

From: Phil plzweig@aol.com
Subject:
Date: June 13, 2017 at 7:36 PM
To:

P



FOR IMMEDIATE RELEASE

TO: Healthcare/HC Business/HC Policy reporters and editors
Chairman Lamar Alexander, Ranking Member Patty Murray, and Members of the Senate Committee on Health, Education Labor & Pensions

RE: June 13 U. S. Senate HELP Committee hearing on “The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay”

June 12, 2017

Physicians Against Drug Shortages (PADS) urges Senate HELP to STOP the artificial shortages and skyrocketing prices of prescription drugs by repealing the misguided 1987 Medicare anti-kickback “safe harbor” provision for healthcare group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs)

Pro bono patient advocacy group calls on Congress to restore competition, integrity to drug/healthcare supply industries by reinstating criminal penalties for GPO and PBM kickbacks and rebates

NEW YORK, June 12, 2017— By our count, tomorrow’s Senate HELP hearing will be the 13th congressional hearing in nearly six years, and the third conducted by this committee, dealing with the unprecedented shortages and soaring prices of prescription drugs. Yet countless Americans are dying, and millions more continue to suffer from lack of access to affordable, lifesaving drugs. Most recently, a critical national shortage of injectable sodium bicarbonate (a/k/a baking soda) has forced doctors to postpone countless heart surgeries.

We continue to hear a steady stream of drug shortage horror stories from physicians and other healthcare professionals. Two recent examples:

- A skin cancer surgeon reports that he’s “desperately” trying to find lidocaine and sodium bicarbonate to operate on patients. Without these meds, he wrote, “our practice will close and melanoma pts. and squamous cell pts. will have severe morbidity and mortality.”
- Doctors at one hospital were forced to amputate the feet of three infants after attempting unsuccessfully to treat them with calcium chloride solution (a/k/a road salt) instead of injectable calcium gluconate, which has been in short supply.

Absurdly, the U. S. has been importing sterile injectables and other generics, including sterile saline (salt water) from Spain, Norway, and Germany; propofol from Germany; and chemotherapeutic agents from an unsanitary plant in China, and now, injectable sodium bicarbonate from Australia. This simply is not supposed to happen in a market economy.

The reason: The unsafe “safe harbor,” which exempts GPOs and PBMs from criminal prosecution for taking kickbacks and rebates from drug makers and other healthcare suppliers, created a “pay-to-play” scheme that has decimated market competition and grossly inflated prices in the entire prescription drug and healthcare supplies marketplace. The GPO and PBM middlemen have broken this market and “Venezuelized” our healthcare system

middlemen have broken the market and monopolized our healthcare system.

PADS chairman Robert A. Campbell M.D., a Lebanon, Pennsylvania anesthesiologist and past president of the Pennsylvania Society of Anesthesiologists, said “Congress is at a crossroads in one of the worst public health emergencies of modern times. The choice is clear. Members must decide whether they’re in favor of kickbacks or against them. Doctors simply can’t treat their patients—including members of Congress—if neither they nor their patients can obtain effective medications.”

He added: “Congress must stop kicking this can down the road with interminable deliberations and cancel the GPO/PBM ‘stay out of jail free card.’ Eliminating the unsafe safe harbor would be the most consequential thing to improve medicine in my 29 years as a physician. We urge every American who shares our outrage over this scandal to contact their congressmen and senators immediately to demand that they end the kickbacks.”

The bipartisan bill that would accomplish that was drafted in 2005 by Senators Herb Kohl (D-WI) and Mike DeWine (R-OH), who presided over four Senate Antitrust Subcommittee hearings on GPO abuses. It was never enacted because of opposition by the Healthcare Supply Chain Association (the GPO trade group), the American Hospital Association, and other monied special interests. Here’s the link to the “Discussion Draft” bill: <http://nebula.wsimg.com/689d312a26a89ad5cabb9dea9f5ea1?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>.

- The exhaustively documented anticompetitive GPO contracting and pricing practices, self-dealing, conflicts of interest, and “legalized” kickbacks have caused the ongoing shortages and outrageous prices of drugs, notably sterile injectables sold through GPO contracts to 5,000 health systems and thousands of non-acute care facilities.
- By literally selling market share, in the form of exclusionary, sole-source, long-term contracts, to the highest bidders, GPOs have slashed the number of domestic suppliers of many of these drugs to one or two, or none at all. Winning an exclusive contract, however, is a double-edged sword. Because suppliers have had to pay exorbitant but undisclosed administrative, marketing, advance and other “fees” to secure contracts, they have skimmed on quality control and plant and equipment, forcing plant shutdowns. Documents in a federal whistleblower case show that these “fees” have even exceeded 50% of a drug maker’s annual revenue for a single drug!
- GPO executives have even accused each other of unethical and anticompetitive contracting practices in connection with the shortages, as reported in *Modern Healthcare* of October 24, 2015; hospitals pharmacists have had to do end runs around GPOs to obtain essential drugs, according to *Modern Healthcare* of March 10, 2016, “Surviving Drug Shortages by Eliminating the Middlemen.” For a primer on this issue, read our *New York Times* oped of Sept. 3, 2013, “How a Cabal Keeps Generics Scarce.” For these articles and more information, see our GPO/PBM FACT SHEET, attached, and our website: www.physiciansagainstdrugshortages.com.
- In 2003, the Office of the Inspector General of the Department of Health & Human Services, which is responsible for administering the 1991 “safe harbor” rules, quietly and inexplicably extended GPO “safe harbor” protection to PBMs. Until then, federal prosecutors had regarded PBM rebates as bribes and kickbacks. The “de-criminalization” of PBM rebates has given rise to an unceasing upward spiral in the prices of drugs sold through these middlemen, as manufacturers competed to get their products on PBM formularies by offering increasingly larger rebates. In turn, drug makers have raised their prices to offset the rebates. GPOs and PBMs are joined at the hip through the misbegotten unsafe “safe harbor” exemption.
- To be sure, many manufacturers, most notoriously Valeant, Turing, and Mylan, are predators that have taken advantage of this rigged and broken market to recklessly jack up prices. But the GPOs and PBMs have played the central role in enabling them to do so. For documentation, see pages 24-25 of this 2003 HHS OIG document: <https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf> and pages 83-84 of this article: <https://nebula.wsimg.com/5efe0adcbfce646fc337d17fcf67e9ed?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>

In fact, in testimony before the September 23, 2011 House Energy & Commerce Committee hearing on drug shortages, Dr. Howard K. Koh, assistant secretary for health at the Dept. of Health and Human Services and the Obama administration’s point person on drug shortages, explained how these middlemen undermined the economics of the prescription drug industry:

Mr. SHIMKUS. And the question is why is that distorted? I think that is the basic fundamental question of this problem. What has distorted the fundamental principle of supply and demand, and my time has expired, but I think that is the heart of this issue.

Mr. KOH. Sure. And I am sure Dr. Kweder [deputy director of the Food and Drug Administration’s Office of New Drugs] can add, too. First of all, these agreements are made often through these long-term contracts and so also this whole process involves multiple stakeholders, especially and including the pharmacy benefit managers and the group purchasing organizations. So it complicates this environment and sort of does not make relevant the sort of standard supply and demand economic principles that we see in other businesses.

Mr. PITTS. Dr. Kweder?

Ms. KWEDER. You have said what I would say. Thank you.

He later reiterated this explanation in response to a question from Rep. Phil Gingrey:

Mr. KOH. Yes, Congressman, so we have come to understand that this is a complex business situation where the standard economic principles of supply and demand do not easily apply. And we have manufacturers, we have purchasers, providers, hospitals, we have group purchasing organizations and pharmacy benefit managers, so we have multiple forces here all working to the final outcome that ordinarily you would see with a rise in pricing profit, but that doesn't apply here.

Here's the link to the transcript: <https://www.gpo.gov/fdsys/pkg/CHRG-112hhrg77032/pdf/CHRG-112hhrg77032.pdf>.

Dr. Koh nailed it, but no one listened. Still, his testimony has since been corroborated in numerous government reports and independent research studies and articles. These documents are posted on our website.

- For years, the GPO industry has engaged in a well-financed PR and lobbying campaign to promulgate the fiction that the causes of this debacle are “complex and multifactorial” and that there is no single solution. These putative “causes” have included alleged “price-gouging” by so-called “gray market” drug distributors; raw materials shortages, “just-in-time inventory practices,” and most recently, a backlog in FDA applications. They disseminate this self-serving claptrap for one reason and one reason only: to protect their billions in exorbitant but undisclosed kickbacks and rebates, which benefit only well-heeled GPO, PBM and hospital executives, lobbyists, insiders, and certain members of Congress. While the causes of cancer may remain among the great unsolved mysteries of the universe, the cause of the shortages of the drugs used to treat it most certainly is not.
- These and other putative “causes” were thoroughly discredited, debunked, or downgraded as “secondary” or “proximate” causes in the GAO's drug shortage report of February 10, 2014 and in independent research. Indeed, that GAO report cited GPOs as a “potential underlying cause.”
- Despite the harm that shortages have inflicted on patients, executives of many GPO shareholder hospitals are happy with GPO kickbacks and inflated supply prices, because they get a piece of the action. That's why they have for years vehemently opposed repeal of the safe harbor. Incredibly, their financial conflicts of interest were revealed in a July 22, 2013 article in *Health Care Matters*, a GPO industry mouthpiece:

“As a member-driven enterprise, it is common knowledge that Premier [the second largest GPO] and other GPOs “share back” with their members and owners. In fact, many hospital executives who are part of the Premier alliance have learned to rely on that share back as an integral part of their annual compensation.” Link to entire article:
<http://nebula.wsimg.com/09cac886d7a44b22d0e78cef17f1c4ee?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>.

With Premier Inc. and the GPO industry, as with Rosencrantz and Guildenstern, “Their defeat does by their own insinuation grow.” Hamlet, Act V, Scene ii.

- Although the Food and Drug Administration has been working through a backlog of drug maker applications, a March 2016 analysis by the respected Center for American Progress found that few of those applications were for drugs in short supply or for which there was little competition. Drug makers have stopped producing many of these drugs because steep GPO “fees” and other questionable GPO practices have rendered them unprofitable. They're not besieging the FDA for permission to make them. Here's the link to the CAP report:
<https://www.americanprogress.org/issues/healthcare/reports/2016/03/09/132850/fda-is-not-the-problem/>.
- The GPO industry has apparently persuaded Congress that legislation is required to force the FDA to prioritize applications for drugs in short supply or for which there is inadequate competition. This is patently false. A recently introduced bill, Senate 1115, the “Making Pharmaceutical Markets More Competitive Act,” is nothing more than a superfluous “codification” of what the FDA has been doing for years. It will do absolutely nothing to foster competition. Indeed, for long-suffering patients and practitioners, it is a cruel hoax. Of course, HSCA and its members support it enthusiastically in the hope that it would deflect attention from their own culpability in causing this travesty. Other legislative proposals to address this crisis, like allowing drug imports from Canada, are either unnecessary, unworkable, or just plain ludicrous.
- What's more, extensive empirical and anecdotal evidence, accumulated over nearly 20 years, indicates that GPO abuses have inflated healthcare supply costs by about 25% to 35%, or upwards of \$100 billion annually (“legalized” kickbacks plus monopoly premium). That's because of the perverse financial incentives embedded in the “safe harbor.” Because GPO “fees” are calculated as a percentage of a drug's contract volume, higher prices mean more revenue for GPOs. HSCA and its members have never been able to provide **any independent evidence whatsoever** that they save

hospitals money, which is the sole purpose of a GPO. Instead, they have hired “academics” and consulting firms to publish specious “sponsored research studies” obfuscating their central role in causing the drug shortage crisis and/or falsely claiming that GPOs save hospitals billions of dollars.

- One such consulting firm is Avalere Health, whose president, Dan Mendelson, is scheduled to testify at tomorrow’s hearing, according to the Senate HELP website. Avalere has produced at least two such reports for HSCA defending the GPOs’ role in the drug shortages: 1) “HSCA, Avalere Health Report Details Critical Role of GPOs in Mitigating Impact of Prescription Drug Shortages,” HSCA press release of May 5, 2014; and 2) “Group Purchasing Organizations (GPOs) Work to Maintain Access to Product Supply for America’s Health Care Providers— A publication of the Healthcare Supply Chain Association (HSCA) with research and compilation of findings by Avalere Health,” undated. The GPO industry trade group is Avalere’s client, creating an irremediable conflict of interest. Mendelson cannot possibly be an independent, unbiased witness at tomorrow’s hearing on the “Cost of Prescription Drugs.” Accordingly, Senate HELP must rescind its invitation for him to testify.
- Using confidentiality, non-disclosure agreements and other tactics, the GPO industry has made it next to impossible to compare GPO and non-GPO prices. However, because most of our members are anesthesiologists and critical care specialists, we are able to compare prices of certain critical anesthetics. For example, one member who practices at a surgicenter that does NOT buy through GPO contracts reports that his facility currently pays \$22 for a 10-vial box of propofol, compared with \$55 at another member’s GPO-affiliated surgicenter. At one point during the ongoing shortage crisis, the price of propofol soared 3,161% above pre-shortage levels.
- Similarly, another PADS member found that she could have purchased over-the-counter supplies, such as Advil, bandages, and cotton balls, from Costco for up to 50% less than what her health system was paying through its GPO contracts, but her superiors wouldn’t allow her to do so.
- HSCA derailed a Government Accountability Office investigation, requested on November 15, 2012, by then-Representative Ed Markey and five senior House colleagues into the role of GPOs in causing the shortages, the deadly 2012 fungal meningitis outbreak, and skyrocketing prices of drugs sold through anticompetitive GPO contracts. On May 7, 2015, we filed a citizens complaint with the U. S. Justice Department documenting HSCA’s actions and charging that HSCA and its CEO violated federal criminal statutes [18 U.S.C. 1505] against obstructing congressional or administrative proceedings. We have no information on what action, if any, was ever taken. A copy of our complaint will be provided on request.

Congress must finally confront the real root cause of this crisis by repealing the unsafe GPO/PBM safe harbor. Patients can’t wait any longer.

We request that the Senate HELP Committee include this statement in the public record of this hearing.

ABOUT PADS: ***PADS** is a non-partisan, pro bono patient advocacy group that was organized in 2012 to end the artificial shortages and outrageous prices of generic prescription drugs. Members include physicians, pharmacists, attorneys, a journalist and concerned citizens. We have no financial conflicts of interest. We have no budget and receive no outside funding.*

Contact: Phillip L. Zweig M.B.A.
Executive Director, PADS
plzweig@aol.com
(212) 490-0811
(347) 920-8188 (cell)
www.philliplzweig.com

