
POLITICO's Prescription Pulse: States impatient for opioid declaration — No pomp, circumstance for user fee bill — FDA moves ahead on drug supply chain

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RESTLESS STATES AWAIT EMERGENCY OPIOID DECLARATION - Public health advocates cheered President Donald Trump's announcement earlier this month that he would declare the opioid epidemic a national emergency. But state health officials need more specifics before they can act on the announcement.

"There's been no real declaration of what the national emergency declaration actually means," said Jay Butler, chief medical officer for the state of Alaska and president of the Association of State and Territorial Health Officials.

Six states have already declared an opioid disaster or emergency, but Butler told Prescription PULSE the potential resources that come with a federal declaration could provide a significant boost to states' ongoing response to the epidemic, which is killing 142 people every day. The details of how this plays out depend on whether the declaration comes under the [Public Health Service Act](#), or the [Stafford Act](#), and whether there's a real commitment of resources - by tapping disaster funds or new congressional appropriations.

"There's a genuine agreement and hope that this would not just be another unfunded mandate for the states - that this would be funded and supported, not a direction to use funds that are currently being used to fund a Zika response, for instance," Butler said.

Even members of Trump's opioid commission, which recommended the declaration, are in the dark about when or if it will get beyond the rhetorical stage. Former Rep. Patrick Kennedy, who sits on the commission, told Pro's Brianna Ehley and David Pittman that he and the commission were slated to meet with HHS Secretary Tom Price and FDA Commissioner Scott Gottlieb in September to talk about strategies to combat drug use.

A declaration could boost federal personnel detailed to help states, free up or fast-track new funding, and potentially facilitate faster and broader access to supplies and drugs through the National Strategic Stockpile. Those could include the overdose reversal agent naloxone or medication-assisted therapies for opioid misuse.

A declaration could also give Price the ability to loosen regulations on providing opioid misuse treatment by telemedicine, and could relax privacy regulations related to a patient's history with opioids, David reports. Price might also wield greater flexibility in granting waivers for states to move people covered by programs such as Medicaid or CHIP into treatment faster. And he might lift, at least temporarily, the so-called IMD exclusion, which sharply limits the size of facilities that states can reimburse for treatments.

None of this will be clear until it's put in writing, Butler said. "There are a good number of vagaries," he said.

TRUMP SIGNS FDA BILL - The president waited until nearly the last possible second to sign the FDA Reauthorization Act of 2017 ([H.R. 2430](#)) into law Friday. The move was a disappointment to lawmakers who were hoping for a bigger victory lap for the bipartisan health care bill that helps pay for thousands of FDA jobs, and takes small steps to address one of Trump's stated priorities - tackling drug pricing. A House GOP aide described the process of working with the White House on the bill, including getting clarity as to whether the president would sign it, as "incredibly frustrating."

... The White House was never thrilled with the FDA package, arguing drug and device companies should pay even more in user fees than they already do. However, Trump never threatened a veto.

Happy Monday and welcome back to Prescription PULSE, where we note that this month in 1955, FDA hired four dozen temporary investigators to crack down on the black market for the new Salk polio vaccine, developed at the University of Pittsburgh. [#FDArecesstrivia](#)

FDA MOVES FORWARD ON SECURING THE DRUG SUPPLY CHAIN - The agency this week will kick off a [series of meetings](#) designed to help drug companies implement the 2013 Drug Supply Chain Security Act. The law requires drug makers and others who distribute and sell medicines to participate in what is scheduled by 2023 to be an interoperable electronic system to track drugs as they move from factory to wholesaler to pharmacies - and ultimately to hospitals and patients. This will help FDA protect consumers from exposure to drugs that may be counterfeit, diverted, stolen, adulterated or otherwise harmful. It should also make it easier and more efficient for medicines to be recalled when necessary.

[Topics](#) to be discussed at Thursday's meeting include the roles different participants of the drug supply chain play and FDA's role in this future track and trace system. The agenda also includes discussion of how U.S. requirements will fit within the global supply chain and marketplace for medicines, and how this could be made more efficient and secure.

FDA Friday also put out a [draft guidance](#) that should help different players in the drug supply chain understand their particular responsibilities under the 2013 law, such as whether they require licensure and are subject to annual reporting requirements.

REPORT: REFERENCE PRICING EXPERIMENT DRIVES PATIENTS TO CHEAPER OPTIONS - When a large group of Catholic employers placed a limit on how much they would contribute toward the cost of prescriptions within a certain therapeutic class - so-called reference pricing - patients began opting for the drugs that would cost them less, according to a paper by University of California Berkeley researchers published last week. The New England Journal of Medicine study found that use of the cheapest option in each therapeutic class jumped by 7 percentage points to about 69 percent of prescriptions filled. The average price per prescription fell by almost 14 percent, though patients' out-of-pocket costs climbed by 5.2 percent. Much more in [the paper](#).

PHARMA IN THE STATES

New York insurance company's drug programs show promise. Faced with increasing insurance premiums, a New York company is flagging patients who have difficulty taking their medication as prescribed and intervening to get them back on track. Our POLITICO Pro New York colleague Dan Goldberg reports that Independent Health has not estimated the savings from its efforts over the past two years, but expects its programs should help improve key rankings, like those kept by CMS, which impact incentives the insurer receives. You can read his full story [here](#).

Ohio ballot language finalized — Voters in Ohio now have the final wording for a November ballot initiative that is shaping up to be a redux of the California fight over drug prices. Issue 2 features two brief paragraphs. The language is different from what California voters considered in that it does not directly mention drug manufacturers and does not contain a fiscal impact statement. You can read the language [here](#).

THE TRADE AND BIOLOGIC EXCLUSIVITY DEBATE ... PART 2 — Renegotiations for the North American Free Trade Agreement are underway, and drug industry watchers should prepare themselves for another battle over the length of marketing exclusivity for biologic medicines, our Pro Trade colleagues report. It's a replay of an issue that helped block the Trans-Pacific Partnership trade deal from becoming law after the U.S. drug industry and many Republicans in Congress didn't get what they wanted.

The United States has 12 years of exclusivity protection for biologics under the Affordable Care Act, in contrast to eight years in Canada and five in Mexico. Senate Finance Chairman [Orrin Hatch](#) spearheaded the effort to get countries to agree to the U.S.'s 12-year standard in TPP and now has his sights set on NAFTA. Twelve years of biologic exclusivity is the United States position for NAFTA, a U.S. official confirmed.

But one veteran of the TPP biologics battle doubts that Canada, in particular, would agree to Hatch's demand. "I cannot see Canada doing that," said Burcu Kilic, an intellectual property expert and legal counsel for [Public Citizen's](#) Global Access to Medicine Program. "Canada has a really good team, they will be tough," Kilic said, noting that Canada recently resisted Europe's proposal to move toward 11 years of protection during talks on the Canada-EU Comprehensive Economic and Trade Agreement.

MYLAN STILL IN LAWMAKERS' SITES AFTER DOJ SETTLEMENT - The \$465 million settlement with Mylan on charges that it overbilled Medicaid for the EpiPen did little to satisfy the company's critics on and off the Hill.

"There are serious problems here," said Sen. [Chuck Grassley](#) (R-Iowa). Grassley has been investigating Mylan's decisions to raise the price for the emergency anaphylaxis drug from about \$100 to over \$600 in the past decade. He cited an HHS Office of the Inspector General [estimate](#) that Medicaid may have overpaid for EpiPen by as much as \$1.27 billion over 10 years because it was billed as a generic drug instead of a branded product. Companies are required to give larger rebates for branded products. "It looks like the settlement amount shortchanges the taxpayers," Grassley said.

- Rep. [Lloyd Doggett](#) (D-Texas) called the deal "unacceptable. ... Once again, the Trump Administration adds another brick to the wall of broken promises, letting one of the companies that Trump said is 'getting away with murder' keep so much of its ill-gotten gains," he said.

Although Trump's Department of Justice only confirmed the agreement Thursday, a preliminary deal appears to have been reached nearly a year ago, when Mylan first announced the \$465 million top-line figure. Nearly \$214 million will go to states, according to the settlement [agreement](#).

Mylan is subject to a corporate integrity agreement and must pay the branded rebates as of April 1, under the deal. More [here](#).

HOW AMAZON COULD IMPACT THE DRUG INDUSTRY - AND WHAT IT MEANS FOR GENERICS - [CNBC](#) dug into a 30-page Goldman Sachs report that tries to predict how the giant internet retailer could enter the pharmaceutical business. Goldman thinks initially Amazon won't try to start its own pharmacy, but would instead partner with a pharmacy benefit manager, and that Amazon's early focus will be on speeding up the drug delivery process and facilitating at-home delivery. Ultimately, according to the report, Amazon could play a role in improving price transparency for the consumer.

... Bernstein financial analysts note Amazon's entry into the drug world likely won't relieve the downward pricing pressure already being felt by the generic drug industry, and could intensify pressure given Amazon's size. Ronny Gal, of Bernstein, said one way generic drug makers could get around the current pricing pressure, driven by consolidation, would be to sell their products directly to the consumer for cash. This wouldn't be easy, he said, but could work better if generic companies banded together. Another option would be for drug companies to complain to FTC that there is too much consolidation between wholesalers of generic medicines and retailers.

PATIENTS GROUP URGES NOVARTIS TO CONSIDER COST OF CAR-T — Patients For Affordable Drugs said last week that while it applauds the recent approval of the treatment by an FDA advisory committee, it wants to ensure that Novartis understands just how much money taxpayers have invested in what could be a breakthrough cancer therapy. CAR-T is a new therapy that trains a patient's immune system to eliminate cancer cells unique to that individual. But as a [Time Magazine report](#) documented, the treatment is not expected to come cheap - some analysts estimate costs in the six figures. David Mitchell, co-founder and president of the patients group, wants Novartis to account for the more than \$200 million

taxpayers have invested into CAR-T research by accepting a value price from an organization like ICER and holding the U.S. price of the therapy to the average of other wealthy nations.

FDA OFFERS ZIKA PLASMA SAMPLES TO BLOOD TEST DEVELOPERS - The agency announced that it would provide standardized human plasma samples to companies developing blood tests for recent Zika infections. The samples will include blood infected with Zika, West Nile or dengue viruses to help developers distinguish Zika from the others and assist the agency in better assessing how well the tests work, FDA said. [More](#).

QUICK HITS

PhRMA criticizes FDA ad studies — PhRMA is taking the FDA to task over the agency's research on prescription drug advertising and promotion, according to a RAPS [report](#). The industry has long sought to ease the FDA's restrictions on advertising and promotion of its products, seemingly to no effect. PhRMA says the FDA is pursuing new studies on the effects of advertisement without a clear rationale of how this will improve public health. PhRMA added that the agency has increased these research efforts "exponentially," in the past year.

Docs take aim at Express Scripts opioid program - A new Express Scripts initiative aimed at addressing the opioid epidemic is facing pushback from the American Medical Association, The Associated Press [reports](#). The program calls for shortening the length of opioid prescriptions for first-time users and requires shorter-acting drugs and lower dosages. It also monitors trends in how patients use opioids as a way to prevent them from getting pills from multiple doctors. AMA says the program is promoting a one-size-fits-all approach to a complex issue, and would create an administrative burden for prescribers.

PHARMA MOVES

- The Alliance for Biosecurity, a coalition of biotechnology and pharmaceutical companies, has signed Squire Patton Boggs as its new lobbying firm after parting ways with Drinker Biddle & Reath last month. Squire Patton Boggs will lobby for the coalition on the reauthorization of the Pandemic and All-Hazards Preparedness Act and "appropriations for programs that fund the development and acquisition of medical countermeasures," according to a disclosure filing.

- Kathy Hudson [announced](#) on Twitter she is joining the People-Centered Research Foundation as the organization's executive director. Hudson was previously the deputy director of science, outreach and policy at NIH.

- Juliet Johnson is joining PhRMA's public affairs shop as deputy vice president. Johnson served as director of the office of communications at CMS during the Obama administration, and has also worked for Rep. [Diana DeGette](#) (D-Colo.).

DOCUMENT DRAWER

- FDA issues a [manual](#) on how it handles requests for emergency access to experimental drugs during and after business hours.

- Amgen and Humana are [partnering](#) to conduct research they hope will lead to better and more cost-effective management of serious medical conditions.

- JAMA publishes a [study](#) on the quality of clinical trials used in FDA approval of high-risk medical device applications.

- The PCORI Board of Governors has [approved](#) \$115 million to support patient-centered comparative clinical effectiveness studies.

- The Alliance for Regenerative Medicine released its [second quarter report](#) on industry statistics from 822 regenerative medicine companies.

CATCHING OUR ATTENTION: DID ELI LILY SPREAD FAKE NEWS TO TRY TO WIN A CANADIAN PATENT FIGHT? The Indiana-based drug maker Eli Lilly was so desperate to hold onto its patents for two drugs that it tried to concoct a legal doctrine out of thin air, according to an [op-ed](#) in STAT, written by Richard Gold, a Canadian law professor. Gold, who teaches at McGill University, said he and his students tracked the various legal statements, news reports and other evidence Eli Lilly put forth to preserve patents on Zyprexa, an antipsychotic drug, and Strattera, an ADHD drug.

... What's interesting is not just that Lily lost its NAFTA case, but rather the extensive lobbying efforts the company employed on both sides of the border to buttress its arguments. Gold said Lily enlisted the help of U.S. lawmakers and think tanks that received its money, and tried to skew data in a way that made it look like a larger number of companies were experiencing similar problems. In late June, the Canadian Supreme Court threw out the basis for Lily's case, but Gold says the episode shows how far drug companies will go to protect their patents.

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