

Tackling the high cost of prescription drugs

December 4 2017, by Sharon Driscoll

The high cost of prescription drugs in the United States came under scrutiny in a new report from the National Academies of Sciences, Engineering, and Medicines, "Making Medicines Affordable: A National Imperative," co-authored by Stanford Law Professor Michelle Mello (former Senator Jeff Bingaman, JD '68, co-chaired the committee). Published on November 30, the report aims to increase both affordability and accessibility to crucial—often lifesaving—drugs for Americans, with recommendations such as better government negotiated prices, quicker turnaround for generic drugs, and increased financial transparency for biopharmaceutical companies. In the discussion that follows, Mello explains some of the key challenges facing Americans in need of prescription drugs and key recommendations in the report.

You note in the report that Americans are paying significantly more for their healthcare but are significantly less healthy when compared to developed countries. Do we also pay more for prescription drugs?

Yes. In fact, many countries use "reference pricing" schemes, through which the price that their national health programs pay for [prescription drugs](#) is actually calculated as a percentage of what we pay! One of the ethical issues that weighed on the Committee as we deliberated was that interventions that tamp down prices in the U.S. could have ripple effects in other, less wealthy countries if [drug](#) makers seek to recoup their losses by giving fewer price concessions elsewhere.

What is the most important factor leading to higher prescription drug costs in the U.S.?

The old adage that "every system is perfectly designed to get the result it gets" really came to mind as we investigated why drugs cost so much. It's not just one factor, but a whole ecosystem in which multiple actors and factors are contributing. At the root of it, though, is that there are distortions in the market for drugs that permit things to happen that wouldn't occur in a truly competitive market.

Which of the 27 action points recommended by the report stand out to you as a priority—and achievable?

We view our recommendations as a package that should be implemented together, but there are three that we think are especially promising. First, the federal government should directly negotiate drug prices on behalf of all federal programs (and any state programs that want to join in). To create leverage in these negotiations, federal programs should have the flexibility to exclude certain drugs, such as when less costly drugs provide similar clinical benefit. Second, to improve transparency about where the money is going and where opportunities exist to recapture some of it, biopharmaceutical companies and insurance plans should make public information about the net prices they receive and pay for drugs, including discounts and rebates. Third, insurance plans—especially Medicare plans—should provide better protection against out-of-pocket drug costs. There should be limits on total out-of-pocket costs, and patients' deductibles and coinsurance payments should be based on the net price of the drug, not the list price.

A number seem quite procedural such as eliminating misapplication of funds and inefficiencies in federal

discount programs, ensuring financial incentives are not extended to widely sold drugs, and increasing information sharing about reimbursement incentives. Is part of the high cost we pay due to bureaucracy and inefficiency?

We identified ways in which federal programs are being misused, to the detriment of consumers. One example is what is known as the "340B program," which was intended to ensure that hospitals and other facilities that serve low-income populations receive deep discounts on drug prices, but is being used by a broad range of facilities that don't necessarily pass those savings on to patients. Another example is the orphan drug program, which provides very valuable financial incentives for manufacturers to develop drugs for rare diseases. Companies have obtained these rewards even when they also sell their drug for other indications for which there is a huge market, and in some cases have gotten the rewards multiple times for the same drug. These problems aren't about bureaucracy; they're about gaming the system. These programs were good ideas that have been very successful in achieving their goals, but have had unintended effects that need to be addressed.

Biopharmaceutical companies have gotten a bad rap in the press, but you note that the cost of developing drugs is very high, and success rates low, with 9 out of 10 investigational products never making it to market. So, there is an acknowledgment of the high stakes, high cost nature of the sector. The report recommends accelerating market entry and use of generic and biosimilar drugs. How can this be implemented

without discouraging development of new drugs?

Ensuring affordability of drugs while not discouraging innovation is the central tension that our committee had to grapple with. It's not easy. The recommendations in the report strike a balance between these two important objectives. With regard to generics, our patent system creates a workable deal with drug innovators: create a useful new product, and we'll give you a period of market exclusivity; generics can't enter until after that period is up. One problem that our report addresses, though, is that companies have developed ways to extend that period of exclusivity. One is to pay generic companies to delay market entry. Another is to seek follow-on patents on incremental changes to their drug. For example, one company got a new patent by demonstrating their drug could be administered by crushing it up and mixing it with applesauce. The use of this tactic, called "evergreening", should be curbed.

One recommendation in the report is that the federal government consolidate and apply its purchasing power to directly negotiate prices with the producers and suppliers of medicine, and strengthen formulary design and management. Do government sponsored medical plans, such as Medicaid and Medicare, already do this?

By law, the federal agency that runs these programs isn't allowed to negotiate directly for [drug prices](#) for Medicare patients. Instead, all the individual, private plans that provide drug coverage under Medicare Part D do the negotiating. They get discounts, but we think the discounts would be deeper if the bargaining was consolidated in one mighty purchaser.

You noted that private investment is increasingly important to drug development. How much of drug development is supported by public funding, via grants to universities, etc., that then go on to become small startups with private investment? If it is significant, does the public get a good deal on its seed investments?

American taxpayers foot the lion's share of the bill for the basic-science research that generates information about which molecules are promising to pursue. Private companies pay most of the development costs—that is, testing the molecule in clinical trials to see if it's safe and effective. The public has gotten a great return on investment in the sense that the industry, particularly in the last decade or so, has been turning out a lot of very innovative, useful products. The work that remains to be done is ensuring that those products are financially accessible to everyone who needs them.

One recommendation is that biopharmaceutical companies and insurance plans disclose net prices received and paid, including all discounts and rebates, at a National Drug Code level. Would this cover all international transactions too, so that we could see costs/prices in other countries?

No, our recommendation relates to the drug supply chain in the U.S., which is highly complex and highly opaque.

Can you talk about this a bit—why this transparency

is important?

One of the things that was frustrating about studying drug affordability is that the various players in our system—such as drug manufacturers, health insurance plans, and intermediary organizations called pharmacy benefit managers, or PBMs—all point fingers at one another when you ask them who is responsible for consumers' high [drug costs](#). Yet, there's very little information available by which to assess their claims. Is the problem that [drug makers](#) launch their products at excessive list [prices](#)? Or that PBMs buy them at a discounted price, which is kept confidential, and don't pass those savings along to health plans? Or that health plans get drugs at a deep discount but make subscribers pay cost-sharing (for example, the 20% coinsurance you pay at the pharmacy) as though the drug's cost was the list price? Nobody will cough up the data necessary to make these judgments. Our recommendation addresses that problem.

Are there any next steps for you and the authors of this report? Will there be subsequent research by the group—or coordination with policy makers?

We are working hard to make sure policy makers, journalists, and key stakeholders understand our recommendations and the evidence behind them. This week, for example, our report was presented to a packed room of Senate staffers. We have also identified some areas where additional research is needed, and hope that research sponsors will respond to that need. There is a lot of work to be done.

Provided by Stanford University

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