

PROPOSALS FOR CHANGE

*Drug prices in the United States are too high and sharply rising prescription drug prices threaten the affordability of health care and the vitality of our entire economy. CSRxP has developed market-based reforms that restore a functioning market by increasing **transparency**, promoting **competition** and innovation, and that result in **value**.*



the campaign for
**SUSTAINABLE
Rx PRICING**
Transparency. Competition. Value.



TRANSPARENCY

- **Releasing details of a drug's unit price, cost of treatment, and projection on federal spending before FDA approval.** Given the significant impact pharmaceuticals have on overall health care spending, manufacturers should be required to disclose information on the estimated unit price for the product, the cost of a course of treatment, and a projection of federal spending on the product.
- **Annually reporting increases in a drug's list price.** Reporting requirements are already in place for other entities like health plan issuers, hospitals, and nursing facilities and this level of transparency should simply extend to the pharmaceutical sector as well. Furthermore, HHS should provide an annual report to the public to include the top 50 price increases per year by branded or generic drugs; the top 50 drugs by annual spending and how much the government pays in total for these drugs; and historical price increases for common drugs, including those covered by Medicare Part B.
- **Disclosing true R&D cost for drugs.** Manufacturers marketing a drug should be required to disclose how much drug research was funded by public entities like the National Institute of Health (NIH) or other academic entities or by other private companies, so regulators and taxpayers can properly weigh return on investment.



COMPETITION

- **Speeding FDA approval of generic drug applications – especially for lifesaving drugs.** The FDA faces a backlog of nearly 4,000 generic drug applications, yet approval times can be three or more years. The FDA should be provided necessary resources to clear this backlog and prioritize generic drug approval applications.
- **Reducing drug monopolies by incentivizing competition for additional market entrants.** Several FDA programs are intended to expedite review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and encourage a second or third market entrant.
- **Strengthening post-market clinical trials and surveillance.** Currently, expedited drug approvals often involve small clinical trials with a narrow patient population, and trials are not regularly reported publicly. Once a drug enters the market, research into the long-term efficacy and side effects should continue with specific timelines and reporting requirements. Even if a product is not approved, manufacturers should be required to report data for all trials that summarizes non-identifiable demographics and participant characteristics, primary and secondary outcome results, and adverse event information.

- **Target exclusivity protections to most innovative products.** Currently, pharmaceutical manufacturers can extend market exclusivity protections by seeking approval for a “new” product that is essentially the same as the original. Prohibiting such tactics will bring consumers more options and lower prices more quickly. Anti-competitive pricing schemes should be closely monitored by federal agencies and prosecuted if violations of antitrust laws are found.
- **Curb misuse of REMS.** Currently, FDA requires manufacturers to submit detailed Risk Evaluation and Mitigation Strategies (REMS) to weigh a drug’s risks and benefits. While this type of information can create additional safety information for patients and safeguards for providers, manufacturers often manipulate REMS to block generic manufacturers from obtaining samples of brand drugs under the guise of addressing patient safety concerns. This practice can stifle the introduction of generic competition, thus preventing lower price options from being available.
- **Promote uptake of biosimilars.** Regulatory policies should encourage market entry and uptake of biosimilars, as they have significant potential to expand treatment options and reduce costs of expensive biologics through increased competition.



VALUE

- **Increase funding for public and private research on drug pricing and value.** Policymakers should increase funding for private and public research efforts like the Institute for Clinical and Economic Review (ICER), a non-profit organization that evaluates evidence on the value of medical tests and treatments. Investments in objective information is critical for physicians, patients, and payers as more and more high priced drugs are introduced into the health care system.
- **Require drugmakers to compare cost and outcomes of new versus existing drugs.** Through comparative effectiveness research (CER) studies, manufacturers should have to demonstrate their product is better than others, so that physicians and patients can make smart decisions about the value of different treatments, particularly those with very high costs. Many other countries currently require drug manufacturers to provide CER studies; they should be expanded in the U.S. to reduce spending on unnecessary or ineffective treatments.
- **Expand value-based pricing in public programs.** Federal programs like Medicare and Medicaid purchase prescription drugs for their beneficiaries, but most are not structured to accommodate value-based payment models. Steps should be taken to ensure these programs can best take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. health care system can benefit from market-based negotiating efforts to lower drug prices.