

Thank you for the opportunity to present at the conference and to provide comments suggesting improvements of the pharmaceutical supply chain dynamics that result in critical drug shortages. I believe the following suggestions would help prevent drug shortages in the future.

1. The President/Congress should require and authorize the FTC/DOJ/FDA to form an interagency committee (like that of the CFIUS) with the broad authority to suspend and stop any merger/acquisition/joint venture of any size under an exceptional public health interest standards if it can be shown that the transaction has the likelihood of creating or exacerbating drug shortages and harming public health. Such a showing would be sufficient to stop a transaction if for example a merger will result in a product having risk of shortage because it will only be manufactured in one place. This public interest authority already exists in other segments of the US economy, including communications (FCC) and national defense (CFIUS), and is also used in other countries outside the US. See e.g., Defense cases: <http://www.businessinsider.com/green-paper-mergers-national-security-2017-10>; <http://www.newsweek.com/pentagon-bill-mergers-and-acquisitions-weapons-national-security-ash-carter-408412>; Communication cases: <http://blogs.reuters.com/great-debate/2013/07/08/the-mysterious-agency-that-can-block-a-global-merger/>; <https://www.fcc.gov/news-events/blog/2014/08/12/fcc-transaction-review-competition-and-public-interest>;

As the FTC has already recognized:

“Certain mergers may also be subject to a separate review by a specialized regulatory agency; that agency may be charged with applying different standards, which may include a broader public interest in addition to competition goals. For example, the Federal Communications Commission (FCC) employs a “public interest, convenience, and necessity” standard in the review of transactions involving licenses and authorizations in the telecommunications sector. In cases of concurrent review of telecommunications mergers, the DOJ and FCC work in close cooperation, consulting extensively to coordinate their reviews and to create remedies that are both consistent and comprehensive.

As part of a process separate and apart from the Agencies’ review of mergers, acquisitions of U.S. businesses by foreign persons that may affect national security may be reviewed by the Committee on Foreign Investment in the United States (CFIUS), an inter-agency committee chaired by the Secretary of Treasury.<sup>28</sup> Parties may voluntarily notify CFIUS of a proposed merger, but CFIUS has the power to review transactions regardless of whether they are notified. If a transaction raises national security concerns, CFIUS can apply mitigation measures or recommend that the President block or suspend the transaction.” [https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/1606public\\_interest\\_merger-us.pdf](https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/1606public_interest_merger-us.pdf).

Certainly, the availability of drugs needed by hospitals to treat seriously ill or injured Americans rises to the same level of public health concern as defense and communication mergers.

Under this public health interest standard, the new interagency commission could determine whether factories remaining after the transaction are actually functioning and operating according to cGMP to ensure a continued and adequate supply of medications. Methods of meeting that standard would be for firms to sign consent orders with the FTC to require

companies to have a business continuity plan if there are problems with production and to require the companies to keep separate, backup manufacturing facilities.

2. Require drug companies to disclose the actual manufacturer and location of manufacture in the Orange and Purple Books to ensure that clinicians can make quality based purchasing decisions based on the quality data FDA provides. Janet Woodcock has argued that this transparency may improve quality of production and thereby improve drug shortages as almost all shortages are due to a quality issue at the factory.  
<http://onlinelibrary.wiley.com/doi/10.1038/clpt.2012.220/abstract>.
3. Provide FDA and FTC the ability to impose fines on companies that don't disclose shortages, or reasons for shortage to FDA. Currently all FDA can do is post their name publicly.
4. Critical medications such as saline, morphine, heparin, antibiotics, and other essentials should be considered to be critical infrastructure as a component of homeland security. Manufacturers of these essential products should have business continuity plans including backup production facilities.
5. FDA should consider production facility abilities and intent to manufacture – such as business continuity plans as part of the approval process for ANDAs and NDAs, and all new products. The current process of approvals does not always result in medication production and availability.

Thank you for considering these suggestions. Please do not hesitate to contact me if I can provide further information or additional assistance.

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