

# Doctors in US and Canada launch sweeping pharmaceutical reform proposal

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The skyrocketing cost of prescription drugs is one of the biggest concerns for American voters. However, in his proposal last Friday, President Donald Trump failed to offer any new policies that would expand access, reduce costs, or increase the safety and efficacy of prescriptions.

Today, a group of 21 prominent physicians published a comprehensive proposal to ensure universal access to safe, innovative, and affordable medications. "Healing an ailing pharmaceutical system: prescription for reform for the U.S. and Canada," identifies seven critical areas for reform, along with both short- and long-term solutions to improve the development, approval process, affordability, and marketing of medications:

1. **Access:** Even insured patients face high out-of-pocket costs, leaving them unable to fill prescriptions. To achieve universal access, the proposal calls on the U.S. and Canada to establish national formularies of the safest, most effective, and least expensive medications, and provide all residents with full coverage of formulary drugs without copays or deductibles.

2. **Affordability:** The industry's pricing strategy is to charge whatever the market will bear, regardless of the actual cost of development. As a result, the U.S. spends about twice as much per-capita on prescriptions than any other nation. Under this proposal, public agencies would negotiate with manufacturers to make branded medications more

affordable, and if negotiations fail, issue a "compulsory license" to allow generic manufacturing. The U.S. and Canadian governments also would create a publicly owned manufacturing capacity to produce needed products, along with an increase in public funding for the development of non-patented medications.

3. Preclinical development and patent protection: The current patent system encourages the development of "me-too" products that offer only trivial modifications and higher costs. Under this proposal, patents would be limited to medications that provide real innovation. While current law allows publicly funded researchers to patent and sell their discoveries to private firms, this proposal would keep publicly funded research in the public domain. The plan also calls for health agencies to fund a new public research program to develop and test new treatments outside of the patent system, prioritizing medications with high clinical value, and for conditions deemed unprofitable and ignored by the industry. Such treatments could be sold cheaply as generics as soon as they are brought to market.

4: Clinical testing: Most clinical trials are conducted by [private firms](#), often using unsound methods and selective reporting, calling into question the objectivity of research and the usefulness and safety of new therapies. Corporate ownership of trial data can hide safety problems and obstruct further research. The proposal calls on approval agencies to increase standards for clinical trials and increase transparency by making all trial data publicly available. Experts believe that most [clinical trials](#) should be funded and supervised by public health agencies to maintain safety standards and to facilitate innovation for needed treatments.

5. Approval reform: Regulatory agencies are funded primarily by industry fees, creating conflicts of interest. Too many unsafe products are approved, and the increased use of "expedited reviews" and weaker standards of evidence threatens to bring more unsafe or ineffective

products to market. This proposal would strengthen regulators' independence by funding them exclusively with public funds. Approval agencies would strictly limit expedited reviews and the use of surrogate endpoints only to treatments likely to offer genuine clinical advances.

6. Postmarketing surveillance: Due to weakening of the approval process, postmarket studies are critical to confirm the efficacy and safety of medications already in use. However, regulators fail to penalize firms that don't complete them. The proposal would require that companies promptly perform and submit safety studies after their products are on the market, increase regulators' funding for postmarketing surveillance, and give regulators the power to order safety warnings and remove unsafe therapies from the market.

7. Promotion: : Pharmaceutical corporations spend more on marketing than on research and development, and their promotional materials often include inaccurate or misleading claims. This proposal would improve monitoring and stiffen sanctions for misleading or off-label promotions. Companies would be prohibited from funding continuing [medical](#) education programs for providers.

"Our pharmaceutical system prioritizes industry profits over public health, but it doesn't have to be this way," said Dr. Adam Gaffney, a critical care physician and faculty member at Harvard Medical School, and co-chair of the Pharmaceutical Reform Working Group. "Through a series of commonsense reforms, we can increase the affordability, safety, and effectiveness of medicine for our patients."

Dr. Gaffney warned that combating the power of major pharmaceutical firms won't be easy, noting that the industry spent a combined \$171 million on lobbying last year. "Every year we wait for reform means another spike in drug prices," he said.

"The pharmaceutical industry directly funds the regulating arm of the FDA, and paid more than \$800 million in user fees in 2017," said Dr. Sidney Wolfe, founder of Public Citizen's Health Research Group. "The FDA's independence is too important to expose to the influence and money of the industry." Dr. Wolfe added that increasing affordability of lifesaving therapies should be a national priority. "Lack of access to medicines results in preventable deaths and serious illness to hundreds of thousands of patients a year," he said.

**More information:** "Healing an ailing pharmaceutical system: prescription for reform for U.S. and Canada," *British Medical Journal*, [DOI: 10.1136/bmj.k1039](https://doi.org/10.1136/bmj.k1039)

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