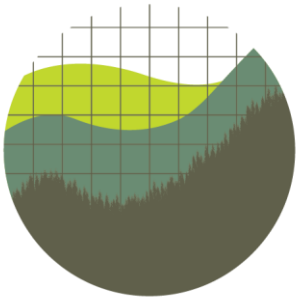

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

March 21, 2015

VIA ELECTRONIC SUBMISSION

Food and Drug Administration

Subject: Comments on the "General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products" Proposed Rule, Docket No. FDA-2015-N-1765, RIN 0910-AH14

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 restrict the use of sunlamps, 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.

To strengthen the justification for the proposed rule we recommend FDA take the following steps:

- Reevaluate the time-cost estimate of the risk acknowledgment form to further support the rule.
- Consider the negative externalities that accompany sunlamp use to avoid overestimating the consumer welfare loss from the restriction.
- Fully account for the health benefits of restricting sunlamp use.
- Avoid underestimating the habit effect by considering the addictive qualities of tanning.
- Account for existing state regulations to ensure an accurate assessment of the proposed rule's costs and benefits.

FDA should reevaluate the time-cost estimate of the risk acknowledgment form to further support the rule.

FDA estimates that sunlamp users will spend approximately two minutes reading the risk acknowledgment form each time it is presented to them, culminating in a total of 678,630–746,500 hours, at a cost of $14.5 million to 16.0 million.[2] However, studies show that users will spend far less than two minutes reading consent forms. In one such study, 70.7% of the participants spent approximately 30 seconds or less reading a 665-word informed consent document before signing.[3] Only 10.3% of participants spent more than a minute reading the document.[4] FDA's risk acknowledgment form, as currently drafted, contains 419 words.

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[1] No part of this document purports to present New York University School of Law's views, if any.
[2] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 26 (2015).
[3] Louise-Anne McNutt et al., *Are We Misjudging How Well Informed Consent Forms Are Read?*, 3 J. EMPIRICAL RES. ON HUM. RES. ETHICS 89, 91 (2008).
[4] *Id.*

Additionally, it is highly unlikely that users will continue to spend two minutes reading the form once they have seen it several times. Studies indicate that once a warning label is displayed repeatedly "people may engage in schematic or scripted behavior and systematically ignore part of [the label], not because the information is irrelevant, but because it is already known or avoided."[5] Authors of another study observed decreased attention to various warning messages, positing "consumers who are already familiar with the nature and content of a warning may not expend the effort required to attend to a warning once its contents are known"[6] and stating that consumers become "desensitized to warnings after repeated exposures."[7]

Accordingly, the evidence suggests that FDA's allotment of two minutes for users to read the form is unnecessarily high. If the time-cost of the risk acknowledgment form were reduced to one minute to better reflect consumer practices (still perhaps a conservative estimate), the cost of the form would be only $7.25 million – $8.0 million per year, 50% of FDA's current estimate.

FDA should also consider revising the risk acknowledgement form to include a more specific description of the risks of indoor tanning. As noted in one meta-study of warnings, "an explicit statement of the consequences associated with a particular action and the probability that a particular action will reduce the potential for harm may be more important in a message designed to persuade than one designed only to inform."[8] If FDA hopes to persuade users to reduce or cease indoor tanning use, it may be helpful to include an explicit statement of the probability of harm. However, there is some disagreement within the scientific literature as to whether readers are able to appreciate the meaning of specific statistics on warning forms.[9]

To that end, Appendix A provides alterations to the risk acknowledgement form to provide express statistics regarding the consequences of tanning to the individual. The proposed additions include the fact that indoor tanning before age 35 can increase the risk of melanoma by 59%[10] and this risk increases with each use,[11] and comparative statistics indicating that annually approximately 420,000 cases of skin cancer in the United States arise from indoor tanning, while approximately 203,500 cases per year of lung cancer in the United States arise from smoking.[12]

FDA should use its expertise to determine whether the inclusion of quantified risks as presented in Appendix A on the form would make the warning more effective, or if they would only detract from the effectiveness of the warning, and the current form should remain. As a recent Executive Order on behavioral sciences instructs, "agencies shall . . . improve how information is presented to consumers . . . by considering how the content, format, timing, and medium by which information is conveyed affects comprehension and action."[13]

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[5] J. Craig Andrews et al., *Effects of Consumption Frequency on Believability and Attitudes Toward Alcohol Warning Labels*, 25 J. CONSUMER AFF. 323, 328 (1991).
[6] *Id.* at 6.
[7] *Id.* at 4–5.
[8] David W. Stewart & Ingrid M. Martin, *Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical Research*, 13 J. PUB. POL. & MARKETING, 1, 3 (1994).
[9] W. Kip Viscusi & Richard J. Zeckhauser, Hazard Communication: Warnings and Risk, 545 ANNALS OF THE AM. ACAD. OF POL. AND SOC. SCI. 106, 111 (1996), http://www.jstor.org/stable/pdf/1047897.pdf ("People often cannot process and act on quantitative risk information in a reliable manner. Indeed, explicit quantitative information plays a prominent role only in pharmaceutical warnings, which are written for physicians… Rather than telling people the explicit probabilities involved, warnings typically use qualitative mechanisms to alert people to risk.").
[10] FDA, INDOOR TANNING: THE RISKS OF ULTRAVIOLET RAYS, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm186687.htm (last visited Mar. 11, 2016).
[11] AM. ACAD. OF DERMATOLOGY, INDOOR TANNING, https://www.aad.org/media/stats/prevention-and-care.
[12] Mackenzie R. Wehner et al., *International Prevalence of Indoor Tanning: A Systematic Review and Meta-analysis*, 150 JAMA DERMATOLOGY 390, 396 (2014).
[13] Exec. Order. 13707 § 1(b)(ii) (Sept. 15, 2015).

To strengthen the justification of the rule, FDA should consider the negative externalities that accompany sunlamp use to avoid overestimating the consumer welfare loss from the restriction.

FDA's economic analysis of the rule admits that it "indirectly estimate[s] the value of the utility lost by users who, as a result of this proposed rule, do not use sunlamp products."[14] Similarly, FDA "assigns no utility loss for persons under the age of 18 who would be prohibited from indoor tanning,"[15] claiming that it is "standard practice [to] assign[] zero utility loss or gain for the revealed preferences of minors over commodities."[16] The nearly complete lack of explanation contravenes 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, and FDA should weigh the countervailing factors that suggest the lost welfare is currently overestimated. FDA should consider the best evidence from behavioral economics, as instructed by recent Executive Order, "to reflect our best understanding of how people engage with, participate in, use, and respond to [federal] policies."[17]

First, sunlamp use generates interpersonal market failures that FDA must consider when determining the lost consumer welfare. Since the value in using sunlamps is heavily influenced by the positional value of having a tan, FDA should account for the negative externality associated with positional goods, and adjust their calculation of lost welfare accordingly. Any potential loss in consumer welfare will be mitigated by the reduction of the negative externality inflicted on other consumers through the positional goods effect.

A positional good is one whose value is dependent in part on how it compares with the things owned by others because it acts as a marker of social status.[18] Cigarettes, cars, and jewelry are common examples of positional goods; they are highly visible signals of social status that perpetuate competitive consumption. Additionally, theory dictates that more observable goods are likely to be positional.[19] The great visibility of suntans and the conceptualization by several scholars of tans as a possession that confers social status makes it highly plausible that suntans are a positional good. Scholars have posited that tanning can be an avenue for "performing and demonstrating social class," arguing that "an all-body tan is akin to stating to others that one has luxury time to spend and discretionary money to use. In effect, an all-body tan is a social class marker for the individual—a possession—that represents and symbolizes one's social class standing as well as, incidentally or ironically, a symbol of supposed health."[20]

Several studies of adolescent behavior have confirmed that indoor tanning practices are socially influenced and motivated. A 2007 study found that tanning behavior was linked to having parents and peers that used indoor tanning.[21] The study found that "adolescents who believed that their friends like to be tan were significantly more likely to have tanned indoors in the last 12 months."[22] Another study found that social influences, such as having friends who like to be tanned, and

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[14] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 27 (2015).
[15] *Id.*
[16] *Id.*
[17] Exec. Order 13707, preamble (Sept. 15, 2015).
[18] Robert H. Frank, *The Demand for Unobservable and Other Nonpositional Goods*, 75 AM. ECON. REV. 101, 101 (1985).
[19] *Id.*, at 107.
[20] WILLIAM MING LIU, SOCIAL CLASS AND CLASSISM IN THE HELPING PROFESSIONS: RESEARCH, THEORY, AND PRACTICE 166 (2011).
[21] Katherine D. Hoerster et al., *The Influence of Parents and Peers on Indoor Tanning Behavior: Findings from a Multi-city Sample*, 57 J. AM. ACAD. DERMATOLOGY 990, 991 (2007).
[22] *Id*.

perceived norms, such as the proportion of friends who have tanned indoors, were strong predictors of previous use of indoor tanning, as well as the intention to initiate and to continue indoor tanning.[23] Accordingly, it is very likely that the positional goods effect is at work in the tanning context.

The drawback of positional goods is that they decrease overall consumer welfare by generating a negative externality. When one consumer has a good that is anticipated to confer social status, the relative benefit to everyone in terms of status is diminished when others obtain that good. If Jane gets a tan to increase her status in her peer group, John may feel worse about his pale appearance and could then be driven to also get a tan.[24] John being tanned as well makes Jane's tan less unique, so the value of Jane's tan is diminished and her relative social standing falls back to a baseline level. Thus, individuals push each other to increase their consumption in order to derive a status benefit relative to others that will not materialize for any one person as long as everyone continues their consumption of that good. The ban on sunlamp use is therefore a cooperative solution to help consumers avoid the competitive and socially unproductive race to tan resulting from the positional goods effect. The loss in welfare for those affected by the rule will be limited since the benefit derived from tanning was dampened by the positional goods effect in the first place.

Second, FDA should address the alternatives to indoor tanning to avoid overestimating net lost consumer welfare. Consumers have the option of a number of non-UV substitutions for tanning, including bronzers, lotions, and spray tans that allow the individual to achieve the outward appearance of a tan without incurring the health risks of ultraviolet radiation. The active ingredient in such sunless tanners, dihydroxyacetone, is a safe alternative to UV tanning, serving as a substitute that will not reduce the health benefits of the ban.[25] A 2010 study of U.S. adolescents aged 11–18 found an association between indoor tanning use in the past year and the use of sunless tanning products, such as lotions or bronzers.[26] This correlation suggests that indoor tanning users may already be aware of non-UV forms of self-tanning, which could mean the users would rely more heavily on these products in the event of a ban.

While opponents to the ban may argue that the health benefits of the ban are limited by the potential for individuals to substitute natural tanning for sunlamps, research indicates that this poses a limited risk.[27] FDA should acknowledge the substitution potential, but support the rule by relying on scientific studies that show that the doses of UV radiation emitted by sunlamps can be 10 or 15 times higher than the radiation emitted by the midday sun, and that sunlamps produce an "amount of [UV] exposure that does not exist in nature."[28] Thus, even if outdoor tanning were substituted for sunlamps, most health benefits of the rule would still accrue. Additionally, FDA can point to studies by the CDC that indicate some of the highest rates of indoor tanning are found in

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[23] DeAnn Lazovich et al, *Characteristics Associated With Use or Intention to Use Indoor Tanning Among Adolescents*, 158 ARCHIVES PEDIATRIC AND ADOLESCENT MED. 918, 919 (2004).

[24] Alternatively, John could be driven to engage in fruitless spending on other positional goods, such as cigarettes or flashy clothing, in an attempt to match Jane's social status. Regardless of the specific status good purchased, be it tans or cigarettes, the result is the same: John's purchase of a status good diminishes Jane's welfare from her tan, and John's welfare will likewise suffer as other peers continue to compete in a never-ending battle for status that ultimately has no winners.

[25] ENVIRONMENTAL WORKING GROUP, DIHYDROXYACETONE, http://www.ewg.org/skindeep/ingredient/701979/DIHYDROXYACETONE/ (last visited Mar. 11, 2016).

[26] Vilma E. Cokkinides et al., *Use of Sunless Tanning Products Among US Adolescents Aged 11 to 18 Years*, 146 JAMA DERMATOLOGY 987, 987 (2010).

[27] B. Gerber et al., *Ultraviolet Emission Spectra of Sunbeds*, 76 PHOTOCHEMISTRY AND PHOTOBIOLOGY 664 (2002).

[28] *Id*

the Midwest, where natural sunlight is only a limited substitution option.[29] FDA must consider the ancillary costs of the rule, and can strengthen its justification by discussing the healthy substitution options that will lower the loss in consumer welfare.

Third, FDA can better justify the calculation of lost consumer welfare by acknowledging that artificial tanning creates time-inconsistent preferences. Scientific studies have demonstrated that artificial tanning has similar effects on individuals as addictive goods: creating both positive and negative reinforcement through the release of endorphins and potential for withdrawal if tanning is withheld. These side-effects indicate that indoor tanning creates intra-personal market failures where an individual makes a choice today that inflicts an uncompensated cost on their future self.[30] FDA should consider the benefits of preventing people from acting against their own better judgment and the increased impact on the number of future users from the habit effect of the ban.

Finally, FDA should justify its decision to ignore the preferences of minors. Contrary to FDA's position that the preferences of minors need not be counted,[31] "there is a clear consensus that children should be counted" in cost-benefit analysis.[32] FDA should support its decision to ignore the lost consumer welfare of minors in order to strengthen the justification for the proposed rule. The positional goods effect, the role of substitutes, and the addictive nature of tanning all may help FDA justify why minors will not experience measurable welfare losses from the ban.

Overall, these negative externalities that accompany the use of sunlamps provide guidance for the transparent justification of FDA's estimation of lost consumer welfare. In the absence of direct empirical data, FDA should avoid arbitrarily assuming that consumer welfare loss will equal some set percentage of total benefits,[33] and should avoid arbitrarily excluding a segment of consumers.[34] Instead, FDA should conduct a sensitivity analysis using a range of costs and then exercise its professional judgment to select the appropriate figure for measuring lost utility. As OIRA's *Circular A-4* recommends, "In the absence of adequate data, you will need to make assumptions. . . . [Y]our analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Worst-case or conservative analyses are not usually adequate because they do not convey the complete probability distribution of outcomes. . . . Use numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions."[35]

FDA seems to have chosen 25% of total benefits as a conservative assumption of the welfare losses potentially imposed by the rule.[36] Instead, FDA should consider a full range of potential values, from 1%-25%. While the rule likely will not be totally without welfare loss, there is also reason to believe that the externalities and inter-personal market failures described above indicate that the welfare loss will be lower than FDA's current conservative estimate.

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[29] CDC, USE OF INDOOR TANNING DEVICES BY ADULTS, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6118a2.htm (last visited Mar. 11, 2016).

[30] Stephen J. Hoch & George F. Loewenstein, *Time Inconsistent Preferences and Consumer Self Control*, 17 J. CONSUMER RES. 492 (1991).

[31] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 27 (2015).

[32] Dale Whittington & Duncan MacRae, Jr., *The Issue of Standing in Cost-Benefit Analysis*, J. POL'Y ANALYSIS & MANAGEMENT, Vol. 5 No. 4, 665, 666 (1986).

[33] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 27 (2015) ("Without any direct evidence…that value of lost utility is 25 percent of the willingness-to-pay for the reduced risk.").

[34] *Id.*

[35] *Circular A-4*, 40-41.

[36] *Id.*

To further justify the rule, FDA should fully account for the many additional benefits of restricting sunlamp use.

FDA "limit[s] [their calculation of] monetized benefits in this analysis to reductions in cases of melanoma, melanoma in situ, and other forms of skin cancer,"[37] even though the *Circular A-4* urges the monetization, whenever feasible, of all important effects, including ancillary benefits.[38] FDA admits that its calculation is "conservative," [39] but instead should include, to the extent feasible, a full calculation of monetized benefits including reductions in skin aging and cataracts.

The benefits calculation includes only an estimation of cancers averted, and fails to quantify the benefits of reductions in the other harms of indoor tanning and UV exposure. "Exposure to UV radiation can cause skin cancers including melanoma, burns to the skin and eyes, actinic keratosis, premature skin aging, and other health problems. The social costs associated with skin cancer alone are in the billions of dollars, so even a small percentage reduction in incidence would result in substantial benefits."[40] Yet despite these claims, FDA does not include these benefits in its calculation. If the impacts cannot be quantified, FDA should consider the qualitative impact of these benefits and conduct a break-even analysis to indicate the level at which the non-quantified benefits are significant to the overall analysis.[41]

Moreover, FDA "could not find suitable direct measures" of estimation, and relied on the value of a statistical life ("VSL") to estimate willingness to pay.[42] For cancers, the VSL does not sufficiently account for the dread and suffering associated with long-latency diseases. FDA should adjust its valuation of health outcomes to account for dread and suffering. FDA should consider to value morbidity and mortality risk reductions.[43] Additionally, 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."[44] While FDA states that relevant benefits include the discounted costs of reduction in cases of melanoma, it ignores the present cost of dread that may alter the traditional time preferences. Dread may be especially significant during a long-latency, life-threatening disease, 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.[45]

FDA can strengthen the justification for the rule by more accurately estimating the willingness to pay to avoid skin cancer. Many long-latency diseases entail not just 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.[46] The earliest studies on the value of statistical life were based on data from instantaneous accidents, not latent harms. FDA admits

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[37] *Id.* at 30.
[38] Office of Information and Regulatory Affairs, *Circular A-4*, at 26 (2003).
[39] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 30 (2015).
[40] *Id.* at 7.
[41] Office of Information and Regulatory Affairs, *Circular A-4*, at 2 (2003).
[42] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 31 (2015).
[43] *See* RICHARD L. REVESZ & MICHAEL A. LIVERMORE RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH 77–94 (2008) (describing the flaws in failure to consider the shift in individual discounting based on dread).
[44] *Id.* at 96.
[45] *Id.* at 104.
[46] *Id.* at 105–06.

that its estimated range for the value of life-years may need to be adjusted upward to fit more recent studies.[47]

To better justify the rule, FDA should fully avoid underestimating the habit effect by considering the addictive qualities of tanning.

FDA is underestimating the impact a change in habit caused by the restriction on minors will have on future sunlamp use. FDA should consider that artificial tanning is potentially addictive according to a number of studies. "When exposed to UV and non-UV under blinded conditions, frequent tanners can distinguish the two conditions and undertake further UV exposure, indicating that UV is a reinforcing stimulus."[48] "The relaxing and reinforcing effects of UV exposure contribute to tanning behavior in frequent tanners."[49]

Similar restrictions in other addictive products have had large impacts, reducing use by more than double the amount FDA assumes in this Rule. Currently, FDA estimates only a 5% reduction in future 18-year-old sunlamp users based on the restriction for individuals under the age of 18.[50] FDA acknowledges that "individuals who do not use sunlamp products as minors may be less likely to use them upon turning 18.[51] However, despite noting "a 10 percent decline in alcohol consumption… that carried over," and "a 14 percent reduction in lifetime smoking," FDA estimates the impact on tanning will be far lower.[52]

Finally, FDA should account for existing state regulations to ensure an accurate assessment of the proposed rule's costs and benefits.

A growing number of states and municipalities have already restricted or limited the use of indoor tanning for those under 18 years of age.[53] FDA should avoid double counting the effect of the rule on welfare in states with a ban already in place for those under 18, since there will be no change in access to sunlamps of those under 18 in these states. Eleven states, including California, Delaware, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, Oregon, Texas and Vermont, as well as the District of Columbia, already have a complete ban on indoor tanning for those under 18.[54] In total, 42 states have in place restrictions of varying degrees of stringency limiting access to tanning beds for those under 18. In states that have bans at age cutoffs other than 18,[55] a national ban set at 18 will have a partial impact on welfare. FDA can justify the rule as bringing uniformity to the national market and preventing individuals from driving across state lines to avoid a ban in their home state. Where feasible, FDA should account for these existing regulations when considering the costs and benefits of the rule in order to avoid the double counting of the rule's impacts.

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[47] FDA, Preliminary Regulatory Impact Analysis for Docket No. FDA-2014-N-0189, at 52 (2014).
[48] Steven R Feldman et al., *Ultraviolet Exposure Is a Reinforcing Stimulus in Frequent Indoor Tanners*, 51 J. AM. ACADEMY OF DERMATOLOGY 45 (2004).
[49] *Id.*
[50] U. S. Food & Drug Ass'n, FDA-2015-N-1765-0060, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products, 15–16 (2015).
[51] *Id.*
[52] *Id* at 11.
[53] NATIONAL CONFERENCE OF STATE LEGISLATURES, INDOOR TANNING RESTRICTIONS FOR MINORS – A STATE BY STATE COMPARISON, http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx (last visited Mar. 11, 2016).
[54] *Id.*
[55] Alabama bans those under 15, Connecticut 17, Georgia 14; Idaho 14; Maine 14; NJ 17; NY 17; ND 14; PA 16; WV 14; WI 16. *Id.*

Conclusion

The proposed rules take a significant step in reducing the risks of artificial tanning. However, before FDA finalizes new standards for the warnings and use of sunlamps, it should refine its regulatory impact analysis and rethink some of its policy choices. In particular, FDA should more realistically account for the time that will be spent reading risk acknowledgment forms. Moreover, it should fully and transparently justify the estimates of both lost consumer welfare and health benefits by considering the negative externalities associated with tanning and the wide range of health benefits not captured by an estimate of cancers avoided.

Respectfully submitted,

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Appendix A:

Risks of Indoor UV Tanning

Food and Drug Administration (FDA) regulations require all users to certify that they have read the information below regarding both the dangers of exposure to ultraviolet (UV) radiation from indoor tanning devices and the proper use of these devices.

- UV radiation from indoor tanning devices can cause:
    - Skin cancer, including melanoma, the type of skin cancer responsible for the most deaths
        - Indoor tanning before age 35 can increase your risk of melanoma by 59%[56] and the risk increases with each use[57]
        - Approximately 420,000 cases of skin cancer per year in the United States arise from indoor tanning, compared to approximately 203,500 cases per year of lung cancer in the United States arising from smoking[58]
    - Eye burns which can cause intense pain and negatively affect vision
    - Sunburn (discomfort, pain, tenderness on the skin)
    - Early skin aging, such as wrinkles and age spots

- You must not use this device if you are under 18 years of age.

- Do not use if you have skin that easily sunburns or does not tan, as you are unlikely to tan with these devices and you are at a higher risk for developing skin cancer.

- Do not use if you have any rashes or open wounds.

- Do not use beyond the manufacturer's recommended exposure schedule to avoid burns and over exposure. The manufacturer's recommended exposure schedule can be found on the device.

- Please consult your doctor or your pharmacist about any medicines that you are taking before using indoor UV tanning devices. Certain medicines (for example, tetracycline) or skin products (for example, some cosmetics) can increase your sensitivity to UV radiation.

- Use appropriate protective eyewear. Failure to do so may result in short-term and long-term injury to the eyes such as severe burns, cataracts, or eye cancer. Unprotected exposure to the intense visible light from some indoor tanning devices can cause damage to your vision, which may be permanent.

- Consult your doctor if you or someone in your family has a history of skin cancer because UV tanning (whether indoors or outdoors) carries a higher risk for you.

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[56] FDA, INDOOR TANNING: THE RISKS OF ULTRAVIOLET RAYS, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm186687.htm (last visited Mar. 11, 2016).
[57] AMERICAN ACADEMY OF DERMATOLOGY, INDOOR TANNING, https://www.aad.org/media/stats/prevention-and-care (last visited Mar. 11, 2016).
[58] Mackenzie R. Wehner et al., *International Prevalence of Indoor Tanning: A Systematic Review and Meta-analysis*, 150 JAMA DERMATOLOGY 390, 396 (2014).

- If you use indoor UV tanning devices and/or tan regularly outdoors, get regular skin cancer checkups from your doctor because you are more likely to develop skin cancer.

- Even if you follow these safety instructions, you are still at risk for skin cancer if you use indoor UV tanning devices.

- Report any injury, including burns, from the use of indoor UV tanning devices to FDA. You should make this report as soon as possible after the injury. Instructions for reporting are available at https://www.accessdata.fda.gov/scripts/medwatch/ or call 1-800-FDA-1088.

  I, _____, am at least 18 years of age and have read, understood, and acknowledged the risks and proper use information stated above.