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Markey, Top Democrats Call for GAO Investigation into Link Between Drug Shortages and Increased Reliance on Compounding Pharmacies

Lawmakers voice concerns in light of meningitis outbreak linked to drugs from Massachusetts compounding pharmacy

WASHINGTON, D.C. – As the number of drug shortages has risen over the past several years, doctors and hospitals have increasingly turned to compounding pharmacies to fill a void. Representatives Edward J. Markey (D-Mass.), Henry A. Waxman (D-Calif.), John Dingell (D-Mich.), Frank Pallone (D-N.J.), Diana DeGette (D-Colo.), Anna G. Eshoo (D-Calif.) today requested an investigation by the Government Accountability Office (GAO) into whether contracting practices by Hospital Group Purchasing Organizations (GPOs) are a driving cause of drug shortages that force hospitals and other providers to rely on compounding pharmacies. A Massachusetts-based compounding pharmacy, New England Compounding Center (NECC), has been found to be the source of contaminated drugs that have caused a nationwide meningitis outbreak that has killed 32 patients and sickened 461 more. The lawmakers are asking the GAO to investigate the role that GPOs play in triggering the drug shortages, with a focus on their fee structure.

“As Congress fully investigates all the causes of the tragic meningitis outbreak in an effort to protect patients in the future, we need to look at the role GPOs play in the occurrence of drug shortages that could lead to increased reliance on compounding pharmacies,” said Rep. Markey. **“Increased hospital reliance on compounded drugs should be a result of increased need not unfair pricing. The investigation we are requesting will shed light on any possible linkages between drug shortages and reliance on compounding pharmacies and help address gaps in our oversight of this industry.”**

A copy of the letter to the GAO can be found [HERE](#).
(<http://markey.house.gov/document/2012/letter-gao-group-purchasing-organization>)

“We look forward to GAO helping us understand the role General Purchasing Organizations play in avoiding, ameliorating, or contributing to the occurrence of drug shortages, and the role drug shortages play in hospital use of compounded drugs,” said Rep. Waxman. “In light of the tragedy of the meningitis outbreak linked to contaminated compounded drugs, we need to look carefully at all factors that might be contributing to the increasing use of compounded drugs by hospitals and other health care providers.”

“Through our investigation into drug shortages and the meningitis outbreak, we have discovered that medical professionals have increasingly been turning to compounding pharmacies for their prescription needs,” said Rep. Dingell. “It is important we study every potential cause of this outbreak in order to get to the bottom of this health crisis. I look forward to working with my colleagues in the coming weeks to explore legislative approaches that will address this matter.”

“In the drug shortage crisis of recent years, doctors and hospitals were increasingly forced to turn to compounding pharmacies like the one that caused the devastating meningitis outbreak,” said Rep. DeGette. “While we've begun to address drug shortages legislatively, it is clear we must aggressively investigate the factors that led to this deadly outbreak and determine possible remedies, so we can take steps to save patients lives.”

“If group purchasing organizations are taking advantage of their unique role in facilitating a safe and reliable drug supply, then we need to know about it,” said Rep. Eshoo. “Drug shortages are dangerous and affect our entire country. It's critical we examine all possible contributing factors to this problem.”

GPOs are designed to leverage the purchasing power of their client hospitals to obtain the lowest prices for drugs and devices. However, a number of experts say that anticompetitive, exclusionary contracting by GPOs have “rigged the market” in favor of a few manufacturers and distributors. Current law allows GPOs to charge the drug manufacturer a fee that is based on a percentage of the total value of the purchase. Some experts consider this a “kickback” that creates a perverse incentive structure, whereby the more the hospital pays for the products, the higher the kickback and profit for the GPO. Shut out of the lucrative GPO contract and unable

to make a profit, other manufacturers cease production and leave the supply chain more limited, fragile, and vulnerable to shortage.

Compounding pharmacies, like NECC, are intended to operate on a limited basis and provide patients with drugs that are tailored for a specific need. In reality, however, many compounding pharmacies have been producing a far larger quantity of products than FDA guidelines permit, at least partially in response to demand from hospitals unable to acquire the drugs they need at a reasonable cost.

The lawmakers are asking GAO to investigate questions that include:

- What market factors contribute to the reliance of hospitals and other healthcare providers on compounding pharmacies?
- What impact have contracting practices by market participants such as manufacturers, distributors, group purchasing organizations, and providers had on competition and innovation in medical devices and drugs, access to medical devices and drugs, including an impact on drug shortages, and pricing of medical devices and drugs?
- 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?
- Do the incentives in the current GPO model lead to inflated prices for drugs and devices? Put another way, 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?
- 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?

Expert statements in support of the GAO request:

“The drug shortage crisis in America is nothing short of a public health emergency,” said Joel B. Zivot, MD, FRCPC, Medical Director, Cardiothoracic Intensive Care Unit, Emory University Hospital. “As a physician, my duty lies with my patients. It is on their behalf that I demand access to the critical and powerful medicines they must have to regain their health and reduce their suffering. This broken generic drug market, which is the direct consequence of unethical GPO drug purchasing contracts legalized by Congress, must be fixed immediately. I commend Congressmen Markey and Waxman for taking this important step.”

“This initiative is a courageous step forward in addressing the foundational reasons behind both the tragedies caused by drug compounding and the broader issue of preventable drug shortages,” said Peter J. Pitts, President, Center for Medicine in the Public Interest and a former FDA Associate Commissioner. “The anticompetitive manipulation of American healthcare by GPOs is an urgent topic for congressional action.”

“GPOs are a major, if not the primary, contributor to the market distortions in the healthcare industry in the United States,” S. Prakash Sethi, Ph.D., University distinguished professor, Baruch College, The City University of New York.

“Through exclusive contracting, which has given GPOs effective monopolistic control of this industry, they have contributed to product shortages and disincentives for legitimate producers to manufacture and stock essential drugs. At the same time, they have given rise to unscrupulous manufacturers to produce and market substandard drugs and thereby expose the patient population to serious health risks.

It is ironic that this tragic state of affairs is the result of a Congressional mandate, and I wholeheartedly support Congressmen Markey and Waxman’s efforts to finally address it.”

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