# Comment on FDA's reliance on lost consumer surplus as a cost of tobacco regulation

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Summary: The reliance upon lost consumer surplus as a cost of tobacco regulation is inconsistent with the spirit and letter of the Family Smoking Prevention and Tobacco Control Act of 2009. Recent critiques of the FDA's assumptions have emphasized the fact that a very large proportion of tobacco consumption starts at a young age and that the product is addictive. These two points are well established in tobacco research and behavior science, but as or more important, they are explicitly mentioned in the statutory Findings section of the FSPTCA (Section 2, Findings 3 and 4). Hence the equation of cigarette consumption with a benefit, and the concomitant assumption that regulation-induced reduction of tobacco products carries a reduction in consumer surplus, is in direct contradiction to the express findings of the Congress and thus inconsistent with the law governing the agency's regulation of tobacco.

## Introduction

The Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA) is an organic statute that covers a range of manufactured products that enter into interstate commerce and gives authority over these products to a single agency: the Food and Drug Administration. The core of these authorities rests in gatekeeping (Carpenter 2010). Gatekeeping authority rests in two institutional planks: (1) it is illegal to market new or revised products until, and unless and only if, the regulatory agency approves them explicitly for marketing, and (2) the regulator's decision as to whether or not to approve the product for marketing is explicitly premised upon a review of scientific evidence, at least part of which is produced before submission of the marketing application or "dossier." Gatekeeping authority is delegated to the FDA only for those products that are deemed to be of serious risk, but unlike the law governing drugs and devices, the FSPTCA recognizes no individual or social benefit from tobacco use and speaks at length about its dangers and the "public health crisis" caused by tobacco manufacturers (Section 2, Finding 29).

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The law differs in at least three critical respects from other laws governing FDA-regulated products: (1) it begins with an extensive discussion of the risks and harms associated with tobacco products; (2) it substitutes a public health standard for the safety and efficacy standards that have governed drugs and devices, and (3) it not only refrains from acknowledging the possibility of valuable innovation in tobacco products, but expresses doubt about the likelihood that innovation in tobacco products will yield individual or public health improvements. All three of these differences are critical for understanding the meaning of the law

## The Findings Section and Tobacco as an Addictive, Youth-Initiated Product

One of the most important sections of the FSPTCA – a sure guide to any interpretation of legislative intent and the meaning of the law – is found in the legislative "Findings" Section 2. That section is an extensive recitation of the factual and legal conclusions of Congress, summarizing a long national experience with tobacco products and their manufacturers over the course of the twentieth and twenty-first centuries. It summarizes a vast scientific literature and calls attention to legal decisions that shed doubt upon the business practices and veracity of tobacco product manufacturers.

[Table 1 about here.]

Table 1 displays a comparison of the FSPTCA with other FDA-related statutes and other statutes in the larger field of government regulation of health, safety, environment and economy. Save for the most recent legislation of the 1990s, statutes in the food and drug arena have largely been bereft of findings sections. The Federal Food Drug and Cosmetic Act of 1938, which gave the FDA pre-market authority over "new drugs," had no findings section. Nor did the 1976 Device Amendments, which officially extended FDA gatekeeping authority to medical devices, contain a findings section. The Kefauver-Harris Amendments of 1962, which added an efficacy requirement to the safety standard of the 1938 law for drugs and which strengthen the burden of proof for drug sponsors, contained one small paragraph of findings. When more recent statutes

are considered, we see that the Prescription Drug User Fee Act of 1992 (PDUFA) offered three findings sections scattered variously through the statutory text.

By comparison, the FSPTCA places its "Findings" section at the beginning of the statute and offers 49 separate planks of findings, totaling 2,280 words. In terms of placement and length, it is by far the most extensive and prominent "Findings" section in any statute governing the FDA. By comparison, an extensive bundle of statutes governing air pollution regulation that have been passed over a four-decade span – The Clean Air Act (CAA) of 1970 and its various amendments of 1977, 1990 and other years – have in total 45 planks with just over 1,700 words of findings sections, none of these located at the outset of the statutory text.

It is of course possible that the FSPTCA offers more legislative findings because it is a more recent statute, reflecting a trend that statutory and administrative law scholars have noted in their discussion of congressional findings. Yet if we consider an even more recent statute, one passed by the very same Congress that passed (and signed by the very same President who signed) the FSPTCA – the Dodd-Frank Financial Reform Act of 2010 – we observe far fewer findings planks and text, and note again that these are scattered throughout the text, pertaining most commonly to the immediate sub-sections they precede. When one controls for the number of words in the entire statute, the FSPTCA is again uniquely outspoken in the proportion of its text dedicated to congressional findings, with more than one findings plank for every two statutory pages (0.59 planks per page), fully three times (and almost four times) higher than the Clean Air Act (0.15 planks per page) and dozens of times higher than any other organic act concerning FDA activities.

It is therefore a reasonable conclusion that the Congress placed an extensive and multi-part "Findings" section at the beginning of the FSPTCA as a guide to those who would interpret it, including courts and agencies. What general judgments does this section express about tobacco products?

The FSPTCA begins with a presumption of doubt about tobacco products, calling tobacco use "a pediatric disease" (paragraph 2) and the "foremost preventable cause of premature death"

(paragraph 13), for which the "best alternative" to use is "cessation" (paragraph 34). Pointing to the severity of the "public health crisis caused by the tobacco industry" (paragraph 29), the Congress also holds that the tobacco industry should be "subject to ongoing oversight" (paragraph 8).

In characterizing tobacco products as objects of regulation, the law states clearly and quite early that the active ingredient in the products is addictive and that users start before they are legally able to purchase the products. Specifically, Findings 3 and 4 of the FSPTCA hold that

> "(3) Nicotine is an addictive drug.
>
> (4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products."

## Inconsistency of FDA Cost-Benefit Analysis with the Statute

As has been noted in recent press coverage, numerous criticisms have emerged to contest the FDA's assumption that reduced consumption induced by regulation represents lost consumer surplus. Chaloupka et al (2014, p. 12) offer an extensive methodological critique, yet they also make reference to the fact that this question has largely been decided by "society."

> "In discussing the issue of how to treat lost consumer surplus in this type of economic impact analysis, we decided that it was most informative to separate smokers into those who became regular smokers before the legal age of smoking, and those who become regular smokers thereafter. For the former group, society has clearly decided that the decision to initiate smoking is an irrational decision and any changes in their conventionally-calculated consumer surplus resulting from changes in their tobacco use in response to GWLs or other actions should not be counted as a cost in the economic impact analysis of FDA's rules on tobacco. This is illustrated by laws regulating youth access to tobacco products, including FDA enforcement of a national legal purchase age of 18 for tobacco products over which it has jurisdiction. We refer to this as the 'principle of insufficient reason' approach and argue that the benefits to those who started using tobacco products regularly before 18 years of age and who quit in response to FDA regulatory actions should not have any offset for lost consumer surplus."

The fraction of "consumer surplus" to be offset once young-age initiation and addiction is taken into account, in percentage terms as expressed by Chaloupka and others (2014), from 73.8

percent to 91.2 percent. Which is to say from three-quarters to over nine-tenths of the consumer surplus assumed by the FDA. Chaloupka et al (2014, p. 15) summarize the point as saying that "nearly all" of the consumer surplus calculation must be discarded.

> Given these issues, we conclude that nearly all of the 'lost pleasure' from tobacco use, as represented by conventionally measured consumer surplus, should not be included as a cost in FDA analyses of the economic impact of its tobacco regulations" (Chaloupka et al, 2014).

The point here is methodologically different from that advanced by Song, Brown and Glantz (2014) and Chaloupka et al (2014). In the form of the FSPTCA, "society" has indeed decided that the smoking initiation decision is irrational. Indeed, quite apart from any science, the first substantive section of the law states that the product is addictive and that "nearly all" tobacco users start before they are legal adults. **That the smoking decision is irrational is not only a result of science but a conclusion of law**, the very statute that alone gives the FDA powers to regulate tobacco products.

Another clue to legislative intent and statutory meaning regarding the possibility of consumer surplus experienced from cigarette consumption comes in how the FSPTCA treats product innovation. If there were clear benefits to be had from smoking that were recognized by Congress, then it would follow that product innovation over time might deliver heightened benefits by means of technological change. Yet *Congress in the FSPTCA concludes the opposite*, namely that "innovation" in tobacco products has been used not to deliver value but to heighten addiction and to increase the rate of initiation among young persons.

When it concerns the regulation of innovation in tobacco products, or changes in tobacco products, the FSPTCA's "Findings" section also counsels caution and doubt about innovation and its industrial sponsors. As concerns product innovation in the tobacco industry, there are at least two relevant findings in Section 2 of the FSPTCA. Congress expresses doubt about past innovations, stating that "light" and "low tar" cigarettes were no safer than the products they were, for some users, intended to replace, and that consumers were misled concerning the safety of these products (paragraphs 37 and 38). And in perhaps the most direct discussion of product innovation in the tobacco industry, the Congress in paragraph 49 cites the Kessler decision of

2006 to suggest that the tobacco industry deliberately manipulated their products to heighten their addictive potential.

> In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99-2496 (GK), August 17, 2006).

By contrast, it is notable that in other statutes in the drug and device regulation field, the Congress has explicitly recognized the value of possible product innovation in other domains of FDA product regulation. In drugs, for instance, the Food and Drug Administration Modernization Act of 1997 argued that "prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease" [P.L. 105-115, Title 1, Section 101, Findings; 111 Stat. 2298]. In other words, the Congress in FDAMA explicitly recognized certain new drugs as valuable to the public health. Not only is there no such direct analogous language in the FSPTCA, but the Findings section again sheds doubt upon two practices of industry innovation – the low tar and lights products and on manufacturing and packaging changes.

## Conclusion: Counting Reduced Tobacco Product Consumption as Lost Consumer Surplus is Unlawful under the FSPTCA

The FDA's authorities over tobacco products come from the FSPTCA *and only from that statute*. Previous attempts to regulate tobacco products as devices were declared unconstitutional (FDA v. Brown and Williamson Tobacco, Corp., 529 U.S. 120 (2000)). In approaching the analysis of a tobacco product, the meaning of law is not merely one among many considerations but is paramount. When the Congress directly states – at greater length and with greater clarity than it has with many other landmark pieces of legislation (see again Table 1) – that a product carries enormous risks and society-wide damage (findings 1 and 2), that the product is addictive and that initiation starts at a young age (findings 3 and 4), that the goal of legislation is to reduce smoking

and the damage ("the public health crisis") caused by smoking (Findings 6 and 29), it seems dubious and quite possibly unlawful for the agency that is granted powers under that statute to adopt an assumption that consumption of the regulated product has benefits which must be computed dollar-for-dollar by the amount of consumption reduced. Put simply, to assume that smoking reduction is a consumer surplus loss is to assume that smoking is directly beneficial for smokers and that the benefit is revealed in their individual and consumption smoking patterns. This precept is grossly inconsistent with the clearly stated purpose of law.

That fact that cost-benefit analysis is mandated by presidential executive order does not change this conclusion. Cost-benefit analysis of regulations is authorized from a series of executive orders, *all of which recognize that statutory law supercedes the provisions of these orders* when the statute speaks clearly and specifically on a matter. Hence the regulatory planning process proposed by President Clinton in 1993 in Executive Order 12866 stated that "these procedures shall be followed, to the extent permitted by law." And the Obama Administration's Executive Order 13563 recognizes explicitly that the net benefit criterion of regulation is itself subject to statutory law, which may supercede it: "As stated in [Executive Order 12866] and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify)" (emphasis added).

I conclude that the FDA's assumption that reduced smoking represents a consumer surplus loss is inconsistent not only with science but with the clear intent and meaning of the law that gives that agency its powers over tobacco products. This applies not only to the deeming rule but also to any other rule to which this assumption might be applied.

# References

Carpenter D. 2010. *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton: Princeton University Press).

Chaloupka F, Warner K, Acemoglu D, Gruber J, Laux F, Max W, Newhouse J, Schelling T, Sindelar J. 2014. "An Evaluation of FDA's Analysis of the Costs and Benefits of the Graphic Warning Label Regulation," Tobacconomics working paper, available at http://tobacconomics.org/wp-content/uploads/2014/08/TREW-manuscript_FINAL1.pdf (accessed most recently August 8, 2014).

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Song AV, Brown P, Glantz SA (2014). When health policy and empirical evidence collide: the case of cigarette package warning labels and economic consumer surplus. *American Journal of Public Health* 104(2):e42-e51.

| Table 1: Comparison of Findings Sections from Various Statutes in the Public Health and Regulatory Domains | | | | | | |
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| Statute | Total Planks of Statutory Findings | Words of Statutory Findings | Total Size of statute (words, pages) | Findings Planks per Page | Placement of Findings Section in Statute | Sources of Findings |
| Federal Food Drug and Cosmetic Act of 1938 | 0 | 0 | | 0 | No findings section. | 52 STAT. 1040 |
| Kefauver-Harris Amendments of 1962 http://www.gpo.gov/fdsys/pkg/STATUTE-76/pdf/STATUTE-76-Pg780.pdf | 1 | 116 words | 11 statutory ("stat") pages | 0.09 | Middle | 76 STAT. 780 |
| Medical Device Amendments of 1976 http://www.gpo.gov/fdsys/pkg/STATUTE-90/pdf/STATUTE-90-Pg539.pdf | 0 | 0 | 43 stat pages | 0 | No findings section. | 90 STAT. 539 |
| Prescription Drug User Fee Amendments of 1992 http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg4491.pdf | 3 | 166 words | 15 stat pages | 0.2 | Front | 106 STAT. 4491 |
| Family Smoking Prevention and Tobacco Control Act of 2009 | 49 | 2,280 words | 83 stat pages | 0.59 | Front; Section 2 | 123 STAT. 1776 |
| Clean Air Act of 1970 and Amendments of 1977, 1987, 1990 http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/pdf/USCODE-2008-title42-chap85.pdf | 45 | 1,708 words | 293 U.S. code pages | 0.15 | Scattered across numerous sections and laws passed in 1970, 1977, 1987, 1990 and 2005 | 42 U.S.C. 1573, |
| Dodd-Frank Financial Reform Act of 2010 http://www.gpo.gov/fdsys/pkg/PLAW-111publ203/html/PLAW-111publ203.htm | 9 | 465 words | 368,925 words; 848 stat pages | 0.011 | Scattered | 124 STAT. 1803, 124 STAT. 1872 |