FDA Should Use the Public Health Standard Mandated by Congress, Not a Cost-Benefit Analysis, to Evaluate the Impact of Proposed Regulations

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Stanton A. Glantz, PhD and Lauren K. Lempert, JD MPH

Center for Tobacco Control Research and Education
University of California San Francisco

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The FDA should not use the results of any Regulatory Impact Analysis (RIA, also known as cost-benefit analysis) when determining the scope and content of the final rule for four reasons:

1. FDA is required by law to use the public health standard enunciated in the Family Smoking Prevention and Tobacco Control Act to determine whether regulations are appropriate.
2. It is impossible to meaningfully monetize many, if not most, of the benefits of the proposed rule.
3. Discounting future benefits is in fundamental conflict with the intent of the Family Smoking Prevention and Tobacco Control Act, which is forward looking and preventative to modify the tobacco market in ways that improve public health both in the short term and in to the indefinite future.
4. Applying the public health standard requires the FDA to consider nonquantifiable benefits, including effects on vulnerable populations, in developing the final rule.

1. FDA is required by law to use the public health standard enunciated in the Family Smoking Prevention and Tobacco Control Act to determine whether regulations are appropriate.

In 2009 Congress mandated in the Family Smoking Prevention and Tobacco Control Act a public health standard for determining the appropriateness of tobacco product regulations. In contrast to some other legislation that created regulatory processes in other areas (e.g., the Safe Drinking Water Act[1])the FSPTCA makes no mention of the use of cost-benefit analysis as part of the process in developing implementing regulations.

The FSPTCA clearly states that FDA must determine whether a proposed tobacco regulation "would be appropriate for the protection of the public health."[2] Section 906(d) provides:

> The finding as to whether [a] regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the populations as a whole, including users and nonusers of the tobacco product, and taking into account –

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products. [2]

Executive Order 12866 Section 1(a) explicitly states that agencies must not select an approach that maximizes net benefits if "a statute requires another regulatory approach."[3] Indeed, OMB stated in Circular A-94[4] (referenced in and not replaced by Circular A-4) that guidelines enunciated in OMB Circulars do "not supersede agency practices which are prescribed by or pursuant to law…"[4]

The language of the Tobacco Control Act is plain and clear: FDA must evaluate proposed regulations using a public health standard and only a public health standard. Any application of a cost-benefit analysis in a way that would reduce the public health impact of the proposed rule would be contrary to prescribed law.

2. It is impossible to meaningfully monetize many, if not most, of the benefits of the proposed rule.

While cost-benefit analysis may be appropriate for analyzing monetary costs and benefits when the same individual or organization is paying the costs and reaping the benefits, that is not the case here. More important, many of the benefits of the proposed rule will be avoiding anguish and suffering caused by tobacco induced diseases, not only to actual or potential tobacco users, but to their families. As Ackerman and Heinzerling demonstrate in their book *Priceless,*[5] the central problem with this kind of analysis is that it relies on artificial efforts to monetize fundamental human values of life, health, autonomy (freedom of addiction), and the future (Ackerman, Heinzerling p. 8).

Our societal values reflect the universally held belief that human life cannot be monetized. For example, as Ackerman and Heinzerling observe, "[t]he fact that some families may receive, say, $3 million for the wrongful death of a loved one does not mean that we should allow people to kill other people as long as they are willing to pay $3 million for the privilege" (Ackerman, Heinzerling, p. 157) It is illogical, as well as immoral, to monetize the value of human life. While a comparison of net costs with net benefits may be appropriate for considering an individual's personal financial investment opportunities with financial payoffs in the future, the logic does not apply to positive outcomes such as long life and good health that cannot be translated into dollar terms or to opportunities far in the future (Ackerman, Heinzerling, pp. 181-182). **FDA should not equate lives and money.**

3. Discounting future benefits is in fundamental conflict with the intent of the Family Smoking Prevention and Tobacco Control Act, which is forward looking and preventative to modify the tobacco market in ways that improve public health both in the short term and in to the indefinite future.

Computing discounted present values of (inappropriately) monetized benefits further reduces the value of these benefits because many (but by no means all) of the benefits of tobacco control accumulate in the future.[*] Discounting future benefits is intrinsically biased against young people (including those not yet born) because the benefits of the proposed regulation are years into the future as well as biased against old people because they will not live long enough to build a long-term benefits stream. These issues are particularly important since one of the central aims of the Family Smoking Prevention and Tobacco Control Act is to *prevent* youth from starting to use tobacco products. No discount rate could be chosen that would be appropriate because the basic premise underlying discounting is wrong. As Ackerman and Heinzerling observed, **"Since lives are not money, and do not have a meaningful price, they are not eligible for discounting."** (Ackerman, Heinzerling, p. 191)

4. Applying the public health standard requires the FDA to consider nonquantifiable benefits, including effects on vulnerable populations, in developing the final rule.

OMB Circular A-4 on "Regulatory Analysis"[6] provides OMB's guidance on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order 12866Section 6(a)(3)(c) provides that agencies must provide the OMB Office of Information and Regulatory Analysis (OIRA) an assessment of the costs and benefits anticipated from a proposed regulatory action, including "***to the extent feasible***" a quantification of those costs and benefits.[3] However, as discussed above, such a quantification is *not* feasible in cases such as this where one cannot put a price on the value of human life or the cost of suffering, the costs may not be felt until 20-40 years in the future, and the benefits would not necessarily be realized by the same people who would accrue the costs. And even if it were feasible to quantify, to a certain extent, the intangible values of life, health, comfort, dignity, equity, and fairness, Section 1(a) of Executive Order 12866 clearly states that "costs and benefits *shall* be understood to *include both* quantifiable measures… ***and qualitative measures*** of costs and benefits that are difficult to quantify, but nevertheless essential to consider [emphasis added]."[3] The Executive Order explicitly recognizes that agencies must not slavishly rely only on quantifiable measures, but agency analyses are required to also consider qualitative factors.

Precisely because these qualitative benefits cannot be quantified, they cannot be integrated into a quantitative cost-benefit analysis (or discounted). Basing decision making on the quantitative analysis alone has the unstated effect of setting the value of all qualitative benefits to zero.

Indeed, OMB states in Circular A-4:

> It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one

[*] This position is different from what Dr. Glantz elucidated in a previous comment (Glantz S, "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," tracking number 1jy-8c1p-z03c), written before reading *Priceless*, that stated that discounting future benefits is "appropriate." This comment replaces that conclusion. (The other points made in the earlier comment about the fact that the FDA ignoring the short term benefits of the proposed deeming rule stand.)

with the largest quantified and monetized net-benefit estimate. In such case, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis.[6]

FDA should exercise its professional judgment as required by Circular A-4 and (1) give much greater attention to the nonquantifiable benefits of the proposed rule and, (2) not compute a "net benefit" by subtracting the discounted present value of incompletely and inappropriately monetized benefits to the population from costs to industry of complying with regulations designed to protect the public health.

Executive Order 13563, issued in 2011, directs each agency to not only quantify anticipated present and future benefits and costs, but also directs them to consider and discuss qualitatively "values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts." [7]

The tobacco industry has a long history of lying to and deceiving the public about the dangers of tobacco products[8] and of targeting exploitive marketing to particular ethnic groups and individuals of lower socio-economic status. Because of this, the toll of tobacco disproportionately impacts these individuals and groups. Executive Order 13563 requires FDA to consider qualitatively values of fairness and distributive impacts.

The FDA RIA completely ignores these important aspects of the proposed rule. These considerations need to play an important role in ensuring that the final rule equitably protects all Americans, particularly the most vulnerable who are routinely targeted by the tobacco industry.

Any executive summaries and summary tables of the results of the RIA should include nonquantifiable effects at the same level of prominence as any quantified effects. Because these nonquantifiable effects of the final rule are likely to be large, the FDA should not compute an arithmetic net cost or benefit in the RIA of the final rule.

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[1] The Safe Drinking Water Act, P.L. 104-182 (1996), 42 U.S.C. 300f et seq.
[2] Family Smoking Prevention and Tobacco Control Act, P.L. 111-31 (2009), section 906(d)
[3] Executive Order 12866 of September 30, 1993, *Regulatory Planning and Review*, Federal Register Vol. 58, No. 190 (Oct. 4, 1993, Presidential Documents)
[4] Circular A-94, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs* (Revised 1992), http://www.whitehouse.gov/omb/circulars/index.html.
[5] Ackerman F., Heinzerling L., *Priceless: On Knowing the Price of Everything and the Value of Nothing.* The New Press, New York (2004)
[6] OMB Circular A-4, *Regulatory Analysis* (September 17, 2003)
[7] Executive Order 13563, *Improving Regulation and Regulatory Review* (January 18, 2011)
[8] *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part & vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam), *cert. denied*, 561 U.S. ___, 130 S. Ct. 3501 (2010)