

November 19, 2012

The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable John D. Dingell  
Chairman Emeritus  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Diana DeGette  
Ranking Member  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Edward J. Markey  
Member  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
Subcommittee on Health  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Anna Eshoo  
Ranking Member  
Subcommittee on Communications and Technology  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Ranking Member Waxman, Representative Markey and Representatives DeGette, Dingell, Eshoo and Pallone:

I am writing in response to the letter you and several of your Democratic colleagues recently sent to the Government Accountability Office (GAO) regarding the root causes of the recent fungal meningitis illnesses and deaths. Respectfully, the only causes of the tragic deaths are the poor safety and quality conditions at the New England Compounding Center (NECC). Any suggestion that group purchasing organizations (GPOs) are in anyway related to, or responsible for, this tragic outbreak is simply misguided and will only distract from efforts to solve these critical problems.

Drug shortages are a major problem with serious consequences for patient safety, quality of care, and access to essential medications. Questions about the drug shortage and the growth of compounding pharmacies are appropriate, and we would have been happy to talk with you about these issues. The drug shortage did not cause the poor conditions at the NECC – the NECC compounding issue is the result of deficient quality procedures at the center and, potentially, under-regulation at the state and federal levels. NECC is the bad actor, and the letter's effort to blame another industry for the bad acts of this compounding center seems a serious distraction at the very least.

We encourage you to examine with greater scrutiny some of the sources you cite as “expert” in your letter. Phil Zweig, for example, is a paid medical device industry consultant who has implicated GPOs in everything from the rise of the AIDS virus to the murder of two U.S. attorneys, and who, in the very report you cite in your letter, implicates two of your Democratic colleagues in the Senate in a conspiracy to cover up “widespread industry corruption.” The research and claims about GPOs by Litan and Singer, also paid medical device industry consultants, have been widely rejected by everyone from America’s largest hospital systems<sup>1</sup> to the U.S. 8<sup>th</sup> Circuit Court of Appeals.<sup>2</sup> We fail to understand why a GAO letter framed as a concern about the roots of the drug shortage included medical devices in all three points of the first question.

The true cause of drug shortages is manufacturing problems, disruptions and barriers to entry in getting new suppliers on line when there is a disruption in supply. The fact is that GPOs are taking a variety of creative and innovative steps to reduce drug shortages.<sup>3</sup> All GPO contracts are voluntary and a product of competitive market negotiations between sophisticated parties. All hospitals can purchase off contract and often do. Contracts can be and are cancelled, and pricing regularly adjusted. Manufacturers regularly and quickly adjust pricing of GPO contracts when they experience shocks to production. As you note, hospitals use GPOs to aggregate their purchasing power. GPOs do not manufacture, compound, sell, or take title to these drugs or any drugs in shortage. Our industry has every incentive to ensure that patients get the medications they need when they need them. If there is no product, there is no role for the GPO. GPOs do not have the ability—nor would it be in our interest—to force manufacturers into contracts that undermine their ability to deliver product. In fact, GPOs work vigorously with hospitals, manufacturers and distributors to help maintain a safe and reliable supply of products for healthcare providers.

All independent, empirical, and non-industry analyses of GPOs have found that GPOs deliver billions in cost savings every year.<sup>4</sup> GPO cost savings, administrative structure and business practices have all been thoroughly reviewed by the GAO<sup>5</sup>, DOJ, FTC<sup>6</sup>, the U.S. Supreme Court<sup>7</sup>, the 8<sup>th</sup> Circuit Court of Appeals<sup>8</sup>, academia and virtually all of America’s 5,000+ hospitals.

We know that the patients and their families impacted by this crisis are your first concern, as they are ours. We also work daily with the hospitals and healthcare professionals who are treating the

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<sup>1</sup> See, e.g., Letter from Mayo Clinic, Spectrum Health, Sutter Health, NY-Presbyterian, et al, to MDMA Chairman Eamonn Hobbs.

<sup>2</sup> Southeast Missouri Hospital v. C.R. Bard, Inc., No. 09-3325 (8th Cir. June 8, 2011).

<sup>3</sup> See, e.g., *Group Purchasing Organizations (GPOs) Work to Maintain Access to Product Supply for America’s Health Care Providers*, Avalere Health, 2012.

<sup>4</sup> See, e.g., *The Impact of Group Purchasing Organizations on Healthcare-Product Supply Chains*, Schwarz, Hu and Uhan, Purdue University Krannert School of Management, 2011; *Group Purchasing Organizations (GPOs): Issues and Evidence*, Lawton R. Burns and Andrew Lee, Healthcare Management Review, 2008; *The Value of Group Purchasing*, Eugene Schneller, 2009; *The Value of Group Purchasing*, Eugene Schneller, 2009; *Cost Savings and a Marketplace Analysis of the Health Care Group Purchasing Industry*, David Goldenberg and Roland King, 2009.

<sup>5</sup> See, e.g., Services Provided to Customers and Initiatives Regarding Their Business Practices, U.S. Government Accountability Office (GAO), GAO-10-738, Aug 24, 2010.

<sup>6</sup> See, e.g., DOJ and FTC, *Statements of Antitrust Enforcement in Health Care, Statement 7: Enforcement Policy on Joint Purchasing Arrangements Among Health Care Providers* (Washington, D.C.: August 1996).

<sup>7</sup> See, e.g., Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co., 472 U.S. 284 (1985).

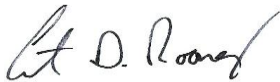
<sup>8</sup> Southeast Missouri Hospital v. C.R. Bard, Inc., No. 09-3325 (8th Cir. June 8, 2011).

ill patients, as well as those impacted by the recall of the NECC and Ameridose products. The extent of the crisis is far-reaching and we are doing all we can to help these healthcare providers fill their medication needs. We would urge you to keep in mind that these very same hospitals are under tremendous pressure to find efficiencies and savings in every decision they make at a time when Medicare and Medicaid payments are being reduced at the state and federal level. GPOs are their partner in finding those savings, while also maintaining quality and improving patient outcomes.

We take issue with the tone of the letter, its serious factual errors, and the absence of a chance to talk with you and your staff before you sent the letter. That said, looking for ways to address the drug shortage is a serious and worthy cause, and if given the chance we would like to work with you to help address it. As an industry, we are committed to mitigating this public health crisis.

I look forward to discussing this matter with you further. Please do not hesitate to contact me if you have any questions or would like additional information.

Sincerely,

A handwritten signature in black ink that reads "Curtis D. Rooney". The signature is written in a cursive style with a large initial "C" and "R".

Curtis Rooney  
President  
Healthcare Supply Chain Association