CHARLES E. SCHUMER
NEW YORK

DEMOCRATIC LEADER

United States Senate

WASHINGTON, DC 20510

December 12, 2019

The Honorable Gene L. Dodaro
Comptroller General of the United States
Government Accountability Office
441 G St. NW
Washington, D.C. 20548

Dear Comptroller General Dodaro:

I write today regarding the serious national security concerns posed by the growing U.S. reliance on China for pharmaceutical products, as well as the public health concerns posed by inadequate safety measures in Chinese pharmaceutical manufacturing plants. To ensure the needs of the U.S. military and veterans in the event of supply disruptions from foreign sources, I request that the Government Accountability Office (GAO) investigate the capability of the United States to manufacture finished pharmaceutical products and active pharmaceutical ingredients.

The Departments of Defense (DoD) and Veterans Affairs (VA) are bound by several laws that generally require finished pharmaceutical products sold to the U.S. Government to be manufactured in the U.S. or in one of the designated countries with which the U.S. has a free trade agreement or other special trade-related arrangement. The Trade Agreements Act of 1979 (TAA) requires these products to be made or "substantially transformed" in the U.S. or a designated country identified in the Federal Acquisition Regulation. There are processes in place to manage exceptions, but finished pharmaceutical products made or substantially transformed in non-TAA compliant countries like China or India typically cannot be sold to the U.S. government.

While DoD reportedly purchases a small quantity of finished pharmaceutical products from Chinese sources, the Department recently expressed concerns with the growing dependence on China for the active pharmaceutical ingredients (APIs) used to produce finished pharmaceutical products sold in the U.S. commercial market. According to recent testimony before the U.S.-China Economic and Security Review Commission by a senior Defense Health Agency official, approximately 80 percent of the APIs used to produce finished products come from China and other non-TAA compliant countries. The official went on to add that the national security risks of increased Chinese dominance of the global API market cannot be understated and that a decision by China to limit or restrict the delivery of APIs would have a debilitating effect on the U.S. pharmaceutical market, including potential shortages for both domestic and military uses.

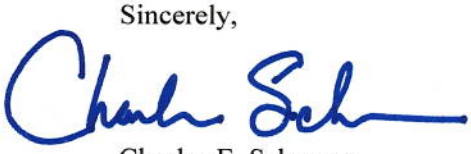
Compounding this problem, there is no federal registry or inventory for API sources from China used by manufacturers to produce finished drugs sold to the DoD or VA. This lack of visibility into the vast but poorly regulated Chinese pharmaceutical industry has raised quality and safety concerns in light of a series of high-profile drug recalls over the past decade. Just last year, the Food and Drug Administration (FDA) had to issue a recall for Valsartan, a popular blood pressure medication used by millions of Americans because they were tainted with dangerous carcinogens. Prior to that, a contamination of pills of Chinese-made Heparin, a blood thinner popular in U.S. hospitals, led to the death of over 200 Americans. According to a 2016 GAO report, the FDA's foreign inspection program has faced important challenges with adequately inspecting and gaining access to thousands of pharmaceutical manufacturing facilities overseas.

I am greatly concerned by the strategic vulnerability created by our reliance on China, a strategic adversary, for the APIs used to manufacture a very wide range of life-saving drugs that are vital to our healthcare system.

To better understand the risks posed by the growing reliance on China and other foreign sources for vital pharmaceutical products, I request that the GAO conduct an investigation into the U.S. pharmaceutical market's dependence on China and other foreign sources for active pharmaceutical ingredients, the kind of data the FDA has on foreign suppliers of finished drugs and APIs, the domestic capabilities of the U.S. to produce critical generic drugs and any other matters the Comptroller General deems appropriate to fully evaluate these issues.

Thank you for your attention to this important matter.

Sincerely,



Charles E. Schumer
U.S. Senator