From: Nardinelli, Clark
To: Glantz, Stanton A
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.
Subject: RE: Response to question
Date: Tuesday, January 15, 2013 2:03:28 PM

We respectfully disagree with your characterization. The data and methods used in our analyses are all specifically documented in the Federal Register. We believe that we have fully responded to your request.

From: Glantz, Stanton A [mailto:glantz@medicine.ucsf.edu]
Sent: Tuesday, January 15, 2013 3:48 PM
To: Nardinelli, Clark
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.; Anna Song
Subject: RE: Response to question

Thanks for the link. Through the magic of Google, I actually found it.

I have now read most of the papers that you listed and must respectfully disagree with your statement that " All the listed references deal with the empirical assessment of consumer surplus to some degree." Many of them do not mention consumer surplus at all and none of the others that I have reviewed (so far) present any *empirical* evidence to support the numbers in the rule. (There are some *theoretical* arguments, but no empirical evidence.)

So, I renew my request for you to point me to the specific papers that you used "in carrying out" the calculation. I would not think that this would be all that hard to do given that you did the calculations.

I look forward to hearing from you.

From: Nardinelli, Clark [mailto:Clark.Nardinelli@fda.hhs.gov]
Sent: Tuesday, January 15, 2013 12:26 PM
To: Glantz, Stanton A
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.
Subject: RE: Response to question

Can you send a link to this document?

http://www.gpo.gov/fdsys/pkg/FR-2011-06-22/pdf/2011-15337.pdf

Which of these references deal with the empirical assessment of consumer surplus for tobacco use?

All of the listed references deal with the empirical assessment of consumer surplus to some degree. The analysis also draws heavily on applied microeconomics and the literature on consumer surplus. We limited references to items directly cited in carrying out or explaining the calculation.

From: Glantz, Stanton A [mailto:glantz@medicine.ucsf.edu]

Sent: Monday, January 14, 2013 5:54 PM
To: Nardinelli, Clark
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.
Subject: RE: Response to question

Can you send a link to this document?

Which of these references deal with the empirical assessment of consumer surplus for tobacco use?

From: Nardinelli, Clark [mailto:Clark.Nardinelli@fda.hhs.gov]
Sent: Monday, January 14, 2013 2:11 PM
To: Glantz, Stanton A
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.
Subject: RE: Response to question

The economic methods and data used by FDA are described in the benefits section of the final rule [*Federal Register* Vol. 76, No. 120 (June 22, 2011): 36628], pp.36719-36728. Additional explanations are in the technical appendixes, pages 36655-36775. The reference list begins on page 36748. Key economics references include numbers 103 -112, 115-117, 121, 131-134, 181-183.

From: Glantz, Stanton A [mailto:glantz@medicine.ucsf.edu]
Sent: Monday, January 14, 2013 4:00 PM
To: Nardinelli, Clark
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.
Subject: RE: Response to question

Thank you for your response.

I do not recall a "collection of papers" that were cited in your consumer surplus discussion on the cigarette warning rule, just one paper by Cutler that raised it as a theoretical issue. Please send citations to the papers you refer to. I am particularly interested in the empirical base that FDA used in selecting the discount it is using.

From: Nardinelli, Clark [mailto:Clark.Nardinelli@fda.hhs.gov]
Sent: Monday, January 14, 2013 12:39 PM
To: Glantz, Stanton A
Cc: Lurie, Peter; Kux, Leslie; Bertoni, Malcolm; Clarke, Elizabeth; Elliott, Kimberly A.
Subject: Response to question

From: Glantz, Stanton A [mailto:glantz@medicine.ucsf.edu]
Sent: Saturday, January 05, 2013 07:27 PM
To: Deyton, Lawrence; Ashley, David
Subject: Consumer surplus

Can you point me to other FDA cost-benefit analyses that included a consumer surplus discount?

I've been told that the tobacco warning rule was the first time it was done, but want to check.

From: CTP EXECSEC
Sent: Monday, January 07, 2013 3:14 PM
To: 'glantz@medicine.ucsf.edu'
Cc: Deyton, Lawrence; Ashley, David; Lindblom, Eric
Subject: Consumer surplus

Thank you for your inquiry regarding FDA cost-benefit and analyses. Since your question pertains to agency-wide regulatory documents, we have forwarded your inquiry to the FDA Office of Policy for a response. This is the office responsible for preparing Regulatory Impact Analyses on behalf of the Agency and the economists working there will be better able to answer your question. We will keep track of the status of your inquiry and forward the response as soon as we receive it.

Executive Secretariat Staff
Office of the Center Director

FDA response:

In all our regulatory impact analyses, FDA calculates the net benefits of regulations as the sum of the estimated net changes in consumer surplus, producer surplus, and government surplus. Our standard practices use the methods of applied microeconomics and follow the general recommendations to all government agencies embodied in Office of Management and Budget Circular A-4. The method we used to calculate the net change in consumer surplus for the cigarette graphic warnings final rule is merely an application of the standard applied microeconomic principles used in the government's regulatory impact analyses. Circular A-4 instructs: "You should include [the following] effects in your analysis and provide estimates of their monetary values when they are significant: ... gains or losses in consumers' or producers' surpluses" (p. 37).

Admittedly, FDA's regulation of tobacco products raises novel issues, as the product carries unique dangers and no recognized medical benefits. However, even for tobacco products, consumer surplus is a key component of the analysis of dissuaded smokers, as evidenced by the collection of peer-reviewed papers we cite in our consumer surplus discussion.

The previous analysis closest to the approach used for our tobacco analyses is the "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk" (*Federal Register*, Vol. 69, No. 28, Wednesday, February 11, 2004, p. 6788). The question was whether the consumer surplus from the effects of these products on weight control and exercise exceeded or fell short of the lost utility associated with the increased acute health risks of products containing ephedrine alkaloids. In that analysis, we estimated a wide range of net benefits (-$47 million to +$125 million) based on the degree that consumer utility incorporated the health risks posed by these products. Ephedra was removed from the market.

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