4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0305]

Possible Role of Independent Third Parties in Industry-Sponsored Tobacco Product Research; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for data, information, and comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket for interested parties to submit to FDA comments on the Institute of Medicine's (IOM) recommendation regarding third-party governance of industry-sponsored tobacco product research.

DATES: Submit electronic or written comments by September 30, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0305, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Electronic Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-0305. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) (Tobacco Control Act). The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding chapter IX (21 U.S.C. 387 et seq.) and grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

FDA expects that tobacco product manufacturers will undertake tobacco product research as part of activities regulated under the Tobacco Control Act, including submission of applications for marketing orders under sections 910 and 911 of the FD&C Act. Section 911 of the FD&C Act requires FDA to issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products (MRTPs). Section 911(l)(2) requires that such regulations or guidance be developed in consultation with the Institute of Medicine (IOM), among others, on the design and conduct of such studies and surveillance. Pursuant to this requirement, the IOM convened a multidisciplinary committee and published a report in December 2011. In the report, entitled "Scientific Standards for Studies on Modified Risk Tobacco Products" (http://www.iom.edu/Reports/2011/Scientific-Standards-for-Studies-on-Modified-Risk-Tobacco-Products.aspx), the IOM notes that "governance of research is critical to the production of credible and reliable evidence."

Specifically, the IOM report states "[t]here is profound distrust of the tobacco industry and of research supported by the tobacco industry. This distrust is the direct result of the tobacco

industry's history of improperly influencing or manipulating scientific findings and messaging about the health effects of tobacco. This history and the lack of trust may prevent independent experts from participating in research on tobacco products and therefore may impede the production of data on MRTPs necessary to assess public health impact." The IOM also notes that "the tobacco industry currently lacks the infrastructure and expertise to independently produce the necessary evidence to support an application to market an MRTP."

As a result of these findings, the IOM recommends in its report that "MRTP sponsors should consider use of independent third parties to undertake one or more key functions, including the design and conduct of research, the oversight of specific studies, and the distribution of sponsor funds for research. Such independent third parties should be approved by the FDA in advance of the research."

The IOM report focuses on research to support MRTP applications, but FDA is also interested in information on third-party governance as it relates more generally to industry-sponsored tobacco research. FDA is interested in receiving information on whether some form of third-party governance should be considered for other types of industry-sponsored tobacco product research, including research to support premarket tobacco product applications and other submissions to FDA, as well as research designed to contribute to general knowledge regarding tobacco products.

II. Request for Comments and Information

As FDA considers how and whether to implement third-party governance of industry-sponsored tobacco product research, we are requesting comments on the IOM's recommendation. We encourage you to submit any available research or evidence to support your comments. FDA specifically requests comments on:

1. What are some potential models of third-party governance of industry-sponsored tobacco product research? What are the strengths and weaknesses of these models?
2. What criteria could FDA use to evaluate any potential model of third-party governance of industry-sponsored tobacco product research?
3. What role would various interested parties (e.g., individual researchers, academic institutions, for-profit and not-for-profit research organizations) play in a third-party governance model of tobacco product research?
4. Who would participate in a third-party governance model? How could a governance model be structured to reduce conflict of interest and bias in industry-sponsored tobacco product research?
5. What barriers, if any, would have to be overcome to encourage the broader scientific community to participate in a third-party governance model?
6. Are there unique research challenges faced by small manufacturers and how should they be addressed in a third-party governance model?
7. What kinds of tobacco product research could be subject to third-party governance? For example, could it be applied to:
    - Product testing?
    - Nonclinical studies?
    - Studies in human subjects? (e.g., health effects research, behavioral research, abuse liability studies, consumer perception research)
    - Computational modeling?
    - Postmarket surveillance?

8. What aspects of tobacco product research could be subject to third-party governance? For example, should both the design and conduct of research studies be subject to third-party governance?
9. Are there governance models or other steps FDA can take that are more effective for overseeing research to produce generalizable knowledge, such as establishing better testing/ research methods and standards, compared to specific product research?

III. Submission of Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: March 27, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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