COMMENTS ON *PRELIMINARY REGULATORY IMPACT ANALYSIS INITIAL REGULATORY FLEXIBILITY ANALYSIS UNFUNDED MANDATES REFORM ACT ANALYSIS*

21 CFR PARTs 1100, 1140, and 1143 (DOCKET NO. FDA-2014-N-0189). Deeming Tobacco Products to be Subject to the FDCA…

Comments submitted by Wendy Max, PhD
Professor of Health Economics
and Yingning Wang, PhD
Research Economist
University of California, San Francisco
May 24, 2014

Regulatory impact analysis of any FDA tobacco regulation has to consider the change in benefits and costs that will result from changes in tobacco use resulting from the new regulation. The proposed deeming rule will impact the use of combustible tobacco products, including cigars, pipe tobacco, and eCigarettes. There is a substantial literature on medical expenditures attributable to smoking, and also studies on the healthcare cost impact of exposure to secondhand smoke (SHS). There is no literature on the healthcare costs of the use of other tobacco products. The components of a comprehensive model of smoking-attributable costs will be described below, indicating how medical expenditures for other tobacco products must also be estimated.

In its Regulatory Impact Analysis of the proposed Deeming Rule the FDA provides an extensive analysis of costs, but makes no attempt to quantify the benefits of the proposed rule, indicating that "we lack sufficient evidence to estimate within acceptable levels of certainty how consumers will use the new label information". Because this correctly reflects the status of the literature at present, the FDA's used of "break even" levels of lives quality of life years that would need to be saved by proposed regulations is a reasonable approach.

As detailed below, however, the FDA should *not* be including a discount for lost consumer surplus

The statement on page 52 on the break-even point is confusing. Life-years and quality adjusted life years are different things, yet the FDA seems to be considering them the same. In particular it is not clear where the QALYs come from. Usually life years are not discounted.

As more information on specific costs becomes available, or if the FDA decides to develop more specific benefit estimates, the FDA should avoid making the mistakes it made in its RIA of the previously proposed rule for warning labels for cigarettes. The comments provided here offer guidance as to how a more detailed RIA should proceed.

Use of Tobacco Products

- ***It is important to consider use of tobacco products by subpopulations.*** Tobacco use is known to differ by gender, age, race/ethnicity, sexual preference, mental health status,

income level, and military status. Prevalence estimates specific to the population of interest are needed in order to estimate healthcare costs.

- ***The role of multiple product use and switching behavior.*** Tobacco is consumed in many forms, including cigarettes, cigars, pipes, smokeless tobacco, eCigarettes, and dissolvable products. Consumers may switch between different products, but are more likely to use multiple products (dual and poly use). This switching and multiple product behavior needs to be incorporated into models to the extent that the data permit. Healthcare cost estimates also need to consider the impact of dual and poly tobacco use; absent specific evidence to the contrary dual and poly use should be costed at the levels associated with cigarettes. The PATH study which the FDA is currently fielding will provide data on the use of many of the newer products, but does not contain information on healthcare costs or utilization. Such data need to be collected.
- ***Changes in intensity of tobacco product use***. Many smokers who are unable to quit completely are able to reduce the number of cigarettes they smoke per day, or even smoke only on some days. They may reduce their use of one product and increase use of another (e.g. smoking fewer cigarettes and smoking more eCigarettes). This may have a positive impact on health and result in reduced healthcare expenditures. Thus, the analysis of the impact of any regulatory program on healthcare costs needs to consider not only changes in prevalence of smoking, but changes in intensity of use. In the absence of specific data on the effects of intensity, however, the FDA should assume the full costs of tobacco use.

Estimating the Use and Cost of Medical Services

Estimates of tobacco-attributable medical expenditures must address a number of issues:

- ***Diseases attributed to tobacco use***. The list of diseases that are causally linked to smoking or exacerbated by smoking continues to grow. Evidence of diseases and conditions associated with the use of other tobacco products is more limited, but is becoming increasingly available, as the FDA acknowledges in the RIA. Data are currently available that can be used to estimate the medical expenditures attributable to the use of tobacco products that have been available for many years, including cigars. These models should be developed.
- ***Type of healthcare services used as a result of tobacco use.*** Healthcare services used to treat tobacco-related illness include: hospitalizations, outpatient care, medications, and home health care. Nursing home care may be necessary when tobacco-users become ill and require institutionalization, or because the caregivers of older users develop tobacco-related diseases and are no longer available to provide care, leading to institutionalization of the patient. The previously reported FDA model is based on the work of Sloan and colleagues (Sloan, Ostermann, Picone, et al, 2004), and this work is also cited in the Deeming RIA. Sloan and colleagues include hospitalizations, physician visits, and nursing home use. Medications, home health care, and other types of outpatient care are not included, nor is nursing home

care necessitated by the tobacco-related illness of a caregiver. The Sloan work is quite dated, based on data from 1992-2000. In the past decade there have been important changes in healthcare service use, and tobacco product use. Newer data are available that reflect these changes.

- ***Health and healthcare costs experienced by nonusers***. Nonsmokers who are exposed to secondhand smoke are known to be at greater risk for a number of diseases, including lung cancer, asthma, and ischemic heart disease among adults; and breast cancer in premenopausal women. Children exposed to SHS are at risk of low birth weight, lower respiratory tract infections, middle ear disease, chronic respiratory symptoms, attention deficit hyperactivity disorder, and asthma. (California Environmental Protection Agency, 2005; Max, Sung, and Shi, 2012; US DHHS, 2006) Since 1964, 2.5 million nonsmokers have died from exposure to secondhand smoke. (US DHHS, 2014) This exposure has also caused large healthcare costs. (King, Peck, and Babb, 2013; Levy, Rigotti, and Winickoff, 2011; Plescia, Wansink, Waters, et al., 2011; Satter, Roby, Smith, et al., 2010; Waters, Foldes, Alesci, et al., 2009) There is also early evidence that thirdhand smoke exposure, i.e. exposure to residual nicotine and other chemicals left on surfaces such as carpets and curtains by cigarette smoke, is associated with negative health impacts. (Martins-Green, Adhami, Frankos, et al, 2014) While no studies have analyzed the healthcare costs of secondhand cigar or pipe smoke or secondhand aerosol from eCigarettes, it is likely that there will also be health impacts associated with exposure. These health effects must be incorporated into a comprehensive analysis of tobacco-related healthcare costs.
- ***Exposure to mother's smoking while pregnant***. Prenatal exposure resulting from maternal smoking has been linked to low birth weight, sudden infant death syndrome, respiratory distress syndrome, and other respiratory conditions of newborns. No studies have yet looked at the impact of prenatal exposure to other tobacco products, but this information should be incorporated into FDA models when available.
- ***Fire and burn injuries***. Injury and death caused by combustible tobacco-caused fires result in medical expenditures. There have been anecdotal reports of eCigarette-caused explosions that resulted in injuries. Data on the healthcare costs associated with these injuries must be obtained and incorporated into models.

Economic Modeling Framework

- ***Lifetime costs.*** The appropriate framework for analyzing the economic impact of regulations on medical expenditures is to use the lifetime cost approach. Because of the challenges of estimating lifetime costs and the lack of longitudinal data, only a few studies have used this framework, including one in Switzerland,(Leu and Schaub, 1983) one in the Netherlands, (Berendregt, Bonneau, and Van Der Mass, 1997) two in the US, (Sloan, Ostermann, Picone, et al., 2004; Hodgson, 1992) and one in California. (Miller, Max, Sung, et al, 2010) The FDA model is based on the US lifetime cost model conducted by Sloan and colleagues, (1)

which used data that are 14-22 years old. They used 3 data sources: the Health and Retirement Study (waves conducted in 1992, 1994, 1996, 1998, and 2000), the Assets and Health Dynamics Among the Oldest Old (conducted in 1993 and 1995), and the 1998 National Health Interview Survey. In the past decade there have been important changes in smoking behavior and products used. Newer data should be used that reflect current patterns of tobacco product use and the speed at which tobacco-induced disease risk drops (particularly for heart and respiratory disease and complications of pregnancy) that were not recognized at the time Sloan wrote his book. Including these rapid changes is particularly important because of time discounting.

- ***Factual vs. counterfactual: the "nonsmoking smoker" model.*** Smokers differ from never smokers in ways other than their smoking behavior, such as income level, insurance status, race/ethnicity, other risk behaviors, and other characteristics. Thus, models of smoking-attributable medical expenditures need to control for these differences. A common approach to control for these differences is to compare factual vs. counterfactual predictions from the models. For the factual predictions, the models predict expenditures for current, former, and never smokers, controlling for the actual values of their confounding factors. The counterfactual predictions, predict expenditures for hypothetical counterfactual "nonsmoking smokers" (including current and former smokers) who are the same as smokers in every way (i.e., also controlling for the actual values of their confounding factors) except that they are assumed to be never-smokers. The difference between the predicted expenditures for the factual and counterfactual smokers (either current or former smokers) is the “excess cost” that can be attributed to smoking. The previously reported FDA model applied this “factual vs. counterfactual” approach to their lifetime cost models of smoking-attributable medical expenditures as laid out by Sloan and colleagues.(Sloan, Ostermann, Picone, et al., 2004) Models of factual vs. counterfactual tobacco users need to be developed for other tobacco products.

- ***Timing of benefits.*** The distribution of benefits over time should reflect fact that some disease risks return to that of a nonsmoker rapidly. For example, there are immediate reductions in risks of heart attacks and stroke after a smoker quits, and most of the excess risk is gone in 1-5 years. Hence early benefits can be quite large. The FDA model has previously assumed that healthcare expenditure reductions are spread out equally over time will underestimate the benefits of cessation and reduction in exposure. The distortion in the previously reported model is further compounded by discounting benefits over an exceeding long time horizon of over 80 years for young smokers.

- ***Treatment of consumer surplus.*** The FDA previously estimated the benefits of new warning label regulation, and then reduced the benefits by 50% to reflect lost consumer surplus – the lost benefits for those who quit smoking but derived pleasure from it. This discount has been increased, without any specific justification, to 70% in the regulatory impact analysis of the deeming rule. There are many reasons why this approach is inappropriate:

- The vast majority of smokers and other tobacco users begin to using these products as adolescents. Their demand for tobaccco does not conform to the assumptions of the competitive model, including rational decision making based on reasoned comparisons of risks and benefits of smoking or other tobacco use. By the time these young tobacco users develop the capacity for making more reasoned decisions, they are addicted to nicotine and find it very difficult to quit.
- Consumer surplus is estimated as the area under the demand curve in excess of the market price. However, in light of the negative externality imposed by secondhand smoke exposure of others, the true demand curve would be to the left of the demand curve reflecting market cigarette prices. This shifted demand curve reflects the marginal social benefits of smoking, as opposed to the individual marginal benefits. Thus, any consumer surplus would be diminished.
- Many adult smokers regret that they ever started smoking, and many began when the tobacco industry was arguing that cigarettes were not addictive. Thus, even adults made the decision to smoke with imperfect information.
- It is likely that the harmful health impacts of some of the proposed deemed products, particularly eCigarettes, will become apparent in the future. Those deciding to consume these products today are faced with incomplete information, and thus the assumptions of the market demand curve used to estimate consumer surplus are violated.

References

Barendregt J, Bonneau L, Van Der Mass P. The health care costs of smoking. New England Journal of Medicine. 1997;337:1052-7.

California Environmental Protection Agency. Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant. Sacramento, California: California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, 2005.

Grosse SD. Assessing cost-effectiveness in healthcare: history of the $50,000 per QALY threshold. Expert Rev Pharmacoecon Outcomes Res. 2008 Apr;8(2):165-78. doi: 10.1586/14737167.8.2.165.

Hodgson T. Cigarette smoking and lifetime medical expenditure. Milbank Quarterly. 1992;70:81-125.

King, B.A.; Peck, R.M.; Babb, S.D., "Cost-savings associated with prohibiting smoking in U.S. subsidized housing," American Journal of Preventive Medicine [Epub ahead of print], April 16, 2013.

Leu R, Schaub T. Does smoking increase medical expenditures? Social Science and Medicine. 1983;17:1907-14.

Levy, D.E.; Rigotti, N.A.; Winickoff, J.P., "Medicaid expenditures for children living with smokers," BMC Health Services Research 11: 125, 2011.

Martins-Green M, Adhami N, Frankos M, Valdez M, Goodwin B, Lyubovitsky J, et al. Cigarette smoke toxins deposited on surfaces: implications for human health. PLos ONE. 2014;9(1). Epub January 29, 2014.

Max W, Sung H-Y, Shi Y. Attention deficit hyperactivity disorder among children exposed to secondhand smoke: A logistic regression analysis of secondary data. Int J Nurs Stud. 2012;50(6):797-806.

Miller L, Max W, Sung H, Rice D, Zaretsky M. Evaluation of the economic impact of California's Tobacco Control Program: a dynamic model approach. Tobacco Control. 2010;19(Suppl 1):i68-i76.

Plescia, M.; Wansink, D.; Waters, H.R.; Herndon, S., "Medical costs of secondhand-smoke exposure in North Carolina," North Carolina Medical Journal 72(11): 7-1, January-February, 2011.

Satter, D.E.; Roby, D.H.; Smith, L.M.; Wallace, S.P., "Costs of smoking and secondhand smoke exposure in California American Indian communities (anniversary report)," Los Angeles, CA: UCLA Center for Health Policy Research, October 2010.

Sloan F, Ostermann J, Picone G, Conover C, Taylor D. The price of smoking. Cambridge, MA: MIT Press; 2004.

U.S. Department of Health and Human Services. The health consequences of involuntary exposure to tobacco smoke: A report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, Office on Smoking and Health, 2006.

U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 [accessed 2014 Apr 11].

Waters, H.R.; Foldes, S.S.; Alesci, N.L.; Samet, J., "The economic impact of exposure to secondhand smoke in Minnesota," American Journal of Public Health 99(4): 754-759, April 2009.