



Healing an ailing pharmaceutical system: Prescription for reform in the U.S. & Canada

Problem	Solution
Millions of patients are unable to access prescription drugs because of high out-of-pocket costs .	Establish a national formulary of medically necessary drugs to include the safest, most effective, and least expensive options. Provide all residents with full coverage of formulary drugs without copays or deductibles .
The U.S. spends more on prescription drugs than any other nation. Each year, prices rise far beyond the cost of development and production , straining family and government budgets.	Negotiate with manufacturers to lower prices of branded drugs. If negotiations fail, issue a "compulsory license" to allow generic manufacturing. When no other option is available, create a public manufacturing capacity to produce needed drugs. Increase public funding for development of non-patented drugs.
Today's patent process keeps drug prices high and discourages innovation by rewarding minor tweaks to existing medications. Research funded by tax dollars can be patented and sold to private manufacturers.	Prohibit new patents for trivial changes to existing drugs or "me too" drugs. Publicly fund development of treatments through non-commercial researchers, prioritizing drugs with high clinical value and for conditions neglected by the industry. Repeal the Bayh-Dole Act that allows publicly funded researchers to patent and sell discoveries.
Most clinical trials are now conducted by private drug firms , often using unsound methods and selective reporting. Regulators approve drugs based on small increases in "surrogate" endpoints, which are less safe and reliable than clinical results. Corporate ownership of trial data can hide safety problems and obstruct further research.	Require regulators to fund and supervise the majority of clinical trials to maintain safety standards and facilitate innovation for high-need treatments. Increase standards for clinical trials, which should compare new drugs to existing drugs instead of placebos, and assess hard clinical outcomes instead of surrogate endpoints. Increase transparency by making all patient-level trial data publicly available.
Regulators often allow unsafe drugs to reach the market. Agencies are funded primarily by drug company fees, creating conflicts of interest. A majority of drugs receive "expedited review," with weaker standards of evidence.	Fund regulators with public money to ensure independence and objectivity. Strictly limit expedited review and surrogate endpoints to drugs offering genuine clinical advances. Limit market exclusivity to drugs demonstrating superiority over existing treatments.
After approval, regulators neglect to monitor drug safety and efficacy in the field , or enforce mandated postmarketing studies by drug firms. Agencies fail to issue safety warnings or remove unsafe drugs from the market.	Increase funding for regulators' postmarketing surveillance and increase their power to issue safety warnings and remove drugs from the market. Require drug firms to promptly perform and submit safety studies after drugs are in use.
Drug firms spend billions on marketing , including gifts and education programs for health providers. Drug ads often make misleading or inaccurate claims, but are poorly monitored by regulators who delegate most oversight to third parties.	Eliminate conflicts of interest by ending the corporate funding of approval agencies. Strengthen funding for direct monitoring of drug marketing and increase sanctions for misleading or off-label promotions. Prohibit drug firms from funding continuing education programs for medical professionals.