

Congressman Lloyd Doggett  
CAP Prescription Drug Panel Keynote Address  
April 26, 2016

Thanks to the Center for American Progress for organizing what I know will be a robust discussion. This forum was originally scheduled in January during a blizzard with a federal government shutdown that Ted Cruz did not cause. That offers a fitting metaphor for what's been happening with pharmaceuticals--a blizzard of price hikes about which the federal government has been largely shutdown. Health care professionals and patients have been calling 911 for some time, seeking relief, but Congress keeps putting them on extended hold.

And as is usually the case in Washington, the blizzard of price gouging has been accompanied by a blizzard of lobbying and campaign contributions. Last year, 9 of the country's 10 largest pharmaceutical companies increased their spending on lobbying Congress, collectively spending over \$50 million. The title of CAP's report last fall correctly captures the urgency of our task: "Enough is Enough: The Time Has Come to Address Sky-High Drug Prices," and the report identifies many needed public policy responses.

This is not about just the smirking face of one smug bad-boy who engineered a 5000% overnight price hike. It's not about one pharmaceutical manufacturer, or one class of drugs, or one disease; it is a pervasive industry-wide problem.

Major pharmaceutical companies have become giant marketing operations, expert at defending their monopoly pricing, expert at public relations, expert at avoiding taxes and wielding political influence, but some are not so expert at innovation except by purchasing someone else's successful research. Nine out of the ten largest companies spend more on marketing than on R&D, but there is undoubtedly some public benefit--who knows if we would even have any television network news without their ad buys. And the underwhelming performance of the pharmaceutical industry comes despite all of the tremendous advantages that it has long enjoyed.

In Congress, most all of the health care debate has centered on how many times we could vote to repeal Obamacare—now over 60—not how many times drug prices were arbitrarily hiked. For almost a decade, PhRMA has won the ultimate victory—removing the issue of exorbitant prices from the legislative agenda. Our Task Force is the product of Member discussion of how to change that.

The true breadth and scale of the accessibility problem were outlined by a February AARP report. Retail prices for a combined set of widely used prescription drugs consistently increased faster than general inflation in every recent year reviewed, with the average cost doubling over seven years. Almost half of those surveyed, who were ill, indicated that they were having trouble paying for their medicines.

Of course, the industry sees price hikes somewhat differently. At the annual JP Morgan Healthcare Conference this January in San Francisco, Ron Cohen, chairman of the big industry group BIO, condemned anger at drug companies as “an abomination,” insisting that all of the talk about profiteering is “a perversion of reality.”

Apparently, they have not heard from folks whose cancer diagnosis is accompanied by a bankruptcy prognosis, nor the Texas physician who denounced “appalling” pharma price hikes where “even the new drugs that treat routine conditions, such as diabetes, often cost over \$300 a month.” Nor do Presidential candidates need a hearing aid to understand this outcry; both Secretary Clinton and Senator Sanders have outlined specific legislative initiatives. Even Donald Trump has supported Medicare negotiation and called for making drug prices in America, not so great again.

Within just the last month, we have an important CMS proposal, Medical Payment Advisory Commission or MedPac proposals, and yesterday recommendations from the Campaign for Sustainable Rx Pricing. We need vigorous discussion of each of these. None are a panacea, but each one seeks to get at parts of the problem.

Legislation is certainly needed. As the struggle for the Affordable Care Act got underway, Dr. Emanuel’s brother Rahm decided that he could not pass healthcare reform over PhRMA opposition, and he actually reached such a good deal for the drug industry that it devoted millions to promoting Obamacare. And given the political muscle of PhRMA, Rahm may well have been right about that decision.

After Democrats took control of the House in 2007, the first major bill we had approved was John Dingell’s Medicare Drug Negotiation bill. Though it received the vote of every Democrat and 24 Republicans, PhRMA killed it in the Senate. The Obama Administration left that negotiated price proposal on the ACA cutting room floor. I recognize that most of our panel remains less enthusiastic about this approach than we Democrats were in 2007, and clearly the 2007 version of the bill would require some updating, but I believe this approach still has merit.

The VA is negotiating prices that are a fraction of the prices that seniors face. While realizing that it serves a unique and smaller population than Medicare, the Veterans Administration uses a formulary based on drug effectiveness, considers value by reviewing clinical records, seeing how well a drug works, and then comparing it to other drugs with the same effectiveness.

An important California ballot initiative also demands that the State pay no more for drugs than VA negotiated prices. With this effort, the AIDS Healthcare Foundation in Los Angeles is reportedly attracting about a \$100 million of industry opposition and objections from most every group that PhRMA has ever funded, which is many. Though usually bottled up in committee or challenged by PhRMA lawsuits, legislative action is being considered in at least half a dozen other states across the country.

Federal legislative action should focus on reducing monopoly power with more competition and more transparency. The problems are not new, the solutions on many of these issues like “pay for delay” are not new, what is needed is the will and the leadership to get something implemented.

Since there’s no pill to cure the obstructionism of this Republican Congress before November, I began exploring how the Administration could use its existing legal authority. Administration insistence that the Republican Congress pass a bill we know it will not pass is sometimes just a convenient excuse for inaction. CAP research identified one such step forward--protecting Americans from being overcharged on drugs that are the product of taxpayer-funded research.

Under the Bayh-Dole Act of 1980, the National Institutes of Health may require a patent holder to license federally-funded intellectual property to third parties. Fifty House members urged Secretary Burwell and NIH Director Collins to use this authority to respond to the soaring cost of pharmaceuticals. Since NIH had not previously offered guidance regarding the situations when what are called “march-in rights” should apply, we suggested that rule-making could define reasonable guidelines that would discourage predatory drug pricing and provide guidance to pharmaceutical manufacturers regarding when such rights would be exercised.

Declining our request for additional general guidance, Secretary Burwell replied that NIH was “prepared to use its [march-in] authority,” but would evaluate it on a case-by-case basis. Thanks to the dedication of Jaime Love there is in fact a case pending at NIH today. And now is the time for NIH to get on the march. We House

members have now been joined by Senators Sanders, Leahy, Franken, Whitehouse, Warren, and Klobuchar requesting a public hearing to establish whether march-in rights should be exercised for a pending petition for a prostate cancer drug, which was developed at UCLA through taxpayer-supported research grants from the NIH and the U.S. Army. A Japanese licensee is charging Americans \$129,000 for this drug, Xtandi, while selling it in Japan and Sweden for \$39,000 and in Canada for \$30,000.

The NIH Director's answer to Senator Dick Durbin earlier this month at the Senate Labor-HHS appropriations subcommittee is not encouraging. In response to the Senator's recommendation that using march-in rights "sparingly" would "send a message" to industry, Director Collins seemed more concerned about maintaining industry partnerships with NIH. Senator Durbin pushed back noting that "Doing nothing sends the opposite message, that's it's fair game, open season, to [set] whatever prices they wish." If the Administration wants to slow the spike in drug prices, an NIH hearing on Xtandi is one place to start.

The Administration could also join the Members of our Task Force, who have urged the Patient-Centered Outcomes Research Institute (PCORI) to invest more in comparative effectiveness research on prescription drugs. Created by the Affordable Care Act, PCORI has devoted too little of its resources to direct research comparing the effectiveness of treatments, particularly drugs.

This Institute should publish the results of its research in a form that is easily understood by consumers regarding how to get the best value for their money. While PCORI's recent response suggests some modest increase in research on the comparative effectiveness of drugs, it should be tracking and evaluating drugs as they enter the market, investing more in research on high-cost specialty and oncology drugs, and rating the comparative effectiveness of medications in a clear, understandable way. I look forward to the CAP follow-up report on PCORI.

With the Institute of Medicine conclusion that over half of all treatments are delivered "without clear evidence of effectiveness," the FDA could also be doing more. Instead of only testing whether a drug is better than a placebo, it could look at whether a drug is actually better or worse than existing treatments.

And there are a number of additional steps the FDA should take, including prioritizing the review of drugs that would provide competition for expensive treatments.

And the Administration could do much more about transparency. While its 2017 budget proposed increasing transparency and evidence development for Medicare Part D, the Administration has never bothered to even suggest specific implementing legislation. I have previously called on Secretary Burwell to request from pharmaceutical companies the same information sought in the Budget proposal, including research and development. Yes, it would be better for Congress to mandate this requirement, but, while we await a better Congress, there is no good reason why the Administration should not request this information now.

I'm eager to get every idea this panel has about getting the most true healthcare value per patient dollar. But the experience with Sovaldi shows that even a drug that works can break budgets at \$84,000 per treatment.

The drug industry, through its paid consultants, has created wildly inflated figures on what R&D costs. The data is intentionally opaque and padded with all kinds of costs not related to direct research, including legal costs, pre-clinical costs, a cost-adjusted risk of failure formula and an opportunity cost of capital. With accurate information on R&D costs, the Administration could calculate its own estimates of what it costs to produce a drug, instead of accepting the preposterous November 2014 industry claim of \$2.6 billion/drug.

There are other pending issues for which we await an Administration response -- from gag orders on pharmacists advising customers about lower cost alternatives, to recent reports on waste in the packaging of costly cancer drugs in oversized vials. But our basic approach is this: if something should be done about pharmaceuticals legislatively, why isn't some part of it already being done administratively? And with obstruction reduced but hardly going away in 2017, these questions will remain very relevant for the next Administration.

All of us want innovative pharmaceutical and biotech companies. I am eager for them to find a cure for a string of dread diseases before I get any of them, and so is most everyone. Industry plays on fears that any accountability will ensure that these cures never come.

There are a number of answers to the phony argument that predatory pricing is essential to innovation.

First is the limited current commitment of some major companies like Pfizer and Merck to research, spending only about 17 percent of their revenues on finding new drugs, according to their financial statements.

Second, the price of a drug does not have to include every dollar lost on unsuccessful research efforts on other drugs because taxpayers are already subsidizing these research expenses. The industry gets a tax credit of about 57 cents on every dollar it can classify as research. And it is asking Congress to sweeten the pot further by increasing that subsidy to about 70 cents, with what industry calls a “Patent box” but what should more appropriately be called a “Giveaway Box.”

Third, there is no justification for the industry model that compels American consumers -- patients, insurers and governments -- to finance research for the entire world. In its recent effort to dodge its already low effective tax rate by adopting a new corporate address in Ireland, Pfizer was not interested in American consumers having the “luck of the Irish” on the price of its top-selling drugs. Americans are charged 12 times more than Irish consumers. If the industry needs a premium to innovate, that premium needs to be shared with other advanced economies not borne almost exclusively by Americans being charged grossly higher prices.

The pharmaceutical industry believes in entitlements—its entitlement to incredible tax advantages and massive taxpayer-funded research, while setting prices that bear little relationship to either the actual cost of developing and producing a pharmaceutical or its medicinal value to the patient. When it comes to setting monopoly prices, the industry does believe that the sky is the limit—whatever a sick or dying patient will pay for a little less misery or perhaps a few more months of life.

The incoming President should know that there are a number of Members of Congress who care deeply about this unacceptable situation, are already exploring the best ways to respond, and are willing to offer strong support for effective action. People of good intent and judgment can disagree, here and beyond, on how best to correct this problem, but there can be no legitimate disagreement that there is a very real, major problem. We need action on all fronts: from Congress, the Administration, the States, physicians, insurers, private partners, and patients. But we don’t need new laws or regulations to know one thing about drug effectiveness: An unaffordable drug is 100% ineffective.

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