Proposed Executive Order on "Buy American" and Defense Production Act Designation for Health-Related Goods Production

According to press reports, the Administration is considering an executive order that would affect the production of essential medicines (as defined by the World Health Organization), FDA-regulated emergency medical countermeasures, and Active Pharmaceutical Ingredients (API). The EO would reportedly terminate application of the WTO Government Procurement Agreement and U.S. FTAs with respect to essential medicines and medical countermeasures, a move that would disrupt existing supply chains, exacerbate supply shortages, and elicit foreign retaliation. The EO would also designate the aforementioned industries as "critical technologies" for purposes of the Defense Production Act (DPA), with far-ranging repercussions.

Amid the present national emergency, compelling industry to undertake massive changes to global production chains would be damaging

The EO is seeks to impose major changes on critical industries in the midst of a public health crisis. The ability of businesses to move quickly to "repatriate supply chains" at a time when many business functions are shut down is close to nil. While some sectors may be able to boost production of relatively simple products domestically on an emergency basis, forcing industries with complex value chains to shift suddenly is a different matter.

Additionally, at a time when U.S. and global financial markets are under tremendous strain, moves by the world's largest economy to break it trade agreement commitments would send the wrong signal to markets and add to the present financial uncertainty.

- *Recommendation: Any discussion of measures to carry out the Administration's stated objective of "repatriating supply chains" for these sectors should be deferred until the current national emergency is past. The EO should focus on measures to facilitate production of key products and avoid undermining current production that relies in part on global value chains.*

"Buy American" expansion would exacerbate shortages, spur retaliation

The EO will reportedly terminate application of the WTO Government Procurement Agreement and U.S. FTAs with respect to essential medicines and FDA-regulated emergency medical countermeasures. Such a move would contribute to shortages of critical goods and invite immediate retaliation. It would also hurt the long-term competitiveness of key U.S. industries by depriving them of access to foreign markets.

First, terminating U.S. obligations under these international agreements is not necessary as they have broad exceptions for "measures necessary to protect human health" that would cover reasonable actions to promote production of medicines and medical equipment under current circumstances. To recover from this crisis, we will

need export markets for U.S. manufacturers. Undermining the GPA will sabotage recovery by provoking retaliation by our best markets for high-value-added U.S. goods and services.

One possible unintended consequence of terminating coverage would be that many products — even many made largely in the United States by U.S.-headquartered firms — may fail to qualify under rigid "Buy American" rules. To illustrate, in the wake of the 2008-2009 recession, many U.S. water and wastewater equipment manufacturers could not comply with new "Buy American" rules due to the presence in their global value chains of content from abroad. As a result, the expansion of those rules directly harmed U.S. industry and slowed economic recovery.

Further, for the United States to abrogate its international agreements would contribute to the expansion of forced localization measures and export restraints internationally. A number of countries are pursuing such measures, including with regards to medical equipment and APIs, and the ability of U.S. officials to push back and ensure access to supply from diverse sources will be compromised if U.S. policy is seen as hypocritical.

- *Recommendation: In this environment, the United States must avoid embracing export controls or abrogating its international commitments relating to procurement as such steps would frustrate the international cooperation President Trump and other G7 leaders embraced in their March 16 statement. Expanding the reach of "Buy American" rules during the current national emergency may even undermine the ability of U.S. public health officials to procure certain badly need equipment during the emergency.*

Defense Production Act designation is a blunt instrument

The EO would reportedly invoke the Defense Production Act for essential medicines, medical countermeasures, and APIs. The Act authorizes the President to require businesses to sign contracts or fulfill orders deemed necessary for national defense and to regulate the allocation of materials, services and facilities for defense purposes.

A broad designation of industries under the Act could easily backfire. The Act was designed for defense industry products with a single supplier (often with purely or largely domestic production chains) and no alternative source. Imposing new strictures on U.S. firms that require flexibility as they strive mightily to boost production in the cooperative spirit demanded by the present national emergency would be counterproductive. In these circumstances, an expansion of government regulation would be unhelpful and risky.

Further, the Act imposes restrictions on foreign equity, which could cut enterprises off from current funding sources — the opposite of the intended effect. Finally, the WHO list of essential medicines is not particularly relevant to the needs facing the country in the current public health emergency.

- *Recommendation: Any designation of industries under the DPA should be narrow targeted and avoid a broad-brush approach. Instead, government and industry need to continue to work closely together in a collaborative manner to devise specific responses to shortages for identified products.*