ALEX FINE

A PHARMA PILE-ON

To hear politicians tell it—especially the ones seeking President Obama's job—pharma is motivated by profit and needs to be brought to heel. The reality of the situation, inside DC and out, is just a tad more complex. **Larry Dobrow** takes a closer look at what might be coming down the policy pipeline

To listen to the rhetoric emanating from Washington and the campaign trail, there would appear to be an issue or two on which Democrats and Republicans don't see eye to eye. There's the economy, for example, and prescriptions for fixing it and/or the question of whether it needs further fixing. There's climate change, gun control, tax reform, immigration, reproductive rights, military spending, Syria, Russia, the size of government, the scope of government and time-travel-aided reckoning with Baby Hitler. It would not be a surprise to learn that the two parties are unable to find consensus on the precise number of candles in the title of "Sixteen Candles."

Yet when it comes to all things pharma, Democrats and Republicans seem largely in lockstep. Pharmaceutical companies, it has been argued by politicians in office and on the stump, make too much money. They overcharge for their products, depriving needy patients of the most innovative and life-changing drugs. They are just the worst and they're bad and terrible and they need to be put in their place.

Does this overstate the actual impressions that even the mouthiest politicians on both sides of the aisle have about the industry? By a bunch. "Candidates are just responding to polling data," shrugs John Kamp, executive director of the Coalition for Healthcare Communication. "The American public is grumpy that it has to pay for the share of the drugs that it has to pay for. It's become a political issue."

To that end, whatever she has said while campaigning, Hillary Clinton has not exactly been shy about accepting campaign cash from pharma; she's taken more, in fact, than any other presidential candidate. An analysis by Stat, a recently launched online publication backed by Boston Globe Media Partners, concluded that Clinton accepted $164,315 from drug companies during the first six months of the campaign. By comparison, Ted Cruz led the GOP field with $96,405.

Too, it's worth noting that the next President's opinion about matters relating to industry and drug pricing only counts for so much. He or she can shake a fist and promise to do something about the price of pharmaceuticals, but there's no Constitutional precedent for a chief executive ramming through such a proposal. Congress will have to pass a bill and, well, the odds of a Republican-controlled and Tea Party–influenced Congress imposing price controls on pharma are about the same as the same groups inviting Alec Baldwin to keynote their annual klatch.

So, heading into 2016, what will the industry do to counter

all the criticism coming its way vis-à-vis the pricing issue? Is there a policy salve for what some insiders believe is in no small part a persistent PR thorn in the industry's paw?

Not surprisingly, a majority of pharma and healthcare execs aren't too keen on the idea of waiting out the offensives being waged against them. They want to move quickly to distinguish the bad actors—Turing, recently booted from the Biotechnology Industry Organization for its perceived misdeeds, and Valeant, which wonks say acts more like a hedge fund than a traditional pharma institution—from the rest of the business.

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—PETER PITTS

"The good news about everything with Turing and Valeant is that people are finally paying attention to the value of pharmaceuticals. The bad news is that they're focusing on price and either don't understand or don't care that price is just a piece of the larger value conversation," says Peter Pitts, president and cofounder of the Center for Medicine in the Public Interest and a former FDA associate commissioner. "I don't think you can just let that go without comment." Decision Resources Group principal analyst Matt Arnold agrees, adding, "You can't answer with radio silence when the entirety of the presidential field is dragging your industry name through the mud."

As one might expect, PhRMA has been heard from early and often, with its SVP, communications Robby Zirkelbach and Celgene SVP, corporate affairs and market access Rich Bagger singled out by their peers as the industry's most effective advocates. Zirkelbach doesn't shrug off the venom but neither does he paint the current state of affairs as anything remotely approaching a crisis. "We understand why people are focusing on list price, because that's an easy bumper-sticker slogan," he says. "But our industry has a very good story to tell. There are 7,000 medicines in the pipeline. We've cured hep. C. Things are happening in cancer that would've been considered science fiction 15 years ago … The data tells a different story than the rhetoric you hear on the news."

THE PRICE YOU PAY

Perhaps pharma might start pointing fingers at the payer community. During the hep.-C contretemps of 2014, payers told anyone who would listen that the cost of Gilead Sciences' Sovaldi would uproot the financial underpinnings of the American healthcare system. At the same time, those same organizations were negotiating discounts of up to 50% off list price with Gilead. Does it need to be said that those savings didn't eventually find their way to consumers? Under the doctrine of turnabout is fair play, then, perhaps pharma might point out payers' complicity in the pricing game.

"When people say, 'The price of drugs is too high,' what they really mean is that their co-pay is too high," Pitts notes. "That's a factor of the healthcare ecosystem, not something that's directly pharma's fault. The problem is that people in pharma don't point that out. They tell me, 'I don't want to attack payers or insurers, because we have to work with them.' What I say to that is, 'Well, they don't seem to have any problem putting you out in front to take all the blows.'"

Another potentially effective strategy would be for pharma companies to explain how they settle upon a price for a given drug—to give their customer base a glimpse behind the curtain, so to speak. While pharma companies have never been much for transparency, perhaps on the pricing issue they can part with established practice and, in doing so, shift at least some of the perceived blame off its shoulders.

"The cost of failure [during drug development] is a tough concept for the average person to grasp. I don't say that in the sense of 'people aren't smart enough to understand,' but more 'that's not something that fits in a sound bite,'" Pitts continues. "Let's say some of these companies stand up and say, 'When we have a new product in Phase III, we have conversations with a range of people—payers, the formulary community—and together as a group we come up with a price. Here's how that works.' Hopefully the response to that is, 'Oh, I had no idea it was more than one party involved.'"

BEYOND PRICING

While pundits believe that the pricing issue will tower above all others in 2016, they expect movement elsewhere on the policy front. They like what they've heard from Dr. Robert Califf, soon to be confirmed as the new commissioner of the FDA. In fact, they believe that one of his supposed drawbacks as a candidate—his close ties to industry—is what could make him an extraordinary leader of the organization.

While current perception is that the FDA has regained its mojo in the last 18 months or so—"FDA is actually one of the bright spots nowadays. It's moving forward on approvals at record rates and is back up at peak efficiency," enthuses Kamp—most pharma and healthcare execs believe that it needs to adapt its line of attack to the business climate at hand.

"FDA needs more of an intramural approach, to collaborate with existing experts in academia and industry. Some people may be wary about this, but FDA can't do everything all by itself," Pitts says. "I think that's why Rob is a really good choice. You'll see more action when it comes to clinical trials and expedited pathways to review. You'll see them asking patient groups what kind of data they have."

On the digital front, Arnold suggests OPDP may soon take a look at the communication of risk information in character-constricted formats, "especially if they decide the way we currently do risk isn't working, which many people think it isn't." He also expects a dam-burst moment for telemedicine. "You have Hillary Clinton talking about telemedicine as, essentially, the next leap forward for our healthcare system. You have the AMA developing telemedicine reimbursement codes. I think it's inevitable."

In the broadest sense, though, there's a belief that pharma is in no worse shape than it's been in recent years—and that, given the nigh-miraculous scientific progress, it's likely better off. "This is a storm that blows over the industry every four years," Zirkelbach says. "It's going to be a lot of hot air. There isn't any struggle on the level of the Affordable Care Act."

Pitts, on the other hand, compares the industry with Congress itself. "The old saying is that people hate Congress but love their congressperson—well, people hate pharma but they love their medicines," he quips. "I'm not sure what you can do to change that, especially during an election cycle, but it's something for all of us to remember when we're listening to the debates." ■