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Hello, everyone, and hope your day is going well. Here are today's updates, along with our usual [morning menu of headlines](#). And of course, please follow us at [statnews.com](#).

STAT Plus: Harris calls for probe into Alkermes and its Vivitrol promotion for opioid treatment

By ED SILVERMAN



CHIP SOMODEVILLA/GETTY IMAGES

Amid a worsening opioid crisis, a U.S. senator has opened a probe into Alkermes and its controversial promotion of the Vivitrol monthly shot for combating opioid addiction.

The move comes as Alkermes is scrutinized for aggressive lobbying and marketing. The company has spent heavily on contributions to lawmakers who are trying to mitigate opioid abuse. In state legislatures across the country, the drug maker has pushed bills that favor its treatment over rival medicines. And Alkermes has provided thousands of free doses to encourage usage in jails and prisons.

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In the absence of any movement by the Trump administration or Congress to directly address prescription drug prices, many states legislatures are taking some form of action:

Nearly two dozen states have bills that would demand transparency from drug makers and, in some cases, pharmacy benefit managers;

More than two dozen states have bills directed at pharmacy benefit managers, specifically, and address incentives for mail order pharmacy and penalizing pharmacists who discuss costs with consumers, among other things.

The transparency effort, by the way, is increasingly focusing on diabetes medicines, in particular, given the prevalence of diabetes in the country;

A growing number of states are also devising bills that create a mechanism for state resident to purchase medicines that are imported from Canada;

And consumer advocates who succeeded in getting a passed in Maryland to punish generic drug makers for price gouging are actively pushing such legislation elsewhere.

California governor signs drug price transparency bill that infuriates pharma

By ED SILVERMAN @Pharmalot / OCTOBER 8, 2017



California Gov. Jerry Brown is expected to sign the bill on Monday.

RICH PEDRONCELLI/AP



In a blow to the pharmaceutical industry, California Gov. Jerry Brown on Monday signed a bill into law that requires drug makers to explain and justify price hikes, making this the latest state to actively address the high cost of medicines.

[The bill](#), which was vociferously fought by the pharmaceutical industry, is set to become one of the more comprehensive state efforts to address pricing transparency.

For instance, drug makers have to provide 60-day notice to insurers and government health plans before increasing list prices of any medicine that costs more than \$40 by at least 16 percent in a two-year period. And health plans have to provide detailed information about prescription drug costs and the portion of premiums attributed to this expense. (Here is a [fact sheet on the bill](#).)

Q&A: Can the California law on drug pricing transparency make a difference?

By ED SILVERMAN @Pharmalot / OCTOBER 10, 2017



State Sen. Ed Hernandez led the charge for California's new drug price transparency bill.

RICH PEDRONCELLI/AP



On Monday, California [adopted](#) a law that requires drug makers to explain and justify price hikes, making it only the third state in the country to demand some transparency in response to rising medicine prices. Although [the law](#) does not actually allow the state to control pricing, the pharmaceutical industry fought the effort over concerns other states will now pursue similar legislation, since California is often seen as a bellwether. We spoke with state Sen. Ed Hernandez, the Democratic legislator who shepherded the bill — and who believes it can force a change in the national conversation about drug pricing.

What do you hope to gain by pursuing transparency, as you call it?

There are two ways to think about how you can control prices. One is setting rates or capping fees. But we still live in a system where we don't need to do that right now. And transparency has worked elsewhere in the health care industry — Medicare, provider fees, hospitals, health plans. Every segment of the health care market, with the exception of prescription drugs, has some type of checks and balances. We have to have a conversation about controlling the cost of prescription drug bills, which are getting larger. It's time for this to happen.

We're now requiring everybody to purchase health care. So if we're going to require our citizens to buy that, we as policy makers have to need to make sure they have the best price and are not gouged.

Q&A: Vermont legislator says drug pricing law is the start of a 'long battle'

By ED SILVERMAN @Pharmalot / JANUARY 3, 2017



ALEX HOGAN/STAT



Last June, Vermont became the first state in the country to pass a [law](#) requiring drug makers to justify their price hikes. The move, which was opposed by the pharmaceutical industry, was borne out of frustration that the federal government had not acted on the rising cost of prescription medicines. But the law has its limits, as indicated by the [first report](#) by the state attorney general, which was issued last month. Confidential data will not be publicly released and the state has no power to do anything about prices, other than issue \$10,000 fines to companies that fail to comply. We spoke with Chris Pearson, a Vermont legislator who was vice chair of the House Committee on Health Care and championed the bill, about the results and where this is headed. This is an edited version of our conversation ...

Pharmalot: What was the hope when you pushed for this law?

Pearson: Very simply, we hoped to put pressure on the industry and Congress to make drugs more affordable.

Pharma sues California over its new transparency law for drug pricing

By ED SILVERMAN @Pharmalot / DECEMBER 9, 2017



ALEX HOGAN/STAT



In a widely anticipated move, a pharmaceutical industry trade group has filed a lawsuit seeking to stifle a new California law that requires drug makers to explain and justify price hikes.

The law has been hailed by supporters as a key attempt to provide transparency into opaque pricing practices amid growing public outrage over the cost of medicines. Not only is the law one of the more comprehensive efforts to address the issue, but California is seen as a bellwether for the rest of the nation and drug makers fear other states will attempt to adopt similar measures.

The pharmaceutical industry, however, argued in its [lawsuit](#) filed on Friday that the law is unconstitutional by violating interstate commerce and free speech principles. And the trade group maintained the law unfairly holds drug makers largely accountable for prices, instead of pharmacy benefit managers that negotiate undisclosed rebates and discounts for insurers, a favorite complaint of pharma executives.

Two states advance bills to create programs for importing medicines from Canada

By ED SILVERMAN @Pharmalot / FEBRUARY 16, 2018



SPENCER PLATT/GETTY IMAGES



Angered by rising prescription drug prices, legislatures in two states — Utah and Vermont — this week advanced bills that would create programs to help residents purchase medicines from Canada.

In Utah, a [bill](#) that was sponsored by a Republican lawmaker and received notable GOP backing passed the House and now goes to the Senate for approval. In Vermont, [legislation](#) passed a key Senate committee and will now be reviewed by other committees before going to the full Senate floor.

Unlike bills that have been repeatedly introduced in Congress, both measures would compile lists of the 15 to 20 most expensive medicines purchased by their residents, and then create a program to designate wholesalers that would be authorized to buy those drugs from wholesalers in Canada.

Nevada's law on diabetes drug-pricing transparency may gain 'trade secret' option

By ED SILVERMAN @Pharmalot / JANUARY 9, 2018



JOERG SARBACH/AP



Nevada officials have crafted a draft regulation that would allow companies to mark certain diabetes drugs pricing data as confidential when they begin complying with a new transparency law this coming spring.

The move by the state Department of Health and Human Services appears designed to deflect a [lawsuit](#) filed recently by two pharmaceutical industry trade groups, that argued the law is unconstitutional and robs drug makers of their right to protect trade secrets. The law was adopted last summer and the draft regulations were released to provide guidance for companies, including pharmacy benefit managers.

State officials maintain the [regulation](#) does not actually concede that any information is a trade secret, according to two sources familiar with the matter. Instead, drug makers would have to go to court to protect trade secrets if anyone filed a public information request for company data. In this way, the state hopes to avoid becoming a party to a lawsuit, but would still have to abide by any decision.

Pharma sues Nevada over diabetes drug transparency law

By ED SILVERMAN @Pharmalot / SEPTEMBER 5, 2017



JEAN-FRANCOIS MONIER/AFP/GETTY IMAGES



Less than two months after Nevada enacted a controversial law requiring more transparency from drug makers over their pricing of diabetes medicines, the pharmaceutical industry is pushing back.

In a lawsuit filed last Friday, two large industry trade groups claim the law is an “unprecedented and unconstitutional” action that interferes with well-established patent law by robbing drug makers of their right to protect trade secrets. Consequently, the trade groups also argue the law impedes the ability to successfully to do business in other states by tying penalties to wholesale, or list, prices.

“If the provisions ... go unchallenged, then Nevada’s law will conflict with and, in many cases, override federal law and the laws of 49 other states — laws that foster pharmaceutical innovation and protect intellectual property and trade secrets,” said James Stansel, executive vice president and general counsel of the Pharmaceutical Research and Manufacturers of America, in a statement. The [lawsuit](#) was also filed by the Biotechnology Innovation Organization.

Colorado lawmaker pushes pricing transparency bill for diabetes drugs

By ED SILVERMAN @Pharmalot / JANUARY 16, 2018



APSTOCK



The pharmaceutical industry may be fighting a first-in-the-nation law in Nevada to demand pricing transparency on diabetes drugs, but Colorado legislator Dylan Roberts is not deterred.

Last week, he introduced a bill to similarly demand that drug makers report pricing histories, explain price hikes, disclose costs, and reveal the rebates paid to pharmacy benefit managers. And as in Nevada, he hopes the legislation will slow the cost of caring for diabetes. In Colorado, about \$720 million, or 19 percent, of all diabetes care is spent on prescription drugs to control the disease, according to the bill.

“There are people who struggle every day to pay for a drug they need to survive,” Roberts told us. The [legislation](#) also would demand that pharmacy benefit managers disclose rebates received from drug makers.

Generic trade group sues Maryland over 'unconstitutional' price gouging law

By ED SILVERMAN @Pharmalot / JULY 6, 2017



MIGUEL MEDINA/AFP/GETTY IMAGES



The trade group for generic drug makers has filed a lawsuit charging that a new [Maryland law](#) designed to punish companies for price gouging is unconstitutional.

In making its case, the Association for Accessible Medicines argued the law violates interstate commerce by giving Maryland officials the right to govern business outside the state, effectively providing “unprecedented powers to regulate the national pharmaceutical market.” The trade group also maintained the law too vaguely defines “excessive” pricing, which would violate due process.

“Maryland would become the first state to reject generic competition in favor of more government regulation of generic drugs, the only segment of health care costs that is actually declining,” Chip Davis, who heads the trade group, said in a [statement](#). If the law goes into effect in October, as planned, “it will harm patients and our communities by reducing choice.”

So far, only a very few bills have become law and it is too to say whether these will deliver.

Vermont has a transparency law that requires companies to disclose price hikes, but to what extent this effort will lead to change is unclear.

In any event, there is a concerted effort – led, in part, by the National Academy for State Health Policy – to push more state legislation. And even Republicans are joining the fray (see the Utah bill).

The upshot is that consumers are frustrated, Washington is paralyzed, and the pharmaceutical industry is playing whack-a-mole.