

# FDA's Opioid Systems Modeling Effort



The opioid crisis is a complex problem with a lot of unknowns and an ever-changing landscape. There is no one-size-fits-all solution to the problem, so regulators and policy makers like FDA need a toolkit of approaches to questions and decisions about the crisis.

## Systems modeling and systems thinking are important elements of FDA's toolkit.

In 2017, the National Academies of Science, Engineering, and Medicine recommended that FDA employ a systems approach to help understand the ripple effects that FDA actions may have on the opioid crisis. FDA's systems modeling effort, which kicked off in 2018, combines **dynamic simulation modeling** with **systems thinking principles**.

The goals of the effort are:

1. Identify strategies and actions that may have the greatest positive impact on the crisis,
2. Assess the potential for unanticipated consequences of actions, and
3. Identify important areas for further research.

### System dynamics modeling helps map the crisis with quantitative insights.

**SOURCE** (Simulation of Opioid Use, Response, Consequences, and Effects) is at the center of FDA's modeling effort. SOURCE simulates the national population's transitions through opioid use, use disorder, treatment, and recovery, and influences on those transitions. The model provides both qualitative and quantitative insights about potential effects of changing one or more parts of the system.

FDA conducts research to update and enhance SOURCE and to provide other fit-for-purpose modeling tools. These efforts include researching specific components of the crisis, adding system outcomes to SOURCE, building interactive interfaces, diagramming, and developing models collaboratively with stakeholders.

### Systems thinking helps maximize the utility of modeling to stakeholders.

FDA's modeling team is incorporating a supporting analysis service that can guide FDA stakeholders through their systems-based assessments of potential opioid-related policies. This facilitative process helps analysts and decision-makers determine when modeling may add value and support them as they refine their policy questions, articulate their assumptions, and interpret model results with an understanding of context, framing, assumptions and caveats. It also helps FDA decision-makers place modeling findings within the broader set of information available to support decision making. The analysis service emphasizes interdisciplinary collaboration and creates opportunities for engagement throughout the modeling process.

## FDA works with academics and colleagues across HHS to share learnings.

Want to learn more about our approach? Check out our white paper, publications, and partnerships.