TELLING THE PUBLIC HEALTH STORY 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 commercial tobacco products.[1] The FDA exercises this authority through a process called rulemaking, which requires active public involvement in order for the best regulations to be adopted.

Unfortunately, the voice of the public health community can be drowned out by the often voluminous comments from those that oppose regulation, like tobacco product manufacturers. This fact sheet is intended to give the public health community an overview of the rulemaking process and information on how to be an active participant.

Q. What does the Tobacco Control Act do?

A. The law added a new section to the Food, Drug, and Cosmetic Act, establishing and governing the regulation of tobacco products[2] and tasked the Center for Tobacco Products with enforcing its provisions.[3] The law directly mandated several tobacco control measures, including imposing restrictions on tobacco product marketing and advertising,[4] strengthening cigarette and smokeless tobacco warning labels,[5] and setting a nationwide standard for youth access to certain tobacco products.[6] The law also vested the FDA with the authority to establish tobacco product standards,[7] review new tobacco products,[8] regulate the marketing of certain "modified risk tobacco products,"[9] and more. Since the enactment of the Tobacco Control Act, the FDA has expanded its authority and many of its regulatory powers to all products made or derived from tobacco, including e-cigarettes. In carrying out its regulatory duties, the FDA must use the rulemaking process and follow the Administrative Procedures Act.[10]

Q. What is rulemaking?

A. In short, rulemaking is one of the processes by which agencies create federal policy. While Congress is the only entity with the authority to enact federal statutes, an agency's properly issued rule, also called a regulation, has as much force of law as a statute passed by Congress. Agencies typically have greater subject matter expertise than Congress and are better equipped 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 is the requirement that the public have the opportunity to comment on proposed federal rules.

Q. How can I comment on proposed federal rules?

A. An agency may request comments at various stages of the rulemaking process. It may issue a request for information, an advanced notice of proposed rulemaking, or a notice of proposed rulemaking, depending on whether or not it has already prepared a proposed rule. The easiest way to find out about comment opportunities for FDA regulation of tobacco is to go to the Public Health Law Center's FDA Tobacco Action Center. There you will find direct links to proposed regulations as well as fact sheets and other resources about federal regulation of tobacco.

Q. How detailed should my comments be and what information should I include?

A. Comments need not be detailed, but should be sufficient to tell the agency information it may not know — whether it's something unique to your circumstances, an explanation of the importance of the issue in your community, preliminary data you have collected, interventions you have introduced in your community and their effects, a new scientific study, or simply your opinion. It is also proper to address issues and present evidence that the FDA may already know, but you believe need to be reiterated or to address foreseeable arguments or evidence that those opposed to regulation may submit. Comments that tell the public health story and counter the tobacco industry's self-interested comments should increase the likelihood of regulations that advance public health. Comments that cite to scientific research should include copies of the published articles to make it easier for the FDA to find the relevant information.

Q. How will the agency use my comments concerning proposed rules?

A. The FDA will respond to all comments and reanalyze proposed rules in light of the comments submitted.[11] If the revised rule is substantially the same as the proposed rule, the rule is then finalized. If the agency makes significant changes to the proposed rule after reviewing the comments, the revised rule may be resubmitted for further public comments before it becomes final.

Q. Could a final rule be challenged in court?

A. Rules are occasionally challenged in court. However, a court will overturn a rule only if one of the following things can be shown: the rule is arbitrary and capricious; the rule violates a constitutional right or privilege; the agency exceeded its statutory authority; or the rule was issued without the agency following proper procedures.[12] The first challenge in particular makes it critical that the agency has a strong record of comments supporting a public health position.

Q. What if I need advice or help in this process?

A. Public Health Law Center staff attorneys can answer questions about FDA regulation, the FDA's processes, and drafting effective comments. The FDA Tobacco Action Center is your go-to resource for all of your FDA tobacco regulation questions.

This publication was prepared by the Tobacco Control Legal Consortium, a program of the Public Health Law Center at Mitchell Hamline School of Law, St. Paul, Minnesota.

Endnotes

1 21 U.S.C. § 387a (West, Westlaw Next through P.L. 112-89 (excluding P.L. 112-55, 112-74, 112-78, and 112-81)); Family Smoking Prevention and Tobacco Control Act, Pub.L. No. 111-31, 123 Stat. 1776 (codified primarily at 21 U.S.C. §§ 387–387u. (2009)); 21 C.F.R. §§ 1140.30, 1140.32 (2010).

2 21 U.S.C. §§ 387–387u.

3 *Id.* § 387a(e).

4 Family Smoking Prevention and Tobacco Control Act § 102(a).

5 *Id.* §§ 201, 204.

6 *Id.* § 102(a).

7 21 U.S.C. § 387g.

8 *Id.* § 387j.

9 *Id.* § 387k.

10 *Id.* § 387a(d).

11 5 U.S.C. § 553(c) (2006).

12 *Id.* § 706(2).