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## The Medical Innovation Act

American medical innovation has been an extraordinary success. For generations, taxpayer investments in medical research have provided the foundation for some of the greatest scientific advancements and health improvements in human history. The research has also helped launch and sustain a thriving pharmaceutical industry.

But in recent years, the great American engine of medical innovation is in trouble. Critical federal investments in medical research have been flat for more than a decade, and today 9 out of 11 research proposals are left unfunded, threatening the pace of new discoveries and undercutting America's status as the world's leader in medical innovation.

Over the past decade, there has also been a worrisome increase in the number of major drug companies that have been caught breaking the law. Repeated instances of major companies defrauding Medicare and Medicaid, withholding critical safety information drugs, marketing drugs for uses they aren't approved for, illegally incentivizing doctors to prescribe drugs, and other serious violations have come to light. The companies have settled nearly all these claims with the Justice Department for billions of dollars, treating the fines as a cost of doing business.

The *Medical Innovation Act* is designed to reverse both trends by making it easier for drug companies to develop the next generation of cures and making it harder for them to profit from breaking the law and defrauding taxpayers. Over the last five years, this proposal would have meant a nearly 20% increase in funding for research programs through the National Institutes of Health.

**Increase Funding and Increase Accountability, Without Increasing Taxes.** The Act requires that whenever drug companies enter into a settlement agreement with the government to avoid trials for breaking the law and defrauding taxpayers, they must pay a small portion of their annual profits over five years to NIH to reinvest in the next generation of life-saving research. The payment would vary according to the severity of the settlement penalty and would only be required of companies that –

- *Break the law* and enter into a settlement agreement with the federal government;
- *Sell “blockbuster” drugs* with annual sales over \$1 billion; and
- *Relied on federally funded research* in whole or in part to develop their blockbuster drugs.

**Support Medical Innovation.** Payments collected under the Act will directly provide funding for –

- *The National Institutes of Health*, to support over 300,000 innovative health scientists and researchers at more than 2,500 universities, medical schools, and other US institutions.
- *The Food and Drug Administration*, to support research to get treatments to patients faster by improving our understanding of which drugs will successfully complete the development process.

**Save Money and Save Lives.** To ensure that the Act results in a net increase in funding for medical research, money from the payments fee will be made available only in years that annual appropriations to NIH and FDA keep pace with inflation, and initiatives supported under the Act must fall in at least one of four categories –

- *Radically innovative research* to develop treatments and diagnostics for unmet and under-met medical needs, evaluate new approaches to disease treatment, or identify new biomarkers.
- *Fundamental research* to advance the understanding of cellular processes, protein science, immunology, genetics, or neurology to lay the foundation for the next generation of drugs.
- *Money-saving research* that focuses on diseases that disproportionately impact government spending through Medicare, Medicaid, CHIP, VA, TRICARE, and the Affordable Care Act.
- *Supporting the next generation of scientists* through research grants for young, independent investigators and universities with innovative training programs.