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Eli Lilly's insulin announcement backfires with Congress

10-13 minutes

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By Nicholas Florko

Welcome to another installment of D.C. Diagnosis. I can't believe I'm saying this, but we are in for another week jam-packed full of drug pricing events. There's no less than five congressional hearings on health care costs this week; FDA Commissioner Scott Gottlieb is set to speak on "access to innovation" at an event sponsored by Eli Lilly; and MedPAC, Congress' official advisers on Medicare, is discussing ideas to bring down drug prices later in the week. Please. Send. Coffee. (In lieu of coffee, tips work, too. Send those to nicholas.florko@statnews.com.)

I'd also be remiss if I didn't take a second to shout out my Washington correspondent colleague Ike Swetlitz, who's heading

off next week to start as an investigative reporter for a nonprofit called Searchlight New Mexico after three years here at STAT. Go uncover some injustice, Ike!

Eli Lilly's decision to sell a half-priced version of its best-selling insulin, Humalog, seemed like a stellar PR move for the company, which is facing no less than three congressional investigations about its pricing of insulin. But by midday Monday, it became abundantly clear that lawmakers in both parties weren't willing to cut Lilly much slack, and in some cases, I think the decision may have backfired entirely.

Here's some of my favorite lawmaker reactions:

Senate Finance Ranking Member Sen. Ron Wyden (D-Ore.)

insinuated that the move was "PR acrobatics," and even said that the Senate Finance Committee will investigate Lilly's decision "to offer a generic version of a several decade old drug."

Rep. Peter Welch (D-Vt.) argued that Lilly offering a so-called "authorized generic" only "raises the question how in the world can you justify the price for the non-generic?" He also called Lilly's decision "exhibit A of how broken the pricing system is."

Finance Chairman Sen. Chuck Grassley (R-Iowa) signaled to drug makers that this wouldn't shield them from scrutiny. "Looking fwd to getting THOROUGH responses from insulin cos to letters we sent," Grassley tweeted, referencing the letters he and Wyden sent last month to Eli Lilly, Sanofi, and Novo Nordisk requesting a slew of sensitive information about insulin pricing.

Ways and Means health subcommittee chair Rep. Lloyd Doggett (D-Texas) alleged Lilly's decision was "designed to

strengthen Lilly's market dominance, maintain consumer brand loyalty, and whenever possible to promote the brand over the generic.”

Diabetes Caucus co-chair Rep. Diana DeGette (D-Colo.)

likewise said Congress would continue to investigate insulin makers. She also called on other companies to take similar steps, “because what we have learned through this announcement is that lowering the cost of this important drug is much more doable than previously thought.”

I'll also flag my colleague [Ed Silverman's story](#) — he asks, smartly, whether this move will actually appease Lilly's critics. (No surprise, after all those lawmaker reactions: It doesn't look like it.)

Lilly's decision isn't the only insulin news I'm watching. Sens. Dick Durbin (D-Ill.), Tina Smith (D-Minn.), Bill Cassidy (R-La.), and Kevin Cramer (R-N.D.) wrote to Gottlieb Friday urging the agency to reconsider a set of policies that some say have unnecessarily delayed cheaper insulins from coming to market. I'd be remiss if I didn't mention that I [wrote about this issue for STAT](#) a few weeks ago. The story prompted a tweetstorm from Gottlieb, who — though he didn't reference my article directly — pushed back on my argument that FDA deserves some of the blame for the fact that there's no generic insulin on the market right now. (I see you, Dr. Gottlieb.)

Also worth watching: Rep. Bobby Rush (D-Ill.) is trying to drum up support for his “Insulin Access for All Act,” which would eliminate cost sharing on insulin for Medicare and Medicaid beneficiaries. “Diabetes is an epidemic, and we must ensure access to affordable medication for this disease,” Rush wrote in a recent

“Dear Colleague” letter.

I caught up briefly with Oversight Committee Chairman Elijah Cummings (D-Md.) late last week to ask how his probe of drug makers is going. He told me Thursday afternoon he was “very pleased” with the information he’s received from drug makers. (A reminder for readers: Cummings demanded a slew of information from 12 drug makers back in January.)

But Cummings also dropped something of a bombshell, at least to me: Not all the companies have complied with the committee’s request. That’s a risky gambit, especially given Cummings has the power to subpoena companies who don’t comply, even forcing them to come before the committee. (This is how Martin Shkreli ended up before Congress in 2016.) At least so far, Cummings doesn’t seem ready to take that step. “I haven’t decided who I’ll call,” Cummings told me, when I asked him whether he still wanted to call drug companies before the committee.

The Senate Aging Committee will hold two days of hearings this week on drug pricing. The committee, headed by Sen. Susan Collins (R-Maine) and Bob Casey (D-Pa.), will hear on Wednesday from five patients, all of whom have experience with struggling to afford prescription drugs. On Thursday, the committee will hear from a panel of experts.

It’ll be interesting to see whether that committee — which actually has no formal legislative authority — once again begins shaping the debate over drug pricing. Until she lost her seat last fall, Sen. Claire McCaskill (D-Mo.) frequently used her position on the committee to investigate failures in the drug pricing system. Issues like the high cost of insulin, how hedge funds jack up the price of

old off-patent drugs, and so-called gag clauses were all first broached in earnest by the Senate Aging Committee.

The Senate's favorite health policy wonk, Sen. Bill Cassidy (R-La.), is working on two proposals to rein in drug rebates, he told reporters Thursday. Cassidy was cagey on the specifics of the proposals (though he said they were currently being scored) but he mentioned one idea that really caught my attention: banning biologic companies from using rebates when lower-cost biosimilars are on the market.

The idea would tackle the so-called rebate trap, when branded drug makers might threaten to take back a drug's rebate if an insurer decides to prefer a cheaper biosimilar. If the threat works, the branded company effectively starves the biosimilar of market share. "I'm not saying we decided on that," Cassidy told me. "But I'm trying to understand this issue and is this what we need to do in order to drive biosimilar adoption here in the United States?"

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Traditional clinical trials are the gold standard for determining that a new medicine is safe and effective for its intended use. But some companies, as well as the Food and Drug Administration, are increasingly focused on the question of whether "real-world evidence" can change the way medical researchers study patients — and perhaps even replace control groups in some cases.

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The FDA officially took a stand Friday and said large-scale

pharmacies can no longer compound two drugs, vasopressin and nifedipine hydrochloride, using bulk powders. On its face, it seems like a wonky issue, but it has sweeping public health consequences. (Remember, the FDA started regulating these large-scale compounders after contaminated compounded drugs killed 64 people back in 2012.)

It's also a shockingly politically charged issue. Reps. Trey Gowdy (R-S.C.) and Jim Jordan (R-Ohio) wrote to the FDA back in December questioning the legality of the FDA's move (which they first announced in draft form back in August). The agency is also locked in a legal battle over its compounding policy for one of these drugs.

When [ProPublica](#) journalist Marshall Allen was given a "Top Doctor" award, he started digging and uncovered a shady industry that sells vanity plaques to just about any doctor — or journalist — with the money. — *Ike Swetlitz*

It's hard to imagine any of our D.C. readers weren't glued to the Michael Cohen hearing last week — but I'll still take a minute to flag this [smart STAT story](#) about Novartis, which once again got a spotlight at that hearing for hiring Cohen to get access to President Trump that it surely would have liked to avoid. — *Erin Mershon*

The [New York Times story](#) on "poop wars" has everything I want in an article: a cogent explanation of how FDA regulation is impacting pricing of medical treatments, a money trail connected to a cryptically named lobby group and one of the most elegant — if not haunting — turns of phrase to describe poop I've ever heard. — *Nicholas Florko*

Correction: Last week's edition of D.C. Diagnosis incorrectly

spelled the name of Sen. James Lankford (R-Okla.).

Thanks for reading! Until next week,

Handwritten initials in cursive script, appearing to be 'N JL'.