

THE FEDERAL REGULATORY PROCESS

An Introduction



Understanding the federal regulatory process is an important step to being able to fully participate in agency rulemaking and the implementation of federal laws such as the Tobacco Control Act.

To provide the federal government with a public health perspective, you may want to take advantage of the tools available to citizens to engage with agencies. This factsheet provides a brief introduction to the federal regulatory process, with a focus on how citizens can engage with the U.S. Food and Drug Administration to move commercial tobacco regulation in a health-equity focused direction.

I. The three branches of government

While you are likely familiar with the basic structure of the federal government, it might be useful to review some of the foundational principles. To recap: the U.S. federal government is divided into three separate branches of government: the executive, the legislative, and the judicial. The legislative branch is comprised of the U.S. Congress, which is itself made up of two houses — the House of Representatives and the Senate. The judicial branch is comprised of the federal court system, which is generally divided into three separate tiers — District Courts, Courts of



Appeal, and the U.S. Supreme Court. Finally, the executive branch includes the President, Vice President, Cabinet, and all the executive agencies — including the Department of Health and Human Services, of which the Food and Drug Administration (“FDA”) is a part. The three branches of government are intended to operate in concert, as part of a system of checks and balances, to ensure that no one branch becomes too powerful.

II. Creating a law

Again, this is likely quite familiar to you, particularly those of you working in the policy world, but it is helpful to ensure that everyone is on the same page before we delve into the complexity of the Tobacco Control Act. So, let’s briefly review the process of enacting a federal law. Laws, which start out as bills, are written by members of Congress—this can be any member or group of members in the House or the Senate. A bill is often considered by various Congressional committees and subcommittees and debated and amended before it is eventually voted on by both houses. If both houses of Congress approve a bill, it goes to the President who has the power to either approve the law or veto it. If approved, the bill becomes a law. In the commercial tobacco context, this is the process that occurred in 2009 when President Obama signed the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act” or “TCA”). The law is then published, or “codified” in the United States Code (“USC”) and is available to the public to look up. The published law is often referred to as a “statute.”

III. Putting the law into practice

Though Congress writes statutes, it does not have the capacity or expertise to enforce them. To solve this problem, Congress authorizes government agencies in the executive branch — including the FDA — to implement and enforce laws on a day-to-day basis. This includes the creation of rules (also called regulations) and enforcement of statutes and rules. Regulations set requirements for what the regulated community can or cannot do, within the confines of the subject matter of the statute written by Congress. For example, in the Tobacco Control Act, Congress outlawed what it called “characterizing flavors” in cigarettes. The Act unfortunately explicitly exempted menthol from the list of prohibited flavors. However, Congress specifically gave the FDA the ability to outlaw menthol, by setting a new “tobacco product standard” in the form of a regulation.

When it comes to enforcement, the Tobacco Control Act spells out many specific penalties for violations of its terms, including monetary penalties. The FDA has the ability to issue more detailed regulations related to how it exercises that enforcement power, including the ability to issue warning letters, or how it might implement its power to require products to come off the market.

IV. Citizen participation in the regulatory process

Another important law that governs agency processes is called the “Administrative Procedure Act” or “APA.” The APA provides the framework for the procedures all agencies must follow, including in issuing regulations. One of the APA’s purposes is to ensure that citizens have an opportunity to participate in agency rulemaking. While unfortunately the law is not structured in a way that provides for public participation at every stage of rulemaking, the APA does provide an opportunity for the public to comment on proposed rules, and sometimes guidance documents. An agency might also request citizen involvement in providing information on a particular subject of potential regulation.

Importantly, the APA also provides a mechanism for citizens to petition the agency to regulate in a specific way. This can have the benefit of enabling citizens to frame a particular issue at the outset, by providing data and information related to the proposed regulation. Additionally, the APA requires the agency to respond to any citizen petition, as well as to allow comments on a citizen petition. If the agency fails to follow the procedures of the APA, or the requirements of the law it is charged with implementing, the APA also provides citizens with a mechanism to sue the agency in court.

The public health community has used all these tools to participate in agency rulemakings. It has also, more recently, successfully sued the FDA, securing court orders requiring the agency to follow the requirements spelled out in the Tobacco Control Act. For example, recent lawsuits have resulted in court orders requiring the FDA to issue a rule requiring graphic warning labels on cigarette packages and advertisements, as well as to properly implement the agency’s authority to prevent new tobacco products from entering the market without FDA approval.

Citizen petitions, comments, and litigation each play a role in ensuring that the public remains involved in the federal regulatory process. While the resources involved in engaging with the federal government (particularly when it comes to litigation) can be significant — even prohibitive — it is critically important that members of the public directly impacted by federal policies speak up and draw attention to health disparities exacerbated by federal policies. The FDA, like many federal agencies, is a large, slow-moving, bureaucratic machine. While it has wide latitude to enact laws that are protective of public health, community pressure is crucial to ensuring that it moves in a direction that takes into account health disparities.

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