

THE HILL



Executive order targets critical drug shortages

By Julian Pecquet

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President Obama took unilateral action Monday to help stem the nation's shortage of lifesaving drugs, a level of personal involvement in health policy not seen since passage of the healthcare law almost 20 months ago.

Tied to the slogan "We can't wait," Obama has been rolling out a series of executive orders to show he's doing everything he can to help the economy despite the impasse in Congress over his jobs bill.

The latest presidential action ensured a moment of positive coverage on the healthcare front after a difficult stretch that saw the demise of the long-term care program and the release of a poll that found most Americans disapproving of the reform law.

Republicans dismissed the president's executive order as too little, too late. The Republican National Committee said Obama ignored "years of headlines warning about drug shortages" and "finally decide[d] to look like he's doing something for political expediency."

But not everyone in the GOP was critical. Some Republicans even praised the president for urging passage of bipartisan drugs legislation that's been stuck in both chambers of Congress.

"I've heard from patients and doctors in my district and nationwide who are experiencing limited, and sometimes zero, access to life-saving drugs, from commonly used anesthetics to cancer therapies," Rep. Tom Rooney (R-Fla.) said in a statement. "I'm very pleased that President Obama is addressing this critical issue and supporting our bipartisan bill."

In June, Rooney introduced legislation with Rep. Diana DeGette (D-Colo.) that would require drugmakers to report to the Food and Drug Administration (FDA) shortages of numerous drugs. A similar effort in the Senate championed by Sen. Amy Klobuchar (D-Minn.) has 17 co-sponsors, including Republican Susan Collins of Maine.

Patient advocacy groups and the pharmaceutical industry also responded favorably to Obama's executive action.

The Generic Pharmaceutical Association applauded the order and urged collaboration between industry and government. The Pharmaceutical Research and Manufacturers of America said it “echoes a priority of America’s biopharmaceutical research companies — the well-being of patients and their ability to access life —saving prescription medications.”

And the American Cancer Society Cancer Action Network called it an “essential step to address the growing drug shortage crisis.”

“The drug shortage crisis is making it difficult or impossible for some cancer patients to get the medications they have been prescribed,” network President Christopher Hansen said in a statement. “On behalf of people with cancer and their families nationwide, ACS CAN commends the president for taking action.”

The new executive order gives federal regulators more power to track drug shortages, quickly approve replacement manufacturing sites and punish price gougers. The administration simultaneously increased staffing at the FDA’s Drug Shortages Program, sent a letter urging drugmakers to voluntarily disclose more potential prescription drug shortages and released two new reports on the underlying causes of shortages and the FDA’s role in preventing them.

Efforts announced Monday “will give us extra time to work with the industry to prevent, reduce or mitigate the shortage,” Health and Human Services Secretary Kathleen Sebelius told reporters on a conference call.

“While we can’t control all the factors that cause the shortages — starting with the fact that demand is outpacing supply — there are steps we can take,” she said. “We can work with manufacturers to fix quality issues. We can work with other firms to increase production. And [the new order] will lead to earlier FDA notification of any impending shortages of certain prescription drugs.”

Critics of the executive order said it would not be effective because it does not eliminate artificially low federal reimbursements in certain government health programs.

“President Obama is not responding to the real cause of the problem, which is price controls,” said health economist [Devon Herrick](#) of the free-market [National Center for Policy Analysis](#).

Several factors have been blamed for the shortages, including manufacturing decisions, drug industry consolidation, stockpiling, shortages of raw materials and FDA regulations that critics say make the drug approval process slow and cumbersome.

But the administration released new reports Monday blaming industry shortcomings, rather than heavy-handed regulations, for the shortages that affected a record 211 drugs last year — three times more than in 2005.

“An important factor in many of the recent shortages appears to be an increase in demand that exceeds current manufacturing capacity,” Obama wrote in his order. “While manufacturers are in

the process of expanding capacity, one important step is ensuring that the FDA and the public receive adequate advance notice of shortages whenever possible.”

Shortages of medicines, including lifesaving antibiotics and cancer drugs, are on track to top last year’s record. As of mid-October, the FDA had identified shortages of 82 medicines, based on voluntary self-reporting by manufacturers. But a national expert at the University of Utah who tracks national drug shortages told NPR that the real number is 213.

The shortages are putting patients in danger: Eighty-two percent of hospitals reported that drug shortages have caused treatment delays, according to a recent survey by the American Hospital Association, and more than half were not always able to provide the patient with the recommended treatment.

“Three out of four hospitals report rationing or implementing restrictions for drugs that are in short supply,” the July 2011 report said.

Sebelius said the agency has helped stave off 137 shortages over the past 21 months but that the president wants FDA to redouble its efforts.