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### DAILY NEWS

# HHS Reverses Course On Importation, Leaves Drug Industry Reeling

July 19, 2018

FDA sent shock waves through the pharmaceutical industry Thursday (July 19) by announcing it will study how to import drugs as a response to price spikes. The directive, coming despite FDA Commissioner Scott Gottlieb's previous criticism of importation, appears to have come from HHS Secretary Alex Azar, who in June also called importation a “gimmick” that wouldn't save money and proposed an alternative solution to price spikes.

All three top drug industry trade groups swiftly criticized the plan. While they reiterated their long-stated criticisms of importation -- that it wouldn't be safe and wouldn't save money -- one drug industry lobbyist said the plan is most concerning because the government will now be judging the reasonableness of price increases. Advocates for drug reimportation believe they may now have an opening to push wider reimportation -- a proposal which has been opposed by both Republican and Democratic administrations, despite having bipartisan support in Congress.

**FDA will form a working group to “explore various policy frameworks that, through the exercise of enforcement discretion or otherwise,”** would allow for importation when a single-source off-patent drug has experienced price hikes, the agency said Thursday. There are hundreds of sole-source off-patent drugs, according to a list on FDA’s website, [and the problem appears to be getting worse](https://insidehealthpolicy.com/node/104718). But importation, up until now, was never considered as a solution.

Gottlieb, prior to leading FDA, criticized Donald Trump’s calls for drug reimportation. “[W]hen importation of foreign drugs is done under a regulated scheme, it really wouldn't save money,” Gottlieb wrote in a 2016 Forbes op-ed titled, “What Trump Should Have Said On Drug Prices.” **But FDA insists this isn’t a policy shift, given importation would only be temporary.**“Our position on broad importation is unchanged. Any policy that involves the importation of drugs would be temporary until adequate competition enters these categories,” an FDA spokesperson told Inside Health Policy when asked about Gottlieb’s previous remarks. FDA already allows importation during drug shortages. Gottlieb approved importation of saline from Brazil, Australia, Canada, Ireland and Mexico following the spate of hurricanes in Puerto Rico, which knocked out U.S. production in 2017.

**An HHS email sent to media outlets Thursday revealed that Azar directed FDA to establish the work group.**However, Azar has also been critical of reimportation -- most recently [calling the proposal a “gimmick” at a May 16 event](https://insidehealthpolicy.com/node/103836) hosted by the American Enterprise Institute. HHS’ drug pricing blueprint proposed allowing Part D plans to adjust their formularies during the benefit year to address these sorts of price spikes. The plan made no mention of importation. An HHS spokesperson did not respond to a request for comment on this shift.

**Former FDA Commissioner Mark McClellan joined three other former FDA commissioners in a March 2017 letter to Congress criticizing importation proposals.** “There are far better ways to improve access to safe and effective drugs,” they wrote. But McClellan was hesitant to criticize Gottlieb’s plan on Thursday. “Our opposition involved importation of drugs where the manufacturer was not supportive of importation, so that the drugs couldn’t be reliably tracked from manufacturer through distribution all the way to the patient,” McClellan said. McClellan emphasized in a follow up interview with IHP that under the scenario FDA is eying, the manufacturer of the ex-U.S. drug would want it imported, making it easier to track and less of a safety risk for patients.

**When asked whether this would make an impact on drug prices, McClellan responded: “I think it can be a short-term help.”** The former FDA commissioner, who now heads the Duke-Margolis Center for Health Policy, emphasized that while he understands why the current administration is pursuing this short-term solution, a better approach would be to encourage regulatory alignment for approval of generics and biosimilars between the United States and other similarly situated countries. He noted that FDA is already moving in this direction with its recent Biosimilar Action Plan announcement.

While lawmakers on both sides of the aisle have pushed the idea of importation for years, the drug industry -- which is united in opposition to the idea -- up to now has not faced an administration, Republican or Democrat, that has advocated importation. “As HHS Secretaries from both Republican and Democrat Administrations have clearly and consistently determined over the years, importation of medicines is a dangerous approach that would undermine the integrity and safety of the American drug supply,” Biotechnology Innovation Organization President and CEO Jim Greenwood wrote in a statement, adding that the group will “work to ensure that any HHS actions on importation do not endanger patients or import foreign price controls on American innovation.”

The Pharmaceutical Research and Manufacturers of America also issued a statement saying “importation of non-FDA approved medicines is not the solution.”

The generic lobby, the Association for Accessible Medicines, appeared concerned such a plan would harm its industry. AAM has praised HHS for considering whether generic prices are too low, but AAM President and CEO Chip Davis emphasizes that importation is unlikely to solve those underlying issues.

“With Secretary Azar testifying that generic prices are being forced too low, the most important goal of the new HHS task force should be to address why there are sole source off-patent drugs in the first place. While AAM appreciates the Administration's efforts through its Blueprint to increase generic and biosimilar competition to bring down high brand name drug prices, importation of prescription drugs manufactured overseas will not solve the underlying under-reimbursement issues that Secretary Azar identified,” Davis added.

**One drug industry lobbyist called the idea a “slippery slope,” noting that the government will now be determining when a price increase is unreasonable.** The lobbyist also worried this could give advocates for importation more fodder to advocate for a wider importation scheme. And advocates do see an opening for wide-scale importation. “I think the wall may have just came down whether they realize it or not,” one health policy consultant who has advocated for importation, said.

Multiple bills have been introduced in Congress allowing importation on a wider scale than is being proposed by FDA. The sponsor of one of those bills, Sen. Chuck Grassley (R-IA), called Thursday’s announcement “movement in the right direction in the fight against high drug prices, but it’s long overdue.” Sen. Mike Lee (R-UT) also praised the announcement as a good first step. He also plugged his bill, which also goes further than FDA’s proposal.

“More needs to be done, including passing the Short on Competition Act which would allow a company to sell a drug that faces little competition in the U.S. if the company already had approval to sell it in another country,” Lee said.

**State legislators also have been writings bills setting up state-specific importation programs.**Earlier this year, Vermont became the first state to sign such a law, which directs the state to come up with an importation scheme that can then be certified as safe by HHS. Eight other states have introduced similar legislation, according to a tracker from the National Academy for State Health Policy. -- Nicholas Florko(*nflorko@iwpnews.com*)