Lawmakers seek to close drug company loophole

Riley Beggin USA TODAY

WASHINGTON – Sen. Elizabeth Warren, D-Mass., and Rep. Pramila Jayapal, D-Wash., are pushing federal regulators to "crack down" on companies they say are preventing their competitors from producing lower-cost generic drugs for Americans.

In a letter sent to the Food and Drug Administration on Thursday night and seen exclusively by USA TODAY, the progressive lawmakers urged the agency to close loopholes that discourage competition among drug companies and keep prices high for crucial medication. That can include inhalers to help with chronic lung diseases.

Under the system Warren and Jayapal are trying to address, the FDA keeps a list of all federally approved drugs, known as the Orange Book. The agency requires pharmaceutical companies to list in the book any valid patents they hold on drugs they created, signaling to competitors that they can't create a generic alternative. Those alternatives often provide more affordable options for Americans.

But Warren and Jayapal have been arguing for months that major drug companies are exploiting that structure by updating listings with insignificant changes to extend the time their products are protected from copycats.

The Federal Trade Commission – the government's consumer protection agency – has already agreed with the lawmakers. It issued a new statement in September noting that improper listings may be illegal and "have likely been distorting pharmaceutical markets for decades."

Prescription drugs in the United States are more than twice as expensive as they are in other large countries, according to the Department of Health and Human Services. Brand name drugs are even pricier – more than three times more expensive as in other nations.

In November, the FTC sent letters to 10 drug companies warning them that



Jayapal

Warren

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they believe they are collectively listing more than 100 improper patents.

Warren and Jayapal sent letters to each of the companies following up on the FTC's warning. Three of the 10 companies did not say the flagged drugs were improper but did take them off the list, including several types of epinephrine injectors (often known by the brand name EpiPen) and inhalers.

But the other seven did not take down their listings, arguing in letters reviewed by USA TODAY that the government's rules are murky or that their patents do qualify.

Warren in a statement urged the FDA to "crack down on this abuse."

It's the latest in lawmakers' inquiries into the way pharmaceutical companies affect drug pricing and availability in the U.S.

On Feb. 8, the Senate's Health, Education, Labor and Pensions Committee grilled the CEOs of three major drug companies over the cost of necessary medications. The Biden administration is also bargaining with drug companies to make 10 widely prescribed drugs cheaper for older Americans.

The pressure from federal officials and outcry from Americans have pushed drug companies to change some pricing. In January, the industry implemented its lowest median price increase in over a decade.

President hails cleanup efforts in East Palestine

Michael Collins USA TODAY



The Kingdom Sanctuary of Eden & Outreach Ministries



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may be found in our communities. Our purpose is to protect life and health and to ensure respect for the human being. We promote mutual understanding, friendship, cooperation and lasting peace amongst all peoples. The Kingdom Sanctuary of Eden is a voluntary relief movement not prompted in any manner by desire for gain.

WASHINGTON – He drank the water.

President Joe Biden saw firsthand on Friday the cleanup efforts in East Palestine, Ohio, more than a year after a Norfolk Southern train derailment released hazardous chemicals into the soil, water and air. Biden praised what he called the "herculean" cleanup and announced grants from the National Institutes of Health to study the shortand long-term effects of the containment released by the derailment.

"We're not going home, not matter what, until this job is done," he said. "And it's not done yet."

During a brief stop at a candle company, Biden demonstrated his confidence in the cleanup efforts by sipping a glass of tap water and drinking coffee that had been brewed with tap water.

The Environmental Protection Agency said ahead of Biden's visit that it had confidence in the safety of the air, water and soil. White House press secretary Karine Jean-Pierre told reporters on Thursday that Biden had "no concerns about drinking the water."

The accident occurred Feb. 3, 2023, when a train that included five cars carrying vinyl chloride derailed, later igniting large flames and sending plumes of smoke into the air when the railroad vented and burned the chloride to prevent a larger explosion. The wreck forced people out of their homes, and residents continue to worry about the long-term health and economic effects of the derailment.

Biden has faced relentless criticism from Republicans for not visiting East Palestine for the past year. They've accused him of ignoring a blue-collar town that former President Donald Trump carried by 40 percentage points in the 2020 election.

Trump, the front-runner to secure the 2024 presidential nomination, visited East Palestine weeks after the accident. A day later, Transportation Secretary Pete Buttigieg traveled to East Palestine.

White House press secretary Karine Jean-Pierre said President Joe Biden had "no concerns about drinking the water" in East Palestine, Ohio, during a visit Friday, more than a year after a train derailment released hazardous chemicals into the soil, water and air. MANDEL NGAN/AFP VIA GETTY IMAGES

On Friday, Biden received a briefing from local officials on the cleanup efforts and said the derailment could have been avoided.

"While there are acts of God, this was an act of greed that was 100% preventable," he said. "Let me say it again: An act of greed that was 100% preventable."

Cleanup crews "have done in a year what would typically take many years," Biden said. "And we're going to keep going."

Biden stressed that the federal government is holding Norfolk Southern accountable. He called on Congress to pass legislation sponsored by Ohio's two U.S. senators, Democrat Sherrod Brown and Republican J.D. Vance, that would require stronger protective measures for trains carrying hazardous material.

Norfolk Southern said it has spent more than \$1.1 billion in its response to the derailment. Since the fire began, the company says it has invested \$103.2 million in the community, including \$21 million distributed to residents.

Contributing: Joey Garrison, USA TODAY; The Associated Press As a visionary, the Prophet Joshua who leads the Kingdom Sanctuary of Eden is implementing

a community credit improvement course and training to increase the purchasing power of individuals and their family members. His efforts continued by establishing a Kingdom of Heaven community marriage enrichment in the ministry to strengthen the foundation of Christian marriages. A community clothing ministry closet was established within the Kingdom Sanctuary of Eden to assist with

clothing needs. Amongst his future vision, one is to establish a community "food bank" that will feed families in time of necessities for children and their family members.

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