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Subject:
Date: November 26, 2018 at 10:05 PM
To:



Physicians Against Drug Shortages (PADS)

MEDIA ALERT: REQUEST FOR COVERAGE

Attn: Healthcare/Healthcare Business/Policy Reporters & Editors

November 26, 2018

Has the Hospital Group Purchasing Industry Hijacked Tuesday's FDA Meeting on Drug Shortages? Sure Looks That Way

Presenters Employed by or Have Financial Ties to Industry Responsible for Chronic Shortages, Skyrocketing Prices

New York—On September 8, when the Food and Drug Administration announced that it would hold an all-day public meeting Nov. 27 in Washington on the “root causes” of the drug shortage crisis, we were hopeful that the agency finally planned to address what we, generic drug makers, and top healthcare officials have known for years: that the unprecedented artificial shortages and exorbitant prices of lifesaving drugs were caused by the anticompetitive contracting and pricing practices, self-dealing, conflicts of interest, kickbacks and rebates of giant hospital purchasing organizations (GPOs) and pharmacy benefit managers (PBMs).

These abuses have been exhaustively documented in four Senate Antitrust Subcommittee hearings, federal and state investigations, media reports, antitrust lawsuits, and independent studies. They were enabled by the unsafe 1987 Medicare anti-kickback “safe harbor” statute, which exempted GPOs and later, PBMs, from criminal prosecution for taking kickbacks and rebates from suppliers. This misguided legislation gave rise to a “pay-to-play” scheme in which GPOs literally sell sole-source, long-term contracts to vendors in return for outrageous “fees” and rebates—thereby undermining competition, crimping

drug makers' ability to maintain quality control, and inflating healthcare costs. PADS was founded in 2012 to restore competition and integrity to the healthcare drug and supply chain through congressional repeal of the safe harbor.

For a primer on this issue, read the *Journal of the American Medical Association (JAMA)* of October 18, 2018 and *Wall Street Journal* op-ed of May 8, 2018, "Where Does the Law Against Kickbacks Not Apply? Your Hospital." For these and other articles and documentation, visit www.physiciansagainstdrugshortages.com. See also attached GPO/PBM Fact Sheet and *DRUG SHORTAGES: THE MOVIE!*: <https://www.youtube.com/watch?v=aQhsPLcFwN8&t=20s>.

Our optimism was bolstered by several earlier developments, including:

- *Associated Press* report of July 12, in which FDA Commissioner Scott Gottlieb M.D. blamed GPOs and PBMs for causing the shortages by undermining the profitability of the generic drug industry: <https://apnews.com/998a244e3ac849b787bcd3c893eb6806>
- Proposal of July 18 by Department of Health and Human Services to rescind GPO anti-kickback "safe harbor" protection for PBM rebates, which was quietly extended to PBMs in 2003 by the HHS Office of Inspector General: <https://www.reginfo.gov/public/do/eAgendaViewRule?publd=201810&RIN=0936-AA08>.

So we were alarmed when the Duke-Margolis Center for Health Policy, which the FDA tapped to organize the meeting, released the final agenda: https://healthpolicy.duke.edu/sites/default/files/atoms/files/duke-drug_shortage_task_force_agenda_2018-11-19_3.pdf. The participants are a "Who's Who" of the GPO cabal: Blair Childs (Premier Inc., 2nd largest GPO), Todd Ebert (Healthcare Supply Chain Assn. the GPO trade group), Erin Fox (Vizient, largest GPO), David Gaugh (former Vizient, Ben Venue Laboratories), AmerisourceBergen (a "Big Three" GPO-authorized distributor), and others with a vested financial interest in protecting the kickbacks and rebates.

What's more, the advisory board of the Duke-Margolis Center includes none other than Premier Inc. CEO Susan DeVore; Geisinger Health, whose subsidiary Geisinger Systems is a Premier Inc. shareholder; and Dan Mendelson, president of Avalere Health, whose "consulting" clients include HSCA. [Avalere has produced at least two "sponsored studies" bought and

... [The report was prepared at least five sponsored studies, begun and paid for by the trade group, defending the industry's role in the drug shortages.] Here's the link to the advisory board:

<https://healthpolicy.duke.edu/advisory-board>. Even though PADS chair Robert A. Campbell M.D. had met with top FDA staff on this issue and was designated an "external drug shortages stakeholder," neither he nor I, nor any of our other members was invited to participate. It is also very troubling that the agenda was released two days before Thanksgiving and allows just 30 minutes for public discussion.

As FDA commissioner and administrator of the Centers for Medicare and Medicaid Services (CMS) during the administration of President George W. Bush, Center Director Dr. Mark B. McClellan would surely be aware of the GPO industry's checkered history. At CMS, he was presented with this report on the failure of surveyed hospitals to properly report GPO net revenue distributions [share backs] on Medicare cost reports as required by law: <https://oig.hhs.gov/oas/reports/region5/50300074.pdf>.

In fact, since 2011, GPO abuses have been cited in congressional testimony and multiple government and independent studies as an "underlying" cause of the drug shortages:

- **Government Accountability Office drug shortage report of Feb. 10, 2014, which was mandated by Congress, identifies GPOs as a key "underlying cause" p. 31:**
<https://www.gao.gov/assets/670/660785.pdf>
- Testimony of HHS Assistant Secretary for Health Howard K. Koh M.D. and FDA Deputy Director Sandra Kweder M.D. before the House Energy and Commerce Committee hearing of September 23, 2011, pages 47 & 60: <https://www.gpo.gov/fdsys/pkg/CHRG-112hrg77032/pdf/CHRG-112hrg77032.pdf>.
- Testimony of HHS Assistant Secretary Sherry Glied PhD before the Senate HELP Committee, Dec. 15, 2011: <https://www.gpo.gov/fdsys/pkg/CHRG-112shrg88253/html/CHRG-112shrg88253.htm> [plus interviews, articles, studies].
- American Antitrust Institute, white paper, May 7, 2012: <https://nebula.wsimq.com/9eac00b40b600ecec8d5d752e948f6c8?>

<https://nebola.wsimg.com/de59574b9bab201bfe74214d2d74a059?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>

- House Oversight & Government Reform Committee report on drug shortages, June 15, 2012, p. 9:
<https://nebola.wsimg.com/de59574b9bab201bfe74214d2d74a059?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>
- Request by Rep. Ed Markey *et al* to Government Accountability Office for investigation into GPO role in drug shortages, fungal meningitis outbreak, Nov. 15, 2012:
<https://nebola.wsimg.com/ed50521c4abf43dd01aa0f3c2acd0732?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>.
[Investigation derailed by GPO lobbyists].
- Report on Drug Shortage Summit of Apr. 18, 2013, p. 8:
<https://nebola.wsimg.com/ad5cd3aea84567f1a3b2f1197f039ead?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>.
- Federal Trade Commission conference on drug market competition, GPO panel, Nov. 8, 2017: <https://www.ftc.gov/news-events/audio-video/video/understanding-competition-prescription-drug-markets-panel-3>.

A bipartisan bill to repeal the safe harbor was drafted in 2005 by Senators Herb Kohl (D-WI) and Mike DeWine (D-OH) of the Senate Antitrust Subcommittee but was killed by GPO and hospital lobbyists:
<https://nebola.wsimg.com/c99adc9e677ccde51187b87fa5de42a7?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>. If it had been enacted then, the drug shortage debacle arguably would never have happened. The bill was resurrected in 2017 but never introduced.

FULL DISCLOSURE: PADS is a 140+ member, *pro bono* patient advocacy group whose sole mission is to stop the shortages and skyrocketing prices of drugs by restoring market competition and integrity to the healthcare supply chain. That can only be accomplished by congressional repeal of the anti-kickback safe harbor for GPOs and PBMs. We have no budget and no conflicts of interest. We cover expenses out of our own pockets.

Several PADS physician members and I will be available during and after the meeting to discuss this urgent healthcare issue with the media. Here's the link to sign up to watch online: <https://healthpolicy.duke.edu/events/drug-shortage-task-force>.

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