Institute *for* Policy Integrity

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Food and Drug Administration

Subject: Comments on the "Deeming Tobacco Products" Proposed Rule, Docket No. FDA-2014-N-0189, RIN 0910-AG38

The Institute for Policy Integrity at New York University School of Law[1] respectfully submits these comments to the Food and Drug Administration (FDA) on its proposed rule to deem certain tobacco products as subject to regulation, and on the preliminary regulatory impact analysis for that proposal. Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

FDA does not quantify the net benefits of the proposed rule, citing insufficient evidence on how the rule will affect the incidence of smoking. Instead, FDA engages in break-even analysis: by monetizing benefits per positive health outcome from reduced smoking, the agency calculates how many discounted, quality-adjusted life-years would have to be saved so that benefits at least equal costs. Break-even analysis is a useful tool in these circumstances, but the analysis should be as balanced and accurate as possible. Here, FDA may be dramatically understating the monetary value of the benefits from changes in consumer behavior following regulation of new tobacco products. Developing a more balanced and accurate presentation of benefits is essential, not just to highlight the social value of this proposed rule, but also to set the right precedent for analyzing future agency regulations of tobacco and other addictive and status-driven consumer products.

FDA must transparently justify its choice to discount potential benefits to account for any assumed lost welfare. The regulatory impact analysis states—with little explanation—that it will use "a welfare gain ratio of 30 percent," in effect discounting 70% of the rule's potential benefits.[2] FDA presumably intends this ratio to account for any lost consumer welfare experienced by those who will stop or never start smoking due to regulation of these additional tobacco products: in other words, to account for the lost pleasure of smoking. The percentage seems to have been arbitrarily selected from a range of internal welfare gain estimates calculated by a single study.[3] No further justification, reference to precedents, or balanced review of the academic literature accompanies this key and drastic decision to cancel out 70% of the rule's health and welfare benefits. The nearly complete lack of explanation violates best practices for regulatory analysis, as distilled by the Office of Information and Regulatory Affairs' *Circular A-4* (2003). In the final rule and final regulatory impact analysis, FDA must transparently justify all key assumptions, including any discounting of benefits to account for lost consumer welfare.

FDA must weigh the potential magnitude and duration of consumer welfare loss against a variety of countervailing factors, including the beneficial reduction of tobacco's positional externalities. Regulation of new tobacco products may trigger some amount of consumer welfare loss over some amount of time. However, determining the exact magnitude and length of any such

[1] No part of this document purports to present New York University School of Law's views, if any.

[2] FDA, *Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189*, at 52 (2014).

[3] *Id.* (referencing p.16, which cites a study by Gruber).

loss requires careful consideration of a number of factors. FDA's assumption that lost consumer welfare would cancel out 70% of all health benefits is under-explained, but on its face is potentially an extreme over-estimate that overlooks offsetting factors. Other commenters and economists have already noted how consumers' perceived benefits from smoking may actually be tempered by the presence of *intra-personal market failures*, like addiction, self-control problems, optimism bias, and time-inconsistent preferences, as well as *informational market failures*.[4] One economic study found empirical evidence suggesting that, over both the short- and long-term, cigarette taxes in fact increased the reported happiness of likely smokers, a result perhaps explained by correcting the intra-personal market failure of time-inconsistent preferences.[5]

Tobacco products also generate *inter-personal market failures*, including negative positional externalities, which may further offset any potential lost consumer welfare. Because consuming a positional good like tobacco inflicts a negative externality on other consumers, some of the assumed consumer welfare may never have been realized to begin with.

A "positional good" is something for which value depends strongly on how it compares with the things owned by others.[6] The owner of a positional good potentially derives more welfare from that good than expected when considering only its functional qualities. In particular, highly visible consumption acts as a signal for status,[7] and people value status because they anticipate it will translate into more favorable treatment in economic and social interactions.[8] For example, jewelry and silk ties have very little functional value, but their consumption is conspicuous and conveys status to others.

Tobacco products generally—and perhaps especially some of the tobacco products at stake in this proposed rule, such as premium cigars, e-cigarettes, and novel products—are likely to be valued by consumers at least partially for their positional value. Theory predicts that more visible goods are more positional; empirical evidence finds that among 31 expenditure categories (from food to mobile phones), U.S. consumers rate tobacco products as the single most visible purchase, beating out even cars,[9] the most classic example of a good with positional value.[10] (In contrast, other expenditures affected by smoking, like health care and life insurance, ranked as the 23rd and second-to-last categories on visibility.[11]) That evidence came from a 2004 survey, which predated

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[4] *E.g.*, Comments from Anna V. Song, Paul Brown, &Stanton A. Glantz, to FDA, on the Inappropriate Application of a Consumer Surplus Discount in the FDA's Regulatory Impact Analysis (May 30, 2014); *see also* Frank J. Chaloupka et al., *An Evaluation of FDA's Analysis of the Costs and Benefits of the Graphic Warning Label Regulation* (2014), *available at* http://tobacconomics.org/wp-content/uploads/2014/08/TREW-manuscript_FINAL1.pdf.

[5] Jonathan H. Gruber & Sendhil Mullainathan, *Do Cigarette Taxes Make Smokers Happier?*, 5 ADVANCES IN ECON. ANALYSIS & POLICY 1 (2005).

[6] Robert H. Frank, *The Demand for Unobservable and Other Nonpositional Goods*, 75 AM. ECON. REV. 101, 101 (1985).

[7] *Id.* at 107.

[8] Y. Weiss & C. Fershtman, *Social Status and Economic Performance: A Survey*, 42 EURO. ECON. REV. 801, 802 (1998). Status can be instrumental, in that higher status can carry better consumption opportunities, access to better employment, and even better marriage prospects. Ed Hopkins & Tatiana Kornienko, *Running to Keep in the Same Place: Consumer Choice as a Game of Status*, 94 AM. ECON. REV. 1085, 1087 (2004). Factors like psychology, biological hardwiring, and envy also should not be ignored.

[9] Ori Heffetz, *A Test of Conspicuous Consumption: Visibility and Income Elasticities*, 93 REV. OF ECON. & STAT. 1101, 1106 (2011).

[10] *See*, *e.g.,* Fredrik Carlsson et al., *Do You Enjoy Having More than Others? Survey Evidence of Positional Goods*, 74 ECONOMICA 586, 588, 593 (2007).

[11] Heffetz, *supra* note 9.

the recent rise of many novel tobacco products. Anecdotal evidence about these more novel products indicates that consumers already romanticize the flashy brands and technical specifications of vaping devices.[12] In fact, the expanding catalog of branded flavors for new products may increase their visibility, as the smell can linger even after the consumption is over.[13]

The positional value of goods can vary depending on the relevant population competing for social status.[14] In recent years and in certain segments of the U.S. population, especially at higher incomes, smoking may no longer be used to advertise social status and may in fact risk conveying the negative signal of self-control problems: "while smoking an expensive brand is likely to be perceived as more prestigious than smoking a cheap brand, forgoing this expenditure altogether (by not smoking) might be perceived as more prestigious than both."[15] Stigma generated by regulation and informational requirements for tobacco products has contributed to this shifting social norm. Nevertheless, within certain populations, for certain products, and under certain regulatory scenarios, tobacco will continue to have strong positional value. Youth (and others) remain highly susceptible to peer pressures,[16] and novel products are already winning footholds in high school parties.[17] Premium cigars will remain status symbols. Flashy advertising and lax regulation could work to reverse some of the more recent social norms and increase tobacco's status value.[18]

The trouble with positional value is that it may never increase aggregate consumer welfare, because positional goods generate a negative externality. If Joan buys the newest, most conspicuous vaping device to move up the status hierarchy in her peer group, John's own flashy vaping device is no longer as rare. John feels relatively worse off, and would have to invest in other symbols of status just to restore his previous social position. John's subsequent expenditures make Joan feel once again behind the social curve, despite her tobacco purchases.

Because smoking decisions are made non-cooperatively but in fact alter the welfare and consumption patterns of others, consumers get stuck on a "positional treadmill," continually chasing after enhanced welfare that never materializes.[19] Yet it would be exceedingly difficult for

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[12] One user describes his three regular vaping devices as "a Kanger Pro II with a 2.4-ohm coil atomizer and 2,900-milliamp battery and Caribbean-peach flavored nicotine; a Copper Nemesis; and the LA Edition Sentinel, with a 22-millimeter drip tip," referring to the last as "the Lamborghini." Matt Richtel, *Where Vapor Comes Sweeping Down the Plain: E-Cigarettes Take Hold in Oklahoma*, N.Y. Times, Apr. 26, 2014.

[13] *See* Heffetz, *supra* note 9, at 1105 n.12.

[14] *See* Carlsson et al., *supra* note 10, at 590.

[15] Heffetz, *supra* note 9, at 1110 n18.

[16] FDA, *Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189*, at 13 (2014).

[17] Matt Richtel, *E-Cigarettes, by Other Names, Lure Young and Worry Experts,* N.Y. Times, Mar. 4, 2014.

[18] According to Michael Eriksen, former director of CDC's Office on Smoking and Health, "The marketing of it is of particular concern because not only is it glamorizing and in some ways sexualizing e-cigarettes, there is a concern that it is going to renormalizing smoking. . . . A lot of the progress we've made around the world is to denormalize smoking, from it becoming a popular and attractive thing to do to in some ways a deviant behavior. The way e-cigarettes are being marketed, it really may have the effect of making not only e-cigarette use but smoking in general more desirable." Interview with *The Take Away*, Jan. 27, 2014, *available at* http://www.thetakeaway.org/story/look-e-cigarettes-whos-using-and-where.

FDA briefly acknowledges without further analysis that the effect of tobacco regulation on social norms can generate benefits. FDA, *Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189*, at 13 (2014). Positionality is related to, but analytically distinct from, social norms.

[19] *See* Robert H. Frank, *Positional Externalities Cause Large and Preventable Welfare Losses*, 95 AM. ECON. REV. 137, 137 (2005).

any individual consumer to opt out of this "expenditure arms race" and voluntarily move backwards on the status hierarchy.[20]

Tobacco regulation, therefore, is a cooperative solution that allows consumers to achieve what they could not in the non-cooperative open market: an aggregate reduction in the incidence of smoking without radically upsetting the status hierarchy. If John had never bought a flashy vaping device to begin with, Joan would have never experienced the negative externality that motivated her to engage in the fruitless effort to catch up on the status hierarchy by consuming tobacco.

FDA should consider what portion of the allegedly positive consumer welfare from smoking is actually derived from tobacco's positional nature, and so would be offset by the negative externality of positionality.

FDA should clarify which externalities it is considering, and should quantify the full range of costs and benefits, including ancillary benefits. FDA's analysis mostly focuses on benefits generated from the correction of intra-personal and informational market failures. FDA seems to equate "the full value of the welfare gains attributable to the reduction in tobacco product use" with "the full welfare gains *accrued to the dissuaded tobacco product user*."[21] Of course, the dissuaded tobacco user is not the only person who benefits from regulation, because tobacco inflicts harmful inter-personal externalities. At times, FDA does briefly allude to a few social benefits, including "medical services freed for other uses"[22] and "reduction in second-hand smoke exposure."[23] Yet there is no analysis of these external benefits, even though the *Circular A-4* requires the monetization, whenever feasible, of all important effects, including ancillary benefits.[24] Important externalities for FDA to consider include effects from second-hand, third-hand, and maternal smoke; lost productivity from smoking-related diseases; fires linked to smoking; healthcare burdens; environmental effects from production and disposal of tobacco products; and positionality.

FDA should adjust its valuation of health outcomes, to account for dread and suffering, and to harmonize with other agencies' values. FDA states that the relevant benefits include "the discounted value of life-years gained, health status improvements, and medical services freed for other uses." First, FDA should consider moving away from the quality-adjusted life-years framework and toward valuing morbidity and mortality risk reductions.[25]

Second, while discounting is generally appropriate when monetizing benefits that accrue to the same individual over time, the conventional wisdom on discounting "needs a mild corrective. People may generally prefer receiving benefits now rather than later, but they do not always hold that preference. Sometimes people are affected by dread."[26] Dread may be especially significant during a long-latency, life-threatening disease, like the kind of illnesses caused by smoking, in the period between diagnosis and mortality. Discounting of adverse consequences during the latency period, therefore, should be coupled with an increase in the estimated harm as a result of dread.[27]

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[20] Frank, *supra* note 6, at 105-06.

[21] FDA, *Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189*, at 15-16 (2014).

[22] *Id.* at 16.

[23] *Id.* at 18.

[24] Office of Information and Regulatory Affairs, *Circular A-4*, at 26 (2003).

[25] For arguments against the quality-adjusted life-years framework, see RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH 77-94 (2008).

[26] *Id.* at 96.

[27] *Id.* at 104.

Similarly, many long-latency diseases entail just not ultimate mortality, but significant periods of morbidity and suffering. The willingness-to-pay to avoid a cancer death may be roughly double the valuation of avoiding instantaneous death.[28] The earliest studies on the value of statistical life were based on data from instantaneous accidents, not latent harms. FDA admits that its estimated range for the value of life-years may need to be adjusted upward to fit more recent studies.[29] More generally, FDA should harmonize its valuations of health outcomes with those used by other federal agencies, unless there is a valid reason for divergence. For example, EPA's National Center for Environmental Economics believes there is sufficient evidence to warrant an additional 50% cancer differential to the value of statistical life, to account for morbidity and suffering from cancer deaths.[30] FDA should follow EPA's more updated, state-of-the-art methodologies for valuing health outcomes wherever possible, and should harmonize with EPA and other agencies on a consistent value for avoided cancer deaths.

FDA should announce a timeline for retrospective review. FDA commendably commits to conduct a retrospective review of costs and benefits down the road.[31] The agency should announce a clear timeline for that review (for example, five years after regulations take effect).

Respectfully submitted,

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[28] *Id*. at 105-106.

[29] FDA, *Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189*, at 52 (2014).

[30] EPA Nat'l Ctr. for Enviro. Econ., *Valuing Mortality Risk Reductions for Environmental Policy: A White Paper* (2010); *but see* Letter from EPA Science Advisory Board to EPA Admin. Lisa Jackson, July 29, 2011 (encouraging EPA to further refine the cancer differential before using it in analysis).

[31] FDA, *Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189*, at 52 (2014).