Presidental candidates from both parties are tapping into public anger over prescription drug prices and responding by repeating old proposals, like controlling prices or lowering FDA approval standards, that won’t be enacted and probably wouldn’t work if they were put into practice.

Out of the limelight and far from the political pontification, the renewed attention to drug prices is stimulating quieter discussions about new approaches to drug spending that might benefit patients, the healthcare system and developers of innovative medicines. These include efforts to increase the transparency of drug prices, and, taking a cue from the private sector, proposals to reward innovation and reduce spending on lower-value products.

Patient groups and drug companies are also pushing for policies that would change health insurance plan designs in ways that would increase access to medicines by reducing out-of-pocket costs.

It will take time, and a calmer political environment, for new ideas to gain traction in Congress and at HHS. In the meantime, industry lobbyists, trade associations and pundits are gearing up for yet another round of vituperative drug pricing debates.

With the possible exception of acting to increase competition for off-patent drugs serving very small populations, the stalemated 114th Congress will not translate Americans’ anger over drug prices into legislation (see “Unrealistic Prescriptions”).

The Obama White House has also run out of viable options for affecting drug prices.

The lack of immediate action in Washington does not mean that public perceptions of pharmaceutical profiteering are irrelevant, even in the short term.

The corrosive political environment has eroded congressional support for creating new incentives for developing drugs to meet public health needs, allowed CMS to implement a reference pricing scheme for biosimilars, and fertilized proposals to expand NIH’s and FDA’s missions to include cost containment (see “Compounding Prices”).

Inaction in Washington is also prompting efforts to mandate drug price controls at the state level (see “Laboratories of Democracy”).

MOVING TO VALUE

Mark McClellan, who served as FDA commissioner and CMS administrator in the George W. Bush administration, thinks there is an appetite in Washington for moving past the old arguments between supporters of price controls and those who say that unfettered pricing freedom is needed to support innovation.

The discussion is moving toward determining how to “integrate drugs into the big shift in healthcare to accountability payment models based on results,” he told BioCentury. McClellan is director of the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University. He also serves on the board of Johnson & Johnson.

“It has been challenging and certainly not straightforward to implement those kinds of models for doctors and hospitals, and it won’t be easy for drugs,” McClellan said. “That doesn’t mean it won’t happen.”

“There is a significant willingness in the drug industry to explore and try to implement these kinds of models,” he added. He cited experiments with outcomes-based contracts. McClellan pointed to Medicare Part B drug payments as a potential target for change.

The current system of paying physicians who administer drugs in outpatient settings the average sales price (ASP) plus 6% “is not tied to value in any meaningful way,” he said. One potential solution is to replace the Part B reimbursement system with something like Part D, McClellan said. Under Part D, private plans compete to offer drug benefits within broad parameters established by CMS. Plans use formularies to obtain discounts on drugs, and compete on the basis of drugs covered. They can use co-pays and other design characteristics to favor high-value and discourage utilization of lower-value drugs.
We used to think that for very specialized drugs there is only one treatment for a patient, so you can’t create a formulary model to create competition. That is not so true anymore,” he said.

Value-based pricing models, which encompass a range of concepts that tie price to value, such as outcomes- and indication-based pricing, could align economic incentives with public health priorities, but McClellan noted they are not a magic bullet: “Just moving to value-based pricing won’t solve the rise in spending.”

This is one of the lessons from the new generation of HCV treatments, which, because of the large number of potential patients, would have caused economic waves even if they had been priced lower. “Even though by most economic models the drugs were worthwhile” they had a huge impact on the growth of drug spending in 2014 that translated into an increase in the overall cost of healthcare, McClellan noted.

The best way to create economic space for innovation, including new drugs, is to speed efforts to make the entire healthcare system more efficient, McClellan said. He pointed to the creation of accountable care organizations and advancing digital and telemedicine as steps that could create space for increased spending on drugs.

BARRIERS

Legislation might be needed to overcome barriers to value-based drug pricing models.

Regulatory barriers to value-based pricing of drugs — both real and perceived — were on display at a forum on pharmaceutical pricing that HHS convened in November.

Christi Shaw, U.S. country head at Novartis AG, and Kenneth Frazier, chairman and CEO of Merck & Co. Inc., said FDA’s prohibition on discussion of off-label uses of drugs is a barrier to outcomes-based pricing contracts.

“When you run a clinical trial and get approval, what is on the label has to be the basis for outcomes contracts,” Shaw said. For example, she said, if a payer wants to look at total hospitalization and that is not on the label, it can’t be included in an outcomes-based contract.

Frazier, who also is chair of PhRMA, added, “In order to have a good sense of what the true real-world risks are, we sometimes have to look beyond what’s on the label of the drug. We are restricted from communicating about that by FDA.”

However, according to Coleen Klasmeier, a partner at Sidley Austin LLP and former FDA attorney, it isn’t clear whether such communications are actually illegal, and ambiguity can deter companies from taking steps that are legal.

“The current enforcement climate and ongoing regulatory uncertainty makes it hard to determine in advance whether a particular activity is on the right side of the line,” Klasmeier told BioCentury. “Even if you have a sound legal risk assessment that’s supportive, you’re stuck with the risk of an aggressive prosecutor taking a different view. Indeed, there’s so much about the current paradigm that’s subject to debate that the prosecutors themselves don’t always have a good mastery of the relevant legal principles.”

FDA is working to clarify the issue, agency spokesperson Sarah Peddicord told BioCentury in an email.

“The Agency is currently examining its rules and policies relating to manufacturer communications regarding approved drugs, including communications of unapproved use information and dissemination of healthcare economic information to formulary committees and similar entities,” she said. “The purpose of this review is to help ensure that our
implementation of FDA’s legal authorities best protects and promotes the public health in view of ongoing developments in science and technology, medicine, health care delivery, and constitutional law. The Agency continues to be actively engaged in this effort and intends to issue new guidance and solicit public input in the near future.”

According to Shaw, FDA regulations also prevent companies from working with payers to develop creative payment strategies prior to approval. She cited the example of chimeric antigen receptor T cell therapies Novartis is developing to treat chronic lymphocytic leukemia (CLL).

Novartis has achieved dramatic cures of CLL patients, Shaw said, adding, “How do you charge for that?” She warned that CART therapies may create a “Sovaldi situation” because “we can’t talk to payers before approval.”

PhRMA is trying to get provisions lifting restrictions on drug company communications with health plans incorporated into the Senate counterpart for the House 21st Century Cures Act. Democrats in Congress have been reluctant to loosen restrictions on drug company communications, and as an alternative to legislation, the trade association is also actively looking for disputes that could form the basis for First Amendment litigation.

SCHADENFREUDE

International news coverage that has made Martin Shkreli, the former CEO of Turing Pharmaceuticals AG, the world’s best-known ex-pharmaceutical company executive has also prompted Republicans to overcome their reluctance to discuss drug pricing. The leading Republican presidential candidates have taken verbal swipes at Shkreli. Bowing to pressure from Rep. Elijah Cummings (D-Md.), the ranking Democrat on the House Oversight and Government Reform Committee and leader of the Affordable Drug Pricing Task Force, committee Chairman Jason Chaffetz (R-Utah) has scheduled a Jan. 26 hearing on drug prices.

There is bipartisan support for helping clear the massive backlog of FDA generic drug reviews, and for government proactively identifying and speeding ANDAs for essential off-patent drugs that could be hijacked by companies seeking to emulate Turing’s business model. Developers of innovative drugs are enjoying a bit of schadenfreude over the public lashing that Turing and drug companies like Valeant Pharmaceuticals International Inc. that have pursued research-free business models are experiencing.

It hasn’t taken long, however, for the media and politicians to move from criticizing exorbitant prices of small-market generics to scrutinizing routine increases in the prices of new drugs that far exceed inflation. In the U.S., average wholesale price (AWP) often goes up even as competitors enter the market.

The National Drug Index compiled by pharma data services company Truveris Inc. also shows consistent price increases, even in crowded therapeutic classes. The NDI is an index of U.S. average prescription drug prices that includes discounts and rebates. From December 2014 to December 2015, Truveris showed rheumatoid arthritis (RA) drug prices net of discounts and rebates increased 17%, while multiple sclerosis (MS) drugs increased 11%.

UNREALISTIC PRESCRIPTIONS

Affordability of prescription drugs is the most important healthcare issue for Americans according to a national survey the Henry J. Kaiser Family Foundation released in October. A total of 77% of those surveyed put drug prices on the top of their healthcare priority list, and 63% — including 56% of Republicans — agreed “government action to lower prescription drug prices” should be the top priority for the president and Congress.

Politicians are acutely aware of the polling data. Hillary Clinton’s campaign has been running a television advertisement in Iowa ahead of the caucuses that claims, inaccurately, that “in the last seven years drug prices have doubled.” In fact, since more than 80% of prescriptions in the U.S. are generics, overall prices haven’t changed much.

The ad also asserts, “Hillary’s going to take on the drug companies,” and says she plans to “require Medicare to negotiate lower drug prices, let people buy their prescription drugs from countries like Canada at half the price, and cap monthly prescription drug costs for every American.”

The ad concludes with Clinton standing in front of a pharmacy counter saying, “The drug companies have been overcharging for long enough. It’s time to fight back.”

Bernie Sanders is more bellicose in his denunciation of drug companies, but his proposals are similar to Clinton’s.

Both Sanders and Clinton have been around long enough to know that their drug price control proposals have been attempted numerous times over the past 15 years, and they failed to pass Congress even when Democrats had a much stronger position than they will have in 2017. Regardless of who wins the White House in November, there is little chance that HHS will be given power to “negotiate” — a euphemism for “set” — Medicare drug prices. All of the Republican presidential candidates have said they would take steps to lower prescription drug prices.

In a video of remarks at a private campaign event in October, Florida Sen. Marco Rubio said pharmaceutical companies engage in “pure profiteering” when they increase prices to offset declining volumes of prescriptions. Rubio, Sen. Ted Cruz of Texas, N.J. Gov. Chris Christie and Jeb Bush have all pointed fingers at FDA, asserting that drug development could be made dramatically quicker, resulting in lower prices. They offer no evidence, however, of a correlation between FDA review times and drug prices. In any case, Congress isn’t likely to change drug approval standards anytime soon.

— STEVE USDIN
Overall, brand drug prices increased about 15% over the same period, far more than the 4% increase in generic drug prices, Truveris reported.
The Obama administration has tried to take on drug prices, for example by including requests for Medicare drug negotiation authority and shorter biologics exclusivity provisions in budget requests.
PhRMA, BIO and drug companies have shut down these attempts, and there is no evidence that the next administration would have more success in convincing Congress to adopt drug price controls.

PRICING TRANSPARENCY
The White House has also learned that any attempt to unilaterally cut drug spending will be fiercely resisted.
In 2014, CMS announced plans to eliminate two of the six protected classes for which Medicare Part D plans must provide “substantially all” approved drugs. The political blowback from patients who feared they would lose access to medicines forced the agency to backtrack.
CMS lacks the political clout to attack price increases head-on, so it has decided to build support for action by shining a light on pricing practices.
In December, CMS released a “dashboard” of information about Medicare spending on prescription drugs. The dashboard includes spending and utilization data for 40 Part D and 40 Part B drugs; it does not reflect rebates or other price concessions.
Andy Slavitt, acting CMS administrator, acknowledged limitations to the data in a blog posting, including the lack of data on discounts and rebates or information about the medical benefits of specific drugs. “We realize the dashboard doesn’t provide a complete picture, but still believe that, by sharing this information and allowing people to analyze the data, we can increase the knowledge around drug spending and support efforts that are evaluating whether public dollars are being spent most effectively,” he wrote.

More pricing transparency is on the way. The budget bill signed into law in December included instructions for HHS to prepare a more comprehensive report on government spending on prescription drugs.
The report, due in May, will be scrutinized for evidence that Medicare and Medicaid are paying too much for specific drugs or classes of drugs. In any case, it is sure to fuel a new round of headlines and calls for drug price controls.

MESSAGING
BIO, PhRMA and individual companies are using the legislative dead zone created by the presidential campaign to shore up political support in a Congress that includes many members who are unfamiliar with or unsympathetic to the interests of drug developers.
BIO is also putting the final touches on a media and lobbying campaign emphasizing the value of biopharmaceuticals and the high costs of other healthcare products and services, Ron Cohen, president and CEO of Acorda Therapeutics Inc. and chairman of BIO, told BioCentury.
“There are many, many facts we could point out that would indicate why most of the angst about drug prices is misplaced: where drugs have saved costs overall; that drugs make up 10-14% of overall healthcare costs,” Cohen said. “The problem is when you start pointing that out it seems to people you are making excuses for what people believe: drug prices are too high.”
Cohen added that this “perception has been deliberately fueled by an active campaign by the health insurance industry to focus attention on drug prices to deflect attention from their own culpability” for designing plans that hit patients with high co-pays and deductibles.
“There has never been a focused effort to deal with these perceptions and misperceptions in a systematic way,” Cohen said.
This belief has led BIO to decide to invest in a messaging campaign that will involve advertising in traditional and online media, as well as use of social media, according to Cohen.
“Much of the discussion is one-sided, focusing only on the 10% of healthcare spent on prescription pharmaceuticals, and excluding the other 90%,” Kenneth Lissaus, BIO’s SVP of communications, told BioCentury. “Our industry will continue to directly respond to those who choose to focus myopically on one small element of what remains a much larger issue. You’ll see us increase the volume over the next year.”
BIO also plans to create a dialogue with payers and patients, Cohen said.
“We are working on getting a new set of messages out there regarding our commitment to patient access to medicines and the value of what we are producing,” he reported. “And we are starting the discussion among...
stakeholders, now that we hopefully agree to stop pointing fingers, about how to set a value for a drug and set a price that doesn’t kill innovation.”

Cohen said, “BIO and PhRMA need to be going out in a very deliberate way and changing the way in which we engage with society through media, government, with payer organizations in terms of explaining our story. What is valuable about what we are producing, how are we demonstrating value, and what will we sign up to in terms of demonstrating value going forward.”

BIO’s challenge, however, may not be to demonstrate the value of its products, but to convince the public, politicians and payers that its prices are fair and sustainable.

Patients and payers understand that curing HCV, and drugs like those that drove President Jimmy Carter’s cancer into remission, are valuable. They are concerned by prices that impose what oncologists now call “financial toxicity” on patients, and that make specialty drugs the most rapidly accelerating cost for the healthcare system.

Patient groups, including the National Health Council (NHC), are pushing for federal and state policies that address financial toxicity by preventing insurers from turning deductibles into a wall that prevents many patients from accessing life-sustaining medicines. Part of this agenda, capping monthly out-of-pocket drug expenses, has made it into Hillary Clinton’s campaign platform. Insurance plan design reforms, especially if they are combined with steps to move toward value-based drug pricing, could win bipartisan support if the fall elections usher in a cooler political climate.

“IT HAS BEEN CHALLENGING AND CERTAINLY NOT STRAIGHTFORWARD TO IMPLEMENT THOSE KINDS OF MODELS FOR DOCTORS AND HOSPITALS, AND IT WON’T BE EASY FOR DRUGS.”

MARK MCCLELLAN, DUKE UNIVERSITY

COMPANIES AND INSTITUTIONS MENTIONED

Acorda Therapeutics Inc. (NASDAQ:ACOR), Ardsley, N.Y.
AIDS Healthcare Foundation (AHF), Los Angeles, Calif.
Biotechnology Innovation Organization (BIO), Washington, D.C.
Duke University, Durham, N.C.
Henry J. Kaiser Family Foundation, Menlo Park, Calif.
Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Merck & Co. Inc. (NYSE:MRK), Kenilworth, N.J.
National Health Council (NHC), Washington, D.C.
National Institutes of Health (NIH), Bethesda, Md.
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.
Truveris Inc., New York, N.Y.
Turing Pharmaceuticals AG, Zug, Switzerland
U.S. Centers for Medicare and Medicaid Services (CMS), Baltimore, Md.
U.S. Department of Health and Human Services (HHS), Washington, D.C.
U.S. Department of Veterans Affairs (VA), Washington, D.C.
U.S. Food and Drug Administration (FDA), Silver Spring, Md.
 Valeant Pharmaceuticals International Inc. (TSX:VRX; NYSE:VRX), Laval, Quebec

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