



ANESTHESIOLOGY NEWS



AN



Commentary

OCTOBER 25, 2018

Identifying the Root Cause of Drug Shortages: A Call to Action

John G. Brock-Utne, MD, PhD

Professor of Anesthesiology (Emeritus)

Department of Anesthesiology, Perioperative and Pain Medicine

Stanford University Medical Center

Stanford, California

How could drug shortages happen in a free enterprise country like the United States?

Actually, it's pretty simple: There is a kickback system approved by Congress that has undermined competition and profitability in the drug/IV fluid market.

How? Because many drugmakers and other suppliers have been locked out of the hospital marketplace by group purchasing organizations (GPOs), which contract for most of the drugs and supplies used in 5,000 American hospitals and other facilities. Since GPOs award exclusive, often sole-source contracts to favored drug/IV suppliers in return for steep (but secret) "fees" and rebates, companies that don't get contracts can't compete and are forced to halt production.

ADVERTISEMENT

But it gets worse. GPOs mandate that their member hospitals (most U.S. hospitals are members of at least one GPO) buy virtually all of their drugs/IV fluids from contracted suppliers. They're generally not permitted to buy these and other supplies from companies that don't have GPO contracts.

When you attempt to investigate this appalling situation, you hit a stone wall. There is no transparency on GPO contracts and financial arrangements, which include kickbacks and rebates for GPOs and "share backs" and "patronage fees" for hospitals. Not surprisingly, hospitals don't want to discuss this obvious conflict of interest.

Under this perverse system, dominant drug and IV fluid suppliers enjoy a protected market with little or no competition. GPOs, which do nothing more than write exclusive contracts, are making huge profits. The CEOs of major GPO shareholder hospitals often get a piece of the action. Everyone is happy—except the unfortunate patient who may have to endure a very painful operation and side effects due to the lack of suitable analgesics and high hospital/insurance expenses.

ADVERTISEMENT

This debacle was created by an obscure 1987 statute, known in shorthand form as the Medicare anti-kickback “safe harbor,” which exempted GPOs from criminal penalties for taking kickbacks and rebates from suppliers. This is the only industry in America I know of that has gotten a “Get Out of Jail Free” card from the U.S. Congress!

If that wasn't enough, in 2003, the Inspector General of the Department of Health and Human Services (HHS) extended the GPO safe harbor to cover pharmacy benefit manager (PBM) rebates, driving up prices of drugs sold by these predatory middlemen. The Trump administration has proposed rescinding this safe harbor administratively. For more on that, see the *Washington Post* article from Aug. 28, 2018 ([wapo.st/2Re8XEK](https://www.washingtonpost.com/news/energy-environment/wp/2018/08/28/health-care-industry-gets-out-of-jail-free-card-from-congress-but-trump-administration-wants-to-rescind-it/)). But full repeal of the GPO safe harbor requires an act of Congress. So please, Congress, for heaven's sake, repeal 42 US Code 1320a-7b(b)(3)(C) and direct HHS to revoke any and all rules and regulations that protect these “legalized” kickbacks and rebates!

Drug shortages in an advanced country like the United States are a disgrace, but they can easily be ended by those in power. The trouble is members of Congress get paid by the GPO and hospital industries and their cohorts to preserve the kickbacks and rebates. Those payments are called “campaign contributions.”

So what can you do?

1. You can submit a comment in response to an Aug. 27 “Request for Information” (RFI) from the Office of Inspector General (OIG). The OIG is seeking information on any aspect of the anti-kickback statute, including the GPO's “safe harbor,” that impedes “value-

based” care. Click on this link and follow the instructions: bit.ly/2CF8GH1.

If you have insights into and/or examples of how the GPO and PBM safe harbors have also undermined innovation in medical devices, health care access and delivery, competition, jobs and so on, include them too. Feel free to cite the extensive documentation on this national scandal on the website of Physicians Against Drug Shortages (PADS), which for six years has been leading the charge in trying to reform this corrupt system: www.physiciansagainstdrugshortages.com.

THE DEADLINE FOR THE HHS OIG COMMENTS IS: Oct. 26, 2018 at 5 p.m. (EDT)

2. In addition, on Nov. 27, the FDA is holding an all-day public meeting in Washington, D.C., on the root cause of drug shortages. If possible, consider attending in person to make your voice heard. Whether you attend or not, please submit a comment to the FDA. Here’s a link for more information: bit.ly/2RhaE4A. To register for the meeting, click here: bit.ly/2O8j24m. Everyone who can attend should register now, since space is limited.

THE DEADLINE FOR THE FDA COMMENTS IS: Jan. 11, 2019.

3. Contact your Congress members and tell them you are fed up with the shortages and skyrocketing prices of medications. Insist they stop the GPO/PBM kickbacks and rebates by repealing the unsafe safe harbor statute.

4. Help get this message out by contacting family, friends and colleagues via email and your social media pages.

5. Sign the PADS’ Change.org petition calling for repeal of the safe harbor, here: bit.ly/2D3P4xj.

Together, we can restore integrity and competition to the health care supply chain and stop the drug shortage travesty!

6. And if you won’t take my word for it, here are two links that you can also distribute to friends and family:

- This is an online article on GPOs and drug shortages published by the *Journal of the American Medical Association (JAMA)* on Oct. 18, 2018: bit.ly/2yNJxq4.
- You can check out this article from Modern Healthcare, dated Oct. 19, which commented on the *JAMA* “Viewpoint” piece: bit.ly/2yQvcJz.

Editor’s note: The views expressed in this article belong to the author and do not necessarily reflect those of the publication.

Related Keywords

[Drug Shortages](#) [Congress](#) [IV drugs](#)