



June 27, 2019

**VIA ELECTRONIC SUBMISSION**

Food and Drug Administration

**Attn:** Dockets Management Staff

**Re:** Sunscreen Drug Products for Over-the Counter Human Use, 84 Fed. Reg. 6204 (Feb. 26, 2019)

**Docket ID:** FDA-1978-N-0018

The Institute for Policy Integrity (“Policy Integrity”) at New York University School of Law<sup>1</sup> respectfully submits the following comments to the Food and Drug Administration (“FDA”) regarding its proposed rule to put into effect a final monograph for nonprescription, over-the-counter sunscreen drug products (“Proposed Rule”).<sup>2</sup> 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.

Our comments focus on the Economic Impact Analysis for the Proposed Rule. We recommend that FDA:

- make an express finding as to whether the Proposed Rule’s benefits are likely to outweigh its costs;
- assess the benefits of avoided fatal cancer cases using the full Department of Health and Human Services-recommended value per statistical life (“VSL”), rather than quality-adjusted life years (“QALYs”); and
- better explain why and how it used the King et al. study to calculate QALY values for avoided melanoma cases.

**I. FDA should make an express finding as to whether the Proposed Rule’s benefits are likely to outweigh its costs**

In the Economic Impact Analysis, FDA conducts a breakeven analysis to estimate “the number of cases of skin cancer [the Proposed Rule] would need to avoid for the benefits of the [P]roposed [R]ule to equal the costs of the [P]roposed [R]ule.”<sup>3</sup> The agency finds that, at “a 3

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<sup>1</sup> This document does not purport to present New York University School of Law’s views, if any.

<sup>2</sup> Sunscreen Drug Products for Over-the Counter Human Use, 84 Fed. Reg. 6204 (Feb. 26, 2019).

<sup>3</sup> FDA, Sunscreen Drug Products for Over-The-Counter Human Use; Proposal to Amend and Lift Stay on Monograph: Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Docket No. FDA-1978-N-0018, at 49 (2019) [hereinafter “Economic Impact Analysis”].

percent discount rate, the primary estimate of the annualized costs of the [P]roposed [R]ule would equal the annualized benefits” if the Proposed Rule “avoided 11,827 cases of basal cell carcinoma each year, 377 cases of melanoma each year, or 1,183 cases of squamous cell carcinoma each year.”<sup>4</sup> The agency does not indicate, however, whether it believes the Proposed Rule is, in fact, likely to avoid this many cases of cancer. That is, the agency does not ultimately reach a conclusion as to whether the benefits of the Proposed Rule are likely to justify the costs. In the final version of the Proposed Rule, FDA should make such a finding or explain why it is unable to do so.

## **II. FDA should assess the benefits of avoided fatal cancer cases using a full VSL rather than QALYs**

In its breakeven analysis, FDA estimates “willingness-to-pay to avoid the three types of skin cancer – melanoma, basal cell carcinoma, and squamous cell carcinoma – using a quality-adjusted life years approach.”<sup>5</sup> To the extent that any cancer cases avoided by the Proposed Rule would be fatal, however, FDA’s “primary benefit estimate” for these avoided mortalities should be based on a full VSL, as recommended in the Department of Health and Human Services’ *Guidelines on Regulatory Impact Analysis*.<sup>6</sup> QALYs, if used at all, should be confined to a sensitivity analysis, as they have been in previous FDA analyses.<sup>7</sup>

## **III. FDA should better explain why and how it used the King et al. study to calculate QALY values for avoided melanoma cases**

As support for its claims regarding the extent to which a diagnosis of melanoma reduces a consumer’s QALYs, FDA cites a pilot study by King et al.<sup>8</sup> But the data in this study were developed to “provide a starting point for future [cost-effectiveness analyses] evaluating melanoma *treatment and screening programs*.”<sup>9</sup> In other words, the study was designed to assess

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<sup>4</sup> *Id.* at 51.

<sup>5</sup> *Id.* at 49.

<sup>6</sup> Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis* 17 (2016).

<sup>7</sup> See, e.g., FDA, Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products: Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Docket No. FDA-2016-N-2527, at 32-35 (2017) (using VSL for primary estimate of benefits of reduced mortality from oral cancer, and QALYs for secondary estimate); FDA, General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products: Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Docket No. FDA-2015-N-1765-0060, at 31 (2015) (using VSL to value society’s willingness to pay to avoid a case of melanoma, without any secondary QALY analysis). For arguments against the use of quality-adjusted life years in regulatory cost-benefit analyses, see Richard L. Revesz & Michael A. Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* 77-94 (2008).

<sup>8</sup> Economic Impact Analysis at 50 tbl.36 & ref.29 (citing S. King et al., *Melanoma Quality of Life: Pilot Study using Utility Measurements*, 147 *Archives of Dermatology* 353-354 (2011)).

<sup>9</sup> King et al., *supra* note 8, at 354 (emphasis added).

the value of identifying and treating melanoma in patients who already have the disease. Here, by contrast, the Proposed Rule would, by improving the effectiveness of sunscreen, *prevent* the development of melanoma. In the final version of the Proposed Rule, FDA should explain (1) why the utility measures derived in the King et al. study are applicable to the effects of this rulemaking, and (2) exactly how the agency used those utility measures to calculate QALY values for avoided melanoma cases.

Respectfully,

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<sup>10</sup> Policy Integrity thanks Joy Kim and Russell Smith, students in New York University School of Law's Regulatory Policy Clinic, for assisting in the preparation of these comments.