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August 23, 2017

Ms. Maureen Ohlhausen
Acting Chairman
Federal Trade Commission
600 Pennsylvania Avenue, Northwest
Washington, D.C. 20580

Dear Acting Chairman Ohlhausen:

On May 16, 2017, Pfizer Inc. notified hospitals and other customers of shortages on several injectable drugs, including Sodium Bicarbonate, a common drug used in hospitals during surgeries, emergency events, and in some chemotherapy treatments.[1] The pharmaceutical company also referenced shortages on Bicillin, Labetalol Hydrochloride, Sodium Acetate, Calcium Chloride, Dextrose, Atropine Sulfate, and Epinephrine Injection. This reduction in output[2] has postponed important surgeries throughout the country and conspicuously occurred following the finalization of Pfizer's acquisition of Hospira.[3] I have deep concerns that these circumstances could have ultimately been prevented and request more information on what tools the Federal Trade Commission (FTC) can utilize in the future to prevent such a shortage from occurring.

Last year, Pfizer announced it would be reorganizing following its acquisition of Hospira, shutting down four regional warehouses and consolidating its distribution centers by early 2017, with a Pfizer spokeswoman arguing this was done "to be more efficient, improve our overall effectiveness, reduce costs and, generally be better able to competitively supply our products to our customers."[4] Following the consolidation, Pfizer sent notification of drug shortages to hospitals, leading many in Connecticut, including two of our largest hospital networks, to contact my office and share their concerns regarding the public health impact of shortages that seemed to

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[1] Engels, David and Wetterling, Ellen. "Notification On Pfizer Injectables Supply Recovery Update." Pfizer Inc., 16 May 2017, https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM559332.pdf. Accessed 22 Aug. 2017.

[2] In its most recent Horizontal Merger Guidelines issued on August 19, 2010, the U.S. Department of Justice and Federal Trade Commission outline that a "merger enhances market power if it is likely to encourage one or more firms to raise prices, reduce output, diminish innovation, or otherwise harm consumers as a result of diminished competitive constraints or incentives." The Guidelines also state that an enhancement of power as a consequence of a merger "should not be permitted." The Guidelines can be accessed here: https://www.justice.gov/atr/file/810276/download

[3] Communications between my office and Hartford Hospital have revealed that other Hospira products are in short supply, such as Heparin and Hydromorphone.

[4] Palmer, Eric. "Pfizer to Shutter 4 Hospira Distribution Centers, Laying off 104." *FiercePharma*, Questex, LLC, 18 Aug. 2016.

stem directly from the acquisition. Other hospitals noted the timing of this shortage, with the associate chief pharmacy officer at Duke University Hospital saying "it all derailed" following Pfizer's acquisition of Hospira.[5]

While the Food and Drug Administration (FDA) was able to intervene and allow an Australian company to export vials of Sodium Bicarbonate for use in American hospitals, this sort of temporary fix cannot be relied on when a "truly life-and-death kind of drug"[6] like Sodium Bicarbonate is in shortage. Instead, FTC and FDA must work together to determine if there will be reductions in output following a pharmaceutical merger. FTC and FDA have done so in the past. In reviewing Watson Pharmaceutical's proposed acquisition of Actavis in 2012, FTC worked with FDA in taking measures to investigate whether or not the merger would exacerbate a drug shortage.[7] Further, if a merger of this type is approved, FTC and FDA should coordinate to determine what actions must be taken by the company or companies involved to safeguard against a drug shortage.

As mergers and acquisitions become more common along the pharmaceutical supply chain, I request a briefing for my staff by September 15, 2017 as well as responses to the following questions in an effort to better understand what can be done to prevent future reductions in output that lead to drug shortages:

1. Are potential drug shortages considered by FTC when evaluating mergers of pharmaceutical companies?

2. Do you believe FTC has the authority to require a pharmaceutical company to implement a plan safeguarding against drug shortages as part of the terms of a merger that may threaten the supply of a drug?

3. Does FTC have a policy in place that recommends when it should consult with FDA to obtain evidence regarding the potential impact a merger of pharmaceutical companies could have on the supply of drugs manufactured or distributed by the companies involved?
    a. If so, can you share detailed information on that policy?
    b. If not, will FTC consider implementing a policy for these instances?

FTC plays a critical role in protecting consumers from higher prices and reductions in output as a result of lessening competition. While the Sodium Bicarbonate shortage following Pfizer's acquisition of Hospira is disturbing, I believe steps can be taken to ensure that it does not happen again.

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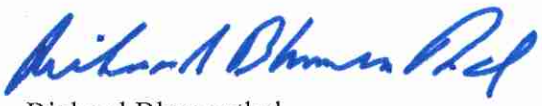
[5] Thomas, Katie. "A Vital Drug Runs Low, Though Its Base Ingredient Is in Many Kitchens." *The New York Times*, The New York Times, 21 May 2017.
[6] Kacik, Alex. "Sodium Bicarbonate Shortage Puts Surgeries on Hold." *Modern Healthcare*, Crain Communications, Inc, 26 May 2017.
[7] "FTC Places Conditions on Watson Pharmaceutical's Proposed Acquisition of Actavis."*Federal Trade Commission*, Federal Trade Commission, 15 Oct. 2012.

Sincerely,



Richard Blumenthal
United States Senate