

FDA user fee bill set for smooth sailing - Republicans soften tax stance - Would the Senate repeal the medical device tax? - FOIA concerns in user fee bill

By [JASON MILLMAN](#) | 05/30/12 9:30 AM EDT

With help from Brett Norman

THE EXCEPTION THAT PROVES THE RULE? The FDA bill will sail through the House today without amendment and without much fuss, Republican and Democratic staffers predicted on Tuesday. That's pretty much how its Senate counterpart cleared that chamber in a 96-1 vote last week, bucking typical health care and election year politics. If someone requests a roll call vote on the House's Food and Drug Administration Reform Act, that would happen around 6:30 p.m., but it could move quietly along on a voice vote earlier in the day, following a brief floor debate. The Congressional Budget Office signed off yesterday on the bill, projecting it will reduce federal deficits by \$370 million over the next decade. That had been one of the few remaining stumbling blocks, which popped up last week when an earlier version was scored in the red. Legislators extended a provision to speed up FDA decisions on certain generic drug applications to biosimilar drugs as well, putting the bill in the black. The new CBO score: <http://politico.pro/MWggwT>

Happy Wednesday and welcome to PULSE, where we think we're pretty cool — but not cool enough to pull off shades at the White House like Bob Dylan did yesterday. But when you've influenced pop culture for the better part of the past half century, well, we guess you get to do things like that.

"And these visions of PULSE, they kept me up past the dawn"

TODAY ON POLITICO PRO:

--ANY CHANCE THE SENATE REPEALS DEVICE TAX? Advocates of repealing the ACA's medical device tax are hoping for a strong bipartisan vote in the House, which they think could force the Senate to tackle the issue this year. <http://politico.pro/M4N9bz>

--ABORTION RIDERS AND NATIONAL SECURITY – Authorization and approps bills for national security measures could be complicated by abortion provisions inserted by lawmakers from both parties. <http://politico.pro/N7wl0x>

REPUBLICANS SOFTENING ON TAXES? Ahead of the looming budget showdown, there are cracks emerging in the GOP's hardline stance against boosting tax revenues to cut the deficit. Interviews with more than a dozen Senate Republicans show them warming to higher tax revenues to reach a "grand bargain" that overhauls Medicare and other safety net programs. "My impression is if you brought rates down, did real meaningful tax reform, the additional revenue would not be a deal-killer for many," said Sen. Mike Johanns (R-Neb.). Thing is, that's setting up a stark contrast with Mitt Romney, who pledged during the primaries that he'll oppose new taxes as part of a debt deal. The Romney campaign is still sticking to this message, but Sen. John Cornyn (R-Texas) suggested Romney's stance could soften a bit if he's elected and deficit talks gain momentum. "There is such a thing as a negotiating [tactic] — you don't negotiate against yourself," said Cornyn, a member of GOP leadership. The POLITICO story: <http://politi.co/KR4xh4>

FOIA CONCERNS REMAIN ON USER FEE BILL – Public Citizen and 20 other public interest groups sent a letter to the chairman and ranking member of the Energy and Commerce Committee on Tuesday asking them to narrow a provision that would deny the public access — at FDA's discretion — to information related to drugs provided by other domestic or foreign government agencies. The measure is part of an effort to help FDA leverage its limited ability to inspect manufacturing facilities around the world by allowing it to rely on inspections performed by other agencies. But concerns about the potential of leaked trade secrets prompted a broad exemption from the Freedom of Information Act for related documents. "The provision would create an overly broad exemption under FOIA — with no explanation of need by the entity that wants to keep the information secret," Julie Murray, a Public Citizen staff attorney, said in a press release. "If passed as is, the legislation could push some of the FDA's work into the shadows." The groups successfully fought to restrict a similar provision in the Senate bill, which was addressed in an amendment by Sen. Patrick Leahy (D-Vt.) that would limit the scope of the FOIA exemption to information voluntarily

provided by foreign governments and specify a time frame for removing the “confidential” tag. The letter: <http://bit.ly/MW7zTj>

FDA WARNS OF COUNTERFEIT ADHD DRUG – The agency announced on Tuesday that it had confirmed that fake versions of Adderall, a popular drug to treat attention deficit hyperactivity disorders, have been sold in the U.S. The counterfeit drugs, purchased through online pharmacies, contain two ingredients meant to treat acute pain and “should be considered as unsafe, ineffective and potentially harmful,” the agency said. Adderall, manufactured by Teva, is currently on the drug shortage list. The FDA release: <http://politico.pro/KaFCY3>

**** A message from America’s Health Insurance Plans:** In the 1990s, Kentucky tried to implement market reforms without a mandate. Before the reforms were enacted, Kentucky residents had a choice of 43 individual insurance providers. By 2000, that number dropped to only two. Learn more about The Link between the individual mandate and market reforms at <http://bit.ly/thelinkahip> **

JUDGE GIVES EARLY BLOW TO LAWSUIT AGAINST WASHINGTON AG – A Washington State judge declined to issue a preliminary injunction requiring Attorney General Rob McKenna to file a new motion in the ACA lawsuit at the Supreme Court to clarify his position, according to local reports. McKenna, a Republican who’s running for governor, has said that he only wants the Supreme Court to strike down the individual mandate and Medicaid expansion — but Democratic-aligned groups argue that the AG has signed onto briefs asking the court to overturn the entire federal law. But the Superior Court judge said that McKenna “has maintained a consistent legal position throughout the health reform litigation” in court filings. McKenna’s camp has criticized the lawsuit as another ploy of a lefty lawyer who they say has a tendency to file lawsuits meant to embarrass GOP candidates. The plaintiffs, however, promised to keep up the lawsuit, somehow framing it as a women’s health issue. The Olympian has more: <http://bit.ly/LchwYr>

KOMEN NUMBERS DOWN IN D.C., TOO — We told you yesterday how registration for Komen’s Race for the Cure in Connecticut is down about 30 percent, even though the state chapter quickly condemned the national group’s original defunding of Planned Parenthood. Registration is down even more in Washington, just days before the event. So far, 25,000 have registered for the race, far from the 40,000 who participated last year. WJLA has the story: <http://wj.la/JNaQjq>

NEWS TO US – Did you know that groups like the libertarian Cato Institute and conservative American Legislative Exchange Council are crisscrossing the country to kill off state health insurance exchanges? Yup, USA Today has the details about how the anti-ACA groups are waging a nationwide exchange war. What a great story, right? We can't believe no one else thought to write it already. Anyway, you can see the USA Today story here: <http://usat.ly/MW3pef>. Or just re-read the story we did on this six weeks ago: <http://politi.co/HJgpyj>

DEMS HIT WALKER ON WOMEN'S HEALTH — As polls show Wisconsin Gov. Scott Walker likely to win his recall election next week, Democrats yesterday accused him of trying to limit women's access to health care. Rep. Gwen Moore, a Wisconsin Democrat, said Walker and supporter Virginia Gov. Bob McDonnell are "birds of a feather," tying Walker to McDonnell's tough time with the mandatory ultrasound bill earlier this year. Moore on Tuesday also criticized Walker for returning grants to implement the ACA.

HEMOCARE GROUP TAPS RANKIN FROM COMMUNITY PLANS — The American Association for Homecare has hired Peter Rankin as its new government affairs manager, according to our friends at POLITICO Influence. Rankin comes from the Alliance of Community Health Plans and Stateside Associates to now represent providers of home medical services and DME.

HAPPENING TODAY – CMS officials join with advocacy groups to discuss a new initiative to improve dementia care. ... Sen. Al Franken (D-Minn.) holds a field hearing on Accretive Health's collection practices. Accretive Health executives, Minnesota AG Lori Swanson, Minnesota Commerce Commissioner Mike Rothman and patients will testify: <http://politico.pro/K1G3lw>. ... The CMS trio of Jonathan Blum, Cindy Mann and Melanie Bella address Day 1 of the National Medicaid Congress. The agenda: <http://bit.ly/JMsg78>

TIMELY CONVOS THAT WE'LL MISS – Sen. Amy Klobuchar and Rep. Erik Paulsen, co-chairs of the Medical Technology Caucus, are holding a roundtable discussion today on medical devices back in their home state of Minnesota. Paulsen just happens to be the author of the medical device tax repeal bill that the House gets to work on this week, and Klobuchar recently said she'd be open to repealing the tax. So, if any of you happen to be near Minnetonka tomorrow morning, give us a shout!

BREAKFAST AND HEALTH POLICY — That's what POLITICO does. Get the tasty scoop on how states are preparing for ACA implementation at this Friday's health policy breakfast for Pros, featuring Josh Sharfstein, Maryland's secretary of Health and Mental Hygiene; Bill Hazel, Virginia's secretary of Health and Human Resources; Ron Pollack, executive director of Families USA; and Daniel Durham, AHIP's executive VP of policy and regulatory affairs. Details and RSVP here: <http://bit.ly/Lh2wl2>

WHAT WE'RE READING, by Jennifer Haberkorn

Glenn Hubbard, a top economic advisor to the Romney campaign, tells the WSJ that the former Massachusetts governor will soon spell out a detailed health proposal. <http://on.wsj.com/JTPQ8O>

Wendell Potter, a harsh critic of the insurance industry, says CO-OPs might be the health reform "sleeper" that "truly transforms how care is financed and delivered in this country." <http://bit.ly/JzoQAA>

Put House Democratic Leader Nancy Pelosi down for a prediction of a 6-3 ruling in support of the health reform law, The Bay Area News Group reports. <http://bit.ly/KqZT9R>
CMS selected two firms to help Porter Novelli in its contract to promote the health care reform law, PR Week reports. <http://bit.ly/LFnCzd>

Professors Eric Segall and Aaron E. Carroll write in The Stanford Law Review that a ruling against the entire ACA would be an "absolute disaster" for the health care industry. <http://bit.ly/JTQBic>

Leavitt Partners' David Merritt runs through the likely scenarios that could result from the Supreme Court's health care case, at The Hill. <http://bit.ly/KalzHC>

**** A message from America's Health Insurance Plans:** In the 1990s, Kentucky tried to implement market reforms without a mandate. Before the reforms were enacted, Kentucky residents had a choice of 43 individual insurance providers. By 2000, that number dropped to only two.

Independent experts, policymakers and elected officials have all recognized the inextricable link between market reforms like guarantee issue and community rating and universal

coverage. Studies from eight states that enacted various forms of guarantee issue and community rating in the 1990s all show what happens when these market reforms aren't linked to a mandate: higher premiums, no reduction in the uninsured and loss of consumer choice.

There's a link between market reforms in the ACA and the individual mandate. Discover important resources at <http://bit.ly/thelinkahip> and connect with us on Twitter at [@AHIPCoverage](https://twitter.com/AHIPCoverage). **