x 760.2/100,000 x 17%). We then predicted the annual death rate from smoking assuming that the death rate and proportion of deaths due to smoking remained fixed at 760.2 per 100,000 and 17% every year (Column G).

We estimated the number of smokers who would quit absent the warning labels based on the fact that about 46% smokers try to quit each year in U.S.[20] but only about 7% of smokers who tried to quit were still abstinent one year later.[21, 22] Using these estimates, we calculated that 46% x 7% = 3.22% of smokers successfully quit each year (e.g., 3.22% x 46.6 million = 1.501 million in 2010) (Column H).

For purposes of argument, we accepted the FDA's estimate that the warning labels would reduce the adult smoking prevalence by 0.212%, or 523,000 smokers in 2010. This reduction is equivalent to a reduction in the number of smokers of 1.12% (523,000/46.6 million). We assumed that the warning labels would reduce the number of smokers by 1.12% each year (Column I).

We obtained the number of smokers in the end of each year (Column J) by adding the number of youth who started (Column F) and subtracting the number of smokers who die (Column G) and the number of smokers who quit because of the warning labels (Column I), then use this number as the number of smokers at the beginning of the next year (Column E on the next line in the table). For example, the estimated number of smokers at the end of 2010 is 46.600 + 0.365 – 0.399 – 1.501 – 0.523 = 44.542 million, which is then taken as the number of smokers at the beginning of 2011.

Finally, we estimated the total number of smokers who quit as the result of the labels over the 18 year period by summing up Column I): 6.843million. This effect is an order of magnitude bigger than the FDA estimates.

As noted above, this calculation does not allow for the effect that the warning labels will have on reducing youth initiation, which means that our calculations underestimate the total effect of the warnings. When the FDA does its proper analysis, it should also include effects on initiation.

A	B	C	D	E	F	G	H	I	J
Year	Total Population (million)	Adult Population (million)	Total Death (million)	Smokers in the Beginning (million)	New Smokers (million)	Death of Smokers (million)	Smokers who Quit (million)	Additional Decrease of Smokers due to Warning Label (million)	Smokers in the end (million)
2010	308.936	246.637	2.349	46.600	0.365	0.399	1.501	0.523	44.542
2011	311.523	248.731	2.368	44.542	0.373	0.403	1.434	0.500	42.578
2012	314.132	250.842	2.388	42.578	0.380	0.406	1.371	0.478	40.704
2013	316.762	252.972	2.408	40.704	0.387	0.409	1.311	0.457	38.914
2014	319.415	255.120	2.428	38.914	0.395	0.413	1.253	0.437	37.206
2015	322.090	257.286	2.449	37.206	0.402	0.416	1.198	0.417	35.576
2016	324.787	259.470	2.469	35.576	0.409	0.420	1.146	0.399	34.020
2017	327.507	261.673	2.490	34.020	0.415	0.423	1.095	0.382	32.535
2018	330.250	263.895	2.511	32.535	0.422	0.427	1.048	0.365	31.118
2019	333.016	266.135	2.532	31.118	0.429	0.430	1.002	0.349	29.765
2020	335.805	268.395	2.553	29.765	0.435	0.434	0.958	0.334	28.474
2021	338.484	270.665	2.573	28.474	0.442	0.437	0.917	0.319	27.242

2022	341.185	272.955	2.594	27.242	0.448	0.441	0.877	0.306	26.067
2023	343.908	275.264	2.614	26.067	0.455	0.444	0.839	0.292	24.945
2024	346.652	277.593	2.635	24.945	0.461	0.448	0.803	0.280	23.875
2025	349.419	279.941	2.656	23.875	0.467	0.452	0.769	0.268	22.854
2026	352.207	282.309	2.677	22.854	0.473	0.455	0.736	0.256	21.880
2027	355.017	284.697	2.699	21.880	0.480	0.459	0.705	0.246	20.951
2028	357.850	287.106	2.720	20.951	0.486	0.462	0.675	0.235	20.064
Total								6.843	

(P. 65942) "The largest health consequence of smoking is the increased rate of mortality from cardiovascular disease, cancer, and certain other illnesses. As a result, the largest benefits of this proposed rule stem from the increased life expectancies for those individuals who, in the absence of this proposed rule, would be smokers and thus susceptible to premature mortality from one of these often-fatal diseases."

COMMENT: As discussed above, the FDA needs to consider the morbidity as well as mortality costs of these diseases.

(P. 69543) "We calculate the number of life-years saved using differences in the probabilities of survival for smokers and nonsmokers. Sloan et al. (Ref. 66) construct life tables for various categories of individuals, including ''non-smoking smokers'' and typical 24-year-old smokers."

COMMENT: The general approach outlined in Sloan et al is *one* way to approach these questions. While the book makes a reasonable contribution, its limitations need to be considered. As noted in a generally favorable review of this book, this commenter observed:

> The second controversy discussed by the authors is whether and how the savings to Social Security because of early mortality should be included as a benefit to society from smoking. The authors show how lower life expectancy from smoking is advantageous to Social Security because the benefits paid to an average smoker are lower than the benefits paid to a longer-living nonsmoker. The authors also find, however, that smoking reduces revenues paid to the Social Security Trust Fund because of smokers' lower wages and productivity. The argument against including these costs, as the authors state, is that it is "ghoulish" to include premature death as a benefit. In the interest of economic completeness, however, they do so. This choice is problematic, however: all of the published work the authors cite on the 'death benefits' to Social Security was done by researchers with ties to the tobacco industry. There is a well-established link between tobacco-industry funding and research results that are favorable to the industry. Although we applaud the authors' desire to include all previous literature, the links between the tobacco industry and the authors of these studies should have been noted.[23]

Since 2004, when this review was written, the evidence of strong biases in tobacco industry-funded work has continued to grow[24-36] Indeed, in 2006 a federal district court ruled that the

major cigarette manufacturers and their affiliated organizations constituted an illegal "enterprise" under the Racketeer Influenced Corrupt Organization Act (RICO) that was engaged in racketeering activities to defraud the American public and was and likely to continue to do so in the future (United States of America, et al. v. Philip Morris USA Inc., et al, 449 F. Supp 2d 1 (D.C. D. C. 2006), aff'd, except for certain remedies, 566 F.3d 1095 (D.C. Cir. 2009), cert. den. 130 S. Ct. 3501 (June 28, 2010)). Corruption and distortion of science is a central element of the illegal enterprise. In hindsight, it would have been better for Sloan et al to have discussed the industry-funded work (for completeness), but *not* included the results of that work in his analysis.

Of most relevance to the FDA's assessment, the agency should take pains not to accept any "scientific" or economic submissions from the tobacco industry or individuals or organizations affiliated with or funded by the industry at face value. If the agency decides to continue to rely on Sloan et al, it should carefully Sloan's findings to ensure that the FDA is not using any such findings that are contaminated with industry material.

The review also noted a further limitation in Sloan et al, which is of particular relevance to the FDA's overall analysis:

> The third controversy discussed by the authors is whether the cost estimates imply that smokers behave rationally (that is, they choose to smoke and set their level of consumption based upon an optimal weighing of all future costs and benefits of continued smoking). Whether smokers behave rationally is an ongoing debate in economics. The authors state that their cost estimates support the conclusion that smokers are not making a forward-looking optimal choice (that is, they are not rational decision makers) because the costs are so high it is unlikely that the benefits outweigh the costs. The authors then take the reader through some mental gymnastics to argue that, for at least a portion of smokers, smoking is a rational choice. The authors do not touch on the growing literature that has illustrated problems with the so-called rational addiction model, and instead compare the costs of smoking to the costs of watching television. Because their empirical results support the view that smokers are not fully rational individuals, it is surprising that the authors have included a defense of rational addiction in their book. [23]

The basic premise of the theory of rational addiction is that addictive behaviors can be explained as an individual's effort to maximize utility of future behavior.[37-39] (The utility is the "positive" benefits an individual may gain from smoking, weighed against negative consequences, including health and financial costs.[38]) The idea that adolescents' smoking behavior is explained by forward-looking efforts to maximize utility based on past consumption is highly questionable for two reasons. First, for initiation, there is no past consumption. Second, research on adolescent smoking behavior[40-46] consistently finds that adolescents do not plan to be smokers beyond adolesence.[47] Particularly because the FDA places so much weight on the effects of the proposed warning labels on smoking initiation among young people, it should ensure that its economic analysis is based on empirical evidence, not theoretical predictions from the rational addiction model.

Another limitation of the Sloan et al approach is that it does not consider the rapid changes in disease risk associated with changes in smoking behavior (and exposure to secondhand smoke) discussed above. Sloan et al cannot be faulted for not considering these effects because the first paper demonstrating such an effect[48] was published in 2004, the same year that Sloan et al was published, so this information was not available to Sloan et al at the time that they were writing their book. This information is, however, now available to the FDA and should be utilized.

Thus, while it is reasonable to consider Sloan et al as one source of information in preparing its economic analysis, it is not appropriate for the FDA to base the entire analysis on this one, somewhat outdated, source.

(P. 69543-4) "Sloan et al.'s life tables allow us to calculate how many additional deaths, per 100,000 population, may be expected among typical smokers than among nonsmoking smokers between the 24th and 25th birthdays, the 25th and 26th, and so on until the 100th birthday."

COMMENT: For the reasons discussed above, this approach will underestimate the effects of the new warning labels, particularly in the short term, an error which will be further amplified by the discounting process.

Another difficultly with this process is that it is focused exclusively on deaths prevented and does not consider morbidity costs, which are substantial.

(P. 69544) "While FDA considers Sloan et al.'s methodology to be the most suitable in the literature for purposes of the present analysis, several other studies of survival probabilities among smokers who quit early in life compared with smokers who persist in smoking into later decades suggest that the average life expectancy gains of not smoking may be much higher for both males and females. Since these other studies have found larger increases in life expectancy attributable to smoking avoidance, the Sloan et al. results may be considered conservative."

COMMENT: As the FDA recognizes, the effects of smoking on life expectancy loss that Sloan et al estimate (2.4 years for females and 4.4 years for males) are much smaller than the authoritative estimates in the literature, which are about 14.5 years for females and 13.2 years for males.[49] The 2010 Surgeon General's report concluded:

> Predictions based on large population studies indicate that one-half of all long-term smokers, particularly those who began smoking in adolescence, will eventually die from their use of tobacco. Furthermore, one-half of the deaths caused by smoking will occur in middle age (35 through 69 years), resulting in the loss of 20 to 25 years of normal life expectancy (Peto et al. 1992, 2006; Doll et al. 1994). In the 45 years since the first U.S. Surgeon General's report on smoking and health was published in 1964 (U.S. Department of Health, Education, and Welfare [USDHEW] 1964), smoking has been the primary underlying cause of more than 12 million U.S. deaths. Each year since 2004, more than 430,000 additional smoking-attributable deaths have been added to the national total (U.S. Department of Health and Human Services [USDHHS] 2004;

> Bonnie et al. 2007; Centers for Disease Control and Prevention [CDC] 2008a).[18, p. 647] [citations in original quote]

Given the limitations of the Sloan et al analysis discussed above, FDA should not be solely relying on this once source of information. Admitting that using the Sloan et al approach is "conservative" (i.e., underestimates the likely effects of reductions in smoking) is not an adequate replacement for presenting an analysis based on the most recent and best available data. Indeed, as noted above, the FDA analysis goes beyond reasonable caution to wild underestimates of the likely effects of the new warning labels.

(P. 69544) "This range tends to overstate the net benefits of reduced smoking because it does not account for lost consumer surplus associated with the activity of smoking. Cutler (Ref. 69) suggests that lost consumer surplus might equal around fifty percent of the dollar value of life-year gains, which necessitates dividing the estimated gross benefits in half. This adjustment is based on a very simple linear model of cigarette demand that is not definitive; a more data intensive model may produce an adjustment factor very different from fifty percent. FDA requests comments, additional data and research on this adjustment."

COMMENT: The FDA's request for "additional data" is remarkable because the paper by Cutler[50] cited by the FDA as justification for cutting all the (already wildly estimated) benefits of reduced smoking in half is based on a theoretical argument not any direct data.

> Most of the reduction in smoking is a result of people voluntarily quitting cigarettes, without aids or other expense. The cost of this change is not monetary (although public health messages have a moderate expense), but psychic. Because the costs are not monetary, comparing these costs to the health benefits of reduced smoking is not straightforward; it depends on why people smoked to begin with. A benchmark model of smoking is the rational model; people smoke because they enjoy it and quit when the costs of smoking are greater than the benefits. In this model, the costs of behavioral change will be approximately equal to half of the health benefits.

As noted above, one cannot assume that the rational addiction model applies to smoking behavior, especially among young people.

The 50% reduction depends strongly on another unsupported assumption; Cutler[50] continues,

> … If the costs and health benefits of reduced smoking are linear in the number of cigarettes given up, the foregone pleasure of smoking will be equal to half of the health benefits.

Cutler does not provide any evidence that the relationship between costs and benefits of reduced smoking are linear.

Cutler goes on to provide the additional explanation,

> In nonrational models, the cost of reduced smoking may be higher or lower than this amount [referring to the value of a year of life in good health]. Models of hyperbolic discounting (Laibson, 1997) suggest that the costs could be lower. In these models, smokers are overly sensitive to short-run costs. Because the costs of quitting smoking are largely front-loaded (the loss of pleasure from an addicted person going without) while the benefits are longer term (the person gets to enjoy more years of life), even small costs of quitting can discourage hyperbolic smokers from quitting cigarettes. In other models, the cost of reduced smoking may be greater than the health benefits. Viscusi (1992) argues that smokers overestimate the risks of smoking-related death (though this argument is controversial; see Schoenbaum, 1997). If the argument holds true, some people who give up smoking may value cigarettes more than the true health cost, and for them, quitting smoking can thus reduce welfare.

In justifying (albeit weakly) this approach, Cutler relies on Kip Viscusi,[51] an economist with close ties to the tobacco industry who has reviewed hundreds of thousands of dollars in consulting and expert witness fees from the tobacco companies.[52, 53] (See earlier comments on the fact that the FDA should not rely on experts affiliated with the tobacco industry.)

Most troubling in terms of whether the FDA can rely on Dr. Viscusi's work (directly or indirectly) is the fact that the data which form the basis for the assertion that smokers overestimate the risk of smoking which form the core of the analysis in his book, *Smoking: Making the Risky Decision*[51] were collected in September 1985 by a private research firm, Audits & Surveys, Inc. for several law firms retained by the tobacco companies (Arnold and Porter, Jones, Day, Reavis & Pogue and Shook, Hardy & Bacon) "in anticipation of litigation" against the tobacco companies.[54-57] In Viscusi's 1997 deposition in the case brought by the Attorney General of Mississippi, Viscusi acknowledges that he knew the 1985 survey was commissioned by the law firm for the purpose of defending the tobacco companies in court.[53] Work commissioned by advocates for tobacco industry defendents prepared for legal defense can hardly be considered neutral scientific evidence. (We do not know, for example, what other questions, if any, the tobacco company law firms tested before fielding this survey.)

In any event, the basis for Viscusi's conclusion that smokers underestimate how dangerous smoking rests on how respondents answered the single question, "Among 100 cigarette smokers, how many of them do you think will get lung cancer because they smoke? (If "don't know," PROBE 'Just your best guess will do.')".[51, p. 155] People are notoriously bad at estimating such abstract low probability events. The fact that the survey company instructed interviewers to "probe" if the respondent did not know the answer makes the result even more unreliable.

Cutler does, however, recognize that Viscusi's conclusion is "controversial" and cites a much more reliable study by Schoenbaum.[58]

In contrast to Viscusi, Schoenbaum[58] examined whether smokers recognize that smoking is likely to shorten their lives and, if so, whether they understand the magnitude of this effect by comparing people's expectations about their chances of reaching age 75 were compared with epidemiological predictions from life tables for never, former, current light, and current heavy smokers. (This is a much more concrete outcome than estimating the low probability event of smokers contracting lung cancer.) He obtained data on expectations of reaching age 75 came from the Health and Retirement Survey, a national probability sample of adults aged 50 through 62 years. He obtained predictions from smoking-specific life tables constituted from the 1986 National Mortality Followback Survey and the 1985 and 1987 National Health Interview Surveys. He found that among men and women, the survival expectations of never, former, and current light smokers were close to actual predictions. However, among current heavy smokers, expectations of reaching age 75 were nearly twice as high as actuarial predictions. These findings suggest that at least heavy smokers significantly underestimate their risk of premature mortality.

Essentially, what Cutler[50] (and the FDA) are saying is that quitting smoking will deprive smokers of the pleasure of smoking. While it is certainly possible that some smokers "enjoy" smoking, this argument ignores the addictive nature of nicotine and tobacco use, the fact that the "relaxation" and "stress relief" associated with smoking are largely the self-administration of nicotine to treat the associated withdrawal symptoms.[18, 59]

This statement also ignores the fact that the vast majority of smokers regret ever having started.[60] Approximately, 80% want to quit, that in any given 40-50% make a quit attempt, most of which are unsuccessful.[60] Rather than arbitrarily assuming a 50% consumer surplus (based on essentially no reliable information), the FDA should consider estimating the consumer deficit associated with smoking.

Lacking proper data to do so, FDA should at the very least drop the practice of arbitrarily cutting benefits of cessation and smoking prevention in half in every step of its analysis.

(P. 69544) "These totals may understate the full value of rule-induced reductions in mortality because they fail to quantify any reduction in either the external effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking during pregnancy. Sloan et al. (Ref. 66) indicate that, historically, the inclusion of spouse and infant deaths increased estimates of smoking's mortality effects by approximately 26.3 percent. We do not incorporate this adjustment into our analysis, however, since recent public smoking restrictions and educational campaigns have reduced external smoking exposure to well below historical levels, though not to zero."

COMMENT: While public smoking restrictions and educational campaigns have reduced secondhand smoke exposure, according to the 2000 National Household Interview Survey, more than 25% of people living in the United States experience secondhand smoke exposure.[61] In 2007-08, 40.1% of nonsmokers (88 million people age 3 and over) were still exposed to secondhand smoke and approximately 54% of young children between aged 3-11 were still exposed.[62] Indeed, one of the warnings FDA

proposes addresses with secondhand smoke exposure and another addresses smoking during pregnancy. The benefits of these warning statements need to be included in the analysis.

(P. 69545) "Sloan et al. (Ref. 66) estimate that smokers use more medical services over their life cycles than do comparable nonsmokers, with a specific net cost of $3,757 per female 24-year-old smoker and $2,617 per male 24-year-old smoker (in 2000 dollars and with a 3 percent discount rate). If these payments are distributed equally from ages 24 to 100, given FDA's projected 20-year reductions in smoking prevalence, smoking-related medical expenditures would fall by $1.87 billion, of which $997.7 million would be realized as savings by smokers themselves and $870.6 million by nonsmokers (in the form of decreases in private insurance premiums or taxes used to fund government health programs such as Medicare). With a 7 percent discount rate, the total decrease in expenditure becomes $915.5 million, with $488.0 million of those savings accruing to smokers and $427.5 million to nonsmokers."

COMMENT: Given that smoking leads to premature death, with about half of smokers dying in middle age,[63] it is not appropriate to distribute the costs of smoking equally over time through age 100. Because of the discounting that the FDA does, doing so will even further underestimate the actual benefits of reduced smoking due to the warning labels. For example, with a 3% discount rate, $100 allocated at $1 per year for 100 years has a discounted present value of only $31.60 compared to $51.46 for $2 per year for 50 years. The corresponding numbers for a 7% discount rate are $14.27 and $27.60. Thus, the decision by the FDA to distribute the smoking related costs over 100 years cuts the present value by 50-60%. Given the effect of smoking on life expectancy, even 50 years is too long.

The combined effect of just using an unreasonably long discount period and the assumption that half the savings due to improved health are lost because of the assumed loss of consumer surplus means that the FDA is underestimating the cost savings due to the new warnings by a factor of 3 to 4.

(P. 69546) "As a final adjustment, we divide the remaining expenditure change in half to account for smokers' lost consumer surplus associated with the activity of smoking."

COMMENT: For the reasons discussed above, dividing this expenditure estimate by two is not justified or appropriate.

(P. 69546) "On the other hand, because FDA has had access to very small data sets, our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject the possibility that the proposed rule would not change the U.S. smoking rate. In this case, the proposed rule would not generate any quantifiable benefits, so the appropriate lower bound on benefits is zero. Ranges of benefits, representing the zero-effect case and the Canada-only modeling approach, appear in Table E6."

COMMENT: Given the huge and systematic downward biases that permeate the health estimates, such a conclusion is unwarranted. In addition, there are data from countries all over the world that have implemented warning labels. If the FDA finds the Canadian data too limited, it should make use of the much larger global experience that is available.

A more serious problem with the "Uncertainty Analysis" is that it ignores the effects of all the serious (downward) biases that the FDA has used in this analysis (justified repeatedly with the comment that the analysis is "conservative"). If the FDA wishes to do an uncertainty analysis, it should do so properly: It should develop the best available point estimates for the different ways in which smoking affects disease, including morbidity as well as mortality costs, for the full range of smoking-induced diseases. Each of these estimates (as well as whether there is a consumer surplus or deficit, if the available data – not theory – justify such estimates) as well as associated estimates of the corresponding variances, then conduct a full Monte Carlo simulation of the likely costs and savings. There are off-the-shelf software packages that will do the arithmetic. (For an example of such a calculation in the context of using smokeless tobacco for "harm reduction" see Mejia et al.[64])

(P. 69547) "The proposed rule would create new burdens for cigarette manufacturers. In particular, manufacturers would incur the large up-front costs associated with a major labeling change."

COMMENT: In the context of tobacco marketing, with the companies spending $12.5 billion on marketing and promotion in 2006,[65] the amounts of money being described here are not "large."

The presentation of costs to the tobacco industry and related organizations reflects exactly the opposite systematic biases as in the analysis of health cost impact: All costs are taken as upper bound estimates. Just as the health estimates should be based on "best" point estimates, so should the costs to the tobacco industry.

(P. 69548) "The front and back of every cigarette package must be redesigned to incorporate graphic warnings occupying the entire top half. This type of change requires what is known as a complete redesign in the 2003 model or as a major change in the forthcoming model. In addition, the requirement to incorporate 9 different warnings will increase costs beyond what the labeling models estimate. FDA accounted for the additional warnings by first calculating the cost of a complete redesign for cigarettes and then inflating the specific cost components expected to increase due to the requirement for 9 warnings."

COMMENT: Inflation of design costs because there are 9 labels is not warranted. All warnings will occupy the same location and size on each package, so accommodating the label in package redesign will be the same for every package for a given brand family regardless of which of the 9 labels is actually applied.

(P. 69548) "The large cigarette manufacturers can plausibly be expected to conduct quantitative studies and focus group testing for each of their brands to gauge the effect of the new graphic warnings and to study how they might best be able to mitigate their effects."

COMMENT: The FDA should not be counting expenses incurred by tobacco companies to undermine the effect of the Congressionally-mandated warning labels as a cost of the rule. If such a cost was counted, it would be equally reasonable to include the tobacco companies' legal fees for the lawsuits that they will file challenging the rule (which will likely be much more than the cost of this marketing research) as well as lobbying costs to get the law changed to repeal the requirement for the labels. This expense is one more example of the FDA's heavy biases in developing this cost-benefit analysis. The FDA should carefully scrutinize all the "costs" associated with the proposed rule to see that the only costs that are included are the minimal costs incurred by the tobacco industry to implement the law efficiently and in good faith.

(P. 69548) "We estimate that 3,234 cigarette UPCs (Ref. 82), would be affected by this proposed rule. FDA conservatively assumes that because the required change is so radical, none of the labeling changes can be coordinated with a previously-scheduled labeling change."

COMMENT: This is another example of the FDA's misuse of the word "conservative" to cover up wildly biased assumptions. While there may be 3,324 cigarette UPCs, this assumption ignores the fact that varieties with brand families share essential trade dress and package design features, so an individual resign of each package (i.e., UPC) would not be required. (For example, the companies have several different package colors for a given brand to thwart the intent the FDA's rule prohibiting the use of the terms "light" and "mild."[66] The essential trade dress for all varieties is the same.)

Here are the numbers of varieties for several common brands (according to Wikipedia):

Marlboro	36
Camel	23
Merit	16
Basic	13
Natural American Spirit	13
Doral	12
Parliament	11
Newport	9
Pall Mall	6

The average numbers of varieties per brand is 15.4. Assuming that this number is higher than for most brands would still lead to the conclusion that the number of cigarette package redesigns the rule would require is an order of magnitude too large. A more realistic (and perhaps even "conservative" in the sense that could be an overestimate) would be 332 as opposed to 3,324.

(P. 69548) "Based on communication with RTI about the forthcoming model (Id.), FDA estimates that, per UPC, administrative labor costs are $375 to $1,014, graphic design labor costs are $1,120 to $3,206, prepress labor costs are $1,482 to $3,816, recordkeeping labor costs are $33 to $434, prepress materials costs are $100 to $2,439, and printing plate costs are $4,840 to $10,580. Summing these costs yields a per-UPC design cost of $7,950 to $21,489."

COMMENT: As noted above, it is not appropriate to simply multiply the cost of designing and preparing one new package design by the number of UPCs. In addition, the FDA also severely overstates the production and printing costs by not accounting for the realities of how such work is actually done. This commenter asked an experienced large job printer to review the FDA analysis; he observed:

> In looking at the costs associated with each label, this might be fairly accurate for 1 label, but they don't take into account the economies of scale. After the first one, the second and subsequent package costs will go down exponentially. The only costs that might remain static would be the cost of printing plates, which depending on how they print them, could be reduced if they gang run several different packages of similar production runs together on the same sheet. All the non-production costs would be amortized over the whole.

In addition, the FDA ignores the fact that, even absent any change to the warning labels, the companies will incur some of these costs on an ongoing basis as part of routine production. For example, the printing plates wear out after a few million impressions and have to be replaced regularly. The cost estimates for printing the new packages should be adjusted appropriately to account for this fact.

To estimate the average turnover of printing plates, the Federal Trade Commission estimated that there were 350 billion cigarettes sold or given away in 2006[65] equivalent to 337 million packs/week (350 billion divided by 20 cigarettes per pack and 52 weeks per year). If each UPC requires its own printing plate and each plate is good for 3 million impressions, then the average printing plate will have to be replaced every 3 weeks. Given the fact that the cigarette companies will have 15 months to prepare for the new labels, they will have plenty of time to integrate production of the new plates into their production stream (just as they will have time to use up inventory that does not have the new labels, a point that the FDA correctly makes). There is no need to include the cost of the new printing plates in the cost analysis.

(P. 69548) "Multiplying by the number of affected UPCs and inflating by 10 percent to account for rush charges associated with a compliance period shorter than 24 months results in total label design costs of $28 million to $76 million (Ref. 83)."

COMMENT: It is not appropriate to add an additional 10% for "rush" processing of these changes. Nothing about this rule is happening quickly. The companies have plenty of time to plan for and accommodate these changes.

(P. 69549) "As stated above, FDA expects that only the large manufacturers will conduct market tests for their brands. Using several state directories of certified tobacco products, FDA estimates that 75 brands are marketed by the 4 largest domestic manufacturers (Refs. 84–89). The cost of focus group tests is estimated to range from $18 to $42 thousand; the cost of a quantitative study is estimated to range from $47 to $453 thousand (Ref. 82). The total cost of both types of market testing is estimated to be $65 to $495 thousand per brand. Multiplying by 75 brands yields a total cost estimate ranging from $5 to $37 million with a medium estimate of $11 million, as shown in Table E11."

COMMENT: As noted above, the FDA should not count such discretionary expenses incurred by the cigarette companies that are designed to minimize the impact of the warning labels as legitimate costs of implementation.

In general, to obtain an adequate cost estimate for the rule, the FDA should take care to base its cost estimate on the *marginal* cost of changing the warning labels that the cigarette companies would incur accounting for ongoing expenses associated with producing cigarette packages and assuming that the companies implemented the new labels using economical strategies.

A more realistic upper bound estimate of the marginal cost of implementing the warning labels would be $30,421 per redesign ($125,641 from the high estimate in Table E-10 less the plate cost of $95,220) times 332 brands (estimated based on the number of UPC's divided by 10), for a total of $10.1 million, plus $45.4 million for removing point-of-sale advertising (Table E-15). (This estimate does *not* include the costs of printing plates, rush charges or market testing to design new packages to minimize the effects of the new warning labels.) Adding these two costs together yields an upper bound estimate of $55.5 million for implementing the new warning labels, well below the $135 million threshold for requiring a cost analysis in the first place.

(P. 69551) "We measure the effectiveness of the proposed rule as the sum of saved life years and quality-adjusted life years. In order to assess the cost-effectiveness of the proposed rule, we must adjust the costs to account for effects that are not captured by life-years or quality adjusted life years. As shown in detail in the previous section, we calculated the first twenty years' costs attributable to the proposed rule and found present values of $266.0 to $556.0 million (using a 7 percent discount rate) or $302.0 to $603.3 million (using a 3 percent discount rate). We add to each total the estimated monetary value of lost consumer surplus (previously netted out of life-years and emphysema benefits estimates); this yields overall costs of $2.14 to $6.17 billion (using a 7 percent discount rate) or $9.47 to $28.10 billion (using a 3 percent discount rate).

COMMENT: For the reasons discussed above, the FDA is grossly underestimating the benefits of the new warning labels and overestimating the costs, including the assumed 50% consumer surplus. These estimates should be replaced with ones that have been more realistically estimated. Use of "conservative" estimates to does not compensate for serious biases in selection of data and methodology.

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