



Encourage the FDA to Implement a Third-Party Governance System for Tobacco Product Research

The U.S. Food and Drug Administration (FDA) is currently considering whether to accept a recommendation from the Institute of Medicine (IOM) to implement a system of third-party governance for tobacco product research. Because of the tobacco industry's "history of improperly influencing or manipulating scientific findings and messaging about the health effects of tobacco,"¹ the IOM has recommended that the FDA implement a third-party governance system that ensures that the tobacco industry use "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."² The FDA is now accepting comments from the public on how and whether to implement third-party governance of industry-sponsored tobacco product research. Comments will be accepted until September 30, 2013.

It is critical that the FDA understand the importance of limiting the tobacco industry's involvement in the research process. The tobacco industry's long history of manipulating scientific research and creating front groups under the guise of independence to create and disseminate its biased study results should inform the FDA's decision-making on this topic. Consider submitting comments outlining the tobacco industry's misuse of science and its use of fake independent third parties to conduct research. Comments could also detail the reasons the FDA should not trust the tobacco industry to be a good faith participant in the research process. Information to supplement comments can be found in our publication, [*The Verdict Is In: Findings From United States v. Philip Morris*](#), a compilation of quotations from Judge Kessler's extensive findings of fact relating to the tobacco industry's history of deceptive behavior.

In addition to providing information on why the tobacco industry cannot be trusted to conduct or oversee scientific research, you can consider responding to the FDA's request for comments on the following issues:

- What are some potential models of third-party governance of industry-sponsored tobacco product research? What are the strengths and weaknesses of these models?
- What criteria could the FDA use to evaluate any potential model of third-party governance of industry-sponsored tobacco product research?

- 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?
- 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?
- What barriers, if any, would have to be overcome to encourage the broader scientific community to participate in a third-party governance model?
- Are there unique research challenges faced by small manufacturers and how should they be addressed in a third-party governance model?
- 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?
- 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?
- 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?

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Notes

¹ *Possible Role of Independent Third Parties in Industry-Sponsored Tobacco Product Research*, 78 Fed. Reg. 19713, 19713-14 (Apr. 2, 2013).

² *Id.* at 19714.