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ONE HUNDRED SIXTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

July 30, 2019

Dr. Norman E. Sharpless, M.D.  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Acting Commissioner Sharpless:

We write to raise concerns to the Food and Drug Administration (FDA) about the potential threat to the U.S. heparin supply due to the outbreak of African swine fever in China, and to learn of any contingency plans in the event of a serious shortage.

Heparin is the only anticoagulant drug used in the United States for open-heart surgeries and kidney dialysis,<sup>1</sup> which reflects the drug's effectiveness and relatively inexpensive cost. One pharmaceutical executive called heparin "an essential hospital product used in very sick people" that "is priced well below a box of Band-aids."<sup>2</sup> It is also the only intravenous anticoagulant with an antidote (protamine sulfate) for overdoses, and is a polytherapeutic with wide clinical applications. Heparin is on the World Health Organization's Model List of Essential Medicines.<sup>3</sup>

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<sup>1</sup> Dialysis is a life sustaining treatment for nearly 400,000 Americans with kidney failure. American Association of Kidney Patients, AAKP & Fresenius Medical Care Team Up to Honor Dialysis Patients (Nov. 11, 2010) ([www.aakp.org/print-version/dsp\\_article.cfm?cat=7&subCat=20&topic=674&art=3268](http://www.aakp.org/print-version/dsp_article.cfm?cat=7&subCat=20&topic=674&art=3268)). At the end of 2010, 594,374 dialysis and transplant patients were receiving treatment for end-stage renal dialysis (ESRD), a 3.8 percent increase from 2009 United States Renal Data System, *Annual Data Report 2012*, Page 166 ([www.usrds.org/2012/view/](http://www.usrds.org/2012/view/)) (2012).

<sup>2</sup> House Committee on Energy and Commerce, *Hearing on the Heparin Disaster: Chinese Counterfeits and American Failures*, 110<sup>th</sup> Cong. (April 29, 2008) (testimony of Clive Meanwell, Chairman and CEO of the Medicines Company).

<sup>3</sup> World Health Organization, *WHO Model List of Essential Medicines 20th Edition* (Mar. 2017) (amended Aug. 2017) ([apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1](http://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1)).

Heparin is a drug derived from pig intestines. Although heparin can also be derived from other animal sources, for more than 20 years the United States and many other countries have adhered to a porcine origin requirement because of concerns over mad cow disease. Given the porcine requirement for heparin, the United States is largely dependent on China for its heparin because almost half of the global pig supply is in China.<sup>4</sup> About 60 percent of the crude heparin used to manufacture finished heparin in the United States is sourced from China.<sup>5</sup>

U.S. dependence on Chinese heparin and on one animal source raises risks of shortages.<sup>6</sup> The pig supply is vulnerable to reductions of availability because of disease outbreak. From 2006 to 2007, an outbreak of the Blue Ear Virus in China is believed to have been a contributing factor to the reduced heparin supply and the volatility of the heparin market immediately preceding the heparin contamination crisis in early 2008.<sup>7</sup>

The latest threat to the pig supply in China is from African swine fever, a highly contagious virus with no known cure, and a near zero survival rate for infected pigs. China is struggling to contain the disease, which has spread to every part of the country since August 2018. Last year, China had about 440 million of the world's supply of about 770 million pigs.<sup>8</sup> Since the outbreak of African swine fever, however, that number has declined sharply. RaboResearch Food and Agribusiness recently predicted China will lose between 25 and 35 percent of its herd this year alone – a loss of about 150 million pigs.<sup>9</sup> China's National Bureau of Statistics says the country's pig supply has fallen by nearly 40 million to 375.3 million from a year earlier because of the outbreak.<sup>10</sup> Moreover, the World Organization for Animal Health

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<sup>4</sup> *Hog Farming in Transition: The Case of China*, The Pig Site (Feb. 28, 2013) (“China is the world’s largest hog producer and pork consumer, accounting for almost half of global pork consumption and production.”)

<sup>5</sup> *Id.* According to an April 10, 2010, industry slide provided to FDA, China-sourced crude heparin is used to manufacture at least half of the world’s finished heparin supply and more than 80 percent of the U.S. unfractionated heparin market.

<sup>6</sup> Janet Woodcock, MD, Director, CDER, FDA, Introduction: Proposal for Reintroduction of Bovine Heparin to the US Market, Slide Presentation before Science Board to the FDA, June 4, 2014, Slide 9 (“Single animal sourcing/single country sourcing is risky due to animal-specific/country-specific risk (e.g., blue-ear disease.”)).

<sup>7</sup> *See* note 2.

<sup>8</sup> *China’s African swine fever epidemic could cause global heparin shortage*, UPI (May 1, 2019).

<sup>9</sup> *Id.*

<sup>10</sup> *Is China losing the battle against an incurable virus?*, BBC NEWS, (April 25, 2019).

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(OIE) stated that it will take years for China to contain the deadly African swine fever outbreak.<sup>11</sup>

Pharmaceutical researchers are raising concerns that the African swine fever outbreak in China “has the potential to cause an unprecedented shortage of heparin’s raw material.”<sup>12</sup> As a former senior fellow for global health at the Council on Foreign Relations recently observed, “Nearly 80 percent of the world’s heparin ingredient supply is made in China, which is why halving of the nation’s swine population should also be a major pharmaceutical concern for the world.”<sup>13</sup>

Currently, there is no apparent evidence yet that the pig shortage in China is impacting the heparin supply in the United States. However, the U.S. heparin supply is already stressed. As of June 19, 2019, FDA added heparin to the drug shortage list,<sup>14</sup> and in recent years there have been periodic heparin shortages, such as when Baxter’s supply of heparin was impacted by the effect of Hurricane Maria on its facilities in Puerto Rico.<sup>15</sup> Further, past experience from the 2006 Blue Ear Virus outbreak indicates that there may be about a six to nine-month lag time before a shortage of this magnitude would have effects on the U.S. heparin market.

In advance of this potential supply problem, please have appropriate FDA staff provide a briefing to Committee staff on how the agency is monitoring the adequacy of the U.S. heparin supply, and on FDA’s plans to address a potential shortage and threat of economically-motivated adulteration.

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<sup>11</sup> *China faces long struggle to tackle African swine fever: OIE*, Reuters (May 28, 2019).

<sup>12</sup> See note 8, quoting Paulo Mourao, a researcher at the Institute of Medical Biochemistry Leopoldo de Meis at the Federal University of Rio de Janeiro in Brazil; See also J Thromb Haemost et al., *Imminent risk of a global shortage of heparin caused by the African Swine Fever afflicting the Chinese pig herd*, *Journal of Thrombosis and Haemostasis* (December 24, 2018).

<sup>13</sup> *Donald Trump and Swine Fever Are Creating an Economic Crisis*, *Foreign Policy* (May 10, 2019).

<sup>14</sup> U.S. Food and Drug Administration, *FDA Drug Shortages* ([www.accessdata.fda.gov/scripts/drugshortages/default.cfm](http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm)) (accessed July 29, 2019).

<sup>15</sup> See Baxter Healthcare’s reverification on November 13, 2018, of heparin shortage on FDA’s drug shortage list (on file with Committee).

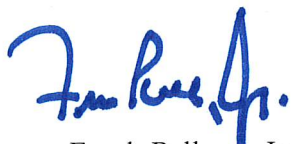
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We appreciate your attention to this matter, and if you have any questions, please contact Kevin McAloon of the Majority staff at (202) 225-2927 and Alan Slobodin of the Minority Committee staff at (202) 225-3641.

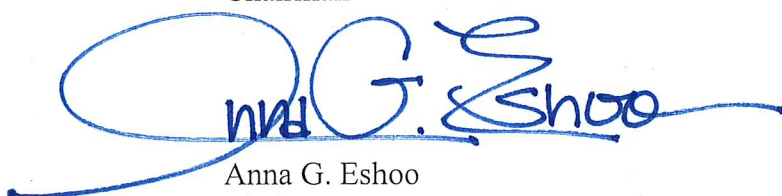
Sincerely,



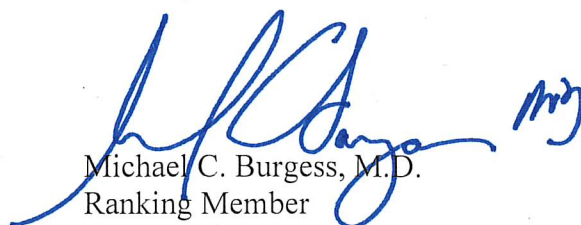
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