Physicians Against Drug Shortages Inc. (PADS)

February 1, 2023

Mr. Adam Chandler
Appellate Attorney
Antitrust Division
U. S. Department of Justice
Washington, D. C.

Dear Mr. Chandler:

On behalf of our pro bono patient advocacy group, whose mission is to expose and address the real root cause of the chronic artificial shortages and inflated prices of generic drugs, devices, masks and other personal protection equipment (PPE) and supplies, we're writing, on an urgent basis, for two reasons:

First, to call on the Antitrust Division to immediately initiate an investigation into the exhaustively documented anticompetitive contracting practices and self-dealing of hospital group purchasing organizations (GPOs) and their role in causing this crisis. Three giant for-profit GPOs—Vizient, Premier Inc. and HealthTrustpg--- control buying of roughly 90% of an estimated $300 billion in drugs, devices, supplies and capital equipment for about 5,000 acute care hospitals and thousands more nursing homes, outpatient clinics and other facilities. By exempting GPOs from criminal prosecution for taking kickbacks from suppliers, the misbegotten 1987 Medicare anti-kickback "safe harbor" amendment to the Social Security Act gave rise to a vast "pay-to-play" scheme—a "legalized" fraud--- that has busted the medical supply chain. Even though government programs account for nearly half of GPO contract volume, there is virtually no oversight, disclosure, transparency or regulation of this corrupt industry.

Although Congress alone can repeal this pernicious statute, federal and state antitrust authorities are empowered to investigate and halt anticompetitive contracting practices but have failed to do so. On at least two occasions, a bipartisan bill that would have repealed the anti-kickback safe harbor was drafted, initially by Senators Herb Kohl (D-WI) and Mike DeWine (R-OH) in 2005 and in 2017 by Rep. Mark Meadows (R-NC). Both bills were killed by the powerful GPO/hospital lobby. We've studied and written extensively about this industry and been involved in the effort to reform it for more than 20 years. We have no doubt that a thorough, arms-length investigation would reveal that these cartels have engaged in price-fixing, market allocation, bid-rigging, and other abuses—in other words, criminal antitrust behavior.

Second, to report what we believe to be the GPO industry's illegal obstruction of a March 2022 National Academies of Science, Engineering and Medicine (NASEM) "Consensus Study Report" on supply chain resilience, and the apparent research misconduct of those responsible for producing it. In reality, it is a consensus of the clueless and conflicted. Entitled "Building Resilience into the Nation's Medical Product Supply Chains, the report was supposed to *objectively* analyze the causes of the breakdown in the medical products supply chain and recommend solutions. However, a careful, independent analysis of this 336-page tome, which was funded by the Department of Health & Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), would show that it was improperly influenced and, in effect, produced by the same industry that broke the supply chain in the first place. In short, the report, like the GPO industry itself, was rigged. It is just the latest of many instances in which this industry and its cohorts have obstructed and even derailed investigations by various federal agencies into their egregious anticompetitive practices.

We're contacting you because you're clearly familiar with these abuses, having worked on the Division's *amicus* brief in support of the plaintiffs-appellates in *Marion Healthcare vs Becton Dickinson et al* (case 18-3735, filed April 25, 2019). We presume you are also aware of former AAG Makam Delrahim's scathing criticism of GPOs in response to a question by Sen. Richard Blumenthal (D-CT) at the Senate Antitrust Subcommittee oversight hearing of Sept. 17, 2019. Mr. Delrahim declared:

"…some of the competition issues raised in that industry [are] due to Congress in [1987] providing an exemption from the Medicare anti-kickback statute, and that exemption has been kicked in, it's a mile long, and it's created a situation where some of these GPOs are buying exclusivity at the risk of innovation, at the risk of cost and at the risk of lives of patients."

On September 27, 2019 Zweig emailed Acting FDA Commissioner Norman E. Sharpless M.D., Principal Deputy Commissioner Janet Woodcock M.D. and other top FDA officials documenting the fact that since at least 2011, the FDA had been intentionally ignoring the pivotal role of GPOs in causing the shortages. In her reply of November 8, 2019, attached, Dr. Woodcock confirmed that the FDA was indeed aware of the GPOs' central role.

GPO Anticompetitive Abuses. The GPO industry has a long and checkered history. In a nutshell, GPOs have undermined competition in the drug and hospital supply chain by literally selling market share, in the form of sole-source contracts, for these goods to the highest bidders. They've even said so publicly. Lee Perlman, a top executive of the powerful Greater New York Hospital Assn. (GNYHA), until recently a GPO in its own right and the largest shareholder of publicly-held Premier Inc., the second largest GPO, told *Modern Healthcare* of February 10, 1997 that "We basically delivered market share." They are literally killing patients and clinicians—and they know it. The evidence is overwhelming. It includes four Senate Antitrust Subcommittee hearings on GPO

abuses; federal and state investigations, including a mid-2000s Justice Department criminal probe of Novation (now Vizient); major media exposés, notably a prize-winning 2002 *New York Times* investigative series entitled "Medicine's Middlemen" and most recently, a May 22, 2022 *60 Minutes* segment entitled "In Short Supply"; multiple successful federal antitrust lawsuits filed by entrepreneurial medical device makers against GPOs and/or their dominant supplier partners; independent scholarly research, even a book and a barely fictionalized Hollywood legal thriller. On November 22, 2022, the American Economic Liberties Project, an anti-monopoly think tank, PADS, Public Citizen and six other advocacy groups wrote to the FTC urging it to open an investigation into anticompetitive GPO practices.

Sadly, despite multiple requests over many years from members of Congress, stakeholders and concerned citizens, to the Justice Department and Federal Trade Commission calling for investigations, neither agency has taken meaningful action. As a result, these abuses continue unabated. Here, for example, is a Nov. 9, 2011 letter, signed by five United States senators, to former FTC Chair Jonathan Leibowitz, requesting an investigation. He declined. But after he left office, he became a partner at Davis Polk, reportedly billing clients at nearly $2000 per hour. One of his clients is the Healthcare Supply Chain Association (HSCA), the GPO trade group. Using figures pulled out of thin air, he even co-authored a 2017 "sponsored research study," bought and paid for by HSCA, falsely claiming that GPOs save hospitals billions. Vizient, the largest GPO, even boasts in its marketing material, attached, that one of the services it offers contracted suppliers is ***"Protection from competitive threats and rebidding."*** By decimating market competition, these buying cartels have driven production of medical supplies offshore to China and other countries. This is now officially recognized as a grave threat to the national security of the United States.

These chronic, unprecedented shortages have persisted for more than 20 years. They arguably began in the late 1990s when Premier Inc. began to take control of the generic drug marketplace by launching its own captive drug maker, American Pharmaceutical Partners (APP). When it went public in 2001, Premier executives profited handily. As documented in the *New York Times* series "Medicine's Middlemen," Sen. Herb Kohl (D-WI), then chair of the Senate Antitrust Subcommittee, called the deal "scandalous" and forced Premier to divest its stake in APP. One need not be a Nobel laureate in economics, or even a freshman student of economics, to know that chronic shortages of *anything* are simply not supposed to happen in a market economy. In a throwback to the disgraced ex-Soviet economic model, the GPOs have undermined the law of supply and demand, which operates in virtually every other sector of our economy. At the first congressional hearing on drug shortages (House Energy & Commerce Committee, September 23, 2011) HHS Assistant Secretary Howard Koh M.D. and FDA Deputy Director Sandra Kweder M.D. said as much (p.47 & 60). To the best of our knowledge, their testimony was ignored.

The GPO “safe harbor” business model serves no useful medical, financial, or social function. GPOs do not deliver medical care, conduct research, manufacture, warehouse or distribute goods. They are a gatekeeper. Or, as one industry critic put it, “They are nothing but a computer and a cash register.” They exist solely for the enrichment of insiders, including top executives of shareholder hospitals. IRS 990 filings by the Greater New York Hospital Association (GNYHA) show that two top GNYHA executives each received “equity distributions” of about $24 million over a four-year period. [UPDATE: About $32 million each over seven years]. And Kevin Sowers, the CEO of Johns Hopkins, a Vizient shareholder facility, received more than $1 million from Vizient in a single year, according to Maryland disclosure filings [UPDATE: $1,419,973 for periods ending June 30, 2019, 2020 and 2022] This confirms a statement in *HCMatters.com* of July 22, 2013, a now-defunct GPO industry mouthpiece:

"As a member-driven enterprise, it is common knowledge that Premier 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."

For more on these questionable payments, see comments to the HHS Office of Inspector General (HHSOIG) of February 16, 2021, in response to the IG's request for comment on the anti-kickback safe harbor. This feckless bureaucracy, which is supposed to monitor the safe harbor, has done nothing to address this urgent problem.

For GPO insiders and CEOs of major shareholder facilities, the anti-kickback safe harbor is the brass ring. The powerful GPO/AHA lobby will do virtually anything to make sure Congress never repeals it. In fact, a 2016 GNYHA lobbying report, attached, to the House of Representatives listed “preserving access to GPOs and protecting the GPO "safe harbor” at the top of its lobbying agenda. After the HHS OIG issued the safe harbor rules in July 1991, they gave rise to a perverse new business model that turned the financial incentive structure of the health care supply chain upside down. GPOs were originally founded in 1910 as nonprofit co-ops to enable hospitals to save money by buying supplies in bulk. Member hospitals gladly paid dues to cover administrative expenses. That worked fine for nearly 80 years. According to the lobbyist who persuaded Congress to adopt the statute, in reality it codified, or legalized, what was already happening: GPOs were already taking kickbacks for awarding exclusive contracts. Since kickbacks are calculated as a percentage of price times volume, GPOs have an incentive to inflate prices, not lower them. As you well know, competition lowers prices. Cartels inflate them.

The GPO industry and its cohorts have propped up their corrupt business model with a well-financed PR and lobbying apparatus, including generous campaign contributions to key members of Congress; donations, grants, and “speaking fees" to prominent health care "thought leaders," including former top federal health care officials, nonprofit organizations, media celebrities like Sanjay Gupta M.D. of CNN, and even medical

societies, whose rank and file members have been forced to cope with shortages of basic drugs. Critics they can't buy, they try to harass, threaten, and intimidate, sometimes successfully. For example, about two weeks after *The New York Times* published our September 3, 2013 oped, entitled "How a Cabal Keeps Generics Scarce," two co-authors received letters (see attachment) from Curtis Rooney, then CEO of HSCA, hinting at a libel suit if they didn't repudiate the article. Zweig didn't get a letter but advised them to frame theirs. Then in 2018, after Zweig commented on the role of GPOs during the Q&A at the FDA/Duke-Margolis conference, a bogus online "investigative" outfit called "Checks & Balances," presumably hired by someone associated with the GPO industry, published this "story":https://checksandbalancesproject.org/philip-zweig-disrupts-health-policy-forum/. Its principal, Scott Peterson, also filed bogus "ethics" complaints with household-name university medical centers that employed PADS members who had written articles critical of GPOs. In the end, nothing came of the complaints, but university "investigations" wasted countless hours of busy academic physicians who had done no wrong.

Many articles have been written over the years on anticompetitive GPO practices. For an overview, read *The New York Times* of September 3, 2013; "Where Does the Law Against Kickbacks Not Apply? Your Hospital," in *The Wall Street Journal* of May 8, 2018; and "Group Purchasing Organizations, Health Care Costs, and Drug Shortages" in the *Journal of the American Medical Association (JAMA)* of November 13, 2018. Of course, none of these were even cited in the footnotes of the NASEM report. Out of the hundreds of articles cited, only one could be found that was critical of GPOs.

The NASEM "Consensus Study Report." The CARES Act of 2020 required ASPR to fund a study by NASEM on the failure of the drug and medical products supply chain before and during the pandemic. We can only speculate on how NASEM came to be designated by Congress for this assignment rather than the Government Accountability Office (GAO), which, as the investigative arm of Congress, has conducted several studies over the years that were highly critical of the GPO industry. Indeed, a handful of journalists understood early on what had really happened. For example, on February 28, 2020, the *American Prospect* published this article on the threat posed by GPOs:https://prospect.org/health/behind-the-coronavirus-threat-a-middleman-destroying-prescription-drug-markets/.

In early 2020, when the acute shortages of N95 masks, gowns, gloves and other PPE began taking their toll on health care workers, we immediately suspected these buying cartels. A Google search turned up two remarkably prescient articles that confirmed our suspicion: 1) an August 14, 2017 *Dallas Morning News* piece in which Texas-based Prestige Ameritech, one of a handful of domestic mask makers, reported that they had blocked the company from selling its products to hospitals; and 2) an October 4, 2008 article in *Infection Control Today* quoting Executive Vice President Mike Bowen as saying that because of the GPO "chokehold" on the hospital market, the U. S. would be unprepared for a future pandemic:

"Selling individual products to individual hospitals became impossible over a decade ago," he said. "In order to gain price-sensitive GPO contracts, America's medical companies utilize cheap offshore labor. The GPO focus on price tends to turn products into commodities and give foreign suppliers the advantage."

What Mr. Bowen may not have understood at the time was that the GPOs' goal was not to obtain the lowest prices, but to maximize kickbacks from suppliers. In a March 31, 2021 webinar on health care monopolists sponsored by the American Economic Liberties Project, Bowen again took aim at the GPOs (48:30 minutes into program).

On April 17, 2020, the *Dallas Morning News* weighed in again in a column entitled "Here's one reason medical costs are so high:We have shortages and Made in America isn't working": https://nebula.wsimg.com/7c8a2b98781f329ce816086f6b532b49?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

On February 24, 2021, less than a year after the CARES Act became law, President Biden issued Executive Order 14017 calling for the White House National Security Council and National Economic Council to coordinate a 100-day review of four critical supply chains, including pharmaceuticals. They were instructed to work with four cabinet agencies, including the Department of HHS, on this assignment. It was intended to complement President Biden's executive order of January 21, 2021 which focused on the shortages of personal protection equipment (PPE) during the pandemic. Released in June 2021, the report stated:

"... GPO contracting practices may lead to limits in diversification of supply. GPOs may contract with certain manufacturers that are willing to pay to become a sole supplier" (p.227).

Although the NASEM committee could hardly avoid referring to the White House report itself, they neglected—intentionally, in our opinion— to cite this key finding. Indeed, the report is replete with 1) egregious conflicts of interest; 2) material omissions; and 3) false, misleading, inaccurate statements and citations. Details appear below.

It's abundantly clear to us that the GPO Industry, led by HSCA, Vizient and Premier Inc., knowingly obstructed this so-called "study," violating criminal statutes:

- **18 U.S.C §1505**. Clearly, the actions by HSCA *et al* meet all three of the essential criteria for prosecution under 18 U. S. C. §1505: 1) there was a pending proceeding before a department or agency of the United States; 2) HSCA *et al* were aware of the proceeding; 3) HSCA *et al* "endeavored corruptly to influence, obstruct, or impede the pending proceeding." [See Doyle, Charles, "Obstruction

of Justice: An Abridged Overview of Related Federal Criminal Laws," Congressional Research Service, April 17, 2014, p. 3] .

- **18 U.S.C. §371.** "Conspiracy to commit offense or to defraud the United States," since this project was underwritten with federal funds.

- In our view, NASEM and/or the University of Michigan committee, engaged in research misconduct, as defined in **42 CFR §93.103 (b**): "Falsification is manipulating research materials, equipment, or processes, or ***changing or omitting data or results such that the research is not accurately represented in the research record. "***

This was not the first time that the GPO industry obstructed a federal investigation into questionable GPO business practices. In October 2012, when Zweig learned that Rep. Ed Markey's health care staff was working on a bill to regulate compounding pharmacies in the wake of the deadly fungal meningitis outbreak, he contacted his staffers to urge them to address the underlying cause: the shortage of the steroid pain killer that had been produced by legitimate, FDA-regulated manufacturers. Those shortages prompted GPOs to steer their member facilities to the New England Compounding Center (NECC), whose Framingham, Mass. plant turned out to be contaminated. Documentation of the contractual ties between these GPOs and NECC is posted on our website.

So on November 15, 2012, Rep. Markey and five senior House colleagues announced in a press release that they had sent a letter to the GAO requesting an investigation into the role of GPOs in causing the shortages, the fungal meningitis outbreak, and inflated prices of hospital goods. This investigation was to be separate from the GAO investigation on drug shortages that was mandated by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). The GAO published the report a few days before Thanksgiving 2014. But it had nothing to do with drug shortages. The GPOs had derailed it.

In early 2015, Zweig contacted the Public Integrity Unit at the DOJ Southern District of New York. After a lengthy discussion with Unit Chief Arlo Devlin-Brown, he encouraged Zweig to send him documentation and file a formal civilian criminal complaint. Zweig's letter of May 7, 2015 and his completed DOJ complaint against HSCA and its CEO, Curtis Rooney, are attached. About two months later, Mr. Rooney resigned suddenly and without explanation, according to *Modern Healthcare* of July 13, 2015. A recent Google search belatedly revealed marketing material, attached, in which of one of HSCA's lobbying firms boasted about killing the GAO study.

Six years after the Markey request to the GAO, little had changed, and drug shortages remained a public health emergency. On November 27, 2018, the FDA sponsored a day-long conference entitled "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." It did neither. The conference, like the GPO industry itself,

was rigged. The meeting was organized by the Duke-Margolis Center for Health Policy, whose director, Mark McClellan M.D., is a former FDA Commissioner and CMS Administrator. FDA Commissioner Scott Gottlieb M.D., who had worked for McClellan at the FDA, had awarded Duke-Margolis a sole-source contract to run this and other FDA conferences, prompting an outcry from other academic health policy organizations and an article in the *Washington Post* of May 16, 2018 [https://www.washingtonpost.com/news/wonk/wp/2018/05/16/fda-reverses-course-on-a-4-2-million-no-bid-grant-to-a-former-commissioner]. PADS had asked to participate as panelists but our request was denied. Many, if not most of the panelists had financial ties to the GPO industry, so there was virtually no mention at the conference of its role in causing the shortages—other than Zweig's comments from the floor during the Q&A sessions. What's more, three of the 16 members of the Center's board of advisers had financial relationships with Premier Inc., even CEO Susan DeVore. We're confident that a thorough, arms-length DOJ investigation would reveal that Premier or the GPO industry was a major donor to Duke, Duke-Margolis, and/or possibly its leadership. Shortly thereafter, PADS filed an ethics complaint with Duke about this flagrant conflict of interest. Although DeVore was listed as a member of the board in the attached 2017 Duke-Margolis annual report, but not in the 2018 report, which was published April 11, 2019.

Nonetheless, McClellan continued to ignore the real root cause. On April 19, 2021, he moderated a webinar on drug shortages in which GPOs weren't mentioned at all. We can only presume that the panelists got the message that GPOs were off limits.

Premier's drive for profits at the expense of patients, rank-and-file physicians, and hospitals is also evident in a shareholder derivative lawsuit filed in March 2022 by a Michigan public employee pension plan against Premier's management and directors. It accuses them of breach of fiduciary duty in arranging a $474 million payout to themselves and other member owners at the expense of the retirement fund and other public investors. At the very same time that health care workers were unable to obtain N95 masks and other PPE because of GPO sole-source contracting, Premier executives with high seven-figure compensation packages were allegedly manipulating Premier shares to further line their pockets.

I Conflicts of Interest

Despite the overwhelming documentation on the role of GPOs in causing the shortages, it appears that no one was invited to present that evidence to the University of Michigan committee. Yet several individuals employed by or associated with the GPO industry were listed as presenters. At least two presenters are on the record as having previously criticized the GPO safe harbor model, but their earlier published views are not reflected in this "consensus" report. If they did express those views in their presentations, they would presumably have been outvoted by the majority. Which raises questions about the validity of a consensus report in the first place. In other words, the consensus view may not be true. And in this instance, it certainly is not.

Victor Dzau M.D., professor of medicine at Duke University School of Medicine, president of the National Academy of Medicine, and former chancellor of health affairs at Duke. As the head of NAM, Dr. Dzau was ultimately responsible for the content of this rigged "study." Documents indicate that he and Duke-Margolis had a longstanding business relationship with Premier Inc. and Ms. DeVore. Additionally, in 2019, he was forced to belatedly disclose corporate conflicts of interest in connection with articles he had written for the *Journal of the American Medical Association (JAMA)*. As chancellor, he was also embroiled in a landmark clinical trial data manipulation scandal that resulted in a "substantial" legal settlement, according to news reports. Although Dzau was not accused of fabricating data himself, he and other top administrators were faulted for mishandling the investigation and ignoring the early warnings of a medical student whistleblower (see attachment).

Erin Fox DPharm and Director of the University of Utah Drug Information Service (UUDIS). Ms. Fox's membership on the NASEM committee raises a red flag for anyone who understands the central role of GPOs in causing the shortages. Although she has represented herself for years to the media, industry panels and in journal articles as an "expert" on drug shortages, she is in fact a huge part of the problem. She functions as a lobbyist, spokesperson, and consultant to Vizient, the largest GPO. What's more, her employer, the University of Utah Health, is a major Vizient shareholder facility, meaning that the CEO and possibly other top executives likely receive "share backs" or dividends from Vizient as a percentage of the kickbacks it receives from suppliers in return for exclusive contracts. Our attempts to obtain this information through Utah FOI requests were unsuccessful.

To the best of our knowledge, the first occasion in which she disclosed her conflicts of interest occurred on Nov. 8, 2017 at an FTC conference on drug market competition, attached. PADS was apparently instrumental in forcing these disclosures. In a conference call with FTC staff about a month earlier, PADS had asked to participate in the GPO panel. Our request was denied. Asked who had been selected for the panel, a staffer listed the occupations of the panelists but not their names. One was a pharmacist. Zweig immediately asked, "Erin Fox?" There was stone silence at the other end of the line, at which point he enumerated her egregious conflicts. Not surprisingly, she has persistently denied that GPOs had anything to do with drug shortages.

Her membership on the committee is a clear violation of NASEM's own stated conflict of interest policy:

"This standard of high quality and integrity requires that staff ensure the membership of these committees be qualified, inclusive, appropriately balanced, and independent from sponsors. Appointed members must be **(A)** free of financial conflicts of interest with rare exception, **(B)** transparent

about their relevant relationships, and **(C)** transparent about their relevant publications. This form will walk you through questions pertaining to these three requirements. The conclusion that an individual has conflict of interest is not an assessment of the individual's behavior or character. The exclusion of an individual from service on a committee is intended to avoid a potentially compromising situation, thereby protecting the individual, the National Academies, and the public interest."

A review of the citations indicates that she appears as an author or co-author on more articles related to drug shortages than any other individual. Many of them were published by the *Journal of the American Society of Health-System Pharmacists.* Although it's unclear whether there are financial ties between Vizient and ASHP, it is clear that there is a close and questionable relationship. That's evident in the fact that Vizient pharmacy executive David Reardon is a contributing editor (attached below), a highly unusual arrangement for a medical journal that would have readers believe it is independent of industry influence.

Other members of the University of Michigan committee appear to have been selected because of their impressive academic credentials—as well as their ignorance of the workings of the GPO-controlled health care supply chain. This is evident in the misinformed statements and recommendations attributed to them.

Other evidence of bias is seen in the backgrounds of several individuals who gave presentations to the committee. For example:

Khatereh Calleja, President & CEO of HSCA [left in June 2019 and joined the Advanced Medical Technology Assn. (AdvaMed) in August 2021.

Blair Childs, As senior vice president for advocacy, Premier Inc., he is the PR mastermind behind the preservation of the anti-kickback "safe harbor."

Michael Ganio, Director of pharmacy practices and quality, American Society of Hospital-Pharmacists. Ganio was a reviewer of the report. According to the report, he and other reviewers were selected "to ensure that it meets institutional standards for quality and objectivity." Hardly. He and Erin Fox collaborate in disseminating the bogus GPO "complex and multifactorial" narrative.

Dan Kistner, Group senior vice president of pharmacy services, Vizient, the largest GPO.

Michael Schiller, Senior director, Association for Health Care Resources and Materials Management, American Hospital Association. The AHA, along with the HSCA, is one of the most vociferous opponents of safe harbor repeal, because many of its member hospitals are also GPO shareholders.

Stephen Schondelmeyer D.Pharm, University of Minnesota. In the attached November 2013 press release, Prof. Schondelmeyer cited group purchasing as a key cause of the shortages. By April 2022, however, after CIDRAP had begun collaborating with Vizient, Schondelmeyer blamed virtually everything for the shortages—everything but GPOs. In an April 18, 2022 press release, he said: "Most drug shortages, Schondelmeyer said, result from issues in the upstream supply chain, such as quality problems, recalls, shipping delays, raw material shortages, and geopolitical and economic issues, all of which the COVID-19 pandemic has thrust into the public eye." Question: Is Vizient or others in the GPO industry paying CIDRAP or its leadership for its silence on the role of GPOs, and if so, how much?

II Material Omissions

- **The NASEM report fails to distinguish between primary and secondary causes**. It asserts that "The single biggest cause of drug product supply chain disruptions under routine conditions is a failure to maintain manufacturing quality, according to an analysis by the FDA (FDA Drug Shortages Task Force, 2020). The 2020 update of the FDA Drug Shortages Report found that quality problems are responsible for 62 percent of the drugs that went into shortage between 2013 and 2017." In contrast, the GAO drug shortage report of Feb. 10, 2014, which was mandated by Congress in FDASIA of 2012, correctly differentiated between *underlying and immediate or secondary causes*: "Quality problems resulting in supply disruptions coupled with constrained manufacturing capacity were frequently cited as the immediate causes of recent drug shortages. However, we also identified multiple potential underlying causes of shortages, all of which were related to the economics of the generic sterile injectable drug market (p.31)." To support its flawed explanation, the NASEM report cites a 14-page January 2019 letter from Premier lobbyist Blair Childs, to FDA Commissioner Scott Gottlieb that includes a laundry list of "multifactorial" causes. The report fails to point out that Mr. Childs and Premier have a vested financial interest in disseminating this fiction. Their entire business model depends on their ability to preserve their kickbacks. NASEM obviously gave more credence to the self-serving views of a GPO lobbyist than to fact-based articles in major media outlets and respected medical journals.

- **Although there are several references in the report to the role of certain GPO contractual provisions, including "low price" and "failure-to-supply" clauses, in the shortages (p. 269), these issues pale in comparison to the underlying cause: the fatally flawed GPO "safe harbor," pay-to-play**

business model. We could find no reference to the outrageous “fees” (aka “legalized” kickbacks)—often double-digit and sometimes even more than half of a drug maker’s revenue for a single product--- demanded by the GPOs in return for access to their member facilities. The documentation includes the Senate Antitrust hearings, other federal and state investigations, media reports, federal antitrust lawsuits, and independent scholarly research—even incriminating statements by GPO insiders themselves. That, not the presence or absence of "failure to supply” clauses, is at the crux of the crisis. Although there is no transparency or required disclosure of the kickbacks paid by suppliers to GPOs, some of this material is in the public domain. In 2002, the Senate Antitrust Subcommittee requested “Excess Fee Reports” from Novation (now Vizient), which the GPO provided on a confidential basis. The reports, which comprised data from 1998, 1999, and 2001 were later obtained in discovery in a 2003 federal whistleblower case against Novation and Becton Dickinson (BD). They are posted on the GPO Documents page of our website.

- **Likewise, there was no reference to the findings of multiple federal and state reports, as well as respected independent investigators, academics, congressional testimony, and at least one former GPO CEO on the role of GPOs in causing the shortages of drugs and personal protection equipment.** These documents include testimony of HHS Assistant Secretary Howard K. Koh M.D. and FDA Deputy Director Sandra Kweder M.D. before the House Energy and Commerce Committee hearing on drug shortages of September 23, 2011 (p. 47 & 60); May 7, 2012 white paper by the American Antitrust Institute; a report of June 15, 2012 by the House Oversight and Government Reform Committee; a November 15, 2012 request by six senior members of the House Energy and Commerce Committee for an investigation into GPOs; the GAO drug shortage report of February 10, 2014; and the White House 100-day supply chain review of June 2021 (pp.226-8). In May 2020, former Consorta CEO John Strong, who had been a longtime defender of the GPO business model, went public in his condemnation of GPOs in a Linkedin post entitled “How Sole-Source Captured My Soul...and Blew My Response to the Pandemic." All of these reports, and more, are posted on www.physiciansagainstdrugshortages.com.

- **The report contains virtually no discussion of the money trail in the drug/ medical supply chain that would explain what the report calls a lack of incentives for supply chain "continuity.”** Although the report states that shortages are more likely to occur with low-margin generic drugs, the authors fail to explain the reasons for the lack of profitability: exorbitant GPO “fees,” aka kickbacks, that have sometimes amounted to more than half of the total annual revenue realized by a manufacturer for a single product. They include, but are not limited to, administrative, marketing, advance, conversion, private label and licensing fees.The report also fails to point out that CEOs of GPO shareholder hospitals often receive so-called “share backs,” or dividends, from their GPOs in return for maintaining compliance with secret, exclusionary GPO contracts.

Share backs are the glue that keeps this venal system in place. For documentation, see comments by PADS, attached, to the HHS OIG in response to its request for comment on the anti-kickback safe harbor. In other words, predatory “middlemen" are making all the money.

- **"Case studies" on the shortages of N95 masks (Box 4-1 p.101), sterile saline (Box 4-2 p.105) and heparin (Box 4-3 p. 108) omit any discussion of the real root or primary cause: GPO sole-source contracts**. Instead, the report dwells entirely on secondary causes. A February 19, 2008 *Wall Street Journal* piece on the shortage of heparin stemming from the contamination of Baxter’s product noted Baxter’s sole-source contract with Novation, now known as Vizient. Similarly, its discussion of the chronic sterile saline shortages echoed the GPO mantra in blaming everything except documented GPO sole-source contracting. Indeed, in the attached Oct. 9, 2007 Baxter Healthcare press release, the company boasts of its new sole-source contract for IV solutions. Instead, the case study relies heavily on articles co-authored by Erin Fox, the Vizient lobbyist. Out of the hundreds of articles and documents in the text or footnotes, we could find only one article that cited the role of GPOs (*Forbes*, July 6, 2020). In fact, a 2020 book, *MONOPOLIZED*, by the *American Prospect’s* David Dayen devotes an entire chapter to this. It’s entitled “Monopolies are why salt water in a bag became a scarce item.”

- **The case study on the mask shortages fails to cite the real reason: For years before the pandemic, GPOs had blocked small domestic mask manufacturers from marketing their products to hospitals.** Although the report mentions Texas-based Prestige Ameritech, it neglects to mention—intentionally, in our view—the company’s unsuccessful attempts over more than a decade to break into the hospital market. As previously noted, Mike Bowen of Prestige Ameritech blamed GPOs for discouraging domestic manufacturing and driving production to China. To anyone familiar with the hospital supply chain, it is clear that the cause of the shortages of drugs and PPE is the same: anticompetitive GPO contracting. Yet in a separate section, Philip Ellis, who is billed as an expert on such matters, offered this: "For a range of reasons, it is useful to distinguish rather sharply between the issues raised by the shortages of personal protective equipment (PPE) and other supplies that arose during the COVID-19 pandemic, and the issues involved in the persistent supply problems for generic drugs. Simply put, they have different causes, involve different orders of magnitude, and will likely require different solutions.” WRONG. Virtually all of these products have at least one important thing in common: they are sold through secret anticompetitive GPO contracts.

- **In praising the non-profit 501c(4) business model of CivicaRx (p. 192), the report neglects to point out that it was founded by Intermountain Health Care, which at the time owned 100% of Intalere, then the fourth largest GPO.** The obvious intent was to ease the potential political pressure on GPOs for creating the shortages while enabling them to continue taking kickbacks for other

goods not in short supply. It is akin to the rogue fireman who starts a house fire, leaves the scene, then returns to rescue the occupants and is declared a hero. CivicaRx is further evidence that the GPOs broke this marketplace. In fact, Martin Van Trieste, the founding CEO, alluded to the GPOs in his attached comment letter of October 31, 2018 to the FDA that "Civica will have a disruptive distribution model that will not pay fees or rebates to “middlemen” in the pharmaceutical supply chain, breaking the grip of sole-source providers and closed distribution systems.” Trouble is, Civica, as a nonprofit, will create a bifurcated market that will further erode margins of existing for-profit generic drug makers. Amid the self-congratulations that accompanied the launch of nonprofit CivicaRx, few seemed to understand that if the hospital owners of the GPO cartels that caused the shortages simply repudiated their kickbacks and share backs by restoring GPOs to non-profit status, the drug shortage crisis would soon come to an end.

- **Ben Venue Laboratories: The “Case Study" that Wasn’t.** Founded in 1938, Ben Venue Laboratories was for decades a successful manufacturer of generic sterile injectables, including lifesaving drugs to treat childhood leukemia, ovarian and breast cancer and other cancers. The company had produced drugs for the military in World War II and was a major, respected employer in Bedford, Ohio. But by the mid to late 2000s, Ben Venue was foundering. Responding to complaints about glass, metal particles, and other contaminants in the drugs, FDA inspectors found a house of horrors, including mold, dilapidated equipment, nonexistent quality control and shoddy maintenance. It became the poster child for BMP (bad manufacturing practice). The FDA repeatedly forced the recall of dozens of products. The inspection that began on November 7, 2011 was the last straw. Inspectors even found a 10-gallon bucket of urine near the production area. Incredibly, according to a drug quality control expert, this was a cost-saving measure. It was intended to save bathroom time by eliminating normal sanitary protocols: de-gowning, walking to the head, re-gowning, and scrubbing back in before returning to the production area. After that inspection, the plant shut down for “remediation” and was later bought and sold at least twice before ceasing production for good. What the inspectors may not have known was that Ben Venue’s primary GPO was Novation. According to confidential Novation “Excess Fee Reports” obtained by the Senate Antitrust Subcommittee and later, the relator in a 2003 federal whistleblower case, the GPO extorted nearly $10 million in “advance fees” (aka bribes) alone from Ben Venue and Bedford in the four years ending December 31, 2001. Ben Venue appears to have paid millions more in other fees over and above the 3% "soft cap” established in the “safe harbor” rules issued by HHS OIG in July 1991. This was the price of admission to Novation’s member hospitals. One immediate consequence of the late 2011 shuttering was an emergency shortage of methotrexate, an essential drug for treating childhood leukemia. Incredibly, the FDA was forced to permit imports of essential cancer drugs like doxorubicin and daunorubicin from a Chinese plant that was “banned” by the agency because of unsanitary conditions, according to *Bloomberg* of July 21, 2016.

- **Coincidentally, in 2014, Christian DeRoo, then a third-year student at American University's Washington College of Law, published an article entitled "Pay to Play: The Impact of Group Purchasing Organizations on Drug Shortages" in the** *"American University Business Law Review."* Unlike the bloated NASEM report, it captured the essence of the problem in just 21 pages. Perhaps he should have been appointed to the NASEM committee instead of the law school's Professor Lewis Grossman.

- At least two presenters, **Rosemary Gibson**, author of *ChinaRx*, and **Medtronic** have publicly criticized the GPO system, but their earlier views do not appear to have been considered by the committee. A co-chair of PADS, Ms. Gibson devoted several pages of her 2013 book, *Medicare Meltdown*, to a stinging critique of GPOs and called for repeal of the safe harbor. In February 2011, pacemaker pioneer Medtronic, then headed by **William "Bill" Hawkins**, announced that it had cancelled its GPO contracts because they increased costs, according to the *Wall Street Journal* of February 25, 2011. The GPOs responded by enlisting the help of Sen. Max Baucus, who announced Senate investigations of Medtronic. **Robert Califf M.D**. resigned as a member of the NASEM committee in April 2021 when he was nominated by President Biden to become FDA commissioner. It's not clear if he had a view on GPOs before May 25, 2022, when he testified before the House Energy & Committee Committee on the baby formula shortages. But in that testimony, he repeatedly urged members to watch the *60 Minutes* segment, "In Short Supply," which had aired three days earlier. He also cited the role of sole-source contracting in causing drug shortages. And as noted earlier, FDA Principal Deputy Commissioner **Janet Woodcock M.D.**, who has been deeply involved in the agency's failed attempts to stop drug shortages but did not appear on the NASEM schedule, clearly indicated in her 2019 letter that she was well aware of the role of GPOs in causing the shortages.

III False, Misleading, and Inaccurate Statements and Citations

The NASEM report contains numerous false, misleading, discredited and inaccurate statements that have been disseminated by the GPOs to distract attention from their role in causing the shortages.

- **The NASEM report disseminates the GPO canard that virtually *everything* caused the shortages——everything, of course, but GPOs.** The GPOs and their allies falsely claim that the causes are "complex and multifactorial," or a "perfect storm." A diagram on page 7 shows eleven causes. Reference to anticompetitive GPO contracting practices is notably absent.

- **The report falsely suggests that GPOs lower prices of medical goods for health systems and contract with multiple suppliers.** On page 39, for

example, the authors write that "Health systems may choose to become a member of a GPO, which negotiates contracts for medical products on behalf of its members with the intent of sourcing from multiple suppliers in order to provide a more reliable supply to members at a lower cost." Nothing could be further from the truth.The report goes on to state that "contracts focused on price alone can drive competitor products from the market in a "race to the bottom" pricing structure. "Race to the bottom" has become a catchy but misleading buzzphrase. It's misleading because exorbitant GPO kickbacks, not fierce competition, have decimated this marketplace. The NASEM report ignores all of the independent evidence that these practices undermine competition and inflate prices, while citing blatantly fallacious industry-funded "studies" claiming that GPOs save billions for hospitals (Leibowitz, fn p. 196). All of the independent empirical and anecdotal evidence indicates that GPOs actually ***inflate*** prices by at least 30%, or roughly $100 billion annually. The first such report by the Government Accountability Office for the first Senate Antitrust Subcommittee hearing of April 30, 2002 found in a survey of pacemaker and safety needle prices that GPOs hospitals often pay more—up to 39% more—for these ;products than they would if they had purchased them directly. In a 2003 letter to then-Secretary of Defense Donald Rumsfeld, Senators Kohl and DeWine cautioned against hiring a GPO to manage health supplies procurement, noting that "…savings figures GPOs frequently cite as benchmarks to demonstrate savings are based on a manufacturer's list price that hospitals rarely, if ever, pay." And in 2010, the Senate Finance Committee (Minority) published a report, sponsored by Senator Charles Grassley, that found that the only "evidence" GPOs are able to present to support their claims of cost savings are "sponsored research" reports by ethically-challenged academics and consultants. Nothing has changed,

The NASEM report parrots the GPO playbook in disseminating false and discredited explanations for the drug shortages and resulting skyrocketing prices. They include, but are not limited to: 1) so-called "gray market" distributors; 2) the change in the Medicare B reimbursement formula under the Medicare Modernization Act of 2003; 3) overzealous FDA inspections; 4) the FDA backlog in processing new drug applications (ANDAs); 5) Hurricane Maria (sterile saline) and 6) COVID lockdown in China (contrast dye). As these and other bogus GPO explanations were discredited by factual evidence, the GPO industry continued to fabricate new ones. There is also evidence that Vizient was complicit in the baby formula shortages. According to a former marketing manager with another baby formula maker, Vizient sole-source contracts enabled Abbott to become the dominant supplier to the hospital market. Most recently, the shortage of amoxicillin has made headlines and the evening news. But it is just the latest antibiotic to earn that dubious distinction. Over the years, many other mainstay antibiotics have been in short supply at one time or another.

- **"Gray Market" Distributors**. As early as 2011, the GPO industry deployed its massive PR and lobbying apparatus to demonize small to mid-sized distributors as "gray market" profiteers (46, 124). In August 2011, Premier published a report

entitled "Buyer Beware: Drug Shortages and the Gray Market." In fact, these "mom and pop" firms perform a vital, and perfectly legitimate, market function, supplying hospitals, clinics and health care providers with smaller quantities of drugs, often in emergency situations. Sometimes scarce drugs have to go through several distributors before reaching the ultimate buyer. So their base prices are higher to begin with than those of the so-called "Big Three" GPO-authorized distributors. What's more, unlike the "Big Three" distributors—McKesson, AmerisourceBergen, and Cardinal—they aren't permitted to receive "charge backs" from manufacturers. So they have to charge higher prices to stay in business. Citing the bogus Premier report, in 2011 politicians and would-be "investigative reporters" jumped on the "gray market" bandwagon. In 2012, Sen. Jay Rockefeller, chair of the Senate Commerce Committee, held a hearing that further reinforced this patently false accusation. However, the GAO drug shortage study of Feb. 10, 2014, which was mandated by Congress, reported that the FDA, DOJ, and FTC had investigated and found no wrongdoing (p. 69). See also "Connecting the Dots" by Patricia Earl and Phillip L. Zweig, Jan. 4, 2012. Yet the NASEM report wrote: "A serious concern that faces hospitals, health care facilities, and other purchasers of medical products are rogue distributors that operate in the gray market (Rockefeller et al., 2012). These distributors charge exorbitant sums of money for products that are in shortage, and knowingly or unknowingly sell counterfeit or substandard medical products. Gray market distributors often seize on the uncertainty in the supply chain once a shortage arises and health care facilities can no longer reliably purchase products from their normal suppliers. However, even compliant distributors may need to increase their prices when upstream supply chain disruptions increase the price of raw materials (Sheridan, 2021)."

- **Medicare Modernization Act.** Another discredited red herring is the notion that the change in the Medicare B reimbursement formula proscribed in the Medicare Modernization Act of 2003 caused the shortages. Effective in 2005, the formula was changed from average wholesale cost (AWC) to average sales price (ASP) plus 6% to bring Medicare reimbursement in line with what providers actually pay. Under the old formula, oncologists were making huge profits on this spread. Studies by Dr. Sherry Glied, Assistant Secretary for Planning and Evaluation (ASPE) of the Department of HHS in the Obama administration, concluded that the change in the formula did not affect payments to generic drug makers at all. In a December 23, 2014 letter to the editor of the *Journal of Oncology Practice*, she refuted the claim by a prominent oncologist in a *JOP* article that the new formula was responsible. Yet Ellis once again demonstrated his lack of understanding of the dysfunctional health care supply chain in writing that "a payment cut is a payment cut," adding that "This change may have been an

important factor behind the rise in shortages that has been observed over the past 15 years (p. 319-20). The facts show that the change had absolutely nothing to do with the shortages.

- **Vizient**. In a footnote on page 123, the report describes Vizient [formerly Novation] as a "company that partners with health care organizations throughout the United States to help improve health care performance by providing data, insights, and purchasing power to their members." In fact, Vizient does nothing of the sort. This description conveniently omits the fact that the company has been the target of an investigation by the Senate Antitrust Subcommittee, a mid-2000s Justice Department criminal probe, numerous successful antitrust lawsuits filed by entrepreneurial medical device companies, and major media exposes. Although this description suggests that Vizient saves hospitals money, there is no independent evidence that Vizient or other GPOs save them a dime, and overwhelming empirical and anecdotal evidence that they inflate hospital drug and supply expense by at least 30%. For that, see attached "Safe Harbor Cost Analysis (Updated 2024)."

- **W. Craig Vanderwagen M.D.** At the end of a one-hour March 3, 2022 webinar to present the NASEM report (57.30 minutes), a questioner asked the authors about the role of GPOs in the supply chain "given their purchasing power…" In reply Dr. Vanderwagen bloviated that "Our view is that they should be critical players in regional and local discussions as well as in the national discussions so that they are actively engaged in that regional and local discussion about how we're going to approach negotiating emergency pricing and crisis price lists and that sort of thing as well as how they can play to facilitate decentralized supply chain capability under that national plan using their capabilities to have inventory stockpiling available to them." To which so-called "drug shortage expert" Erin Fox replied: "That was great...They're definitely part of the solution." **The facts clearly show that they are *THE* problem!**

NASEM Recommendations:

- **Quality Transparency.** This report calls for more data that would provide transparency on drug quality, but says nothing about the lack of *financial transparency* on the secret dealings among GPOs, suppliers, and "authorized GPO distributors, on the one hand, and GPOs and their shareholder hospitals on the other. The only available data on the "fees" (aka kickbacks) paid by suppliers to GPOs are found in Novation "Excess Fee Reports" for 1998, 1999, and 2001 obtained through discovery in a federal whistleblower case against Novation and Becton Dickinson. These reports show that Novation extorted fees from suppliers that were sometimes in double-digits, and in at one case, more than half of the total revenue earned in one year by Ben Venue Laboratories for diltiazem, a cardiac medication. So the middlemen are making huge profits for awarding contracts, while the companies that actually make the drugs are forced to skimp

on maintenance, equipment upgrades, and quality control and ultimately, shut down production lines.

- **Quality Rating System.** NASEM, like the FDA, proposes a quality rating system. This is one of the most absurd recommendations in the report. It raises the question of how to create such a system if only one manufacturer---or sometimes none at all--is making a drug. (See p. 170). The GAO drug shortage report made it clear that there were two types of causes of drug shortages: underlying causes, and intermediate causes. GPOs were identified as a "potential underlying cause," whereas poor drug quality was correctly deemed an intermediate or secondary cause.

- **Contradictory Recommendations: Exclusive GPO contracts vs. Multi-Source Contracts?** Not only is the entire report at odds with overwhelming evidence on how GPOs broke the supply chain, but its own recommendations are also contradictory, to wit: Under the anti-kickback safe harbor business model, GPOs make their money by selling market share to suppliers in the form of sole-source contracts. The more market share a supplier wants, the more it has to pay in kickbacks. A portion of the GPO revenue is paid to GPO insiders and executives of major GPO shareholder facilities. These payments are called "share backs," but this information is not publicly available. On the one hand, the NASEM report states that "health systems that use GPOs could demand that contracts assure sourcing from a diverse array of suppliers for high-risk medical products (p. 191). Incredibly, on page 271, NASEM recommends that "purchasing groups offer incentives such as long-term exclusive contracts or guaranteed orders to motivate companies to invest in backup manufacturing facilities." Like "The Gang that Couldn't Shoot Straight," the NASEM committee couldn't even keep its story straight!

- **Threat to National Security.** NASEM calls for the federal government to "conduct an analysis" to determine whether a "threat to national security exists." Like many other NASEM recommendations, this is superfluous. We already know that these shortages are a clear and present threat to the national security of the United States (p.274). That threat would be eliminated by halting the kickbacks and share backs, enabling domestic generic drug manufacturers to earn enough to make these drugs safely and profitably in the U.S.

- **Proposed GAO Study.** NASEM proposes requiring a GAO study "to examine all aspects of the drug supply chain to see if there are any new issues exacerbating drug shortages." Fact is, the GAO has already done that study. It was published on February 10, 2014 but was all but ignored, most recently by NASEM. It identified GPOs as a "potential underlying cause." Drug shortages have persisted for more than 20 years. The issues are the same today as they were then: the corrupt GPO pay-to-play scheme. (p.274). In addition, in 2012, six senior members of the House Energy and Commerce Committee asked the GAO to conduct a separate investigation focusing specifically on the role of GPOs in

causing the shortages and fungal meningitis outbreak and inflating prices. But GPO lobbyists killed it.

- **Creation of a Separate Agency Outside of the FDA.** One study participant panned this recommendation, suggesting that the FDA create a "new center" within the FDA instead. That's also a nonstarter.

Conclusion: This tome isn't worth the real or virtual paper it's printed on. The evidence of research bias permeates the entire report. Instead of honing in or the real root cause of the unprecedented chronic shortages of lifesaving drugs, it presents a mind-numbing laundry list of putative causes and proposed solutions that are simply not actionable. ***It must be retracted.*** And since it was funded by the federal government, the Antitrust Division, Federal Trade Commission and other appropriate federal agencies should investigate the conflicts of interest that gave rise to this utterly useless report. It's a classic example of Occam's razor, which holds that when many explanations are given, the simplest is usually the right one.

We intend to copy other top federal officials with jurisdiction on this issue at the FTC, FDA, HHS, HHS Office of Inspector General, the White House National Security Council and National Economic Council and other federal agencies.

Feel free, of course, to contact us if you have questions or wish to discuss this further. A PDF file of this email is also attached. Kindly acknowledge receipt.

Respectfully,

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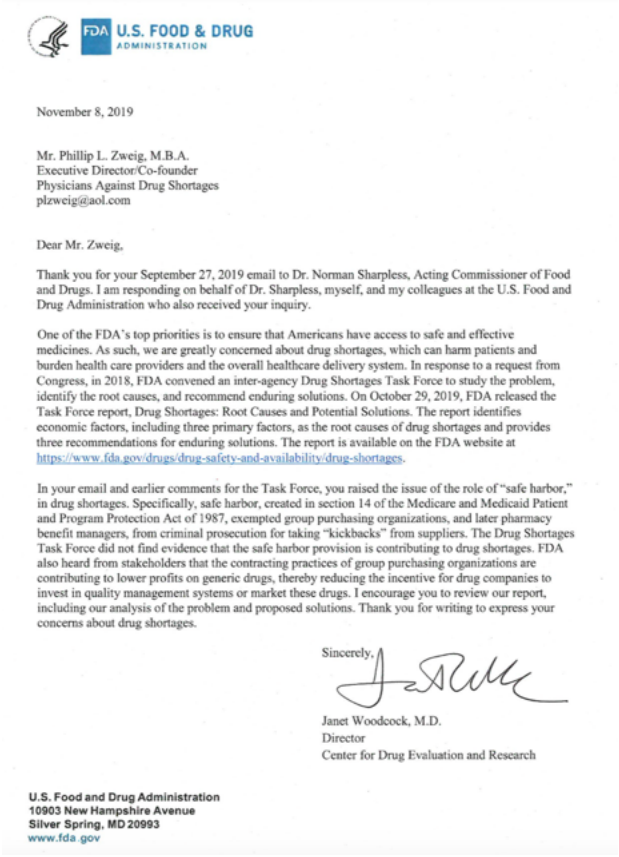

FDA U.S. FOOD & DRUG ADMINISTRATION

November 8, 2019

Mr. Phillip L. Zweig, M.B.A.
Executive Director/Co-founder
Physicians Against Drug Shortages
plzweig@aol.com

Dear Mr. Zweig,

Thank you for your September 27, 2019 email to Dr. Norman Sharpless, Acting Commissioner of Food and Drugs. I am responding on behalf of Dr. Sharpless, myself, and my colleagues at the U.S. Food and Drug Administration who also received your inquiry.

One of the FDA's top priorities is to ensure that Americans have access to safe and effective medicines. As such, we are greatly concerned about drug shortages, which can harm patients and burden health care providers and the overall healthcare delivery system. In response to a request from Congress, in 2018, FDA convened an inter-agency Drug Shortages Task Force to study the problem, identify the root causes, and recommend enduring solutions. On October 29, 2019, FDA released the Task Force report, Drug Shortages: Root Causes and Potential Solutions. The report identifies economic factors, including three primary factors, as the root causes of drug shortages and provides three recommendations for enduring solutions. The report is available on the FDA website at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

In your email and earlier comments for the Task Force, you raised the issue of the role of "safe harbor," in drug shortages. Specifically, safe harbor, created in section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, exempted group purchasing organizations, and later pharmacy benefit managers, from criminal prosecution for taking "kickbacks" from suppliers. The Drug Shortages Task Force did not find evidence that the safe harbor provision is contributing to drug shortages. FDA also heard from stakeholders that the contracting practices of group purchasing organizations are contributing to lower profits on generic drugs, thereby reducing the incentive for drug companies to invest in quality management systems or market these drugs. I encourage you to review our report, including our analysis of the problem and proposed solutions. Thank you for writing to express your concerns about drug shortages.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

U.S. Food and Drug Administration
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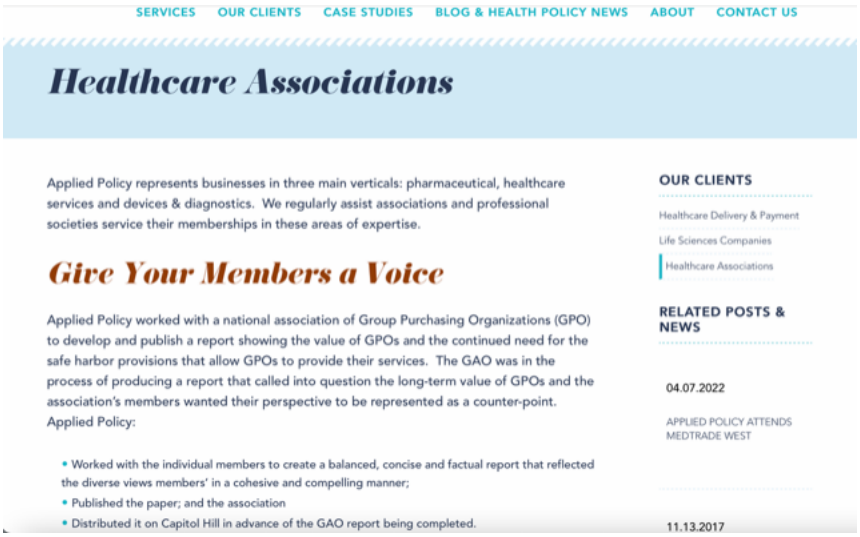

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Healthcare Associations

Applied Policy represents businesses in three main verticals: pharmaceutical, healthcare services and devices & diagnostics. We regularly assist associations and professional societies service their memberships in these areas of expertise.

Give Your Members a Voice

Applied Policy worked with a national association of Group Purchasing Organizations (GPO) to develop and publish a report showing the value of GPOs and the continued need for the safe harbor provisions that allow GPOs to provide their services. The GAO was in the process of producing a report that called into question the long-term value of GPOs and the association's members wanted their perspective to be represented as a counter-point. Applied Policy:

- Worked with the individual members to create a balanced, concise and factual report that reflected the diverse views members' in a cohesive and compelling manner;
- Published the paper; and the association
- Distributed it on Capitol Hill in advance of the GAO report being completed.

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LOBBYING ACTIVITY. Select as many codes as necessary to reflect the general issue areas in which the registrant engaged in lobbying on behalf of the client during the reporting period. Using a separate page for each code, provide information as requested. Add additional page(s) as needed.

15. General issue area code PHA

16. Specific lobbying issues

Reducing the costs of pharmaceuticals, medical devices, and supplies for consumers and health care providers, including implementation of the Drug Quality and Security Act (P.L.113-54) and P.L.112-144; support medical device pricing transparency and prohibition on medical device price "gag clauses"; preserving access to group purchasing organizations (GPOs) and protecting the GPO safe harbor; educating policymakers on hospital drug shortages and significant drug price increases and support draft reform legislation; pharmaceutical labeling of generic drugs (FDA-2013-N-0500); legislation to create a comprehensive Medicare home infusion benefit (H.R.605/S.275) - support; support reforming the durable medical equipment competitive bidding program; supporting "any willing pharmacy" legislation; promoting access to biosimilars (labeling/interchangeability); 21st Century Cures Act (H.R.6) - general support for overall bill, support final pharmacy lock-in policy, oppose PPSA weakening of existing requirements, oppose Section 4004 treatment of infusion drugs furnished through durable medical equipment; Ensuring Seniors Access to Local Pharmacies Act (H.R.793/S.1190) - support; Pharmacy and Medically Underserved Areas Enhancement Act (H.R.592/S.314) - support; MAC Transparency Act (H.R.244) - support; Medication Therapy Management Empowerment Act (S.776) - support; Strengthening Medicare Advantage Through Innovation and Transparency for Seniors - oppose; FDA-2014-D-1524-0002 - comments, Administration and Capitol Hill meetings on draft guidance on repackaging of certain human drug products by pharmacies and outsourcing facilities; FDA-2014-N-1459 - comments and Capitol Hill meetings on draft MOU addressing certain distributions of compounded human drug products between states and the FDA; proposed changes to the 340B prescription drug program - oppose; 21st Century Cures Act (H.R.6) - support; proposed amendments to 340b program (not ultimately included in H.R.6) - oppose; provide comments on proposed 340b omnibus guidance (RIN 0906 AB08); Stopping Medication Abuse and Protecting Seniors Act of 2015 (S.1913)- support (with some concerns about pharmacy lock-in policy); submitted comments on Management Standards for Hazardous Waste Pharmaceuticals (EPA-HQ-RCRA-2007-0932); meeting with DEA on Controlled Substances Act (21 USC 802); proposed changes to regulation of Laboratory Developed Tests (FDA-2011-D-0360-Draft Guidance for Industry, Food and Drug Administration Staff and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests) - oppose; Comprehensive Addiction and Recovery Act of 2016 ((S.524),monitoring for pharmacy lock-in policy, which includes exemption for LTC)- support; Increasing Competition in Pharmaceuticals Act (S.2615)- support.

17. House(s) of Congress and Federal agencies ☐ Check if None

U.S. SENATE, U.S. HOUSE OF REPRESENTATIVES, Centers For Medicare and Medicaid Services (CMS), Food & Drug Administration (FDA), Health & Human Services - Dept of (HHS), Health Resources & Services Administration (HRSA), Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA)

18. Name of each individual who acted as a lobbyist in this issue area

First Name	Last Name	Suffix	Covered Official Position (if applicable)	New
Kenneth	Raske			☐
Lee	Perlman			☐
Aisling	Zaccarelli			☐
David	Rich			☐

Impact Standardization Programs

Melissa Lyon Director Contract Services

vizient.

Impact Value

Vizient's Impact Standardization Programs drive sustainable member purchase commitment to participating awarded suppliers resulting in positive sales performance.

- Protection from competitive threats and rebidding
- Sustainable sales performance
- Pay for performance
- Program managed and administered on behalf of supplier
- Access to membership (80%)

More than
$7B
in sales flow through Impact Program annually


Dinesh S. Thakur Retweeted
Joseph Hill @JosephMHill · 24 Jul 2017
.@foxerinr and her team does a great job of tracking #drugshortages on ashp.org/shortages
vizient


Medication Access – Perspective from a Purchaser
Erin R. Fox, PharmD, BCPS, FASHP
HEALTH
UNIVERSITY OF UTAH

DISCLOSURE

- This presentation represents my own opinions
- University of Utah Drug Information Service receives funding from Vizient (a GPO) to provide drug shortage content
- University of Utah Health is Vizient member

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

Consultancies: Snehal Bhatt (Janssen Pharmaceuticals Inc.); Michael B. Bottorff (Esperion); James C. Coons (Medicure); Erin Fox (Civica Rx, Vizient); Kristen Gardner (Board of Pharmacy Specialties, biostrategies); Ian R. McGrane (Mountain Pacific Quality Health, Montana Mental Health Trust); Jo E. Rodgers (Novartis);

Stock Ownership:

Royalties: Ian R. McGrane (Hogrefe Publishing);

Grants: James C. Coons (United Therapeutics); Jo E. Rodgers (Novartis); Elizabeth K. Van Dril (Midwestern University Chicago College of Pharmacy)

Honoraria: Snehal Bhatt (Portola Pharmaceuticals); Amber Cipriani (Amgen); Erin Fox (Mayo Clinic, European COST Project, ASHP, ACCP, FDA, Drug Information Association, Joint Commission of Pharmacy Practitioners, University of Illinois, National Academy of Sciences, Engineering, and Medicine, American Society of Anesthesiologists, Anesthesia Patient Safety Foundation, Massachusetts Society of Health System Pharmacists, Idaho Society of Health System Pharmacists); Ian R. McGrane (University of Montana Skaggs School of Pharmacy, Montana Pharmacy Association, Northwestern Pharmacy Conference); Amber Cipriani (Amgen)

Other:

Nothing to disclose: Ohoud Almalki; Bassam Atallah; Michael Brenner; Laura Tsu Chen; Estella M. Davis; Katherine E. Di Palo; Shannon Finks; Mona Fiuzat; Gregory Shawn King; James C. Lee; Yee Ming Lee; Joel Marrs; Natasha Nicol; Manish Patel; Carrie S. Oliphant; Kathleen A. Packard; Mary Parker; Kelly C. Rogers; Cynthia A. Sanoski ; Andrew J. Smith; Dustin D. Spencer; Rebecca JC Tran; Benjamin Van Tassell; Ellen B. Yin; Monty Yoder; Eman Younis;

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Press releases

Baxter and Novation Sign Multi-Year Contract Extension Valued at Over $200 Million for Medication Delivery Products

Extension Provides Members of University HealthSystem Consortium With Broad Portfolio of IV Products

DEERFIELD, Ill., October 9, 2007 — Baxter International Inc. (NYSE: BAX) announced today that Novation, the University HealthSystem Consortium's (UHC) contracting services company, has signed a new two-year contract extension on behalf of UHC valued at over $200 million over the contract term. The extension will commence at the conclusion of UHC's previous multi-year agreement in mid-2008.

UHC, which includes most of the prestigious academic hospitals in the U.S., will continue to have access to Baxter's broad portfolio of intravenous (IV) solutions, drug delivery products, nutrition products, IV administration sets and components, and infusion pumps. Baxter received an extended single source award for IV solutions and maintained a previously established multi-source award for infusion pumps and sets.

"We are pleased to have been selected by Novation and UHC to provide life-sustaining drugs and medical devices to their members," said David Bonderud, president of the U.S. Region of Baxter's Medication Delivery business. "The new contract reflects our ongoing commitment to UHC to deliver value with our broad portfolio of Medication Delivery products."

About Novation and UHC

Based in Irving, Texas, Novation is the leading health care contracting services company, delivering unmatched savings and value to nearly 2,500 members of VHA Inc. and the University HealthSystem Consortium (UHC), two national health care alliances and nearly 9,000 members of Provista, LLC (formerly known as Healthcare Purchasing Partners International, LLC (HPPI)). Through its competitive bid process, Novation develops and manages contracts with more than 500 suppliers, both large and small. By combining scale and agility with clinical knowledge and product expertise, Novation offers the most extensive range of advanced contracting services, including: contract development, contract and supplier management, custom contracting, enhanced savings programs, online contract management and analytical tools, order management and online supplier connectivity. VHA, UHC and Provista members used Novation and alliance purchased services contracts to purchase $31.6 billion in 2006.

The University HealthSystem Consortium (UHC), formed in 1984, is an alliance of 97 academic

Masthead of the Journal of the American Society of Health-System Pharmacists

Duke Margolis Annual Report 2017 Advisory Board

Advisory Board Members



The Duke-Margolis advisory board is made up of exceptional leaders from all sectors of health care including payers, providers, researchers, policymakers and patient advocacy organizations. The group met in Washington, DC in February and in Durham, NC in November 2017. In addition, individual members have generously given their time and advice on Duke-Margolis project where they offer particular expertise.

The Duke-Margolis Center is overseen by Provost Sally Kornbluth and Chancellor of Health Affairs Gene Washington, who also serve on the Center's External Advisory Board, chaired by Robert J.

2017 Members

Robert J. Margolis, MD
Chair

Drew Altman, PhD
President and Chief Executive Officer, Henry J. Kaiser Family Foundation

David Brailer, MD, PhD
Managing Partner, Health Evolution

Tony Coles, MD, MPH (M'86)
Founding Investor, Chairman and Chief

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David Feinberg, MD, MBA
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Joseph Jimenez
Former Chief Executive Officer, Novartis

Jessica Mega, MD, MPH

Dan Mendelson, MPP
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Debra L. Ness, MS
President, National Partnership for Women & Families

Peter Orszag, PhD
Vice Chairman of Investment Banking & Global Co-Head of Healthcare, Lazard

Joseph R. Swedish, MHA (G '79)

Duke Margolis Annual Report 2018 Advisory Board

Advisory Board

The Duke-Margolis Advisory Board is an engaged and committed body of leaders who contribute their extensive national experience and perspective from all sectors of health care, including payers, providers, researchers, policymakers, and patient advocacy organizations. Meeting bi-annually, the Board collectively provides guidance on fulfilling the mission and vision of the Duke-Margolis Center. Board members also generously contribute their time, advice, and expertise to Duke-Margolis projects where they offer particular expertise.

The Duke-Margolis Center is overseen by Provost Sally Kornbluth and Chancellor of Health Affairs Gene Washington, who also serve on the Center's Advisory Board. Dr. Robert Margolis is chair of the Advisory Board and Duke-Margolis' director, Dr. Mark McClellan, Greg Daniel, PhD, MPH, deputy director, policy, Gillian Sanders Schmidler, PhD, deputy director, academics, Amanda McBroom, PhD, director of operations, and Patricia Green, director of communications, participate as members of the Center's Executive Leadership Team.

2018–2019 Members

Drew Altman, PhD
President & Chief Executive Officer, Henry J. Kaiser Family Foundation

David Brailer, MD, PhD
Managing Partner, Health Evolution

Tony Coles, MD, MPH (M'86)
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Leavitt Partners

Jessica Mega, MD, MPH
Chief Medical Officer, Verily (formerly Google Life Sciences)

Dan Mendelson, MPP
President, Avalere Health

Debra L. Ness, MS
President, National Partnership for Women & Families

Peter Orszag, PhD
Vice Chairman of Investment Banking & Global Co-Head of Healthcare, Lazard

Joseph R. Swedish, MHA (G'79)
Executive Chairman, Anthem Healthcare

Barbara Wachsman
Senior Advisor at Frazier Healthcare Partners

PADS Comments to HHS OIG of Feb. 16, 2021 on safe harbor: https://nebula.wsimg.com/5e3d638c13fcb2eac4a4049e065dfbe6?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1 (p.4)

TABLE showing compensation, including equity distributions from sale of Premier Inc. [PINC] shares, paid to top executives of the Greater New York Hospital Association (GNYHA) from 2014 to 2020 (p.4): https://nebula.wsimg.com/8a5fc890472c6b75c98983486f596efe?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

Vizient payments to Kevin Sowers RN, CEO of Johns Hopkins Hospital for 12 months ending **6/30/19**: https://nebula.wsimg.com/7561fd0bac0a58342ffc20a4c5c9efbc?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

6/30/20: https://nebula.wsimg.com/2ce9ea752653756f097d20aa5bc7a367?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

6/30/22: https://nebula.wsimg.com/b2f34d68521b9d68ecbb1a97d1cde406?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1 (p.4)

PADS civilian criminal complaint of May 7, 2015 to the Department of Justice, Southern District of New York, Public Integrity unit, against the Health Care Supply Chain Association and its president, Curtis Rooney: https://nebula.wsimg.com/cf7be2f3c304b300bb65074be7bf74fb?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1. (p. 7)

CivicaRx president Martin Van Trieste letter of Oct. 31, 2018 to the FDA explaining that the nonprofit drugmaker would not pay “fees” to middlemen: https://nebula.wsimg.com/: https://nebula.wsimg.com/e5000a11cecd66b74b8cfea74eeab127?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1. (P.14)

"Safe Harbor Cost Analysis” (updated April 2, 2024: https://nebula.wsimg.com/6d8b8a93bb8e7651d4300550dfbebffc?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1. (p.18)

HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

September 17, 2013

Dr. Michael A. Rie
c/o University of Kentucky
800 Rose Street
Lexington, KY 40536

Dear Dr. Rie,

We are writing in response to your recent opinion editorial in the *New York Times* ("How a Cabal Keeps Generics Scarce," 09/04/13), which contains demonstrably inaccurate, damaging and potentially libelous statements about healthcare group purchasing organizations (GPOs). We ask that you retract your statements made in the *New York Times* and everywhere they have been published.

In your piece, you identify GPOs as the cause of the current sterile injectable drug shortages but offer no evidence to support that conclusion. You further claim that GPOs have "reduced the number of suppliers" in the generic drug market and "crimped investment in maintenance and quality control, resulting in adverse F.D.A. inspections and plant closings," but do not offer any evidence in support of those claims.

You characterize GPO contract administrative fees as both "exorbitant" and "undisclosed," neither of which is accurate. A 2010 Government Accountability Office (GAO) report on group purchasing organizations found that the average GPO administrative fee ranged from 1.22 to 2.25 percent. Medical device vendors interviewed for the report indicated that they were now paying even lower administrative fees as a result of transparency initiatives voluntarily undertaken by GPOs. Further, under the same Medicare statute cited in your piece, GPOs are required to disclose their administrative fees at least annually to members and upon request to the Secretary of the U.S. Department of Health and Human Services (HHS).

You identify GPOs as "cartels" and repeatedly cite GPO "kickbacks;" however, Congress codified existing GPO business practices as part of the Medicare Anti-Kickback statute to protect the cost savings that GPOs deliver to the healthcare system and to make express their belief that GPO administrative fees were not kickbacks.

You vaguely cite "antitrust lawsuits" and "more government investigations" into GPO conduct, but do not disclose the outcomes of those lawsuits and investigations: GPOs are properly regulated, deliver cost savings, and are adhering to the law. Instead, you make a vague allusion to the "enormous" political clout of GPOs – an industry roughly one-tenth the size of the medical device industry – and provide no evidence of same.

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