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States Fight For Drug Price Transparency

by Ed Silverman

California's Proposition 61 and a number of other state-led measures to control drug prices failed to gain traction in 2016. But states are likely to remain a battleground in the war against costs in a pharma-friendly Trump administration.

- The pharma industry mounted a tough and ultimately successful campaign against California's measure to control drug prices.
- Even though Proposition 61 was one of many such initiatives to fail in 2016, states are unlikely to be deterred by their lack of success to date in requiring price concessions from drug manufacturers.
- They may in fact be more motivated given the recent election results. Pharma could interpret November's Republican victories as a potential end to federal intervention in drug pricing strategies.
- But any drugmaker that believes the political overhaul in Washington is the proverbial green light to do business as usual may want to think twice. Drug affordability is going to remain a key issue.

As Californians prepared to vote last month on a contentious ballot measure designed to lower drug prices, a shirt-sleeved Bernie Sanders appeared at a Los Angeles rally in hopes of ensuring that Proposition 61 would pass.

Speaking to an enthusiastic crowd, he got straight to the point. “It looks like the people of California are prepared to put an end to the greed of the pharmaceutical industry,” he bellowed to raucous applause. “They understand that a victory here in California will not only lower prescription drug prices here, it will impact every state in the country.”

Not as many were prepared to act as he hoped, however.

Also known as the California Drug Price Relief Act, the ballot measure was an unexpected bust. Although polls showed residents supported the plan, nearly 54% of voters rejected the proposition. This came after months of a bruising campaign in which the chief executives of drug companies were labeled as criminals and the pharmaceutical industry amassed a $109 million war chest for an ad campaign.

All this underscored how much was at stake and how the states will likely remain a battleground in the war over pharmaceutical costs, especially now that Donald Trump has been elected as the next US president.

Proposition 61 was seen as a litmus test for a national debate over rising prescription drug costs. Anxiety has been rising in the US, where prices for new medicines used to combat such hard-to-treat diseases as hepatitis C and various forms of cancer are set higher all the time. Some companies buy old drugs and jack up prices to sky-high levels. And even prices for some generics are climbing to new heights.

These trends have taken a toll. Pharmaceutical costs became a talking point in the 2016 presidential election and social media is regularly flooded with consumer gripes. A recent Kaiser Family Foundation poll found that reducing costs should be the biggest priority for the next president and Congress when it comes to lowering overall health costs, and 63% want the government to take action.

“The people are speaking up, because they have had enough,” says Walid Gellad, MD, an associate professor of medicine and health policy and co-director of the Center for Pharmaceutical Policy and Prescribing at the University of Pittsburgh.

Some government officials are adding their voices. At the *BioPharma Congress* in Washington DC in November, Andy Slavitt, the acting administrator for the Centers for Medicare and Medicaid Services, had nothing nice to say about drug companies. In fact, he compared a growing number of them to *Turing Pharmaceuticals AG*, the company once run by Martin Shkreli, which bought an older life-saving medicine and overnight boosted the price by about 5,000%.

“You know, last year when I spoke here, the price increases at Turing were making

The Math On Drug Costs

- Total prescription drug spending in 2015 was $457 billion, 16.7% of total health care spending
- Average annual spending increases of 6.7% are projected through 2025
- Medicare B spending doubled 2007–2015
- Medicare D spending increased 8.4% 2013–2015

news, and I told you I didn't want this industry to be defined by its worst actors," he said. "I defended the industry then, but the more data that's revealed, the more bad actors you find, and I'm telling you now: it's too many."

Slavitt also tossed out some sobering figures. Total prescription drug spending in 2015 was about $457 billion, or 16.7% of health care spending. And based on recent trends, he noted that CMS is projecting average annual increases of 6.7% through 2025. (*See box*.)

- Specialty drugs accounted for 31.8% of spending but only 1% of total prescriptions
- Top 20 drugs with highest per unit increase in Medicaid include seven generics with increases ranging from 140% to nearly 500% 2014–2015

SOURCE: Andy Slavitt, BioPharma Congress, November 3, 2016

A Flawed Measure

It was against such a backdrop that the AIDS Healthcare Foundation, a non-profit that runs pharmacies and clinics nationwide, spearheaded Proposition 61. A controversial organization, AHF has for years publicly challenged and chastised drugmakers over the prices charged for HIV and, more recently, hepatitis C medicines. But the ballot measure was its most audacious move yet.

Under the plan, state agencies would have been required to pay no more for medicines than the US Department of Veteran Affairs, which receives a federally mandated 24% discount from drugmakers. The plan was to lower drug costs for up to 7 million Californians who get prescription drug coverage through various agencies, including low-income residents on the state version of Medicaid.

But the measure was flawed. It was unclear whether the California Medicaid program, which is called Medi-Cal, could get all needed medicines at a lower price. Moreover, drugmakers could have balked at offering the same discount for a medicine that was given to the VA. This would put Medi-Cal in a bind, since the state agency is still mandated by federal law to provide the drug to beneficiaries.

The VA also negotiates added rebates for some drugs, but those extra rebates, which are paid to the VA, are not always disclosed under confidentiality agreements. Companies might instead have opted to raise prices for other residents to make up for any losses incurred selling to Medi-Cal. Drugmakers might also have raised prices to the VA or refused to sell certain medicines rather than accept lower payments.

"There could have been a waterfall effect," said Richard Evans, an analyst at Sector & Sovereign

Research. “If more states passed these measures, the best path forward for the manufacturer would be to inflate its price to the VA, and they will do that. So when the smoke clears, state prices will be back where they were originally and the VA will be paying more, too.”

For these reasons, the California Legislative Analyst’s Office issued a report that was decidedly lukewarm. The report stated that the “fiscal impact of this measure on the state is unknown. It could range from relatively little effect to significant annual savings.” However, the office conceded that lowering drug spending by even a few percent would yield savings in the high tens of millions annually.

Pharma Fights Back

All of these caveats made it rather easy for the pharmaceutical industry to push back. Company after company donated money to the campaign, which used the $109 million raised to hire consultants who fashioned a steady stream of billboards, bus tours, rallies and television ads. The drumbeat of warnings in those messages also convinced nearly every consequential newspaper in the state to editorialize against Prop 61, although a few practically held their nose as they did so.

“Prop 61 is just a bumper sticker selling change. It lacks thoughtful policies that would help with patient access issues, and might well make things worse,” said Peter Staley, a high-profile AIDS activist and Founder of Treatment AIDS Group, in one of dozens of press statements issued by the No on 61 group that was created by the pharmaceutical industry to defeat the measure.

Both sides, meanwhile, also released vitriolic statements that sought to scandalize the other, offering details about their opponents secretly backing various organizations that were issuing public statements for or against the measure. In short, the battle over Prop 61 was an old-fashioned, mud-slinging event and made for an extremely interesting campaign.

Of course, it was closely watched not only because it was the first such state ballot measure to be placed before voters, but also because it played out in California. As one of the largest and typically most progressive states in the US, California is regularly seen as a bellwether for political trends. And this was the key reason that the pharmaceutical industry marshaled its resources.

But by placing the measure directly before voters, AHF was also trying a different tactic than had been tried by legislators in California and 10 other states around the country. In those locales, lawmakers introduced bills that would either require drugmakers to explain their price increases or disclose many of their costs in hopes the transparency would eventually pressure companies to limit their pricing. (*See Exhibit 1*, *andfor greater detail on these state initiatives see sidebar, "State Drug Cost/Price Transparency Legislation*.")

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Exhibit 1

State	Legislation	Status
California	Proposition 61: The California Drug Price Relief Initiative	11/8/2016 – Defeated on the California ballot
	CA A 463: Pharmaceutical Cost Transparency Act of 2015	2/01/2016 – Failed
	CA S 1010: Health Care: Prescription Drug Costs	8/24/2016 – Failed – adjourned
Colorado	CO H 1102: Drug Production Costs Transparency	3/19/2016 – Postponed indefinitely
Massachusetts	MA S 1048: Transparency and Cost Control of Pharmaceutical Drug	6/02/2016 – From Joint Committee on Health Care Financing; pending, but inactive study to end of 2016 session
Minnesota	MN S 934 and MN H 1060	3/23/2015 – Referred to Senate Committee on Finance Carryover, Senate Committee on Finance
New York	NY S 7686: Prescription Drug Cost Transparency	Pending, Senate Committee on Health
	NY A 8265: Pharmaceutical Cost Transparency Act of 2015	6/16/2015 – To Assembly Committee on Health, pending
North Carolina	NC H 839: Pharmaceutical Drugs Cost Reporting	4/15/2015 – To House Committee on Health, pending
Oregon	OR H 3486: Manufacturer of Prescription Drug	7/06/2015 – In committee upon adjournment

Pennsylvania	PA H 2029: Prescription Drug Program	Pending, House Committee on Health
Rhode Island	RI H 7839 and RI S 2560: Critical Prescription Drug List	4/26/2016 – In House Committee on Corporations, pending
Vermont	VT S 216: Prescription Drugs	6/03/2016 – Signed by Governor
Virginia	VA S 487: Prescription Drug Price Transparency	2/4/16 – In Senate Committee on Education and Health; Continued to 2017.
	VA H 1113: Prescription Drug Price Transparency	1/13/2016 – To House Committee on Commerce and Labor, pending
Washington	WA S 6471: Transparency of Prescription Drug Pricing and Costs	3/10/2016 – 2016 1st special session: by order of resolution reintroduced and retained in present status

Source: National Conference of State Legislatures

All but one of these gambits failed. A bill was enacted in Vermont, but whether it actually leads to lower or stabilized prices remains to be seen. Elsewhere, the pharmaceutical industry succeeded in slapping aside each and every effort. A legislative aide in California complained that, during an assembly committee hearing last August, a bill that was making notable progress was suddenly "gutted."

Despite the setbacks, some state lawmakers intend to push ahead. The Ohio Drug Price Relief Act is set to appear on the ballot in November 2017. Virtually identical to California's Proposition 61, it is also

State Drug Cost/Price Transparency Legislation

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A look at recent state legislation designed to require prescription drug cost and price transparency from prescription drug manufacturers. Data from the National Conference of State Legislatures.

Read the full article here

backed by the AIDS Healthcare Foundation. (*See box*.)

And earlier this year, Joann Ginal, a Colorado lawmaker and Democrat who represents Fort Collins, a small city of about 160,000 people located roughly 65 miles north of Denver, introduced a bill to require each drugmaker to provide a one-time report to the state about any medicine priced at or above $50,000 for a treatment course or per year.

Her bipartisan bill died last March, although she hopes to start anew in January. "I have to keep trying," she says. "I need to look at how I can approach this problem in a different fashion. I still think this is one of the biggest concerns and something has to be proposed." But she admits she is uncertain which path to pursue, given that her own effort flopped and Prop 61 does not appear to be a winning model.

Federal Action Less Likely

Nonetheless, such conviction reflects ongoing concern that Washington will not take action. The Obama administration proposed a program to lower costs for the Medicare Part B program, which pays for injectable and infused drugs for the elderly. The move is designed to lower drug spending by reducing reimbursement fees for doctors, but the pharmaceutical industry has so far delayed its start.

In September, a bipartisan group of lawmakers introduced legislation that was largely modeled after the state bills. Known as the Fair Drug Pricing Act, it would require drugmakers to justify their pricing and provide a breakdown of their costs before raising prices on certain products by more than 10%.

Co-sponsored by US Senator John McCain (R-AZ) and US Representative Jan Schakowsky (D-IL), the bill would also require drugmakers to notify the US Department of Health and Human Services – and submit a justification report – 30 days before they increase the price of certain medicines by more than 10%.

Ohio Drug Price Relief Act

Like failed California Prop 61 before it, Ohio's Drug Price Relief Act requires state agencies to pay no more for prescription drugs than the US Department of Veterans Affairs, a discount of up to 40%. The measure will be on the ballot in November 2017.

The reports will also require companies to provide manufacturing and R&D costs for those drugs, as well as net profits associated with the drugs, and marketing and advertising spending on the drugs. The lawmakers noted the bill will not prohibit drugmakers from increasing prices, but is supposed to give taxpayers notice of price increases and "bring basic transparency to the market for prescription drugs."

Whether this will gain any traction is uncertain, at best, though.

Now that Donald Trump will be moving into the White House and the Republicans will control both congressional chambers – the House and the Senate – the pharmaceutical industry is betting that the lurch toward price controls expected under a Hillary Clinton presidency is less likely to happen.

This explains the initial burst of investor enthusiasm immediately after the presidential election. After lingering in a months-long funk, drug and biotech stocks rocketed upwards on November 9. Of course, Trump remains a wild card and has previously voiced a willingness to combat high drug prices, possibly by allowing Medicare to negotiate with drugmakers. But he has not offered a specific plan.

One reason the industry may be confident is because Rich Bagger, a former pharmaceutical executive is on the Trump transition team. A former Pfizer vice president and chief of staff to New Jersey governor Chris Christie, he took a leave of absence from Celgene, where he was executive vice president for corporate affairs and market access, to work for Trump.

“He’s got a deep understanding of, and a long history with, the brand-name industry,” says James Shehan, senior counsel and head of the FDA regulatory practice at the Lowenstein Sandler law firm, who was once general counsel at Novo Nordisk. “And if he ends up in any kind of policy position, you’d expect that relationship to continue. I think he’s probably going to take the industry view on pricing.” Bagger, however, has been sidelined along with Christie following vice president-elect Mike Pence's ascension to the top of the transition team.

Crossing Borders

If so, state legislators may encounter just as much, if not more, frustration with Washington than during the Obama years. And as Colorado’s Ginal indicated, state lawmakers may increasingly look to swap ideas across borders.

“State legislatures can have a strong sense of independence when it comes to new laws,” says Richard Cauchi, health program director for health insurance, financing and pharmaceuticals at the National Conference of State Legislatures. “However, they also can pay attention to up-and-coming ideas that become law in other states.”

There have already been signs of movement in that direction. Last October, the National Academy for State Health Policy – a working group of state legislative staffers, Medicaid programs, state-based insurance exchanges, corrections departments and attorneys general staffs – issued a white paper to encourage state governments to band together to forestall further damage to their budgets from prescription drugs.

Among the ideas they floated:

- Regulate the pharmaceutical industry like a utility
- Import medicines from Canada
- Prosecute drugmakers that violate consumer protection laws protecting against predatory pricing monopolies
- Form procurement pools
- Pass "transparency" laws requiring drugmakers to disclose their costs or explain price hikes

Of course, these bills are not fail-proof, even if more do become law. There appears to be growing skepticism that transparency laws can make enough of a dent, though, especially given that most of the bills failed to gain traction even as frustration has been rising over drug prices. There is, in fact, speculation that drugmakers will react to any such state law by raising prices below stipulated thresholds to avoid having to explain price hikes.

In effect, that would be the same sort of end run that some predicted would occur if Prop 61 had passed. One of the problems here is that lawmakers are caught between their constituents and the realities of the marketplace. They can demand all sorts of information, but that doesn't necessarily mean that drug companies will be convinced to put a brake on rising prices.

There is no reason to think, however, that this will deter some state lawmakers from trying anyway.

"I don't think the outcome of the elections in Washington will have much effect on this [effort] on the state level," says Erik Gordon, a business and law professor at the University of Michigan. "It's a politically appealing issue. They will keep trying and will be able to get co-sponsors, because it's better to be defeated while trying to do something good."

Even so, the Republican victories in Washington are likely to give the pharmaceutical industry some needed confidence. During the weeks leading to the election, the Pharmaceutical Research and Manufacturers of America, the industry trade group, told its members to cough up another $100 million in dues, collectively, that would be earmarked for battling drug pricing initiatives.

Meanwhile, drugmakers have gradually begun to shift the conversation. Ever since *Mylan NV*chief executive officer Heather Bresch testified before Congress that her company didn't keep all of the price increases that were taken each year, more attention has shifted to the role of the pharmacy benefit managers in the complex pricing maze.

Her argument was that, at the same time drugmakers are raising prices, they are also paying more rebates to the pharmacy benefit managers that negotiate coverage for their medicines with health insurers. Credit Suisse analysts noted in a report last May that rebates grew 28%, on average, between 2009 and 2015, and outpaced net sales growth of 5%.

The point is that rebates are growing faster than pharmaceutical sales. This contention is being repeated by more and more companies that come under attack for their pricing. After Bernie Sanders accused *Sanofi*, *Novo Nordisk AS*and *Eli Lilly & Co.*of price collusion, Lilly fired back by arguing that the net price of its insulins has not increased since 2009 and pointed to "complex reimbursement designs."

Of course, rebates are a cost of doing business, and drugmakers can still try to raise prices to compensate. But this explanation is starting to gain some traction. In fact, after Mylan's Bresch testified before the House Committee on Oversight and Government Reform, lawmakers demanded the company provide documents that include contracts with pharmacy benefits managers and distributors.

In effect, the pharmaceutical industry is trying to deflect attention away from its pricing decisions and cast suspicion on the middlemen. Whether this maneuver will work is uncertain. The industry has tried a similar gambit by blaming higher drug costs on the rising co-pays and premiums that insurers charge their beneficiaries, but with mixed results.

Another key drawback to any transparency law, meanwhile, is that lawmakers are, effectively, counting on being able to shame companies into peeling back the curtain on their strategies. That may be harder to do if the pharmaceutical industry believes Washington is unlikely to take any substantive action to slow or halt drug prices.

The working group acknowledged as much. Still, they argued that "knowledge about what contributes to surging prices, what profit is extracted by middlemen, and what incentives promote high-cost medication sales would help states develop and prioritize policy solutions to limit drug costs." To make this work, the group suggests that confidential reporting requirements could be imposed.

In any event, prices are already high enough for some Americans, and if prices continue to rise – for new and old drugs, alike – drugmakers can expect to continue facing the same harsh criticism they have encountered for the past few years. Indeed, any drugmaker that believes the political overhaul in Washington is the proverbial green light to do business as usual may want to think twice.

The disenfranchised people who voted for Trump – indeed, most anyone who is experiencing rising drug costs – can still be expected to gripe on social media and to their local lawmakers if

they can't afford their medicine. Affordability will remain a key pocketbook issue, no matter what.

State lawmakers, however, may want to shift or broaden their focus and consider requirements to assess the value of medicines, at least where choices exist. This approach – essentially, cost-effectiveness – is increasingly gaining traction among health plans, for instance. And then perhaps place a ceiling on prices. That may bring some companies to the table.