



## Getting Scientific Data to the FDA

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the U.S. Food and Drug Administration (FDA) unprecedented authority to regulate tobacco products.<sup>1</sup> The FDA exercises this authority through a process called rulemaking, which requires active public involvement in order for the best regulations to be adopted. Under federal law, the FDA is required to make its rulemaking decisions based on a record that is comprised of comments submitted by the public during an established timeframe.<sup>2</sup> This fact sheet is intended to give scientists and academics in the public health community an overview of the rulemaking process and information on how to be active participants.

### Q. How does the FDA create tobacco regulations?

A. The most common tool that federal agencies use to create new policy is a four-step process called rulemaking. First, an agency issues a notice of a proposed rule that is published in the Federal Register, a daily publication of all executive agency actions. This notice describes the action that the agency is considering taking regarding a particular topic and provides instructions on how an individual can comment with suggestions or changes to the proposal.<sup>3</sup> Immediately after this notice the comment period begins.<sup>4</sup> During this period, anyone can comment on the content of the agency's proposal, either in favor of or against the proposed regulation. After the comment period has expired, the agency must read and consider every comment that was submitted.<sup>5</sup> Once all comments are considered, the agency can issue its final rule, incorporating the comments. The final rule is also published in the Federal Register.



For more information on rulemaking, see our publication [Laws, Policies and Regulations](#).<sup>6</sup>

### Q. Are federal regulations enforceable?

A. While Congress is the only entity with the authority to enact federal statutes, an agency's properly issued rule has as much force of law as a statute passed by Congress. Agencies typically have greater subject matter expertise than Congress and are well situated to create nuanced policies. However, agency staff members are not democratically elected. As a result, there are several checks on the power of agencies to issue rules. One of these checks on agency authority

is the requirement that the public must have the opportunity to comment on most proposed federal rules.

**Q. Why is it important for the scientific and academic community to be engaged in the rulemaking process?**

**A.** The best way to ensure that the FDA creates effective regulations that reduce the public health burden of tobacco products is to ensure that the FDA has the best, most current data. Establishing the strongest record on which to base a regulation allows the FDA to craft the most effective rule to benefit public health, first and foremost, but it also strengthens the FDA's defense of those regulations in the face of inevitable litigation challenges from the tobacco industry.

As part of the rulemaking process, an agency must solicit comments from the public.<sup>7</sup> The agency must read and consider every comment that it receives.<sup>8</sup> This provides an opportunity for any person or organization to submit scientific data directly to the agency that is engaging in rulemaking. The rulemaking process empowers individuals to engage the agency directly and become a part of the process. This creates an opportunity for the scientific and academic community to personally deliver important data directly into the hands of policy makers rather than waiting for others to provide the data. There are few similar opportunities for individuals to have a role in directly shaping federal policy.

**Q. Why isn't it enough to publish the relevant data? Can't the FDA look at the academic literature and incorporate it into the record?**

**A.** The FDA does its best to review available literature during the rulemaking process but the only way to ensure that your data gets into the rulemaking record is to take the initiative to submit it yourself. It is also important to remember that the FDA must consider any information that is part of the record; it has no such obligation to consider information that is not submitted.

**Q. When a regulation has been proposed, how can the scientific and academic community engage the FDA?**

**A.** One of the most important ways to engage the FDA is to submit comments to proposed rules as discussed above. Commenting and submitting data directly to the FDA in response to a proposed rule will ensure that the FDA has the best information and can create well-informed regulations. The new authority granted to the FDA under the Tobacco Control Act should create many opportunities for the scientific and academic community to submit data to the FDA.

For further information about the FDA's rulemaking process, see our publication [\*Telling the Public Health Story to the FDA: How the FDA Regulates Tobacco through the Rulemaking Process.\*](#)<sup>9</sup>

**Q. Is there a way to engage the FDA on a particular topic when it has not yet proposed a rule?**

**A.** Another way to engage the FDA is to submit a citizen petition. Federal regulations allow an interested person to petition the FDA to issue, amend or revoke a regulation.<sup>10</sup> Any member of the scientific or academic community who believes that the FDA should issue a rule on a

particular topic may petition the FDA to do so. If a newly conducted study identifies a regulatory gap, a member of the scientific community may take this information directly to the FDA and request that the FDA promulgate new regulations or change existing regulations. There is a set of guidelines that outline the form that the petition must take and how it can be submitted to the FDA.<sup>11</sup>

For more information on citizen petitions see our publication *Citizen Petitions: An Underutilized Tool in Tobacco Regulation*.<sup>12</sup> As with the FDA's proposed rules, any person can comment on a citizen petition. There is information on our website, [The FDA Tobacco Action Center](#), about open petitions, proposed rules and how to submit comments to the FDA.<sup>13</sup>

**Q. Are there any informal ways to submit important data to the FDA?**

**A.** Any researcher who believes that he or she has valuable information to share with the FDA but does not wish to comment on a proposed rule or submit a citizen petition may simply send his or her data directly to the FDA. However, keep in mind that the FDA has no obligation to consider such data when it creates policy. Contact the FDA's Center for Tobacco Products directly to find out how and where to submit data. Phone: 1-877-287-1373 Email: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

**Q. Must data be published before it can be submitted to the FDA?**

**A.** Unlike submitting data to an academic journal, data submitted to the FDA does not need to be peer reviewed. If the preliminary data from a study can inform the regulatory process, scientists should feel free to submit that data before a study has gone through the peer review process.

However, members of the scientific and academic community should be aware of potential restrictions imposed by academic journals on articles that are pending publication. Many journals limit an author's ability to publish an article in another context before the journal has published the article. Individuals who wish to submit an article that is pending publication to the FDA may still be able to do so with permission from the publishing journal. Journals may allow authors to submit an article before it is published for the purpose of informing a regulatory agency. Authors should contact the journal directly for details on the procedure. In addition, there may be fewer restrictions on submitting underlying data and preliminary findings to the FDA.

**Q. How can scientific data help the FDA defend regulations in court?**

The process of challenging regulations in court also underscores the importance of getting the best available science directly to the FDA. Any party wishing to challenge one of the FDA's regulations must prove that in making the regulation, the FDA acted in a manner that is arbitrary and capricious, an abuse of discretion, not in accordance with the law, contrary to the Constitution, in excess of its authority, or a breach of required procedure.<sup>14</sup> In deciding whether the FDA has acted improperly, a court must review the administrative record that was before the agency when it made the decision.<sup>15</sup> This includes the comments submitted to the FDA for consideration.<sup>16</sup> Thus, the more extensive the record in support of the FDA's regulation, the more difficult it will be for a challenger to overcome the burden of proving that the FDA created a rule in an arbitrary and capricious manner. Given the tenacity of the tobacco industry to comment on and challenge the FDA regulations, it is important that the public health community support the FDA when its regulations are challenged.

The most recent challenge to one of the FDA's regulations resulted in an important rule being invalidated because of a perceived lack of scientific evidence. Under the authority of the Tobacco Control Act, the FDA issued a regulation mandating graphic warning labels on cigarette packages and in cigarette advertising.<sup>17</sup> This rule was challenged by the tobacco industry in *R.J. Reynolds Tobacco Co. v. Food and Drug Administration*. When reviewing the tobacco industry's First Amendment arguments, the lower court found that the record before the FDA lacked scientific evidence that the graphic warning labels would be effective in raising awareness about the dangers of smoking.<sup>18</sup> In upholding the lower court's ruling, a three-judge panel of the U.S. Court of Appeals also focused on the tobacco industry's arguments about the lack of evidence, going so far as to say that there was not "a shred of evidence" that the graphic warnings would reduce the number of Americans who smoke and, for that reason, the requirement violated the tobacco industry's First Amendment rights.<sup>19</sup> While the FDA has asked the entire U.S. Court of Appeals for the D.C. Circuit to reconsider this case and it is anything but settled, it underscores the need for providing the best, most relevant data available, to the agency during the rulemaking process.<sup>20</sup>

**Q. Are there any restrictions on engaging the FDA that the scientific and academic community should be aware of?**

**A.** Traditionally, commenting on proposed rules would not constitute lobbying under federal lobbying law,<sup>21</sup> but individuals and organizations should be aware of potential restrictions that may apply to them under other federal laws, under state or local laws, or due to restrictions imposed by funders. In particular, individuals and organizations that are funded by monies subject to the 2012 Consolidated Appropriations Act should be aware of the lobbying-like restrictions imposed on funding received under that Act.<sup>22</sup> While the restrictions may not apply to commenting on proposed rules at the federal level, individuals and organizations should speak with their legal counsel to ensure that their activities do not violate any applicable laws or contracts with funders.

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*The Tobacco Control Legal Consortium provides information and technical assistance on issues related to tobacco and public health. The Consortium does not provide legal representation or advice. This document should not be considered legal advice or a substitute for obtaining legal advice from an attorney who can represent you. If you have specific legal questions, we recommend that you consult with an attorney familiar with the laws of your jurisdiction.*

## Notes

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<sup>1</sup> Family Smoking Prevention and Tobacco Control Act, 21 U.S.C.A. §§ 387–387u (West 2009); Pub. L. No. 111-31, 123 Stat. 1776 (2009); 21 C.F.R. §§ 1140.30, 1140.32 (2010).

<sup>2</sup> 5 U.S.C. § 553.

<sup>3</sup> 5 U.S.C. § 553(b).

<sup>4</sup> 5 U.S.C. § 553(c).

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

<sup>6</sup> [http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-laws-policies-regs-terms-2011\\_0.pdf](http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-laws-policies-regs-terms-2011_0.pdf)

<sup>7</sup> 5 U.S.C. § 553(c).

<sup>8</sup> *Id.*

<sup>9</sup> [http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-fda-rulemaking&comments-2012\\_0.pdf](http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-fda-rulemaking&comments-2012_0.pdf)

<sup>10</sup> 5 U.S.C. § 553(e); 21 C.F.R. § 10.25.

<sup>11</sup> *See* 21 C.F.R. § 10.30.

<sup>12</sup> <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fda-citizen-petition-2012.pdf>

<sup>13</sup> <http://publichealthlawcenter.org/topics/tobacco-control/fda-tobacco-action-center>

<sup>14</sup> 5 U.S.C. § 706(2)(A)-(D)(section (E) only applies to formal rulemaking rather than notice and comment rulemaking, the form used by the FDA, and section (F) has been interpreted as only applying to adjudicatory proceedings rather than rulemaking).

<sup>15</sup> 5 U.S.C. § 706.

<sup>16</sup> *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971).

<sup>17</sup> 21 C.F.R. pt. 1141.

<sup>18</sup> *R.J. Reynolds Tobacco Co. v. Food and Drug Admin.*, 823 F.Supp.2d 36, 47 n. 21 (2012).

<sup>19</sup> *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 12-5063, 2012 WL 3632003, at \*10 (D.C. Cir. Aug. 24, 2012).

<sup>20</sup> For more information on this and other litigation involving the Family Smoking Prevention and Tobacco Control Act, see [The FDA Tobacco Action Center](#), and our website at [www.publichealthlawcenter.org](http://www.publichealthlawcenter.org).

<sup>21</sup> 2 U.S.C. § 1602(8)(B)(x).

<sup>22</sup> 26 U.S.C. § 501.