Politics, Policy & Law

Post-election squeeze

By Steve Usdin
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Now that the elections are over, Congress, President Obama and his administration may finally turn their attention to urgent decisions that will determine the size and health of the two poles of the biomedical R&D universe: the basic research that fuels discovery at one end, and at the other, the revenues that are essential for continued investment in innovative products.

Washington’s to-do list for the remaining weeks of 2012 includes forestalling, modifying or acquiescing to the enactment of sequestration, the across-the-board budget cuts that could cripple American science for a generation and limit FDA’s ability to modernize.

Congress and the White House will also be grappling with the second element of the “fiscal cliff,” expiration of tax cuts enacted during the George W. Bush administration.

Horse trading to steer clear of the fiscal cliff will likely resurrect efforts to institute new Medicare and increased Medicaid rebates that could cost biopharma companies tens of billions of dollars annually.

Separately, the election effectively eliminated roadblocks to the Affordable Care Act (ACA), setting in motion a frenzied effort by the Obama administration and states to meet a 2014 deadline to establish health insurance exchanges and expand Medicaid coverage.

Details of ACA implementation, starting with rules for essential health benefits, will determine the kinds of healthcare products and services that will be available to tens of millions of Americans — and the extent to which coverage expansion translates into new revenues for drug manufacturers.

Sequestration consternation

The fates of NIH, FDA and Medicare are all contingent on the outcome of negotiations between Congress and the White House over budgets and taxes.

A Congressional Budget Office report released last week underscored the need for action to reduce the deficit, and illustrated why Congress will have to impose deep budget cuts.

According to CBO, if the Bush tax cuts are extended without modification and the spending cuts imposed by sequestration are completely eliminated, federal debt held by the public would increase from the current 70% of GDP to 90% in a decade and “continue to rise rapidly thereafter” (see “Online Links,” A7).

It wouldn’t take a decade for Americans to feel the pain under the default scenario — allowing the tax cuts to expire and fully applying the sequestration ax.

The confluence of the expiration of $440 billion in tax cuts and the imposition of $108 billion in spending cuts under sequestration “is a genuine threat to the economy and could generate a recession if we went straight over it,” said Douglas Holz-Eakin, president of the American Action Forum.

Holz-Eakin was CBO director from 2003-05 and chief economist of the President’s Council of Economic Advisers from 2001-02.

Unmitigated, the fiscal cliff would cause a 6% decline in GDP and increase unemployment by 2.8 million in 2013, according to Holz-Eakin.

Holz-Eakin doesn’t expect Congress to face up to these challenges in the lame duck session. Instead, he said, it will likely push off decisions until after the 113th Congress is convened in January.

“It could imagine a scenario where they choose to extend current tax rates a while and bring them back up in the context of a budget deal they will unquestionably have to do in the new year,” he told BioCentury.

However, the White House could determine its best strategy is to allow the country to fall off the cliff, at least in terms of taxes, and then force Congress to take separate votes on reinstating cuts for the middle class and for higher income taxpayers.

“The Democrats are in a pretty good negotiating position,” said Mark McClellan, director of the Engelberg Center for Health Care Reform, a think tank that is part of the Brookings Institution. “The default under the current law is tougher on Republican issues like taxes and defense spending than it is for Democrats.”

McClellan added: “Whether modifications happen during the lame duck session or some time in the first part of 2013, either way there will be a fairly similar result.”

He told BioCentury it likely would be smaller, more gradual budget cuts than sequestration would impose, while sunsetting some of the Bush tax cuts.

Dan Mendelson, CEO of healthcare consulting company Avalere Health LLC, had a similar prediction.
“It is relatively unlikely that you’ll see a massive budget deal,” said Mendelson, who served as associate director for health at the Office of Management and Budget (OMB) during the Clinton administration. “The most likely trajectory is expiration of the Bush tax cuts, maybe give a little back, and a reduction in spending.”

Sequestering science

Sequestration was created as a default option if a bipartisan congressional “super committee” failed to agree on deep spending cuts. It was designed to be so unpalatable to both Democrats and Republicans that they would be compelled to find common ground. The threat, however, was not effective — the super committee didn’t come close to agreeing on spending cuts.

Now FDA could be forced to lay off 1,200 employees, and Medicare providers would face a 2% budget cut (see BioCentury, Sept. 17, 2012).

Sequestration would have particularly dire effects on NIH, potentially causing it to eliminate about a quarter of the grants it had planned to award next year or renege on long-term funding commitments.

The kinds of cuts sequestration would impose on NIH could mean “we’re going to lose a generation of great scientists, which would be a real tragedy for biomedical innovation,” said Douglas Doerfler, president and CEO of MaxCyte Inc.

Doerfler, who is a member of the Health and Emerging Companies governing boards at BIO, discussed post-election policy on this week’s edition of BioCentury This Week television.

Research!America, an advocacy organization focused on biomedical research funding, this week is launching a campaign this week to “save science,” Mary Woolley, the group’s president, told BioCentury This Week.

One of Research!America’s messages is that cutting NIH funding is inconsistent with initiatives to enhance American science, technology, engineering and medical (STEM) education, and that it risks eroding national competitiveness.

“We would be very foolish right now to rip the rug out from under what is still a thriving research enterprise,” Woolley said. This would effectively “cede the playing field to other countries that really have stepped up in recent years and are using a playbook that we developed a couple of decades ago to drive their economy and work on the future health and prosperity of their own populations by investing strongly in biomedical research.”

Nevertheless, big budget cuts are inevitable, and NIH is unlikely to be exempted whether or not a “grand bargain” is struck on deficit reduction.

Modification of sequestration would only soften the blow, Mendelson said. The NIH budget “will be cut, but not as much as is called for under sequestration, and not as soon as is called for under sequestration.”

The life sciences research community will have to find other sources of funding or learn to live with smaller budgets, Mendelson added. “The idea that American science has to rely on increasing government funding is not compatible with the kind of budgets we are going to have,” he told BioCentury.

Tevi Troy, a senior fellow at the Hudson Institute, agreed the NIH cuts will not be as severe as sequestration would impose.

“To the extent that there is non-defense spending that Republicans like, it is biomedical research,” said Troy, who served as deputy secretary of HHS in the George W. Bush administration. However, he added, “there is a lot of pain that has to go around,” and NIH will not come out unscathed.

Pharma back on table

Health policy specialists from across the political spectrum agreed the budget climate won’t get easier any time soon. In addition to avoiding sequestration and possibly offsetting a continuation of tax cuts, Congress needs to find money to avoid automatic cuts to Medicare physician fees that are a legacy of a 1997 budget balancing effort.

Failure to act by Dec. 31 would mean a 27% cut in physician reimbursement rates. A one year “doc fix” would cost about $18 billion.

“The budget environment will be extremely tough and you are likely to see costs squeezed in every possible way, especially when we get closer to implementation of the full Affordable Care Act with its expensive subsidies,” Troy said.

Congress is approaching a “Willy Sutton moment,” Holz-Eakin said, referring to the criminal who said he robbed banks “because that’s where the money is.”

Many of the deficit reduction playbooks Congress and the White House will consult include recommendations to suck money out of the pharmaceutical industry. These include a number of proposals that were taken off the table in the PhRMA deal to support the Affordable Care Act.
Near the top of the list: Imposing rebates on drugs purchased under Medicare Part D by so-called “dual-eligibles,” individuals who are eligible for both Medicare and Medicaid.

The Obama administration’s proposed fiscal 2013 budget projected $135 billion in revenues over a decade from dual-eligibles rebates. The idea, which is anathema to PhRMA, was also endorsed by the National Commission on Fiscal Responsibility and Reform chaired by Alan Simpson, a former Republican senator from Wyoming, and Erskine Bowles, President Clinton’s chief of staff.

The White House is also likely to continue to press for reducing the exclusivity period for biologics to seven years from the 12 years established when Congress created a biosimilars pathway in the Affordable Care Act.

Last week, the National Coalition on Health Care, a coalition focused on reducing healthcare costs that includes labor unions, medical societies and insurance companies, issued a report called CURbing Costs, Improving Care. It recommends a seven-year exclusivity period for biologics and reducing reimbursement for Medicare Part B drugs.

“What the pharma industry has to worry about are the historical bad ideas, ranging from rebates to dual-eligibles, to shortening exclusivity on biologics,” Mendelson said. “Everything that was taken off the table is back and will have to be dealt with and will consume a lot of the attention of the pharma industry in the short term.”

ACA Go-Ahead

While the elections reinstated divided government, the voters provided a definitive answer to one of the biggest public policy questions facing the country: The Affordable Care Act now will go into effect.

“The repeal Obamacare effort is over,” said Troy, who served as a healthcare policy advisor to the Romney campaign. “That doesn’t mean conservatives love Obamacare. There are still improvements that could be made, but as long as there was an election looming, conservatives didn’t want to make an unpalatable piece of legislation more palatable.”

Now, he said, Republicans will try to “make market-based, value-driven improvements” to ACA.

According to McClellan, the law can only be changed on the margins. “I don’t think anything that could be regarded as affecting the core of the ACA would get through the Senate let alone be signed by the president,” he said.

Although Republicans and some Democrats will try to eliminate the Independent Payment Advisory Board, the Obama administration and Democratic leaders in the Senate are unlikely to part with IPAB.

Under the ACA, if the cost of Medicare exceeds GDP plus 1% starting in 2014, IPAB will make cost-reduction recommendations. Those recommendations would go into effect unless Congress enacted alternatives that achieved the same level of savings.

Because IPAB’s recommendations must produce immediate savings, its toolkit will primarily consist of payment cuts, Kenneth Thorpe, chair of the Department of Health Policy & Management at the Rollins School of Public Health at Emory University, told BioCentury. Thorpe was deputy assistant secretary for health policy at HHS during the Clinton administration.

“The Obama administration says the near-term solution is to use the IPAB, but the types of recommendations IPAB can make are limited,” Thorpe said. “It will continue to focus on payment cuts to providers, and that’s not sustainable.”

Thorpe recently teamed up with Holz-Eakin to form the Partnership for the Future of Medicare, a bipartisan group that will advise policy makers on options for ensuring the fiscal sustainability of Medicare.

“Going forward the only way to solve the problem over the 15-, 20- or 25-year period is to pull costs out of the system” by cutting the prevalence of chronic diseases, Thorpe said.

Improving access to drugs, as well as medication adherence, will be critical to reducing the cost of treating chronic diseases, he added.

According to McClellan, the political system must be moved away from cutting payment for medical services and products, which would create disincentives for investment in innovation and ultimately create barriers to access.

The only way to do this, he said, is to restructure Medicare.

“The best opportunity for an alternative would be some acceleration in payment reforms away from fee for service and toward more value-based payment systems,” he said.

According to McClellan, such reform would take “more of an approach to price competition in plans that is being used in the Affordable Care Act and employer coverage today.”

Year of change

It will take time to develop a political consensus around Medicare reform, but the private sector already is reacting rapidly to the changing healthcare environment.

“The biggest thing the biopharma industry needs to get its arms around is how the provision of healthcare in this country will change in the next year,” said Mendelson. “Things will be really different a year from now.”

About 30 million currently uninsured Americans will get coverage starting in January 2014, half through subsidized health insurance exchanges and half through expansion of Medicaid.

Coverage provided in the exchanges will be “a lot skinnier” than policies that most Americans have today, Mendelson said. “If you look at the aggregate level of funding for products that will be offered in the exchanges, it is light. This means health plans will do everything they possibly can to bring costs down.”

Mendelson also predicts that the trend of consolidation among payers will accelerate. This is exemplified by Aetna Inc.’s planned $7.3 billion acquisition of Coventry Health Care Inc., announced in August. If completed, the acquisition will bring Aetna 4 million members, primarily in Coventry’s Medicare Advantage and Medicaid managed care plans, as well as 1.5 million Medicare Part D beneficiaries.
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Essential benefits

The biopharma industry’s next and probably best opportunity for shaping ACA will come when HHS publishes a draft regulation on essential health benefits.

Under the ACA, starting in January 2014, most health insurance sold to small employers and individuals must provide minimum levels of coverage. That minimum will be defined in the essential health benefits.

Rather than set a single essential health benefit package for the entire country, HHS has decided to allow each state to select a benchmark plan that will serve as the reference for its own definition of essential health benefits.

More controversially, in a bulletin released in December 2011, HHS said it plans to require that essential health benefits cover only one drug in each therapeutic class that is included in the benchmark plan.

The one-drug requirement is a sharp departure from Medicare Part D, which requires that drug plans provide access to “all or substantially all” medications in six therapeutic classes.

Patient advocacy groups have aggressively lobbied for expansion of the drug requirement. For example, the AIDS Healthcare Foundation wrote to HHS Secretary Kathleen Sebelius on Oct. 31 that for HIV/AIDS patients a one-drug essential health benefits rule “would literally cause significant pain and put their health and well-being at great risk.”

Speaking on BioCentury This Week, Marc Boutin, COO of the National Health Council, predicted the final regulation will revamp the one-drug per class requirement. NHC is an umbrella group for patient advocacy organizations; it focuses on health policies for people with chronic diseases.

“For many people with chronic conditions, they’re on multiple medications within a class, or they take combination therapies,” Boutin noted. “This could potentially be deadly. And the government has said, ‘No, we understand there’s a problem there, we’re going to re-look at that.'”

Boutin added: “We’re seeing a movement to change in that direction, but we still don’t know what the rules will be. So we’re anxiously awaiting that guidance and rules from the government.”

HHS sent a draft essential health benefit rule to OMB last week for review. The budget office is expected to release it soon.