# *Physicians Against Drug Shortages (PADS)*

Request for Investigation/Civilian Criminal Complaint v. Healthcare Supply Chain Association (HSCA) & CEO Curtis Rooney [18 U.S.C. 1505, Obstructing Congressional or Administrative Proceedings]

May 7, 2015

Mr. Arlo Devlin-Brown
Chief, Public Corruption Unit
U. S. Department of Justice
Southern District of New York
New York, N. Y.

Dear Mr. Devlin-Brown:

Thank you for the opportunity in early April to discuss our allegation that the Healthcare Supply Chain Association (HSCA), the Washington-based trade group of the hospital group purchasing (GPO) industry, and possibly one or more of its member companies and other parties, violated federal criminal statutes (18 U.S.C. 1505, Obstructing Congressional or Administrative Proceedings) by shutting down an ongoing Government Accountability Office (GAO) investigation into the role of GPOs in causing the national generic drug shortage crisis and the 2012 fungal meningitis outbreak. I appreciate your inviting me to write you with details and documentation and for offering to share my letter with the Justice Department's Public Integrity unit in Washington. Accordingly, please consider this email our formal request for a Justice Department investigation into this matter. What follows are relevant documents and other information in support of our request.

We recognize that every citizen or organization in the U. S. has a constitutional right to advocate for its position, right or wrong, on any public or private issue. They also have a right to use all legal means available to them to attempt to avoid government investigations. However, we are confident that a thorough DOJ inquiry will show that the actions of HSCA, and possibly other entities, went far beyond this. They did not merely defend their position before the GAO. They derailed a formal, ongoing

investigation into their role in causing a public health emergency that has denied millions of patients access to affordable lifesaving generic drugs. As things now stand, that means there is little hope for an end to generic drug shortages and skyrocketing prices anytime soon.

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]

For a primer on the underlying issue, see our *New York Times* op-ed of September 3, 2013, "How a Cabal Keeps Generics Scarce," which appears on our website, www.physiciansagainstdrugshortages.com. The website includes extensive documentation, including links to four Senate Antitrust Subcommittee hearings and other federal and state investigations, media reports, antitrust lawsuits, and independent studies on anticompetitive GPO contracting and pricing practices, self-dealing, kickbacks and other abuses.

The GAO investigation was requested on November 15, 2012 in a letter from then-Congressman Ed Markey (D-MA) and five senior House colleagues to Eugene Dodaro, then Acting Comptroller General of the United States. That day, Mr. Markey and his House colleagues issued a press release, along with the letter, announcing their request for the investigation. Here's the link to the Markey letter: http://nebula.wsimg.com/b3e478ca03592cc3991d62552a671772?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

Immediately after Markey *et al* released their letter, Curtis Rooney, president of HSCA, and his allies began pulling out all the stops to quash the investigation.

On November 19, 2012, Mr. Rooney wrote to Rep. Markey and his colleagues to complain about their request for an investigation. Mr. Rooney's letter was replete with outright fabrications, factual errors, and half truths about GPOs and me personally: http://c.ymcdn.com/sites/higpa.site-ym.com/resource/resmgr/GR_and_PR_Materials/

HSCA_Letter_to_Reps__Markey_.pdf. Ms. Sara Schaumburg, who handled this assignment for Rep. Markey, later told me that Mr. Rooney and other HSCA officials, in a meeting in Rep. Markey's office, attempted to pressure her into withdrawing the request for the investigation, insisting that GPOs were not the cause of the drug shortages. She replied: "If that's the case, then the GAO's report will reflect that," or words to that effect. But Mr. Rooney knew that the GPO "pay-to-play" business model, and the GPO industry itself, could not survive a thorough, honest GAO investigation. Ms. Schaumburg apparently left Mr. Markey's office in mid-2013, about the time he was elected to the U. S. Senate in a special election. She has not returned emails I've sent to her personal email address seeking to discuss this matter. Neither has her supervisor, Ms. Avenel Joseph, who has continued to serve as Sen. Markey's healthcare legislative assistant.

Several individuals, including myself, provided information and documentation to Rep. Markey's staff that prompted them to conduct their own due diligence and subsequently request the investigation.

During this time, at least two other experts—Dr. Sherry Glied PhD, a former assistant secretary of the Department of Health and Human Services, and Ms. Margaret "Meg" Clapp, R.Ph, then chief of pharmacy at Massachusetts General Hospital---with first hand knowledge of the role of GPOs in causing the drug shortages contacted Ms. Schaumburg to provide information supporting the GAO investigation. According to Ms. Clapp, Novation LLC, MGH's primary GPO, learned about this and attempted to pressure her into signing a document recanting her statements to Rep. Markey's staff. She refused. After she resigned in late December 2012, Novation tried to hire her to keep her quiet. She declined. Instead, she joined PADS to continue to help expose the role of GPOs in this crisis. Her efforts include this January. 20, 2015 presentation to the Society of Critical Care Medicine annual Congress in Phoenix: http://sccmmedia.sccm.org/video/Congress/CCC44/Plenary/default.htm

On April 29, 2013, four of our physician members and I met for two hours with the GAO's healthcare staff at the agency's Washington headquarters. Having published several reports critical of the GPO industry since April 2002, they seemed eager to pursue this investigation and asked for a copy of my slide presentation and other materials. Over the next 18 months, until October 2014, we continued to communicate with GAO staff via email and to provide them with extensive documentation on how the GPOs caused

the failure of the generic injectable marketplace. We were confident that the requesters and the GAO would resist pressure from this powerful cabal. Sadly for patients and providers, we were wrong. I would be pleased to provide you with these emails on request.

Their report was initially scheduled for publication in the summer of 2014. Last August, a GAO staffer informed us that it would be released in the fall. At no time did they give us any indication that the focus of their investigation had changed.

In September 2013, the publication of our *New York Times* op-ed produced more evidence of the GPO cabal's practice of intimidating critics of the industry's dubious business practices. A couple of weeks later, my co-authors received letters (see attachment) from Mr. Rooney hinting at a possible libel lawsuit if they didn't "retract" their statements in the "*New York Times* and everywhere they have been published." Mr. Rooney obviously knew better than to send me such a letter, and I advised them to simply ignore theirs. At about this time, HSCA launched a website to disparage PADS and me personally: http://www.drugshortage.org/p/physicians-against-drug-shortages.html.

These developments were just the latest examples of the heavy-handed tactics this industry has used for years to bully its detractors, including at least two individuals who testified at hearings before the U. S. Senate Antitrust Subcommittee on anticompetitive GPO business practices. A physician who testified told me later that he lost research grants because of his statements; a supply chain consultant said that after he appeared as a witness his hospital practice virtually dried up. More recently, I was informed that Mr. Rooney, an alumnus of Catholic University Law School, threatened to "destroy" the law school career of the student editor of the school's *Journal of Contemporary Health Law and Policy,* if he published an article critical of the GPO industry. To their credit, the editor and his professors ran the article, entitled "An Empirical Analysis of Aftermarket Transactions by Hospitals," in their fall 2011 issue. [The article concluded that if the kickback-based, "pay-to-play" business model were eliminated, U. S. hospitals would save at least $30 billion annually in supply costs.] Contracting officers who have questioned the legality or ethics of their employers' business practices have been summarily dismissed. *The New York Times* of November 18, 2007 recounted the story of Cynthia Fitzgerald, who filed a *qui tam* lawsuit against Novation, one of the three

largest GPOs, after the company fired her: http://www.nytimes.com/2007/11/18/business/18whistle.html?pagewanted=all&_r=0.

We were further encouraged about the GAO's apparent commitment to the GPO investigation by the publication of its February 10, 2014 drug shortages report, which cited GPOs as a "potential underlying cause" (p. 31). That report, entitled "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," was mandated by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA): http://www.gao.gov/assets/670/660785.pdf. Significantly, it described other other putative causes—manufacturing delays, quality problems, raw materials shortages and the like—as "immediate" or secondary causes. Further, the report noted that three of the generic drug makers the GAO interviewed pointed to GPOs as a key cause of the shortages.

This report undermined the false and misleading explanation for the shortages that the GPOs had been disseminating for years. Not surprisingly, a February 10, 2014 HSCA press release completely misrepresented the GAO's conclusions about the causes of the crisis. There was no mention, of course, that the GAO report cited GPOs as a "potential underlying cause."

The GPOs and their allies would have policymakers, Obama Administration officials, the healthcare community, and the public believe that the causes of this unprecedented crisis are "complex and multifactorial," or a "perfect storm"--- in other words, one of the great unsolved mysteries of the universe. Since early 2011, when drug shortages started making headlines in the general media, the GPO spin machine has churned out an endless stream of bogus "studies" and press releases claiming that they were caused by allegedly unscrupulous "gray market" distributors, "just-in-time" inventory methods, manufacturing problems, allegedly "over zealous" FDA inspections, government price controls, and raw materials shortages. The causes of cancer are surely complex and multifactorial, but *not* the causes of the shortages of drugs used to treat it. There is one underlying cause: GPOs. Their "pay-to-play" scheme has decimated the U. S. generic injectable industry and unleashed a global public health emergency.

Other documents, including an article by a senior Food and Drug Administration official (Wosinska, *Bloomberg Brief*, November 11, 2013) and a report published by the FDA ("Strategic Plan for Preventing and

Mitigating Drug Shortages," October 31, 2013), indicated, if somewhat circumspectly, that the agency was well aware of the key role GPOs have played in causing the shortages. A June 15, 2012 report by the House Oversight and Government Reform Committee also cited GPOs as a key contributor.

The healthcare media were also expecting the GAO report to address the GPO role in the drug shortages. On October 21, 2014, *Modern Healthcare* published a "Healthcare GPOs promote positive influence ahead of GAO report," indicating that the GPOs were scrambling to preempt the long-awaited study. Obviously, they succeeded, in part by unleashing a barrage of spurious "studies"—all bought and paid for by the GPO cabal, of course—falsely claiming, among other things, that GPOs save billions of dollars for hospitals.

Instead, on November 24, the Government Accountability Office released a sham report entitled "Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs":http://www.gao.gov/products/GAO-15-13." This report, like the drug shortage crisis itself, is a travesty, to put it mildly. It has nothing to do with drug shortages. In fact, the term "drug shortages" is mentioned only three times in passing, including one footnote. It is an flagrant cover-up. But it also demonstrates beyond any doubt that the GPOs knew that they could not survive a *bona fide* GAO investigation.

We were astonished that this report was based on little more than the responses of the five largest GPOs to a GAO questionnaire. The rest is a rehash of earlier reports and investigations by the GAO, HHS and other agencies. The GPOs were even given a draft copy for their comments. We were not, even though we were instrumental in initiating this "investigation." Clearly, the GPOs were even able to arrange for the report to be released three days before Thanksgiving, when it would receive little media attention. Note also that PADS was cited in the February 10 report as one of the organizations interviewed for the study. There was no mention of PADS in the November 24 report.

The GPOs had managed to co-opt the White House, Food and Drug Administration, the Department of Health and Human Services, Congress, the media, and contributors and editors of respected medical journals like the *New England Journal of Medicine*. They would have us believe that the

GPOs were working heroically to end the shortages, as reflected in this April 21, 2014 Novation press release: Click HERE .

Now they've co-opted the GAO, which has long prided itself as the "independent, non-partisan investigative arm of Congress." It is clear now that the GAO, like Congress itself, is a prisoner of special interests. We have already highlighted this in two op-eds and will continue to do so. We had hoped that this report would pave the way for an end to drug shortages and surging generic drug prices through the repeal of the 1987 Medicare anti-kickback safe harbor, which would restore market competition and integrity to the hospital supply chain. Now we see no end in sight to this crisis.

On or about December 8, 2014, I spoke with Adam Trzeciak, the GAO's Inspector General, to ask him to investigate how this investigation was shut down. He assured me that his top investigator would follow up with me to discuss this. On December 16, Howard Arp, an assistant IG for investigations, called me. After I outlined the problem, he replied by saying that this was not the kind of matter the IG usually investigates, adding that he did not want to go on a "fishing expedition." He seemed to expect me to provide him with internal documents that I would have no access to. By the end of the conversation, I was left with the impression that he would have been more comfortable investigating the theft of a box of ball point pens by a GAO employee than a matter of critical national importance like this one.

You should also be aware that I have been in touch with the Justice Department's Antitrust Division concerning its ongoing investigation into skyrocketing generic drug prices, which has been reported in the media. Last month, I talked with Ms. Sonia Mittal, explaining that this approach puts the cart before the horse. The shortages have caused the price spikes. This is Economics 101. If the Antitrust Division approached the task by seeking to understand the real root cause of the shortages, they would understand the underlying cause of the price spikes. And that would lead them to the GPOs' doorstep.

I should add here that for at least 18 years, countless individuals, companies, organizations and members of Congress have lodged formal complaints with the Justice Department and Federal Trade Commission about anticompetitive GPO abuses. [Several letters from former and sitting

United States senators to various attorneys general are posted on our website]. For reasons that remain a mystery, these agencies never took corrective action. The result: global generic drug shortages. Indeed, the very existence of chronic shortages affecting an entire industry—in the absence of government price controls--- itself implicates anticompetitive activity, according to antitrust attorneys.

Accordingly, we respectfully call on you and your Department of Justice colleagues to investigate this urgent matter at your earliest possible convenience. Not only is the well-being of millions of patients  at stake, so is the much-vaunted reputation of the GAO. I would be pleased to discuss this with your further and provide you with additional information and documentation at your request.

Full disclosure: PADS members have no conflicts of interest and no vested financial interest in this issue. PADS receives no outside funding. We are all working on this project *pro bono* and are covering our expenses out of our own pockets.

I look forward to hearing from you soon. Kindly acknowledge receipt.

Sincerely yours,

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cc Robert A. Campbell MD
Chairman, ***PADS***
President, Pennsylvania Society of Anesthesiologists
[Note: Dr. Campbell is no longer associated with PADS.]