

THE FIGHT TO LOWER PRESCRIPTION DRUG COSTS

\$400

\$350

\$200

\$150

\$100

\$50

\$0

At least 20 outpatient drugs now carry a list price of more than **\$25,000 for a one-month supply**, a March analysis by GoodRx showed.



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Medicine prices keep skyrocketing—as do drug maker profits—despite years of widespread protest. But the momentum is finally beginning to shift as patients, hospitals, regulators and politicians all raise their voices for change. **AARP is rolling up its sleeves, too, fighting for specific changes to make medicine more affordable to all.** Here's how that battle is shaping up, and what role you can play in it.

A 5-POINT PLAN TO LOWER Rx PRICES

POLICY MAKERS AND COMPANIES SHOULD START HERE TO REDUCE MEDICINE COSTS FOR ALL AMERICANS

BY LINDA MARSA

FOR YEARS, even decades, everyone from patients to prescribers has been complaining about the spiraling prices of prescription drugs. Yet little has been done to change that. Perhaps the time has finally arrived.

In May 2017, the *AARP Bulletin* ran an extended report on why drugs cost as much as they do. While the health care system is incredibly complex, the answer boiled down to something simple: In a world of strong patent laws and limited industry regulation of pricing, for-profit pharmaceutical companies have extraordinary power to charge what they want for the medicines they offer.

Little has changed. Drug prices continue to rise far faster than the rate of inflation. The average annual cost of a brand name drug more than tripled in the past decade, jumping from \$1,868 in 2006 to \$6,798 in 2017, according to the AARP Public Policy Institute. Seniors now

take an average of 4.5 medications, which can add up to a total retail cost of more than \$30,000 a year for brand name drugs.

What's different is that prices have gotten so far out of control that Democrats and Republicans have found something to agree on. That's made consumer advocates hopeful that something may soon be done about these skyrocketing costs. In Congress, legislators have introduced several bipartisan bills designed to attack the problem. And last May, the Trump Administration unveiled a blueprint to tackle high drug prices, which contains many common-sense strategies endorsed by AARP.

The solution won't be simple. "Because our health care system is very fragmented, there is no one silver bullet for this problem," says Leigh Purvis, director of health services research in AARP's Public Policy Institute.

But AARP believes that a combination of tactics can bring drug prices under control. These include giving the federal government the ability to negotiate when buying drugs, legalizing the safe importation of drugs →

HOW AARP IS FIGHTING HIGH DRUG PRICES

In March, AARP launched Stop Rx Greed, a national campaign to persuade federal and state lawmakers to curb rising prescription drug prices. Among the actions we are taking:

- ▶ Calling on Congress to work with President Trump to lower drug prices now, including by using the federal government's purchasing power to negotiate for lower prices for Medicare.

- ▶ Pushing to prohibit drug companies from paying off generic manufacturers to delay bringing cheaper versions of medications to market.



- ▶ Advocating for policies such as allowing the federal government and states to safely import prescription drugs from other countries.

- ▶ Backing a federal cap on out-of-pocket prescription drug costs for Medicare enrollees.

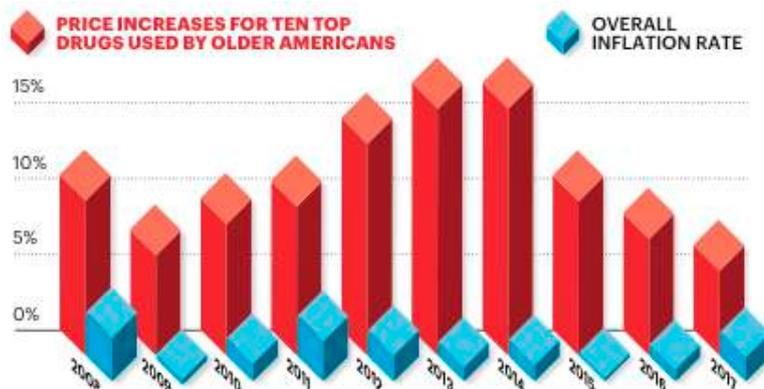
- ▶ Working to pass bills in Congress that would bring lower-priced generic drugs to market more quickly.

- ▶ Asking state legislators and other elected officials to enact policies that will hold drug manufacturers accountable for unconscionable price increases.

- ▶ Organizing events with elected officials in both parties to raise awareness of the issue and solutions.

COSTS KEEP RISING FOR BRAND-NAME DRUGS

For ten of the brand-name drugs most often used by people age 50 and older, price increases far outstripped the inflation rate over the past decade



SOURCE: AARP PUBLIC POLICY INSTITUTE

THE MAKERS

sold at lower prices in other countries, and capping patients' out-of-pocket costs.

A final approach is to change the drug patent rules that currently allow brand-name pharmaceutical manufacturers to freeze out competition from generic alternatives that could lower prices. "Drug companies are incredibly innovative in finding ways to strengthen their monopolies," says Purvis.

To help the fight to lower prescription drug costs, AARP has launched "Stop Rx Greed," a national campaign to convince federal and state lawmakers to take action on the issue. The campaign includes lobbying efforts, consumer information programs, and the release of new research about high drug prices.

Read on to learn more about the different factors behind the drug pricing problem, and what can be done about them.

THE PROBLEM: NEGOTIATING FROM WEAKNESS

One reason the U.S. has the highest prescription drug costs in the world is that we're the only industrialized nation whose government doesn't bargain with drug makers over pricing. The law passed in 2003 to create Medicare Part D outpatient drug coverage shares some of the blame; Medicare, which includes both Part D and Part B (provider-administered) prescription drugs, accounts for 30% of drug spending in the U.S. Medicare Part D plans, which now cover about 44 million adults, are required to provide nearly all drugs in six certain classes of medications, such as antidepressants and anti-cancer drugs, and at least two drugs, assuming they're available, in all other treatment categories. These requirements can limit Part D plans' ability to negotiate with pharmaceutical companies. More importantly, individual Part D plans don't have nearly the same clout that Medicare would if it negotiated with drug companies on behalf of all beneficiaries.

In contrast, Australia, Japan and most European nations have some form of a national health program with drug review boards that negotiate with manufacturers. They analyze whether a new drug is more effective than its previous incarnations, or simply a slightly modified version. They're often able to negotiate significant discounts because they can walk away if companies won't cooperate. So Humira, which treats autoimmune diseases like psoriasis, Crohn's disease and rheumatoid arthritis—and is the top-selling pharmaceutical in the world—fetched \$3,431 →

THE DEVIL IN THE DISCOUNTS

COUPONS AND CHARITY KEEP LIST PRICES HIGH, COSTING INSURERS AND GOVERNMENTS MORE

BY HELAINE OLEN

When Pamela Holt, a retired teacher in Granger, Indiana, was diagnosed with multiple myeloma in 2016, she was soon overwhelmed by the cost of her medications. The largest expense? A \$640-a-month co-pay for Celgene's Revlimid. Holt soon found herself thousands of dollars in debt despite having what she calls a "very good" Medigap plan.

Then a Celgene employee directed her to the HealthWell Foundation, a non-profit group that administers a number of medication assistance funds designed to help patients pay their pharmaceutical bills. Today, Holt, 70, pays nothing for Revlimid.

Sounds wonderful, yes? But it's not so simple. Medicare—that is, taxpayers—still must pay the remainder of the drug's more than \$250,000 annual tab. Experts

say the seemingly generous charitable aid that Holt receives is actually intended to reduce public pressure for drug makers to lower their prices. It helps Holt and others like her, but at the cost of the nation's rising health care budget. "It's really just a racket," she says.

The same can be said for other discounts and help for consumers that are funded by pharmaceutical companies—for example, coupons for brand-name drugs with high sticker prices. While they can make name-brand drug cheaper than generic equivalents for the patient, the health insurance company receives no such assistance, resulting in higher premiums and more cost-sharing for all its customers. In fact, a 2017 paper published in the American Economic Journal found that coupons increased spending on brand-name offerings by 60 percent.

STICKING TO EXPENSIVE DRUGS

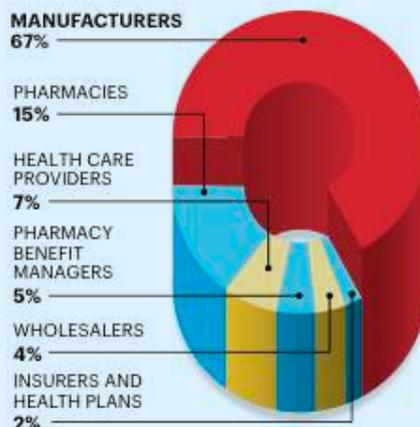
Adding insult to injury: A 2013 study in the New England Journal of Medicine found that when a coupon-based discount ends, consumers often stick with the brand-name drug, rather than switch to a less expensive alternative. "These coupons inflate costs for everyone," says Jon Conradi, a spokesman for the Campaign for Sustainable Drugs, an advocacy group.

The separate charitable aid that manufacturers provide, both directly and indirectly, isn't a fix, either. For example, demand for disease-specific funds, like the one that helped Holt, far outstrips the amount of money available.

Insurers are pushing back on some of these measures that lower costs for individual patients but do nothing about the overall cost of drugs, which ultimately is paid by all consumers. Both UnitedHealthcare and Express Scripts now let employers choose coverage that doesn't count the money picked up by discount coupons towards employee deductibles and out-of-pocket maximums, effectively raising out-of-pocket expenses. The charitable aid, however, is still ok.

RX PROFITS: WHO'S ZOOMING WHO?

Drug makers receive roughly 67% of the total dollars spent on medicines. In other retail industries, manufacturers typically get less than 50%.



SOURCE: HEALTH AFFAIRS, JULY 2018

per month in the U.S. in 2015, but cost just \$982 in France. The asthma medication Advair carried a monthly \$310 price tag here, while Germans shelled out only \$38. The list goes on and on.

The Solutions: Giving Medicare the ability to negotiate with drug-makers is the prime way to attack high drug prices. What would also help: allowing Part D plans more flexibility in creating their lists of covered drugs, or formularies; arbitrating disputes between manufacturers and insurers; and using a drug's price in other countries to help set its price here. "Using their price as the basis for value increases [Medicare's] negotiating ability," says Ameet Sarpatwari, assistant director of the Program on Regulation, Therapeutics and Law at Brigham and Women's Hospital in Boston. "After all, drug makers are still making a profit on their sales abroad."

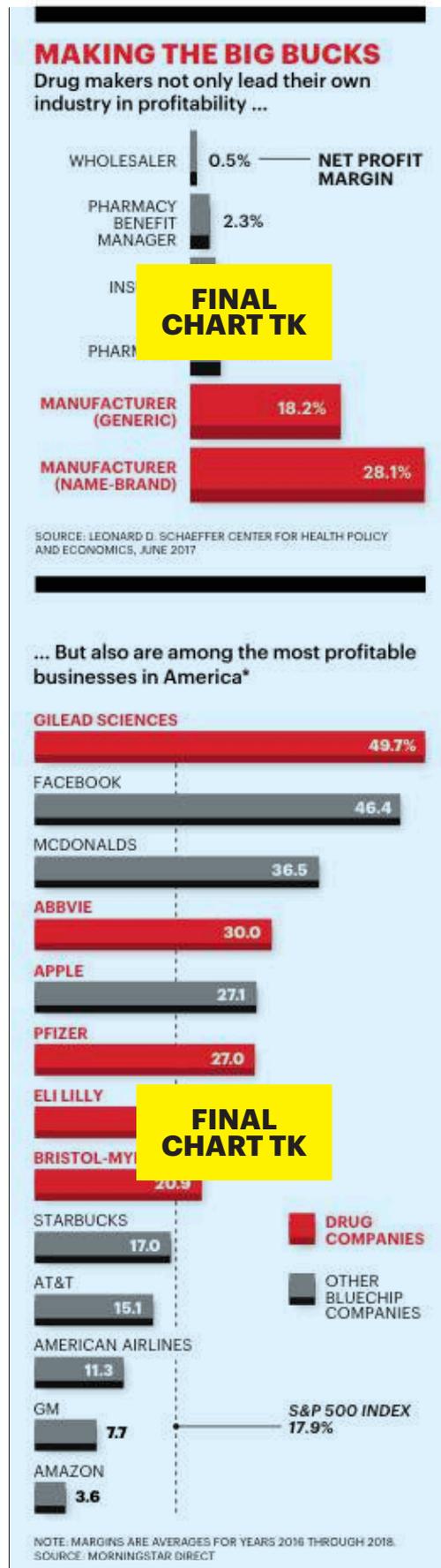
THE PROBLEM: FAILURE TO IMPORT

If prices for the same drugs we use in the U.S. are so much lower elsewhere, why not start importing those pharmaceuticals? Canada is often mentioned as an obvious supplier; prescription drugs, as measured by per-person retail spending, cost 33 percent less there than they do in the U.S., according to 2017 research from the Commonwealth Fund. And individuals here have been getting drugs from Canada for years. But large-scale commercial importation of medications, either through online pharmacies or by purchasing them across the border, is still against the law.

The Solution: Proposed legislation would let patients buy lower-priced medicines from Canadian pharmacies for personal use. Critics say this opens the door to harmful counterfeits. But there are ways to institute safeguards. The FDA has already safely imported drugs to address critical shortages. And more than 40 percent of drugs, both brand-name and generic, are already made overseas.

THE PROBLEM: ENDLESS PATENTS

To encourage innovation and allow pharmaceutical companies to recoup their expenses, the federal government grants 20-year patents on new drugs that give companies the exclusive right to market the medication. Because it takes years to get the drug to market, manufacturers



end up with a monopoly lasting about 14 years on average. At that point, generic drug makers can theoretically begin selling competing versions.

Substituting generics for brand-name drugs can cut costs dramatically. In 2012, the US Government Accountability Office estimated that generics saved the US health care system \$1 trillion during the previous decade.

But drug companies do all they can to retain their monopolies. For example, they can "evergreen" their patents, usually by re-purposing or reformulating medications. These strategies, such as changing dosage schedules, don't necessarily make the drug any better. They can, however, add up to more than 20 years to their monopoly periods. These tweaks effectively prevent less-expensive generics from entering the market.

"Even a minor tweak may be enough to get you past the patent trademark office," says Robin Feldman, author of *Drugs, Money & Secret Handshakes* and a law professor at University of California Hastings. "Conceivably, you can string these out over and over again, and no one asks whether we're getting any value for our money."

In a 2018 analysis, Feldman and her colleagues found that of the roughly 100 best-selling drugs, more than 70 percent extended their protection at least once. For example, Lyrica, used to treat nerve pain, had its monopoly extended from 2009 to 2018 with 16 additions. The cholesterol drug Crestor's monopoly was lengthened from 2008 to 2022 by piling on 32 additions. "These are not outliers," says Feldman. "This is business as usual."

The Solution: There is some talk in Congress about attacking the practice of evergreening, says Purvis. "But doing a complete patent reform would be very complicated and a very heavy weapon," she says. "In the meantime, there are smaller efforts that are nibbling around the edges to get at the abuses."

THE PROBLEM: THE MYSTERIOUS MIDDLE

Standing between Americans at the drug store and the companies making their drugs are a number of different parties. The drugs themselves go from manufacturer to wholesaler to the pharmacies that dispense them. The money takes a

more complicated route. At one end, people and their health plans (both public and private) pay into the system; at the other end, the manufacturer gets paid. In between, there's a confusing flow of money among various parties, including pharmacies, wholesalers and other entities called pharmacy benefit managers (PBMs), which administer drug benefits on behalf of insurers and negotiate with drug manufacturers, wholesalers and pharmacies.

The interactions between these various parties and the deals they make with one another

present various opportunities to keep the ultimate price of drugs down—or drive them up further. Because there's little transparency in the pharmaceutical market—transactions among the members of the supply chain are rarely made public—it can be extremely difficult to tell whether any of them are contributing to higher drug prices or being incentivized not to keep them under control.

The Solution: Given the complexity of the pharmaceutical distribution system, there are no simple answers, but improvements

are possible. For one, says Purvis, health insurers need to be better aware of what types of rebates and fees are being negotiated on their behalf, and where that money is going. And the Federal Trade Commission, she says, must be able to identify, and respond to, any anticompetitive behavior among the players in the market. Other proposed fixes, however, might be counterproductive, says Purvis, such as proposals to publicly reveal all of the transactions taking place within the supply chain. “Many experts, including the FTC,

THE GENERICS

WHY CHEAPER DRUGS ARE HARDER TO FIND

THESE PRACTICES BLOCK ACCESS TO LOWER-COST MEDICINE

BY LINDA MARSA

Generic drug prices can be as much as 90 percent less than branded products, the government has found; pricing differences like that translated into \$265 billion worth of consumer savings in 2017, estimates the Association for Accessible Medicines (AAM), the generic manufacturers' trade group.

AARP believes that greater availability of generics is key to lowering the cost of drugs in the U.S. But making that happen won't be easy. Here are some obstacles standing in the way:

Playing Hard to Get To obtain approval from the FDA to sell a generic drug, a manufacturer must show that its drug is “bioequivalent” to the brand-name drug—that is, it works in the same way and provides the same clinical benefit as its brand-name version. To prove this, companies need adequate samples of the brand-name drug to analyze and conduct tests

with. But, as generic companies have complained in and out of court, brand-name manufacturers sometimes withhold these samples—effectively preventing generic competition. A bipartisan bill co-sponsored by Senators Chuck Grassley (R-Iowa) and Patrick Leahy (D-Vermont), the CREATES Act (Creating and Restoring Equal Access to Equivalent Samples), which AARP supports, would outlaw tactics like these that are designed to stifle generic competition.

Pay for Delay Brand-name manufacturers sometimes offer financial inducements to generic companies to back off patent litigation or wait to introduce their products, thus delaying price competition. As many as 142 brand-name drugs had been involved in these deals from 2005 through 2013, according to an analysis of Federal Trade Commission reports conducted by the U.S. PIRG advocacy group.

Provigil, which is used for sleep disorders and multiple

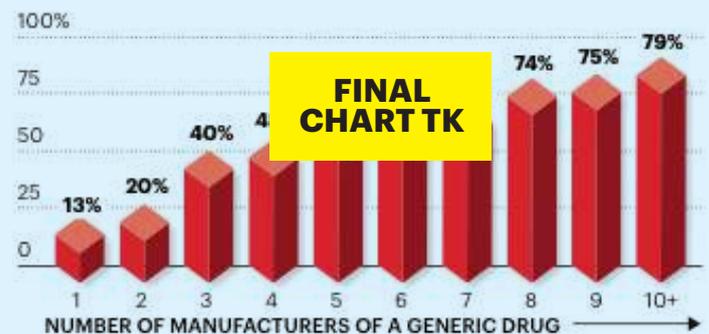
sclerosis-related fatigue, is a good example. Although a generic version of Provigil was scheduled to debut in 2005, its manufacturer, Cephalon, paid more than \$300 million to four different generic drug makers to keep their products off the market until 2012. Patients were stuck shelling out up to \$1,200 a month while Cephalon reaped windfall profits.

Following a Supreme Court ruling that these types of deals were subject to antitrust rules, the Federal Trade Commission cracked down, reaching a \$1.2 billion settlement with Cephalon. And earlier this year, the FTC reached settlements in three pending antitrust suits involving these payment schemes.

Consolidation Tight profit margins and increased competition have reduced the number of players in the generic industry. Some manufacturers are cutting staff or turning their focus to brand-name drugs. Plus, the negotiating power of the top three wholesalers—representing 90 percent of generic drug purchasing—has caused “tremendous” price cuts of about 11 percent per year, says Jeff Francer, general counsel of the AAM trade group. “It takes many years of development and working with the FDA to get a generic drug approved,” he says. “But by the time it's ready to launch, the price might discourage companies from entering the market.”

GENERICS LOWER THE COST OF DRUGS

The more generic alternatives there are to a particular drug, the lower the average price of those generics will be.



SOURCE: NEW ENGLAND JOURNAL OF MEDICINE, DEC. 2017

have noted that there is a high risk of collusion among sellers if all prices, rebates and other arrangements are made transparent," she says.

THE PROBLEM: THE RESEARCH GIVEAWAY

Big Pharma justifies high drug prices by saying they are needed to cover the costs of innovative research and development. That number is pegged at \$2.6 billion per drug, according to a 2014 analysis by the Tufts Center for the Study of Drug Development, which gets 25 percent of its funds from pharma company donations. But experts say that estimate of development costs is somewhat deceptive because it encompasses far more than the actual expenditures for guiding a drug through the lengthy approval process; for example, it also includes capital costs (what the money would make if it was invested rather than tied up developing a new drug).

The reality is that virtually all of today's new drugs, such as blockbuster immunotherapies for cancer, had some basis in government-funded research at the National Institutes of Health or leading academic centers across the country. Every one of the 210 new drugs approved by the FDA between 2010 and 2016 began life in NIH-funded labs, representing grant funding totaling more than \$100 billion, according to a 2018 report by researchers at Bentley University in Waltham, Massachusetts.

Drug companies rarely, if ever, do the fishing expeditions of basic research that might one day lead to a breakthrough drug but don't have an immediate payoff; instead, that work is funded by taxpayers. Sovaldi, a medicine made by Gilead Sciences, is a prime example of how this process plays out. The drug, a highly successful treatment against the hepatitis C virus, was developed by a biotech company cofounded by a Department of Veterans Affairs scientist. Gilead then bought the company for \$11 billion, which included the monopoly rights, and spent an additional \$300 million to steer Sovaldi through clinical trials. In 2013, the drug was priced at \$1,000 per pill, or \$84,000 for the 12-week course of treatment, even though it cost the manufacturer no more than \$136 to produce, according to a 2014 analysis by University of Liverpool researchers. The patent doesn't expire until 2029, assuring the company of generous profits for many years.

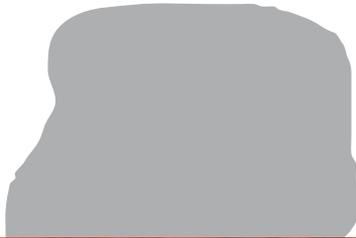
It's all perfectly legal, since taxpayer-funded scientists are permitted to patent their dis-

coveries, in order to speed discoveries from the laboratory bench to a patient's bedside.

The solution: Policymakers are considering a variety of options, such as demanding a higher return on investment for taxpayer-funded research that is ultimately commercialized, or allowing the government to infringe on, or even break, the patents of drug makers that charge unreasonably high prices.

OTHER APPROACHES THAT COULD HELP:

► **Increase generic competition.** Pending bills would beef up FDA budgets for reviewing generic applications to accelerate approvals, as well as implement other measures to increase the availability of generic drugs (see "Why Cheaper Drugs Are Harder to Find" on page 14 to learn more). "The timely introduction of generics is really the most effective way we have right now to consistently reduce drug prices," says Sarpatwari, who is also on the Harvard Medical School faculty.



WHAT YOU CAN DO TO FIGHT HIGH DRUG PRICES

► Visit www.aarp.org/rx. There you can...

...Send a message telling your Senators and Representative to take action now to cut drug prices

...Share your story with AARP and our community

...Learn more about AARP's Stop Rx Greed campaign to rein in prescription drug costs

► Engage with AARP Advocates' Twitter and Facebook accounts and use the hashtag #StopRx-Greed to show your support for the campaign.

► Call your state and federal elected officials and tell them it's past time to lower drug prices.

"It's only when you have a decent amount of competition that prices fall."

► **Limits on out-of-pocket costs.** One fix would be to cap out-of-pocket drug costs for Medicare Part D enrollees. Currently, even after reaching catastrophic levels of spending, they still have to keep paying for high-priced prescription drugs.

► **Value-based pricing.** Right now, a drug's price tag often bears no relationship to its clinical benefits. "When new products come on the market, we often don't know if they're any better, but we treat them like they are," says AARP's Purvis. The Department of Health and Human Services (HHS), which oversees Medicare, has a stated goal, shared by AARP, of better aligning the price of a drug with the value that it provides to patients. There are challenges, however, in measuring a drug's fair price. How much is it worth, for example, to add just a few weeks to a patient's life? How do you distinguish a genuine advance from a mild improvement? "Everyone defines value in different ways," says Gerard Anderson, a professor of health policy and management at the Johns Hopkins University Bloomberg School of Public Health. "Is it that you're cured? Or is it 'it's brought down sugar levels in diabetics'?" No one agrees on how to measure it."

► **Consumer education.** As part of its drug pricing blueprint, HHS is calling for increased price transparency so consumers can make more informed decisions. To this end, Medicare and Medicaid have updated their pricing dashboards, Congress passed an anti-gag clause allowing pharmacists to tell consumers about drugs that are more affordable than ones they've been prescribed, and drug makers are being encouraged to include list prices in their direct-to-consumer advertising. Still, AARP's Purvis says simply knowing the price isn't necessarily as helpful as other information, such as whether a drug works better than similar medications.

The bottom line on all of this is that "real people suffering from real diseases should not have to beg, borrow or steal to control their disease," says Rena Conti, associate research director of Biopharma and Public Policy for the Institute for Health System Innovation and Policy at Boston University. "Our system can be better."