

Trump's US-Made Drug Decree Sows Uncertainty In Industry

By **Daniel Wilson**

Law360 (August 7, 2020, 10:32 PM EDT) -- A White House mandate forcing the federal government to buy critical drugs domestically offers flexibility for agencies, but its vague language creates uncertainty for businesses unsure of which drugs will be covered and whether it applies to existing government contracts.

Under the Buy American executive order issued Thursday, federal agencies will be required to buy domestically produced versions of medicines deemed essential, and drugs and other medical products that would be used as "countermeasures" to fight infectious diseases or respond to emergencies like chemical or nuclear attacks, "to the maximum extent permitted by applicable law."

The order also instructs agencies to use domestic "critical inputs," which likely refers to the raw materials or key components that go into manufacturing medicines and medical devices, although that term is not defined by the order nor by law.

That lack of a clear definition is just one of several aspects of the order that is raising questions about its impact on drug and device makers as well as whether it will help agencies build up the U.S. industrial base as intended, according to Hogan Lovells partner Joy Sturm.

"On some levels, it requires quite a lot to change," Sturm said. "And then on some levels, there are great big gaps and exceptions that might swallow up a lot of what might be perceived as teeth here."

For example, agencies can waive the domestic sourcing requirement when a medicine is needed to respond to a public health emergency or major disaster, or is not produced in the U.S. at the needed quantity. They can also issue waivers when a U.S.-made drug is more expensive than foreign sources by 25% or more.

"Those will be significant, certainly at the outset [of the order going into effect], in light of the current market," said Jennifer Plitsch, co-chair of Covington & Burling LLP's government contracts practice.

Another open question is whether federal contractors will be able to continue to sell foreign-made drugs to the government under orders issued through existing indefinite-delivery, indefinite-quantity contracts.

"While the language of the executive order appears to apply prospectively to new contracts executed by federal agencies, the order's sweeping mandate to agencies to 'develop and implement procurement strategies, consistent with law,' could extend to existing procurement contracts," King & Spalding LLP partner Liz Lindquist said. "In general, agencies have relatively broad authority to modify or terminate procurement contracts."

Particularly important is how broad the U.S. Food and Drug Administration decides to make its list of essential medicines, medical countermeasures and critical inputs, a term that could include active pharmaceutical ingredients and key components of medical devices, or perhaps more, and whether drugmakers will be able to provide input to the FDA.

The World Health Organization's 2019 essential medicine list contains 460 drugs. The White House Office of Trade and Manufacturing Policy's director, Peter Navarro, said Thursday that certain drugs on the WHO list, such as anti-malarials, aren't really essential in the U.S., but it is nonetheless a likely starting point for the FDA.

Navarro has said that the aim of the order is to nudge drugmakers to "onshore" their production, leveraging the government's position as a major purchaser of drugs and medical equipment. The U.S. Departments of Defense and Veterans Affairs, for example, are together responsible for providing health care for more than 16 million beneficiaries.

The COVID-19 pandemic has exposed how "dangerously overdependent" the U.S. is on foreign sources for essential medicines and medical equipment, Navarro said.

Under the definition of "produced in the United States" used in the order, where both critical inputs and the final production must be domestic, the percentage of medicines and devices that will ultimately end up on the FDA's list that are currently made domestically will likely be "very, very low," Plitsch said.

And if the FDA list follows the WHO essential medicines list, much of it will consist of drugs that are off-patent and available as generic versions. That could make it difficult for manufacturers to make a financial case for moving production to the U.S., given generics are open to competition from other manufacturers and typically have lower prices than branded drugs.

Also, moving drug or device production to the U.S. is not a quick or easy process. Setting up manufacturing plants can take years, depending on whether an entirely new plant is needed or an existing facility can be repurposed or expanded. The difficulty of making a particular drug also factors in.

Although the executive order directs the U.S. Environmental Protection Agency to find ways to streamline approvals for new facilities, including accelerating siting and permitting approvals, those processes are not typically a major barrier anyway, Plitsch said. Financial factors are a more significant concern, but the order doesn't make any federal money directly available to assist with establishing new facilities.

"There will likely need to be additional incentives to construct new facilities in the United States, particularly when there is no existing indication that global production is insufficient to meet the needs of U.S. patients," Plitsch said.

Outside of the executive order itself, there is also the complication of a "most favored nation" executive order issued by the president in late July, which will cap the prices of certain drugs to the lowest price

paid by a comparable country within the Organization for Economic Cooperation and Development. That will also make it more difficult for pharmaceutical companies to make an economic case for increased domestic production.

"It's unclear how we will be able to reconcile these seemingly contradictory strategies," Lindquist said. "Many manufacturers rely on foreign supply chains because for a variety of reasons our domestic producers were not able to price competitively as compared to their foreign counterparts. Over time, this adversely impacted demand for domestic producers' products and led to a decrease in their production capacity."

--Editing by Aaron Pelc and Rebecca Flanagan.