It's been a quiet year for healthcare and pharma marketers. The government was open for business and disposed to individuals across the political spectrum. Budget dollars flowed freely. There wasn't one galvanizing piece of legislation that threw institutions and programs into a state of flux. So for anyone in the pharma and healthcare marketing food chain, it was an uneventful year, with no looming anxiety superstorms. None at all. Nope. Nuh-uh.

The preceding paragraph comes to you on behalf of the Institute For Head-In-The-Sand Denial, and many people in healthcare subscribed to that thinking in 2013. But for almost everyone else, the situation prompted concern. Did government policy tweaks and persnickety politics generate migraines among pharma marketers in 2013? Maybe. Are many individuals in wait-and-see mode as the Patient Protection and Affordable Care Act struggles to generate momentum among potential enrollees? Absolutely. But policy wrangling has spurred caterwauling ever since the dawn of government.

Healthcare in America is evolving. Change is constant and, often, a drag—but that doesn't mean that disaster is nigh. And despite talk about gorked-out Obamacare websites and key states balking at Medicaid expansion, there are positive signs, from the expected influx of would-be-eligibles into the system to last month's move by the current administration to allow pharma companies to contribute to patients' out-of-pocket prescription costs.

Don't buy it? Listen, instead, to the analysis of four executives who have long been unknotting the types of thorny problems the system faces: Les Funtleyder, managing director of investment firm Poliwogg and author of *Healthcare Investing: Profiting from the New World of Pharma, Biotech, and Health Care Services*; John Kamp, executive director, Coalition for Healthcare Communication; Wayne Pines, former FDA chief of consumer education and information, chief of press relations and associate commissioner for public affairs; and Peter Pitts, former FDA associate commissioner for external relations and president and co-founder of the Center for Medicine in the Public Interest. Here, they weigh in on what to expect from the government in 2014.

Their message, massively condensed and oversimplified: It's not a time to throw any yay-for-Washington shindigs, but neither should anyone start bolstering underground bunkers or hoarding canned goods for a policy-prompted healthcare apocalypse. Read on.

Money, Morale and the FDA

At this time last year, healthcare policy types expressed less concern about potential ACA-related confusion than they did about the sequester, through which automatic—and severe—cuts would be imposed if the government couldn't get its budgetary act together. Back then, the pundits were quietly optimistic, believing that all parties couldn't possibly be so pigheaded as to fail to arrive at some kind of reasonable compromise.

PHOTO: GETTY IMAGES

Gorked-out Obamacare websites. Key states balking at the Medicaid expansion. One might come to think the evolving healthcare system is the institutional equivalent of a burbling volcano. Not exactly. Change is a drag, but there are still several positive signs to be seen, finds **Larry Dobrow**, who speaks with four sober-minded and esteemed executives

CAPITOL COMMOTION

What a difference a year makes. The sequester came to pass, as did a government shutdown and another tussle over the debt ceiling (still unresolved—see below). And a major victim of the cuts was the FDA, which finds itself limited in major ways. "If we expect more out of the FDA, we're going to have to give it more money to fund its operation," says Kamp.

At the same time, the pundit panel praises the organization for pressing forward—most notably, with an accelerated review process for so-called breakthrough drugs—amid the budgetary restraints. "[The FDA is] processing applications as quickly as they would've without the shutdown or sequestration. The situation has brought out the best in everybody there," says Pines. He does worry about the "demoralizing effect" of the cutbacks, a point with which Pitts agrees. "The FDA has an aging infrastructure and an aging staff they can't bolster with new people. They're underfunded and they're overworked, which is a demonstration of a real lack of faith in what they do." Worse, Pitts adds that the current problems presage future ones: "It's hard to get that train going again once the engine is cold."

Kicking the Can Down the Road

The last government showdown ended without a firm resolution: there wasn't even a low-grade debt deal, much less the "grand bargain" moderates on each side of the aisle were said to be pursuing. As a result, some individuals within healthcare worry that the government has done nothing but push its problems forward into the future. Could there be another government shutdown come February?

It seems so, especially since the rhetoric has continued since the conclusion of the last one. This, combined with the effects of sequestration and ACA-related headaches, has prompted observers to speculate about the possibility of dampened investment in biopharma.

Funtleyder doesn't exactly scoff at the notion, but he responds to a question about it with a borderline flippant, "Nobody's in panic mode." In his mind, the-sky-is-falling tirades about shutdowns and debt ceilings only have so much of an effect.

"Frankly, I don't know that kind of sentiment plays into investment decisions," he says. Nor does ACA play into his decision calculus. "On one hand, even if enrollment is less than we thought it would be, more people will be insured. From a pharma point of view, that's obviously a good thing. But the problems [with ACA] create some questions, because it's hard for anyone to make large investments without knowing what the situation will be going forward."

"If the governent is funding fewer ideas, that will put a damper on spending, at least in theory"

— Les Funtleyder, investment firm Poliwogg

The slightly bigger worry, Funtleyder says, is the stagnation of government spending, specifically in regard to NIH and CDC. "If the government is funding fewer ideas, that will put a damper on investment, at least in theory." But in terms of potential headaches that could stem from shifts in government policy, this barely registers.

Sometime around the end of 2014's second quarter, the FDA will issue its long-awaited social media rules of the road. Given how long these guidelines have been in the pipeline, some marketers expect that the FDA is planning to drop serious knowledge upon them.

Guess what? It won't, not if FDA's history in issuing such guidance is any indication. "Some people think it's going to be [FDA Office of

Can FDA manage to stay above the fray?

The long shadow of Obamacare's dismal rollout falls across everything touching healthcare that Washington will try to do in 2014, be it FDA, DEA, CMS and FTC initiatives, Capitol Hill oversight and legislation, or prosecutions.

Washington's toxic atmosphere will be made even worse by the approach of the November midterm elections and the clutter and tumult this will bring to the process of government.

Although they are not supposed to react politically, federal agencies like FDA have in recent times increasingly tended to respond more sympathetically in election years to the party that holds the White House than to its rivals when constituent or stakeholder concerns are presented. This is especially so the higher in the agency you go, and the closer to its implanted political appointees.

Next year being an election year, expect the Obama agenda and the concerns of Democratic constituencies to get more attention—without anyone openly admitting it. This is what happened with FDA's current trans fat initiative, which attacks a critical cost burden for Obamacare.

In the pharmaceutical arena, FDA is scheduled by next July to issue guidance describing its policy on Internet promotion, including social media, of all regulated medical products.

By the end of FY 2014 (Sept. 30), FDA says it will issue guidance on methodologies for assessing a drug's Risk Evaluation and Mitigation Strategy, which increasingly includes a patient information requirement. This guidance should specifically address methodologies for determining whether a specific Risk Evaluation and Mitigation Strategy with elements to assure safe use is: (i) commensurate with the specific serious risk listed in the labeling of the drug and (ii) considering the observed risk, not unduly burdensome on patient access to the drug.

In the same timeframe, FDA will hold a public meeting to discuss its qualification standards for new-drug development tools, new measurement theory, and implications for multi-national clinical trials supporting new drug applications.

Also in 2014, FDA promises to publish final guidance specifying the completed data standards, formats, and terminologies that drug sponsors must use to submit data in electronic applications, as paper submissions disappear into history.

In 2014, FDA says it will revise regulations for "current good manufacturing practice" for oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

Not later than Dec. 31, 2014, FDA expects to publish final guidance on how data may be used for the efficient and streamlined development of antibacterial drugs to treat serious or life-threatening bacterial infections.

In law enforcement against bad operators in the pharmaceutical marketplace, the Obama administration promises to continue its focus on drug safety, misbranding and adulteration. Misbranding includes making untrue or unbalanced promotional claims and failure to disclose all relevant safety information to FDA and prescribers. Adulteration includes manufacturing quality violations.

The Health Research Institute, a unit of the international accounting and consulting firm PwC (formerly PricewaterhouseCoopers), is expecting increased belt-tightening by healthcare organizations during 2014, aggravated by Obamacare. Notwithstanding this, HRI is predicting increased overall price increases, including higher insurance deductibles, and more use of generic drugs.

—James G. Dickinson

Prescription Drug Promotion director] Tom Abrams in the costume of Moses, coming down from the mountain with the big tablets," jokes Kamp. "Well, Tom's a great guy, but he's no Moses. There won't be the degree of clarity that people seem to be expecting."

There's a statutory mandate for the social media rules, meaning that they will arrive in some form. However, the odds that the FDA will do anything more than add some detail to the communication rules already in place, much less effect a major policy shift, are slim.

"They'll apply the same rules that have applied for years to the Internet," Pines predicts. "There's pent-up demand for the FDA to weigh in, but there's not going to be a dramatic change in their thinking." Pitts is more blunt: "If people are waiting for the FDA to solve all their questions on social media, they better have a serious plan B."

Marketers that haven't dipped their toes in the social media waters are perhaps the only constituency likely to be let down by this; the excuse of "we're waiting for the FDA" won't play anymore. No matter what the FDA says, expect pharma companies to continue to press forward with investment in social media.

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The pharma world may hear from the FDA on another mainstay: potential changes to the regulation of off-label communications. Here, Kamp and Pitts disagree. Kamp hopes to see changes. "The FDA should be spending time developing systems for regulating communications that aren't clearly specified on label," he states firmly.

Pitts doesn't think there will be anything resembling closure anytime soon. "There are so many dicey questions. What is the patient's right to know off-label information? Who should be doing the talking about it?" he explains. He also believes that the issue will remain on the back burner due to the aforementioned FDA budgetary limitations.

Pay for Pounds?

Politically, this would be the mother of all difficult sells, as much for practical concerns as for legal ones. Any politician who proposes, say, levying some kind of tax on obese individuals or pack-a-day smokers would likely be shouted down by both the left and the right.

But maybe, Pitts suggests, we're approaching a time when it might make sense to consider something along those lines. "We've tried a lot of carrots. Maybe it's time for the sticks to come to bear," he says. "Demographically, the healthcare system is under an undue amount of stress. We're a nation of aging, hypertensive, obese diabetics, and we're not dying, and still we only say so much about the importance of a good diet and exercise. Should we have that conversation about charging people for bad health?"

Don't hold your breath waiting for the government to do this or incentivize individuals for healthy lifestyles and practices, even though Pitts believes that it would be effective in just such a role. "The government does really well with bully-pulpit communications: don't do drugs, wear your seat belt, things like that," he continues. "What we keep seeing is that even though people are diagnosed and prescribed, they don't listen to their doctors' advice or take the medicine. At some point, we might have to incent them to do so." ■