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Congress Has To Beat The Clock For 21st Century Cures Act

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Despite continued fighting over the Affordable Care Act, there have been more bipartisan accomplishments in health care since Republicans regained control of Congress in 2010 than in any other legislative arena. Now, after a string of health care successes, the House of Representatives appears close to passage of the 21st Century Cures Act. The legislation would create significant opportunities for drug and device makers and new hope for patients. Enactment, however, depends on swift action as elections and other priorities bear down on Washington.

The bill's sponsors believe that advances like human genome mapping and new biomarker identification have opened a door for new therapies and cures. The 21st Century Cures Act would modernize Washington's regulatory structure to keep up with the pace of change and get innovative treatments to patients. The bill would boost funding for the National Institutes of Health and U.S. Food and Drug Administration, make it easier for researchers and manufacturers to share data, eliminate regulatory uncertainly for medical apps and modernize clinical trials.

The House Energy and Commerce Committee and its subcommittee on health have been a bright spot of legislative productivity over the last few years under the leadership of Chairman Fred Upton, R-Mich., and Subcommittee Chairman Joe Pitts, R-Pa. The two Republicans have balanced their unwavering opposition to the ACA with a willingness to work closely with the committee's Democrats on other matters. They have moved dozens of bills into law, including the Food and Drug Administration Safety and Innovation Act in 2012, legislation to regulate compounding pharmacies and secure the prescription drug supply chain in 2013 and a recent bill that replaced Medicare's deeply flawed system for reimbursing doctors after more than a decade of inaction on the festering issue.

Now, the committee has produced the 21st Century Cures Act, ambitious legislation aimed at bringing new therapies to market faster. The bill is the product of an 18 months-long process of meetings with regulators, industry stakeholders and patient groups. It seeks to increase efficiency in the discovery (i.e., research), development (i.e., testing), and delivery (i.e., regulatory approval and marketing) stages of bringing new therapies to market. Though there has been some controversy over details, the initiative was so well-received that President Obama seemed to be jumping on the bandwagon with the

“precision medicine” proposal announced in this year’s State of the Union.

The 2012 FDA law, the pharmaceutical supply chain law, this year’s Medicare physician payment reforms and the 21st Century Cures Act all moved through the committee via an open and bipartisan process, unusual in today’s partisan environment. In each case, Reps. Pitts and Upton worked closely with stakeholders and Democrats, such as Reps. Frank Pallone, D-N.J., Gene Green, D-Texas, and now-retired Henry Waxman, D-Calif.

They held hearings, negotiated privately and issued public drafts that allowed affected parties a chance to comment. One roundtable in Rep. Pitts’ Pennsylvania district featured committee members from both parties, NIH Chairman Francis Collins, former FDA Commissioner Margaret Hamburg, Biotechnology Industry Organization President Jim Greenwood, executives from innovative pharmaceutical firms and hospitals. After nearly two dozen such roundtables, hearings and forums, the committee finally voted on it on May 21. The bill passed unanimously.

Bipartisanship and an open process have not completely shielded the legislation from critiques, however. Former FDA Commissioner Hamburg said as she departed her post that too much streamlining of the approval process could put patients at risk. Bill sponsors respond that slow approvals of new therapies also put patients at risk. Bipartisan compromises led to a somewhat less ambitious bill than Reps. Upton and Pitts had originally envisioned. A last-minute proposal to rein in a fast-growing discount drug program was removed after opposition from hospitals.

As with most legislation in the modern budget environment, paying for the 21st Century Cures Act is a challenge. As passed by the committee, much of the cost is covered by selling oil from the nation’s Strategic Petroleum Reserve, which some have criticized. The medical device industry, which otherwise supports the legislation, objects to a provision that would apply Medicare’s competitive bidding rates for durable medical equipment to Medicaid. Additional hurdles include other disputed offsets and the potential for jurisdictional tussling with other committees. Rep. Upton, however, appears to be successfully working through these challenges.

Committee and leadership staff are signaling that the bill will come to the floor after the House’s Independence Day break. In the meantime, staff are working to adjust the bill’s cost offsets to ensure House passage. In doing so, they are racing the clock.

As the election season approaches, the window for ambitious bipartisan achievements is closing. Senate Health, Education, Labor and Pensions Committee Chairman Lamar Alexander, R-Tenn., recently said that he will write his own legislation with a goal of Senate floor action “early next year.” This comment has produced some skepticism that the House’s effort will ever make it into law. “The closer we get to the presidential election year,” one cancer advocate told Politico, “the more we could see all of the political goodwill ... erode, and politics creep back into what has been an impressively nonpartisan process.”

The U.S. Supreme Court’s ruling in King v. Burwell, a key challenge to the Obama administration’s implementation of the ACA, is expected by the end of the month. A ruling for the plaintiff could sideline other health-related bills as legislators scramble to respond.

The momentum behind the 21st Century Cures Act may be sufficient, however, to make it through the choppy water ahead. Reps. Upton and Pitts continue to work closely with Reps. Pallone, now the senior Democrat on the committee, and Gene Green, along with lead Democratic co-sponsor Rep. Diana

DeGette, D-Colo. Rep. Upton has been effective at avoiding jurisdictional turf battles among congressional committees, and is well-liked by his colleagues. Rep. Pitts, an across-the-board conservative, has likewise proven able to set aside partisan differences on nonideological issues and is pleased to share credit for legislative achievements with his colleagues.

The Medicare physician payment reform enacted earlier this year was given low odds of success, but nevertheless succeeded after Speaker of the House John Boehner, R-Ohio, and Minority Leader Nancy Pelosi, D-Calif., came to an agreement on cost offsets. Similar top-level engagement may be necessary to get the 21st Century Cures Act through the House.

The 21st Century Cures Act would boost funding for government and university researchers via the NIH and give patients a voice in the regulatory review process. For drug and device makers, it would provide access to more research data, clarify privacy rules and streamline clinical trials. To become law, however, the bill may have to pass the House before the Supreme Court rules and the Senate may have to take it or a companion bill up before the presidential campaign enters full swing.

—By Gabe Neville, Covington & Burling LLP

DISCLAIMER: The author served as a senior congressional staffer for nearly two decades under Rep. Joe Pitts, R-Pa.

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