



## The EFFECTIVE Act

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### The Problem

In 2021, over 107,000 Americans died from drug overdoses — more than twice the number of U.S. traffic fatalities or gun violence deaths during that period.<sup>1</sup> The opioid epidemic has continued to take the lives of loved ones of all ages, but tragically, drug overdoses have become the leading cause of death for 18 to 45-year-olds in the U.S.<sup>2</sup> This problem originated in the 1990s when pharmaceutical companies reassured the medical community that patients would not become addicted to opioid pain relievers, and healthcare providers subsequently prescribed them at greater rates.<sup>3</sup>

In 2016, during Dr. Califf's first tenure as Commissioner of the Food and Drug Administration (FDA), he asked for a report on what more the FDA could be doing to address the drug epidemic. In 2017, the National Academies of Sciences, Engineering, and Medicine (National Academies) published its report, Pain Management and the Opioid Epidemic.<sup>4</sup> The report provided recommendations for the FDA to construct an improved process for the review, approval, and monitoring of opioids to help control the amount of these drugs in our country. In a recent Senate hearing, Dr. Califf was questioned regarding the implementation of the National Academies report, and he stated that additional legal authority is needed by the FDA to require a new drug application to have "superiority" to current drugs on the market.<sup>5</sup>

### **What does the *Ensuring the FDA Fully Examines Clinical Trial Impact and Vitalness Before Endorsement (EFFECTIVE) Act* do?**

The EFFECTIVE Act gives the FDA authority to deny a new drug application for an opioid analgesic if the drug is not more clinically effective or safer than any commercially available drug. The bill applies to applications for new drugs and would not impact the approval of generics. This legislation would give the FDA more power to review the public health impact of every new opioid approval, satisfying Dr. Califf's request to ensure that the FDA is able to completely implement the recommendations from the National Academies report. By conducting a broader review of the impacts of new drugs to public health, the FDA will have a strengthened ability to protect Americans from a surplus of opioids on the market.

<sup>1</sup><https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

<sup>2</sup>[https://www.yahoo.com/now/fentanyl-leading-cause-death-americans-100158708.html?guccounter=1&guce\\_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce\\_referrer\\_sig=AQAAADVEpTTxRYnnW15Eruijj2E8dLTOW9ruhUTT69VWVUS7VYYoi7M10rAdeRoPtG\\_A54RGx-YGWzVUIr5YWuNfNUbXM2zxmhl2Ami6JXEXdT5IAR0maJ6leeVz0CeW6zaprCxx0sjzZtl7K1CeZLvGgJztYD7qSmlEvHKbKlhbK34](https://www.yahoo.com/now/fentanyl-leading-cause-death-americans-100158708.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAADVEpTTxRYnnW15Eruijj2E8dLTOW9ruhUTT69VWVUS7VYYoi7M10rAdeRoPtG_A54RGx-YGWzVUIr5YWuNfNUbXM2zxmhl2Ami6JXEXdT5IAR0maJ6leeVz0CeW6zaprCxx0sjzZtl7K1CeZLvGgJztYD7qSmlEvHKbKlhbK34)

<sup>3</sup><https://www.hhs.gov/opioids/about-the-epidemic/index.html>

<sup>4</sup><https://nap.nationalacademies.org/catalog/24781/pain-management-and-the-opioid-epidemic-balancing-societal-and-individual>

<sup>5</sup>

<https://www.appropriations.senate.gov/hearings/a-review-of-the-presidents-fiscal-year-2023-budget-request-for-the-fda-and-drug-administration>