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The Next President can Lower Drug Prices With the Stroke of a Pen

by Alicia Mundy

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How the next president can lower drug prices with the stroke of a pen.

By Alicia Mundy

It's hard to watch television or read a newspaper these days without seeing stories about outrageous prescription drug price increases. This past summer, the company Mylan was in the spotlight for hiking the price of its EpiPen, an injector containing cheap but life-saving allergy medicine, from $94 for a two-pack in 2007 to over $600 today. Last fall, Martin Shkreli, CEO of Turing Pharmaceuticals, became the face of greed when his company purchased the AIDS drug Daraprim and promptly raised its price from $13.50 to $750 per pill—an increase of some 5,000 percent. Prior to that, Valeant Pharmaceuticals drew widespread scorn for jacking up the prices of two heart medications, Nitropress and Isuprel, by 212 percent and 525 percent respectively. Meanwhile, Medicare, Medicaid, and private insurers were buckling under the $84,000 per-dosage-cycle price of Sovaldi, Gilead Sciences' treatment for Hepatitis C, and of Medivation's prostate cancer drug Xtandi, which costs $129,000 for an annual treatment.

These are not isolated incidents. List prices for drugs in general rose 12 percent last year, on top of similar increases over the previous five years. Drug prices are now on track to account for more than 15 percent of health care costs in America, up from less than 10 percent in 2014. That increase is helping to drive up health insurance premiums and patient deductibles. According to an August 2015 report by Kaiser Health News, 24 percent of Americans taking prescription drugs reported being unable to afford a prescription from their doctors in 2015 over the previous year.

The only thing more depressing than these out-of-control drug prices is the seeming inability of politicians to do anything about the problem. President Barack Obama has called for, among other things, faster approvals of generic copies of expensive biologic drugs and new authority to drive down prices for Medicare Part B. His proposals have gone nowhere in the GOP-controlled Congress. This summer, Hillary Clinton released a more aggressive plan for statutory changes that would make drugs cheaper and cut some

advertising tax breaks for the drug industry. Even Donald Trump said he would break with his own party and support changing the law to allow Medicare to bargain with the pharmaceutical industry over drug prices.

Yet none of these proposals has even the slightest chance of being taken up by Congress during the lame-duck session, and the chances will be hardly better in the new Congress, given Big Pharma's power over lawmakers in both parties. Indeed, legislation introduced in September by a bipartisan group of lawmakers that would merely require drug companies to give warning about upcoming price increases—an effort just to give incumbents up for reelection something they could tell voters they were doing—was widely seen as DOA.

But what if the next president doesn't need Congress's approval in order to act? What if previous statutes have already given the executive branch the authority it needs to beat back extreme drug price increases? And what if the Obama administration, which otherwise has not been shy about using executive power aggressively—to battle climate change, to reform immigration, and to defend transgender rights, for example—simply hasn't used that power to curb drug prices, even though it could?

Government funding played a role in nearly half of the 478 drugs approved by the FDA between 1998 and 2005 and almost two-thirds of the most important and cutting-edge ones.

That's exactly what a group of progressive Democratic lawmakers, including Massachusetts Senator Elizabeth Warren and Vermont Senator Bernie Sanders, have been saying for months. The source of that authority, they say, comes from provisions in a thirty-six-year-old law, the Bayh-Dole Act, that empower the executive branch to get pharmaceutical companies to reduce prices on drugs invented with the help of federal research funds. "We already have leverage in the law to force down prices—why isn't President Obama using it?" asks the group's leader, Texas Representative Lloyd Doggett.

According to a months-long investigation by the *Washington Monthly*—including interviews with a dozen current and former Obama administration officials as well as scores of outside experts—these progressive Democrats have a case. If they're right, the next president could have leverage not only to bring down excessive drug prices, but also to reform the increasingly dysfunctional federally funded biomedical research and commercialization system that gives rise to those insane prices in the first place.

Last September, as public outrage over price hikes by Valeant and Martin Shkreli was spiking, Doggett invited a few fellow Democratic representatives, including Rosa DeLauro of Connecticut, Jan Schakowsky of Illinois, and Peter Welch of Vermont, along with staffers, for a series of meetings in his Rayburn Building office. Doggett is a former Texas state supreme court judge with a bit of a laconic western drawl who represents a safe liberal district that includes Austin. He enjoys a reputation among his colleagues as a non-flashy legislative workhorse who fights hard behind the scenes for his causes. One of those causes is lowering drug costs; he has been pushing legislation to that end since he entered Congress in 1995.

At one of these meetings in Doggett's office, researchers from the Center for American Progress (CAP), a liberal think tank, gave the group an eye-opening presentation on the extent to which federal—meaning taxpayer—dollars support critical drug research. Government funding played a role in nearly half of the 478 drugs approved by the FDA between 1998 and 2005, according to one study, and almost two-thirds of the most important and cutting-edge ones. These more innovative drugs, such as the critical oncology medication Gleevec, not only originated through federal support but continue to receive it thanks to Medicare, Medicaid, and other government programs that subsidize their purchase. Taxpayers, in other words, are paying for these drugs on both the front and back ends, even as the prices drug companies charge escalate seemingly without end. The CAP researchers also explained how the Bayh-Dole Act—officially the Patent and Trademark Law Amendments Act of 1980—could be utilized to lower those prices.

A complex piece of legislation that took four years to write and pass, Bayh-Dole was designed by its sponsors, Indiana Democratic Senator Birch Bayh and Republican Robert Dole of Kansas, to encourage the commercialization of federally sponsored research. At the time, much of that research was sitting on shelves in university and federal labs because companies could not get secure enough title to the discoveries to be willing to invest the extra dollars necessary to turn them into salable products. Bayh-Dole mandated that the labs and universities could patent their discoveries and sell the royalty rights to private-sector firms.

The law was, by most accounts, a big success. Over the next two decades, U.S. universities increased their patent output tenfold and founded more than 2,200 companies to exploit those patents, thus creating 260,00 new jobs and contributing $40 billion to the economy (though some of this increase is probably due to the biomedical revolution, which gave university researchers tools such as gene splicing to more easily create patentable medical applications).

Bayh-Dole also mandated, however, that the federal government retain its own rights to the patents, which it could exercise under certain conditions. If, for instance, a company

failed to use a federally funded discovery to get a product to the market, the federal agency could "march in" and offer the rights to another company to commercialize and sell the drug to the public. Or it could offer "royalty-free rights" on any patent to companies that would manufacture products strictly for government use—say, a drug sold only to the military.

Yet in the thirty-six-year history of Bayh-Dole, there had only been five attempts (petitions from patients, advocacy groups, or corporations) to get the government to invoke march-in or royalty-free rights—together referred to as "retained rights"—against a pharmaceutical company. All five petitions had been rejected by the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS).

The main reason for the NIH'S hesitation, Doggett and his team learned, is that the agency has powerful institutional reasons not to want to exercise its retained rights. The NIH's main mission—the thing Congress funds it to do and holds it accountable for—is encouraging medical advances. It achieves this by partnering with university researchers and pharmaceutical companies. Anything that upsets these partnerships is seen within the agency as hampering its mission, and as a threat to its budget. "NIH won't ever agree to exercise march-in or royalty-free rights, no matter the strength of the case," says James Love of the think tank Knowledge Ecology International, who led three of the five failed NIH petitions and was involved in the other two. In briefings with Doggett and his team, Love suggested that the only way to get the NIH to use its power would be to convince higher-ups in the Obama administration to force it to do so.

So that's what the lawmakers decided to do. In early January, fifty-one House Democrats, including Doggett and his group, sent a letter to HHS Secretary Sylvia Mathews Burwell and NIH director (and Nobel laureate) Francis Collins, saying, "We respectfully urge you to use your existing statutory authority to respond to the soaring cost of pharmaceuticals." Specifically, they asked the NIH and HHS to finally propose guidelines for triggering the use of march-in rights, saying, "We believe that just the announcement of reasonable guidelines in response to price gouging would positively influence pricing across the pharmaceutical industry."

"That's the point," says Doggett. "Just the threat" of exercising these rights, or even of reviewing the amount of U.S. government support that over the years has gone to the companies holding exclusive patents, would probably "cause the pharmaceutical companies to blink."

Like a lot of policy battles in Washington, the one over the government's retained rights on patents to federally funded research revolves around contested interpretations of a few words in a long statute. The Bayh-Dole Act states that the federal government can exercise its retained rights only under certain conditions. The main one is if the company that holds the patent rights has failed to make the fruits of the discovery "available to the public on reasonable terms." Another is if the agency that originally disbursed the research funds determines that exercising its retained rights "is necessary to alleviate health or safety needs" of the public. The fundamental legal dispute is whether, under Bayh-Dole, exorbitant drug prices constitute a violation of "reasonable terms" and/or a threat to "public health and safety."

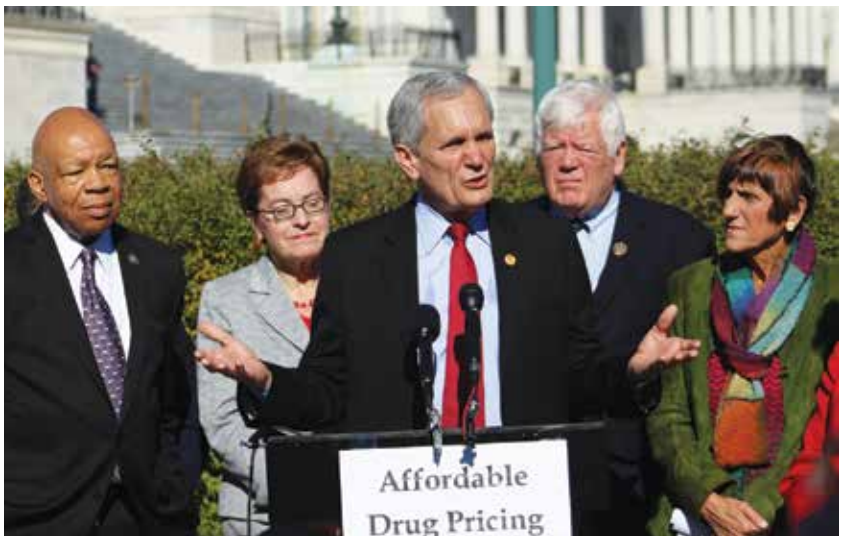
It is fair to say that the vast majority of attorneys who know anything about Bayh-Dole have concluded that the answer is no: high drug prices are not one of the conditions that would trigger the government's ability to exercise its retained rights.

It is also fair to say that most of the attorneys who make this argument represent drug companies. This is the case even of the law's cosponsors. In 2002, Birch Bayh and Bob Dole, by then retired from the Senate and working as lobbyists for law firms representing drug companies (Dole himself was starring in ads for Viagra), wrote a letter to the editor in the *Washington Post*. In it they stated that Bayh-Dole "did not intend that government set prices on resulting products" and that government could exercise its retained rights "only when the private industry collaborator has not successfully commercialized the invention as a product." A few years earlier, Bayh had argued the opposite when he was representing a firm that would have benefited from the government's exercise of royalty rights.

Opposed to the industry's position is a small group of lawyers, researchers, and scholars who have long argued that the government does have pricing rights under Bayh-Dole. They include public interest lawyers such as Love and Robert Weissman, the president of the advocacy group Public Citizen; law professors such as Michael Davis of Cleveland-Marshall College of Law and Rachel Sachs of Washington University in St. Louis; medical policy experts such as Peter Arno of the University of Massachusetts Amherst and Aaron Kesselheim and Jerome Avorn of Harvard Medical School; and the philanthropist and former pharmaceutical patent attorney Alfred Engelberg.

These experts have their differences. The latter three, for instance, believe march-in rights apply only to drugs based on patents that all derive directly from government research. That's a small portion of the drugs on the market, though many of those are the most pricey. (If a drug's patent has expired, as was the case with Daraprim, Bayh-Dole no longer applies.)

In general, however, these experts all agree that "reasonable terms" and "health and safety" can include price, for several reasons. For one, many U.S. laws other than Bayh-Dole use the phrase "reasonable terms," and courts have typically defined that phrase as including price. Also, when the legislation was being considered, many lawmakers and witnesses at hearings raised the very issue of price, out of worry that granting private companies lengthy, exclusive patents on government-funded research—that is, monopolies—would lead them to jack up the prices. March-in and royalty-free rights were the provisions these lawmakers demanded in order to secure their votes for the bill. Finally, there's the fact that the NIH, in its written rejections, has never explicitly stated that Bayh-Dole prohibits using pricing as a factor. Instead, the agency has



Doggett determination: Representative Lloyd Doggett (center) speaking at a press conference announcing the formation of a prescription drug pricing task force in November 2015. Pictured in back, from left: Representatives Elijah Cummings, Marcy Kaptur, Jim McDermott, and Rosa DeLauro.

come right up to the line—stating, for instance, that march-in rights are "not an appropriate means of controlling prices." This, say advocates, suggests that the NIH knows that its own case is not legally ironclad.

So, which side is right? The proponents of march-in rights power certainly have a reasonable case. But it's impossible to say with certainty, because the question has never been litigated. The only way to know for sure would be for the government to actually test its powers. It could do so by proposing a regulation, or even just a regulatory guideline, based on those rights; evaluating the arguments that come back from the public and interested parties; and waiting to see how the courts ultimately decide any lawsuits that challenge those regulations or guidelines. The problem is that, for thirty-six years, the government has been too scared to try.

In addition to parsing the language of the statute, the drug companies deploy a second argument against the government's use of retained rights to regulate prices. It is they, not the government, who put up the lion's share of R&D funding for new drugs, say the companies. So it would be unjust and confiscatory for the government to use its retained rights to lower prices.

As a matter of pure law, advocates note, this is beside the point. Bayh-Dole does not set out any percentages or other metrics for what the government's share of R&D on a drug must be before its retained rights kick in. "It doesn't matter if the government grant was for millions of dollars," James Love says, "or for a few thousand."

In any event, the government's impact on R&D and the amount spent to support drug development is much higher than the drug industry likes to acknowledge and most voters understand. This is especially true of breakthrough drugs (of which there are far fewer coming online than in years past) as opposed to the "me too" variety—modest tweaks on existing treatments—that the drug industry has increasingly produced. A 2011 study published in the journal *Health Affairs* found that government-funded research contributed to most of the new medications that, because of their innovative nature, qualified for "priority review" by the Food and Drug Administration between 1998 and 2005. A 2014 study in the same journal found that the majority of the twenty-six most transformative drugs—those judged by medical experts both to be innovative and to have groundbreaking effects on patient care—developed between 1984 and 2009 were discovered with the help of federal research funding.

The drug industry will on occasion grant that the most innovative drugs require federal research funding—usually when they're lobbying Congress for more such funding. Still, they say, government's share of the research and development costs behind any particular such drug is small compared to the drug company's own R&D costs, which, the industry says, typically exceed $1 billion.

Independent researchers, however, have challenged that $1 billion–plus figure. They note that it is derived from unverifiable industry data, that half is accounted for by federal tax breaks pharmaceutical companies receive, and that a substantial portion of the rest comes from dubiously counting such expenses as "cost of capital"—what companies theoretically would have earned investing in something else. The drug industry vigorously defends the figure.

Whatever the merit of Big Pharma's claim to be a big investor in drug innovation, that claim is less true every year. In the past decade, major drugmakers have cut R&D costs in order to slash expenses and maintain high returns to shareholders. Nine of the top ten drugmakers spend more on marketing than R&D. A McKinsey & Company report called even this reduced level of R&D spending "a luxury that investors no longer tolerate." In general, the big drugmakers are leaving the innovation to small pharmaceutical and biotech firms, which originated 64 percent of the new drugs approved by the FDA last year, up from less than 50 percent a decade ago.

Figuring out the pharmaceutical industry's share of drug R&D costs is made even more difficult by the fact that the government doesn't bother to tote up the overall value of all of its subsidies. Beyond research grants to academia, medical centers, and small start-up companies, Washington spends millions of dollars on the infrastructure that keeps the drug discovery process moving globally. The NIH helps many drug researchers in the earlier stages get through the maze of federal bureaucracy in order to advance a novel medicine. The NIH and the Food and Drug Administration work with drug developers to create frameworks for testing for safety and effica-

Courtesy of Congressman Lloyd Doggett

cy, in order for companies to be certain of the data they must collect and the standards they must meet for approval. The NIH strikes "cooperative research and development agreements" with commercial firms, sharing resources and work on projects that might ultimately lead to new medicines. Many modern medical devices and prosthetics marketed by major corporations start as experiments in Department of Veterans Affairs hospitals and laboratories. The VA and the Department of Defense have conducted large clinical trials in cardiology, diabetes, prostate cancer, and smoking cessation that help shape the direction of industry research in those areas. And universities and medical consortiums win government grants for disease "awareness" and "testing" programs, which all contribute to the ongoing market success of a drug invented to treat a certain condition. Add to this the multitude of tax breaks and seemingly endless extensions of patent exclusivity that government showers on drug companies, strengthening their monopolies. Most of this government largesse is not counted in the many (often industry-funded) studies of drugmakers' R&D investment floating around Washington; government programs like Medicare that subsidize the purchase of the industry's products are also rarely considered.

"Industry always compares individual federal research grants to what they claim to be their overall cost—which they greatly exaggerate," says a senior NIH official who didn't want to be identified by name. "But we finance the whole system that basically keeps global drug development on track and launching successful drugs."

The industry defends high drug prices as necessary for companies to recoup the R&D costs of the many drugs they invest in that don't ever make it onto the market—the "risk-adjusted price." There may be some truth in this. But the same logic also applies to the government's investment. For every federal research grant that leads to a patent sold to a drug company, there are hundreds of others that don't (even if they extend the boundaries of scientific knowledge). Drug companies are beneficiaries of that winnowing-out process, too.

The drug companies' third argument is that any attempt by government to exercise its retained rights on a drug patent would wreak havoc on the whole pharmaceutical industry. Without the certainty of a patent term and end date, pharmaceutical companies would be reluctant to invest in new drugs coming out of universities and biotech start-ups. Moreover, even a whisper of such threats would spook the Wall Street banks and hedge funds that have become increasingly big investors in the pharmaceutical industry.

It's not just the drug companies who make this argument. You hear it from insiders at the NIH, even if they won't say it on the record. You hear it from the Department of Defense, which also funds medical research. In a letter this summer opposing a march-in rights petition, the Defense Department mentioned the concerns of investors three times, saying, "NIH has consistently declined to exercise march-in authority because market dynamics could be affected for all products subject to the provisions of the Bayh-Dole Act."

You hear it from independent market researchers like Ira Loss at Washington Analysis. If the government were to use march-in rights to exercise pricing power, even once, "there'd be widespread panic," predicts Loss. "It would really impact investment in pharma/bio, maybe even the overall medical sector."

Views like this are so widespread that it would be folly to ignore them. Nevertheless, there are good reasons to take them with a grain of salt. Similar warnings were voiced by the telecommunications industry during the long "net neutrality" debate over whether the Federal Communications Commission should apply the same strict regulations to cable broadband providers that it does to telephone companies. In 2015, the FCC ruled in favor of net neutrality. Since then, the telecoms have issued reports based on proprietary data that, indeed, broadband investment has declined. But the current FCC chairman, Tom Wheeler, citing public SEC data, has countered that there has been a 35 percent increase in investment in internet-specific businesses and sizable increases by large network companies like AT&T.

In the case of drugs, as we've seen, pharmaceutical companies have already been cutting back their R&D investments. If Big Pharma's profits can only be supported by greater and greater federal subsidies and monopoly rents that gouge the public, the industry is operating with an unsustainable business model—one that bears an alarming likeness to a real estate sector that, a decade ago, could only be propped up by predatory mortgages. The greater folly, says Robert Weissman of Public Citizen, would be to allow "us to be kept locked into the status quo, because of threats of a market collapse from pharma any time the government tries to control drug prices."

The letter that Lloyd Doggett and fifty other House members sent to the heads of HHS and the NIH in early January of this year landed at a propitious moment for advocates. Martin Shkreli had recently been indicted on securities fraud. The pharmaceutical behemoth Pfizer had just announced major price increases on 100 of its drugs. And the president was unveiling another in a flurry of new executive actions, this one narrowing the loophole that allowed guns to be sold privately—at gun shows, for instance—without licensing or background checks. It seemed at least plausible that he would soon take similar unilateral action on drug prices.

That possibility appeared to become a near certainty later that month, when the *New York Observer* quoted New York Democratic Representative Charles Rangel saying that Obama would "use his executive powers, to deal with this thing [high drug prices] as soon as he gets back" from a trip to Detroit.

Rangel's statements put the pharmaceutical industry and its battalion of Washington lobbyists on red alert. According to one lobbyist, the biopharmaceutical lobby and Big Pharma's official trade group were scrambling to answer angry calls from corporate drug company headquarters around the world.

How had they missed this? Who could get information from the White House? The lobbyist said that pharmaceutical CEOs were particularly annoyed that Obama hadn't warned them first. Didn't the president owe them something for their having supported the passage of Obamacare?

But Rangel's story also surprised the White House. Over the next few days, the administration let it be known that there were no immediate plans for an executive order affecting drug prices.

Still, Doggett and his allies had another card to play, one they thought would give the president the perfect opportunity to take executive action, were he so inclined. James Love's organization, Knowledge Ecology International, along with another nonprofit, the Union for Affordable Cancer Treatment, had just filed a petition with the NIH and the Department of Defense, arguing that the U.S. government should use march-in rights on the prostate cancer drug Xtandi.

What if the next president doesn't need Congress's approval in order to act? What if previous statutes have already given the executive branch the authority it needs to beat back extreme drug price increases?

There could hardly be a better example to trigger Bayh-Dole rights than Xtandi. The drug targets a widespread disease; according to the American Cancer Society, prostate cancer attacks one in seven American men, and killed 27,500 in 2015. It is also outrageously expensive—$129,000 for a year's supply, about four times higher than the same drug sells for in Japan and Canada—putting it in the top ten most expensive drugs for Medicare. Best of all, from a legal point of view, all the patents on the drug came directly from government-funded research at UCLA; no pharma companies had added on patents, which would have weakened—at least in the eyes of some experts—the government's ability to exercise its retained rights.

In February, while Love's petition was making its way through the system, HHS Secretary Sylvia Burwell came to Congress to testify before the Ways and Means Committee, on which Lloyd Doggett serves. The Texan used the opportunity to ask her pointedly if she could assure him and his fifty colleagues that their earlier letter requesting guidelines on march-in rights was "receiving thorough consideration." Burwell answered carefully. "We are continuing to try and pursue every administrative option," she said, adding, "We welcome your letter and your suggestion."

But just a couple of weeks later, she sent Doggett her official dismissal. While the administration had not ruled out using Bayh-Dole rights "when presented with a case where the statutory criteria are met," Burwell wrote, after consulting with the NIH the administration had decided that "the statutory criteria are sufficiently clear and additional guidance is not needed." Doggett said he wished she had just given him a straight "Hell, no!" to begin with.

Love's petition on Xtandi was still alive, though, so Doggett's group decided to bring in the big guns. On March 28, they sent another letter to Burwell, this time including six Democratic senators—among them then presidential candidate Bernie Sanders (who had tried to clarify Bayh-Dole language protecting taxpayer rights in 2001) and Elizabeth Warren.

The lawmakers weren't just requesting general guidelines. They wanted to hear what the NIH had to say about Xtandi. "We do not think that charging U.S. residents more than anyone else in the world meets the obligation to make the invention available to U.S. residents on reasonable terms," they said. They asked HHS to review the facts and issues in the Xtandi case in a public hearing, not behind closed doors.

Burwell rebuffed that request, too, writing on June 7 that "the NIH believes [the current] process allows the agency to collect sufficient information to consider the [Xtandi] petition without a public hearing." The NIH formally rejected Love's petition two weeks later.

The financial press trumpeted the decision as "good news" for Astellas and Medivation, the two firms that share the blockbuster drug's profits. And indeed it was. In August, Pfizer Inc. announced it was buying Medivation for $14 billion, nearly double what the company had been worth six months earlier. This was a pretty good return for a drug that would never have existed without $31.5 million in NIH grants.

Why did the Obama administration refuse to exercise—or even hint at exercising—its power under Bayh-Dole to bring down excessively high drug prices? A White House spokesperson would only say that the president "deferred to HHS," which is more a statement of the obvious than an answer.

One possibility is that administration lawyers looked at the statute, read all the relevant pro and con arguments, and came to the conclusion that Bayh-Dole does not, in fact, give government that power. This seems unlikely, though: Sylvia Burwell's February letter certainly stops short of saying that.

Another possibility is that the administration had political reasons not to want to cross Big Pharma. To be sure, the White House did deals with the industry to pass Obamacare. But with that law secured, the need for the president to play nice with the industry significantly lessened. In fact, taking on the pharmaceutical industry would have been excellent politics in an election year, especially with the Democratic base. More-

over, Obama hasn't been shy about signing executive orders that have infuriated other powerful interests, such as the energy industry and the National Rifle Association.

A third possibility, and a plausible one, is that Obama was briefed on retained rights, concluded that he might indeed have the power to use them to lower drug prices, but then chose not to do so, out of fear of spooking the markets and putting the economy at risk in an election year.

A final possibility—one that fits the known facts and may be familiar to anyone who's served in government—has to do with timing. The issue of high drug prices, though long simmering, didn't reach a political boiling point until last year. By then, many of the long-serving White House officials who might have been most able to see the bubbling crisis as an opportunity to take action—those with policy chops, knowledge of the bureaucracy, and close relationships with the president—were cycling out. And as happens in any administration, those who have taken their place are younger, more inexperienced staffers with less inclination, and less of a mandate, to take risks. It's entirely possible that none of them even raised the idea of exercising march-in rights with the president.

"I know Barack Obama very well," says a former senior White House official who left the Obama administration a few years ago. "When he said he wanted to do something about high drug prices, I believe him." This official also believes that the executive branch probably does have the power to use Bayh-Dole to bring down drug prices, and should have at least tried to exercise it by proposing regulations or guidelines. "My guess is [his current staff] told him there's nothing he can do unilaterally." Evidence for that view is that the president never publicly voiced support for march-in rights, as he did for net neutrality.

On January 20, 2017, a new president will enter the White House, along with a fresh—and, one hopes, capable—White House staff. The new administration will then begin a months-long dance with Congress to win approval of its agency nominees and to build support for its agenda. One item near the top of that list should be high drug prices. The administration's need to woo lawmakers will bring with it a temptation to forswear any intention to act unilaterally on that issue.

It should resist that temptation, however. Long experience shows that Congress is extremely unlikely to take any meaningful steps toward reeling in drug prices. The clout of the pharmaceutical industry and the fear of upsetting Wall Street and the markets are simply too strong. In such an environment, a president who wants to get something done needs leverage.

The threat to exercise the government's retained rights under Bayh-Dole would do the trick. And some powerful lawmakers would like a president to take that step. "March-in rights provide a powerful tool to improve access to federally funded medicines, but that tool has lain dormant for decades, even while drug prices soar out of reach for millions of Americans," Elizabeth Warren told the *Washington Monthly*. "While Congress needs to do more," she added, the executive branch "needs to step up."

There are other statutory powers the next president could draw on. One is the authority of the Medicine Equity and Drug Safety Act of 2000 to allow the re-importation of lower-priced drugs from countries like Canada. (The Canadian drugmaker Biolyse Pharma has already offered to sell a generic version of Xtandi to the U.S. government at a roughly 90 percent discount.) Another is a section of the United States Code that allows government agencies to buy generic versions of drugs at steep discounts. In 2001, during the anthrax scare, then HHS Secretary Tommy Thompson used the threat of this power to force drugmaker Bayer AG to cut the price of its anti-anthrax medication Cipro in half.

The next president could have leverage not only to bring down excessive drug prices, but also to reform the increasingly dysfunctional federally funded biomedical research and commercialization system that gives rise to those insane prices in the first place.

By threatening to invoke Bayh-Dole and other existing powers broadly, the next president could get price reductions on a range of outrageously expensive medications. But perhaps even more importantly, the threat may be the only way to force the drug companies and lawmakers in both parties to sit down with the administration and hammer out a broader array of reforms.

Bayh-Dole was in many ways an inspired piece of legislation, giving rise to a biomedical and commercial research system that has produced some miracles. But in the intervening thirty-six years, that system has grown increasingly dysfunctional, predatory, and dependent on public largesse. Fortunately, the legislation that created the system provides the tools we need to reform it. WM

Alicia Mundy is a former *Wall Street Journal* reporter and author of *Dispensing with the Truth*, about a drug industry scandal. She is writing a new book on the pharmaceutical business and consults for health care analysts.