# Congress of the United States

Washington, DC 20515

November 15, 2012

Gene Dodaro
Acting Comptroller General of the United States
Government Accountability Office
441 G Street, NW
Washington, D.C. 20548

Dear Mr. Dodaro:

As the nationwide meningitis outbreak caused by contaminated steroid injections from the New England Compounding Center worsens, we are interested in understanding more about a potential root cause of this deadly epidemic. Compounding pharmacies, like the one linked to the meningitis outbreak, are intended to provide patients with drugs that are tailored for a specific need, such as a gluten-free version or a liquid formulation for a child who is unable to swallow pills. However, as the number of drug shortages has risen over the past several years, doctors and hospitals have increasingly turned to compounding pharmacies to meet their patients' needs.[1] As a result, compounding pharmacies have been producing far larger quantities of products than Food and Drug Administration (FDA) guidelines permit, as outlined in the Pharmacy Compounding Compliance Policy Guides Manual.

The number of drug shortages in recent years has caused alarm within the healthcare provider community and has forced patients to forgo needed treatment.[2] The primary class of medications in short supply is the sterile injectable generics. Included within this group are highly critical drugs necessary for the safe practice of modern medicine, including cancer chemotherapy and anesthetic agents required for pain relief and safe surgery. Among the drug shortages listed by the American Society of Health-System Pharmacists (ASHP) is methylprednisolone acetate, the injectable back pain steroid used with patients that have been sickened by the meningitis outbreak.

A number of experts maintain that contracting practices of hospital Group Purchasing Organizations (GPOs) are a primary reason behind drug shortages and the resulting increased reliance on compounding pharmacies to fill the gap.[3] GPOs are entities designed to leverage the purchasing power of their client hospitals to obtain the lowest prices for drugs and devices. Virtually every hospital in the United States is a member of at least one GPO, and more than 70 percent of all hospital purchases are made through GPO contracts.

Experts have cited the anticompetitive, exclusionary contracts between GPOs and generic drug manufacturers, coupled with excessive GPO administrative, advance, marketing and other fees, as the reason that manufacturers have little incentive to produce those drugs. The fees drive down the manufacturers' profits to

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[1] Fiore, Kristina. "Drug Shortages Spark Use of Compounders." *MedPage Today* 18 Oct. 2012 <http://http://www.medpagetoday.com/MeetingCoverage/ASA/35406>

[2] Marcia Crosse, Director, Healthcare for the Government Accountability Office. "Testimony on Drug Shortages before the Senate Committee on Health, Education, Labor, and Pensions." Dec. 15, 2011.

[3] Zweig, Phillip L., and Patricia Earl. "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage." N.p., 4 Jan. 2012

such an extent that continuing to produce the drug or piece of equipment becomes unfeasible. As manufacturers leave the market, the supply chain becomes increasingly fragile. The FDA notes that it cannot prevent a manufacturer from discontinuing an older drug in favor of a newer, more profitable product, and it acknowledges that the "small number of manufacturers" making generic drugs results in these products being "vulnerable to shortage".[4]

As we seek to understand the factors that have led to hundreds being sickened and 31 killed by this tragic recent meningitis outbreak, we request that the Government Accountability Office (GAO) investigate the following questions:

1) What impacts have contracting practices by market participants (including manufacturers, distributors, group purchasing organizations, and providers) had on:
    a. Access to medical devices and drugs, including an impact on drug shortages?
    b. Competition and innovation in medical devices and drugs?
    c. Pricing of medical devices and drugs?

2) What market factors contribute to the reliance of hospitals and other healthcare providers on compounding pharmacies?

3) Do drug shortages drive hospitals and other health care providers to rely more heavily on purchases of drugs, including sterile injectable medications, from compounding pharmacies?

The role of a GPO is to leverage the purchasing power of their client hospitals and negotiate low-cost drugs and devices in exchange for buying in bulk. However, current law allows GPOs to charge manufacturers a fee in exchange for including their product in the supply contract. The fee is based on a percentage of the total value of the purchase, though there is little transparency about how much GPOs actually charge. Some experts consider this a "kickback" fee that creates a contrary incentive structure, whereby the more the hospital pays for the products, the higher the fee (kickback) and profit for the GPO.[5]

Unfortunately, it is not clear from available evidence that this payment scheme results either in savings to the hospitals or benefits for the patient. A 2010 study comparing GPO contract prices for capital equipment with prices obtained through open competitive bidding concluded that eliminating the GPO anti-kickback safe harbor exemption from the Social Security Act (which would prevent GPOs from collecting administrative fees from vendors) would save an average of 15 percent, or at least $30 billion, in annual hospital supply expenditures.[6]

4) Do the incentives in the current GPO model lead to inflated prices for drugs and devices? What is known about the competitive and budgetary impacts on both hospitals and the Medicare program that could result from eliminating the GPO safe harbor exemption from the Medicare anti-kickback statute?

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[4] "Frequently Asked Questions About Drug Shortages." *U.S. Food and Drug Administration.* <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>

[5] Zweig, Phillip L., and Patricia Earl. "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage." N.p., 4 Jan. 2012.

[6] Singer, Hal J., Litan, Robert E. & Birkenbach, Anna, "An Empirical Analysis of Aftermarket Transactions by Hospitals,"*Journal of Contemporary Health Law and Policy*, Fall 2011. [Original 2010 study on which this article was based was commissioned by the Medical Device Manufacturers Assn. (MDMA).]

5) What is known about the impact that GPO administrative fees have had on generic drug makers' financial condition, their ability to maintain and upgrade plant equipment, and their ability to conduct quality control?

Thank you for your prompt attention to this request. If you have any questions, please contact Sara Schaumburg (Rep. Markey) at sara.schaumburg@mail.house.gov or 202-225-2836. We look forward to your response.

Sincerely,

Edward J. Markey
Member of Congress

Henry A. Waxman
Ranking Member
Energy and Commerce Committee

John D. Dingell
Chairman Emeritus
Energy and Commerce Committee

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

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