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Prescription Pulse
A weekly briefing on pharmaceutical policy news.

'Cures' speeding toward E&C — GDUFA has its own tension — Upton's timeline for the Senate far less certain

By **BRETT NORMAN** and **SARAH KARLIN** | 5/18/15 11:59 AM EDT

THIS WEEK'S REVEAL: 'CURES' PAY-FOR AND FDA FUNDING — The last big hurdle for the House's 21st Century Cures bill is how to pay for it, and the Congressional Budget Office has yet to name the legislation's price. Pharma-land is plenty nervous over where chief GOP Cures architect Fred Upton and his Democratic collaborators will find the money, including new funding for FDA that both he and Rep. Diana DeGette say will depend on that CBO score. The full Energy and Commerce committee markup is scheduled to begin at 5 p.m. on Tuesday and continue into Wednesday, but that still could slip, especially if the pay-fors draw a mob of lobbyists with torches and pitchforks to the Hill.

... Lobbyists see the timeline as wildly ambitious but are no longer gainsaying Upton's plans given how fast the process has unfolded in recent weeks. "I don't know how to describe it other than surreal," one GOP lobbyist with pharma clients said. "They're going to get an agreement on 10 to 15 billion in offsets by Monday night? The whole thing is just very, very hard to believe, and yet they're not taking no for an answer." On the other hand, once the pay-fors are out, at least the handwringing can stop, the lobbyist said. "Then we'll know what we're dealing with, and we can have a real conversation."

... Negotiations continued over the weekend to hammer out the final details on a range of provisions, which had remained bracketed in the draft bill that unanimously passed a subcommittee markup Thursday. The SOFTWARE Act language remained a big outstanding issue. New rules on what "health care economic information" drug companies can disseminate were also still in play. And the specifics of a boost in Medicare payments for new antibiotic drugs were in flux, along with the reauthorization of a pediatric voucher

incentive program and HHS policies on the oversight of human research subject protections.

HOW MUCH DOES FDA NEED? — The agency's still working to tally the new responsibilities it could be given through Cures. FDA advocates say its funding calculation will likely multiply the average cost of an agency staffer by the number of full-time employees who would be needed to handle the new mandates.

Happy Monday and welcome to Prescription PULSE, your one-stop shop for news on pharma and the medical device industry, where we'll regularly highlight a moment of medical history for your morning edification. Today we note that this was the week in 1997 when a 3-year-old boy in Hong Kong died of avian influenza — the first known human case and the start of an outbreak that would ultimately kill six people and lead to the destruction of 1.6 million domestic birds.

USER FEE LEGISLATION AND CURES COULD COLLIDE — Drug makers are already worrying about getting stuck with the check for Cures, but if the legislation can't get through Congress fast enough, some parts could wind up in the next iteration of the Prescription Drug User Fee Act, one lobbyist said. In that case, there'd be even more expectation that industry would pick up the government's tab. Yet if pharma covers Cures provisions through user fees, that could leave industry supporting FDA to an even greater extent — further skewing a funding relationship that many already consider out of whack, the lobbyist said. The current user fee legislation expires in September 2017.

— On the issue of user fees, mark your calendar for July 15, when FDA will begin its PDUFA negotiations with industry. The agency wants feedback on the current user fee bill PDUFA V and what should be changed for the sixth user-fee period to enhance the efficiency and effectiveness of drug reviews. http://bit.ly/1H6UYUO

GDUFA HAS ITS OWN TENSION — Not to be stuck in the back seat, the generic drug industry will have its negotiations with FDA begin first with a June 15 public meeting. It comes as more generic companies are complaining about a lack of communication with the agency and slow review times, Lachman Consultants Bob Pollock notes in his blog. Pollock, a former acting deputy director in FDA's generic drugs office, writes that manufacturers may be paying FDA close to $1 million prior to an approved drug generating any revenue. Those lagging approval times could change the content of GDUFA II, Pollock writes. http://bit.ly/1IFj2Cj

... And the first MDUFA meeting? It hasn't been officially noticed by FDA, but it will be July 13.

UPTON'S TIMELINE FOR THE SENATE FAR LESS CERTAIN — Upton raised eyebrows in the upper chamber when he proclaimed Thursday that his Cures legislation would be in conference with the Senate HELP Committee by the fall and that a bill would get to the president's desk before the end of the year. That flatly contradicted HELP Chairman Lamar Alexander's announced plans to bring its bill to the Senate floor "early next year." Sayeth one irked Senate aide who declined to be identified: "It's nice that the House has a timeline in mind. The House has lots of ideas that become bills. The Senate, however, has ideas that become law."

FAST TRACK: BIOLOGICS PROVISIONS DOWN TO THE WIRE — The Senate will bring fast-track trade negotiating authority to the floor, and it could pass by the end of this week. That's what President Obama says he needs to close the deal on the 12-country Trans-Pacific Partnership negotiations, which is when we would finally see whether the industry gets its long-shot demand for 12 years of exclusivity for biologics. Such protection could have major consequences at home, blocking future efforts to bring down what critics — including the Obama administration — believe was an overly generous period rolled into the Affordable Care Act. "Yes, BIO and PhRMA won in 2010," Generic Pharmaceutical Association CEO Ralph Neas said, referring to Obamacare's biologics provisions. "The important point here is that if BIO and PhRMA get their way in the TPP ... then that 12 years would be permanent. That's why they're fighting so hard on this."

** A message from PhRMA: Charis was devastated when, at 25, she was diagnosed with a rare, severe form of arthritis. Thanks to innovative medicines, her worst symptoms are gone. "I will not let this disease define me," Charis says. Every day, millions of patients like Charis benefit from groundbreaking work by America's biopharmaceutical researchers. **

DOES IT REALLY COST $2.6 BILLION TO DEVELOP A NEW DRUG? — Harvard's Jerry Avorn doesn't think so. He takes issue with the figure, cited at a press conference in Boston last November and used since to justify the cost of expensive drugs and to support longer exclusivity periods. But Avorn argues that without more information about how the figure was calculated, it's impossible to accept it as fact. "The raw numbers on which the analysis is based are not available for transparent review — and are likely never to be divulged," he writes in the New England Journal of Medicine, going on to enumerate a whole host of factors that may not have been considered or spending and capital costs that may have been overestimated. "We need an accurate determination of all the costs that go into the creation of a new drug, to inform ongoing discussions about how best to foster such development and the most reasonable way of paying for truly innovative medications," he writes. The rest: http://bit.ly/1Pkb735

... The researchers behind the $2.6 billion strike back. In a letter to the NEJM, they counter that the methods underlying their work have been made public. They also offer justification for how they determined drug failure rates, which are a key contributor to development costs. Their critique: http://bit.ly/1HlribV

FTC STILL TARGETING PHARMA — The FTC will take another pharma reverse patent settlement to trial June 1, it told the House Judiciary subcommittee on antitrust enforcement on Friday. FTC alleges that Cephalon entered into anticompetitive deals by paying generic makers to delay marketing copies of its billion-dollar drug Provigil. The case will be heard in the U.S. District Court for the Eastern District of Pennsylvania. FTC updated the committee on its other pay-for-delay activities and says it's in a much stronger position to protect consumers from anticompetitive drug patent settlements that result in higher drug costs since the Supreme Court's 2013 pay-for-delay ruling in *FTC v. Actavis*.

... FTC is also looking into other strategies pharma companies are using that may delay or prevent generic drug entry. The commission is concerned that branded companies are abusing FDA safety protocols for certain drugs — known as risk evaluation and mitigation strategies — to prevent generic companies from developing copycat versions of their drug. It's also monitoring "product hopping," where a brand company introduces new, patented products with minor or no substantive improvements in the hopes of preventing substitution to lower priced-generics. http://1.usa.gov/1EMyNTi

PHARMA ACTION IN THE STATES: RX TRANSPARENCY LAWS — States have been making moves to force drug companies to disclose key costs, such as R&D spending, related to their products. Industry, which says states are laying the groundwork for price controls, has managed to stop many of the measures. The Nevada and North Carolina legislatures had bills introduced that didn't go anywhere during this year's sessions. Oregon's bill has been diverted to a study committee, and California's bill failed to be voted out of committee and is "dead" at least for now, an industry source said. Yet measures are still alive in Pennsylvania and Massachusetts, and New York may soon push its own. The bills have industry on edge. Drug makers say it's very difficult for them to parse out the specific cost of bringing one drug to market; for every product that makes it to consumers, they typically spend money on nine others that fail. Industry also says it's unfair to target drug companies and not look at other parts of the health care system that determine how much consumers spend on a prescription. They also say the laws don't take into account the value medicines bring.

... TENNESSEE 'RIGHT TO TRY' LAW TAKES EFFECT — The state becomes the 18th state to enact a law to give patients with advanced illness the ability to access an investigational drug or medical device. http://1.usa.gov/1IFIcAW

... NEW JERSEY BIOLOGIC SUBSTITUTION BILL ADVANCES — The bill, which would permit the automatic substitution of interchangeable biosimilars, was passed by the New Jersey Assembly and now heads to the Senate. http://bit.ly/1A6Z6XN

... The Biosimilars Council cheers new biosimilar substitution laws in five states, including in Washington, where Gov. Jay Inslee signed a measure into law last week. http://bit.ly/1HlAE7w

BACK TO CURES: HOW BIPARTISAN WAS THAT SUBCOMMITTEE MARKUP? — No amendments. No discussion. After a round of congratulatory statements from members, the subcommittee voted unanimously to send the bill to the full committee. It happened so fast, that Rep. Jan Schakowsky had to ask for time to share concerns about high drug prices after the panel had moved onto another bill (on "microbeads" in water).

... PHARMACY LOCK-IN PROVISION STILL CONTESTED — The National Community Pharmacists Association is still "concerned" that the measure to assign Medicare beneficiaries at risk for drug abuse to a single pharmacy doesn't have enough protections to let the patient choose the pharmacy and could allow the drug plan to choose a pharmacy in which it has a financial stake. And the Senior Care Pharmacy Coalition wants an exemption for patients in skilled nursing or other long-term-care facilities, because they "already have sufficient protections." But Pew Charitable Trusts, CVS Health, the Academy of Managed Care Pharmacy, Express Scripts and the Pharmaceutical Care Management Association, among others, endorse the provisions as "a critical tool for addressing the nation's prescription drug abuse epidemic."

BIOSIMILARS DECISION COMING WITH PRICE, SAFETY IMPLICATIONS — CMS needs to decide how it will code and reimburse for biosimilars, and lobbyists have predictably leapt into the fray. A new biosimilar trade group, the Biosimilars Forum, wants each biosimilar to have its own J-code, which would allow biosimilars of the same branded biologic to charge different prices — unlike in the generic drug world, where all generics of a particular brand are reimbursed at the same rate. The Forum says this is necessary to create a vibrant biosimilar market, but others warn it could cost consumers.

... In the short run, unique codes would probably be in the best interest of health care systems and payers because they'd enable better monitoring of each biosimilar's safety, Harvard University's Ameet Sarpatwari told Prescription PULSE. There are legitimate

concerns that biosimilars may have greater variation than generic drugs, Sarpatwari said. But such codes would probably push biosimilar prices higher in the long run, he continued, and CMS would have difficulty changing the system if safety concerns later became a non-issue.

CATCHING OUR ATTENTION: TUFTS PERZONALIZED MEDICINE REPORT — Pharma companies face a number of obstacles to the more rapid uptake of personalized medicines, including basic science, regulatory and reimbursement policies and adoption by physicians, a new Tufts study finds. Biomarker identification and diagnostic test development rank highest among the scientific challenges, according to industry, which expects to ramp up investment in personalized medicine by 33 percent over the next five years. One-fifth of FDA's 2014 approvals were for personalized medicines. http://bit.ly/1A4QHEy

** A message from PhRMA: In 2009, Warren, an avid runner and hiker, was diagnosed with stage IV pancreatic cancer. Not eligible for surgery or radiation, he was given eight weeks to live. Now it's been six years, and thanks to breakthroughs in cancer care and medicines, Warren's back to hiking the hills outside his Seattle home. There are "a whole host of medicines out there that we can try," he says today. "I couldn't assign a value to that."