

FDA Struggles to Pinpoint Impacts of Proposed Rule

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In brief...

The FDA has released a proposed rule outlining national standards for entities in the prescription drug supply chain, almost a decade after Congress directed it to. But the proposed rule raises many issues, including the direction and size of benefits and effects on cooperation and market competition.

In February, the Food and Drug Administration (FDA) released a [long-awaited proposed rule](#) creating national standards for companies in the prescription drug supply chain. Several industry groups hailed the proposed rule, suggesting that its release clarified obligations for market participants and provided sensible procedures to operate under. However, the FDA's rule provides a highly incomplete picture of its potential costs and benefits and other consequences of the rule to society. In a public comment I filed on the proposal, I argued that, despite the already lengthy delay in this rule's publication, the agency needs to perform further evaluation even if that runs concurrently with the rule's rollout.

As directed by the [Drug Supply Chain Security Act](#) in 2013, the FDA's proposed rule establishes national standards for two types of entities that transfer prescription drugs. Currently, standards related to licensing these entities are determined by state governments, leading to different standards for how drug suppliers operate from state to state. The FDA's proposed rule argues that by nationalizing standards, it makes it easier for these drug suppliers to operate by simplifying the "patchwork" system of regulation they now operate under. It also claims that effectively setting national standards can minimize illicit activities in the prescription drug supply chain—such as drug diversion or substitution of counterfeit drugs—which it claims are more likely when ineffective state licensing standards allow illegitimate drug suppliers to operate.

The FDA's suggestion that national standards could correct for current market failure is certainly reasonable. Instances of illicit behavior by these drug suppliers have multiplied in the 2010s, suggesting they have insufficient incentive to police themselves. There is at least [anecdotal evidence](#) that some entities in the prescription drug supply chain deliberately seek out states with more lax regulation, which could mitigate effective controls on drug supply from other states. And consumers will often be unable to

distinguish legitimate drugs from counterfeit ones, necessitating that another actor steps in to control drug quality.

But while the FDA's rationale for action is sound, the vague and incomplete information furnished in their proposed rule makes it unclear what the rule will accomplish. For one thing, questionable decisions undergird the FDA's analysis of expected costs and benefits. While the FDA acknowledges that diverted drugs can have directly harmful effects to consumers (such as when a diverted drug is substituted with a less effective product) their analysis assumes such drugs have zero costs to consumers, on the basis that consumers' willingness-to-pay is zero rather than negative. It would seem more reasonable to assume such products impose a cost on consumer through health risks, even if such a value is difficult to quantify.

The FDA also largely relies on outdated and anecdotal evidence to estimate the frequency of drug diversion, and thus the benefits the proposed rule could achieve through limiting this diversion. It does not speak to how enforcement actions by other agencies (such as the Drug Enforcement Agency) may have changed the drug diversion landscape since those data were reported, or consider how these actions, or other factors, may have affected the frequency of drug diversion overall. Due to omission of details like these, as well as unclear explanations of the monetized costs and benefits it does provide, the assessed benefits of the proposed rule appear unreliable.

The proposed rule also neglects to consider other downstream impacts, some positive and some negative. For example, national standards on drug suppliers could incentivize states to collaborate more effectively in disciplining errant drug suppliers. Previously, a state might have limited incentive to let other states know when a drug supplier violated a license, since that would not mean it violated other states' laws. Under national standards, a violation in one state could signal to other states they need to investigate the drug supplier's practices. On the other hand, the FDA fails to consider what effects an overall greater regulatory burden will have on market competition. Even the FDA's Small Entity Analysis fails to address whether stricter standards will disadvantage the many small companies that currently operate as drug suppliers.

Failure to consider or acknowledge these issues should disturb those concerned about whether the FDA has conducted due diligence in proposing this regulation, as should the fact that the FDA's [own analysis](#) suggests the rule would, on net, provide more costs than benefits to society. Because Congress has directed the FDA to issue these standards, and because its initial analysis has taken years, more delay might not be in the interest of the American people. This proposed rule may correct for real and significant dangers in the prescription drug supply chain, and there is no guarantee that a future analysis by the FDA would be more comprehensive or offer different conclusions. But even as the FDA rolls out this measure, it bears responsibility for considering these outstanding issues further, finding data to strengthen its analysis, and evaluating the implementation of standards to see if it matches expectations. Only through more rigorous scrutiny can we determine if regulatory actions help Americans and adjust course if not.