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Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
U. S. Department of Commerce
Washington, D. C.

Dear Mr. Longnecker:

As executive director/co-founder of Physicians Against Drug Shortages Inc. (PADS), a pro bono, non-profit patient advocacy group, I greatly appreciate the opportunity to comment on the national security risks created by U. S. reliance on importation of pharmaceuticals and pharmaceutical ingredients.

Our mission is to end the chronic artificial shortages of generic drugs, active pharmaceutical ingredients and other essential medical goods via congressional repeal of the 1987 Medicare anti-kickback "safe harbor" for hospital group purchasing organizations (GPOs). This ill-conceived amendment to the Social Security Act [the Medicare and Medicaid Patient and Program Protection Act of 1987] caused the decades-long shortage crisis by exempting these highly consolidated buying cartels from criminal prosecution for taking kickbacks from suppliers. In effect, Congress awarded GPOs a "Get out of jail free card" and created a "legalized" fraud.

This statute transformed the GPO business model from nonprofit cooperatives that saved hospitals money by purchasing supplies in bulk to a pay-to-play scheme whose goal is to enrich insiders and certain top executives of major shareholder facilities. The documentation on their anticompetitive contracting and pricing practices, self-dealing, conflicts of interest, kickbacks and "share backs" is overwhelming. It comprises four Senate Antitrust Subcommittee hearings on GPO abuses and multiple hearings on drug shortages; federal and state investigations; major media exposés, multiple successful antitrust lawsuits, independent academic studies, even a barely fictionalized Hollywood feature film (PUNCTURE,

2011, starring Captain America's Chris Evans). GPOs literally sell market share, in the form of sole-source contracts, to the highest bidders, reducing the number of suppliers for any given drug to one or two. Exorbitant double-digit "fees" (aka kickbacks) demanded by these middlemen have squeezed the margins of domestic manufacturers to the point where many are unable to maintain quality control and upgrade plant and equipment. This has forced them to discontinue production of certain drugs and in some cases, shut down completely. These shortages, of course, gave rise to U. S. over-reliance on imports, notably from China, an adversary. Here are a few examples involving China:

- **Ben Venue Laboratories, Cancer Drugs**: The 2011-2012 shuttering of Bedford, Ohio-based Ben Venue Laboratories following a scathing FDA inspection report triggered acute shortages of critical cancer drugs, driving production to China. Documents in a federal whistleblower case against Novation (now Vizient, the largest GPO) show that at one point the big GPO was extracting 56.25% of the company's annual revenue for a single drug, diltiazem, a heart medication. The U. S. was soon forced to import some of the same drugs from a plant in China that had been "banned" by the FDA, according to *Bloomberg* of July 21, 2016. More than a decade after Ben Venue shut down for good, the U. S. Is still dependent on China for these old but still effective cancer drugs and active pharmaceutical ingredients. Patients with cancer are still suffering, and dying, because they can't get their drugs.

- **GE Healthcare, Contrast dye**: The acute 2022 shortage of contrast dye, which is used for MRIs and CT scans, is another well-documented example of the dangers of exclusive GPO contracting and the U. S. dependence on China for lifesaving drugs. The *immediate* cause was the shuttering of a major GE Healthcare plant in Shanghai during the pandemic. To the best of our knowledge, there is no evidence that China targeted the U. S. or that the closing was done for malicious reasons. However, this incident demonstrated that China's control over much of the U. S. drug supply could give it immense leverage in any serious confrontation, military, economic or otherwise, with the United States. This problem was foretold in an 11-page letter from another contrast dye maker, Bracco Diagnostics USA, to Senators Herb Kohl (D-WI) and Mike DeWine (R-OH), who presided over four hearings on GPO abuses before their Senate Antitrust Subcommittee. Bracco complained that they were unable to break into the hospital market because Novation blocked their

access: https://www.govinfo.gov/content/pkg/CHRG-108shrg91807/pdf/CHRG-108shrg91807.pdf. Perhaps because of their letter, Bracco was eventually able to compete. But they still couldn't produce enough dye to compensate for the shortfall caused by the closure of the GE plant.

- **Heparin contamination scandal.** In 2008, contaminated heparin, a blood thinner, imported by Baxter from China sickened hundreds of patients and killed 81. According to the *Wall Street Journal* of February 19, 2008, Baxter had a sole-source contract with Novation to supply the drug.

The global drug shortage crisis was "Made in the USA" *entirely* by GPO middlemen, not by "foreign government subsidies" or "predatory trade practices." In a nutshell, these middlemen, which do little more than award exclusive contracts, are making huge profits, leaving the companies that actually make the drugs with crumbs. The GPOs then share a portion of their ill-gotten gains with the CEOs of certain major shareholder hospitals. These so-called "share backs" can amount to seven figures. For documentation, see our comments to the FTC, attached. This is the glue that keeps this scam in place.

Tariffs and/or quotas on generic drugs manufactured in China and other foreign countries will only exacerbate this crisis. In effect, generic drug manufacturers have already paid steep "tariffs" on their drugs, except they're called "legalized" kickbacks. Manufacturers that have shifted production to China won't likely resume domestic drug production until free market competition and integrity are restored to the broken U. S. supply chain. And that can only be accomplished by repealing the unsafe safe harbor for GPOs.

You should be aware that on February 14, 2024, the Federal Trade Commission and HHS announced a joint investigation/request for comment on the role of GPOs in causing the shortages and inflating prices. This initiative appears to have been in response to a November 22, 2023 letter we collaborated on with the American Economic Liberties Project (AELP), an influential anti-monopoly think tank. It was co-signed by seven other advocacy groups. We then submitted a detailed response to the FTC/HHS request. Here's the link: https://www.regulations.gov/comment/FTC-2024-0018-6409. Other key stakeholders, including the

Association for Accessible Medicines (AAM, the generic drug trade group); the American Medical Association, and a coalition of state attorneys general, strongly supported the investigation. Here's the link to their comments on GPOs: https://www.regulations.gov/document/FTC-2024-0018-0001/comment?filter=group purchasing organizations. Much of the material contained in our FTC submission addresses your specific concern about national security. So rather then reformat those comments and other documents, I'm including them as attachments to our submission. A couple have since been slightly revised.

Newly-confirmed FDA Commissioner Martin "Marty" Makary M.D. M.P.H. is also on the record on the role of GPOs in causing the shortages and inflated prices of generic drugs and other essential medical supplies. In his 2019 book, "The Price We Pay," he devoted an entire chapter to the harms caused by GPOs and called for congressional repeal of the safe harbor.

We greatly appreciate your interest in this urgent issue. For more information and documentation, visit our website, www.physiciansagainstdrugshortages.com. Please feel free to contact us with any questions.

NOTE: We have no conflicts of interest on this issue.

Respectfully submitted,

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