The Medical Innovation Act

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Background

For generations, American taxpayers' investments in medical research have provided the foundations for some of the nation's greatest scientific advancements and health improvements. However, in Fiscal Year 2023, the National Institutes of Health (NIH) could fund only 23% of the applications it received, resulting in a huge innovation gap. Meanwhile, the past decade has seen repeated instances of major drug companies engaging in misconduct. Pharmaceutical companies have defrauded Medicare and Medicaid, marketed drugs for unapproved uses, illegally incentivized doctors to prescribe drugs, and violated other criminal and civil laws. The companies have settled many of these claims with the federal government, often receiving nothing more than a slap on the wrist that allowed them to treat the fines as a cost of doing business.

Legislation

The *Medical Innovation Act* would close the innovation gap, making it easier for drug companies to develop the next generation of cures and harder for them to profit from breaking the law and ripping off taxpayers. The *Act* would:

- **Require large pharmaceutical companies that are found guilty of or settle cases involving criminal or certain civil violations to reinvest a small percentage of their profits in NIH and the U.S. Food and Drug Administration (FDA) for five years.** These payments, which would increase with the severity of the settlement penalty, would only be required of companies that rely on federally-funded research to develop billion-dollar, "blockbuster" drugs.
- **Invest in initiatives at NIH and FDA that will save lives.** Funds collected under the *Act* would be used to develop treatments and diagnostics to address unmet medical needs; support research grants for early career scientists; research diseases that disproportionately contribute to federal health care spending; and advance basic biomedical research, among other uses.
- **Promote sustained investments in biomedical research.** To ensure that the *Act* results in a net increase in funding for medical research, money from the supplemental settlement fees would only be available in years that annual appropriations for NIH and FDA are equal to or greater than appropriations for the agencies in the prior fiscal year.

The bill would provide ample funding for research leading to medical innovation. Between 2019 and October 2024, the Department of Justice pursued new actions against or settled cases with at least 40 pharmaceutical companies:

- Akorn Operating Company
- Alexion Pharmaceuticals
- Almirall
- Amgen Inc.
- Apotext Corp.
- Astellas Pharma US
- Avanir
- Bayer
- Biogen
- Bristol-Meyers Squibb
- DUSA Pharmaceuticals
- Endo Health Solutions
- Fresnius Kabi Oncology Limited
- Gilead
- Glenmark Pharmaceuticals Inc.
- Heritage Pharmaceuticals Inc.
- Incyte Corporatoin
- Indivior Solutions
- Insys Therapeutics
- Jazz Pharmaceuticals
- Kaléo
- KYK-TECH
- Lehigh Valley Technologies
- LGM Pharma
- Lundbeck LLC
- Mallinckrodt
- Morton Grove Pharmaceuticals
- Nostrum
- Novartis
- Pacira Pharmaceuticals
- Purdue Pharma L.P.
- Regeneron
- Rising Pharmaceuticals Inc.
- Sanofi-Aventis U.S.
- Sentynl Therapeutics
- Taro Pharmaceticals
- Teva
- Ultragenyx
- US WorldMeds
- Woodfield Pharmaceutical

The *Act* would not require payments to NIH and FDA in all of these cases, but two examples of qualifying lawsuits include:

- In April 2019, **Amgen** agreed to pay $24.75 million to resolve the federal government's allegations that the company violated the *False Claims Act* by illegally paying the Medicare copays for their own products.
- In September 2022, **Biogen** agreed to pay $900 million to resolve the federal government's allegations that the company caused the submission of false claims to Medicare and Medicaid by using kickbacks to entice physicians into prescribing Biogen drugs.