The Medical Innovation Act

Senator Elizabeth Warren (D-MA) and Congressman Peter Welch (D-VT)

Background

For generations, taxpayer investments in medical research have provided the foundations for some of the greatest scientific advancements and health improvements in human history. The National Institutes of Health (NIH), the primary federal biomedical and behavioral research agency, supports 300,000 researchers at over 3,000 research institutions and universities.¹ This research funding has helped launch and sustain the nation's pharmaceutical industry: in the past four decades, NIH-funded researchers have contributed to the development of over 150 Food and Drug Administration (FDA)-approved drugs.²

Federal funding is critical to maintaining America's dominance in medical research. However, in Fiscal Year 2018, the NIH could fund only 20% of the applications it received.³ Meanwhile, the past decade has seen repeated instances of major drug companies engaging in misconduct. Companies have allegedly defrauded Medicare and Medicaid,⁴ marketed drugs for uses they aren't approved for,⁵ illegally incentivized doctors to prescribe drugs,⁶ and engaged in other violations or criminal and civil law. The companies have settled many of these claims with the federal government, treating the fines as a cost of doing business.

Legislation

Senator Warren and Congressman Welch are introducing the **Medical Innovation Act** to make it easier for drug companies to develop the next generation of cures and harder for them to profit from alleged violations of law. The Act would increase funding for medical research by:

- Requiring large pharmaceutical companies that settle alleged criminal violations with the federal government to reinvest a small percentage of their profits in NIH and FDA. These payments, which would vary according to the severity of the settlement penalty, would only be required of companies that rely on federally-funded research to develop billion-dollar, "blockbuster" drugs.
- **Investing 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 healthcare spending; and advance basic biomedical research, among other FDA and NIH initiatives.
- **Promoting 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.

Endorsements

AIDS United Families USA National Women's Health Network Public Citizen Society of Behavioral Medicine University of Massachusetts Medical School. ² Id.

⁴ United States Department of Justice, "Settlements Announced With Two Pharmaceutical Companies Regarding The Medicaid Drug Rebate Program," July 6, 2015, <u>https://www.justice.gov/usao-edpa/pr/settlements-announced-two-pharmaceutical-companies-regarding-medicaid-drug-rebate</u>.

⁵ United States Department of Justice, "Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations," November 4, 2013, <u>https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations</u>.

⁶ ProPublica, "Lawsuits Say Pharma Illegally Paid Doctors to Push Their Drugs," Tracy Weber and Charles Ornstein, October 18, 2010, <u>https://www.propublica.org/article/lawsuits-say-pharma-illegally-paid-doctors-to-push-their-drugs</u>.

¹ Research America!, "National Institutes of Health," <u>https://www.researchamerica.org/advocacy-action/research/federal-funding-research/national-institutes-health</u>.

³ National Institutes of Health, "Research Project Success Rates by NIH Institute for 2018," <u>https://report.nih.gov/success_rates/Success_ByIC.cfm</u>.