Pharmaceutical Research and Manufacturers of America  
950 F Street NW, Suite 300  
Washington, D.C. 20004

Dear Dr. Caforio, Mr. Ricks, and Ms. Sequeira:

We write to request information regarding the potential for human drug shortages as a result of the coronavirus (COVID-19) outbreak.

According to the World Health Organization (WHO), there are nearly 93,000 reported cases of the coronavirus (COVID-19) in 80 countries around the world – including more than 100 reported cases in the United States – with the WHO labeling the global risk assessment level as “very high.” The COVID-19 outbreak raises serious concerns about the consolidation of the supply chain for the manufacturing of active pharmaceutical ingredients and medical supplies in China and other countries that play a large role in the global supply chain. In fact, the FDA has already notified the public that one drug company reported an expected shortage due to difficulties obtaining a raw ingredient from a site affected by the coronavirus outbreak.

As you know, the timely notification from manufacturers of any issue that could lead to a potential disruption of the supply chain is critical to preventing drug shortages. And while the Federal Drug Administration (FDA) is monitoring the supply chain for the potential shortage of critical medical products, human drugs, and active pharmaceutical ingredients in those drugs as a result of the COVID-19 outbreak, Congress also has a critical role to play in ensuring that Americans have access to safe, affordable and effective therapies during this outbreak.

As such, we request that you provide us with detailed information on:

1. The potential for human drug shortages as a result of the COVID-19 outbreak;
2. Efforts your members are taking to evaluate your supply chain and the potential for disruption to the manufacturing of active pharmaceutical ingredients in impacted countries;
3. Efforts your members are taking to identify alternative domestic manufacturing or input sourcing for their products;
4. Any planned or ongoing efforts to stockpile components necessary to the production of their products;
5. The number of drugs that are partially or fully manufactured by your members in China or other countries that are critical to the global supply chain;
6. The number of drugs manufactured by your members that contain an ingredient only found or produced in China or other countries critical to the global supply chain;
7. A list of contracts and subcontractors that do the manufacturing of drugs produced by your members; and
(8) Your recommendations to Congress on the type of assistance your members would require in the event of a severe supply chain disruption.

We look forward to your timely response.

Sincerely,

Mark Pocan
Member of Congress

Pramila Jayapal
Member of Congress

cc: Mr. Richard Gonzales, Chairman of the Board and CEO, AbbVie Inc.; Dr. Ludwig Hanston, CEO, Alexion Pharmaceuticals; Dr. Richard Pops, CEO, Alkermes Biotech; Mr. Brenon L. Saurders, President and CEO, Allergan; Mr. Robert A. Bradway, Chairman and CEO, Amgen Inc.; Mr. Kenji Yasukawa, President and CEO, Astellas Pharma; Mr. Pascal Soriot, Executive Director and CEO, AstraZeneca; Mr. Liam Condon, Bayer; Mr. Michael Vounatsos; CEO, Biogen; Mr. Wolfgang Baiker, President and CEO, Boehringer Ingelheim Pharmaceuticals; Dr. Giovanni Caforio, M.D., CEO of Bistrol-Myers Squibb; Sunao Manabe, CEO, Daiichi-Sankyo; Mr. Haruo Naito, CEO, Eisai; Mr. David Ricks, Chairman and CEO, Eli Lilly and Company; Mr. Rehan Verjee, President, EMD Serono; Mr. Alexander Hardy, CEO, Genentech; Mr. Daniel O’Day, Chairman and CEO, Gilead Sciences, Inc.; Mrs. Emma Walmsley, CEO, GlaxoSmithKline; Mr. Herve Hoppenot, President and CEO, Incyte Corporation; Mr. Richard Paulson, Executive Vice President and CEO, Ipsen Biopharmaceuticals, Inc.; Mr. Alex Gorskey, CEO, Johnson & Johnson; Dr. Deborah Dunsire, President and CEO, Lundbeck LLC; Kenneth C. Frazier, Chairman and CEO, Merck & Co., Inc.; Dr. Vasant Narasimhan, CEO, Novartis Pharmaceuticals Corporation; Mr. Doug Langa, Executive Vice President, Novo Nordisk Inc.; Mr. Kabir Nath, President and CEO, Otsuka North America Pharmaceutical Business; Dr. Albert Bourla, Chairman and CEO, Pfizer, Inc.; Mr. Paul Hudon, CEO, Sanofi; Dr. Jeff Jonas, CEO, Sage Therapeutics; Dr. Antony Loebel, President and CEO, Sunovion Pharmaceuticals, Inc.; Mr. Christophe Weber, President and CEO, Takeda Pharmaceuticals USA, Inc.; Mr. Kare Schultz, President & CEO, Teva US Speciality Medicines; Mr. Jean-Christophe Tellier, CEO and Chairman of the Executive Committee, UCB.