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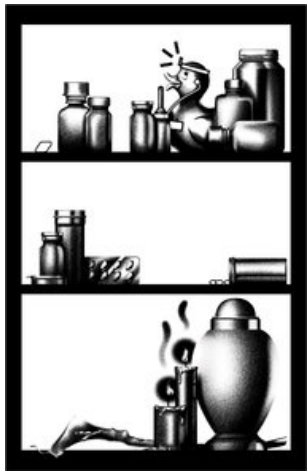
## How a Cabal Keeps Generics Scarce

By MARGARET CLAPP, MICHAEL A. RIE and PHILLIP L. ZWEIG

Published: September 2, 2013 | 158 Comments | 216 Comments | 216 Comments

ABOUT a year ago, President Obama signed a law that was supposed to end chronic shortages of lifesaving drugs. But the critical lack of generic drugs continues unabated. It is a preventable crisis that is inflicting suffering on patients and, in some cases, causing needless deaths.

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Dan Stafford

According to the American Society of Health-System Pharmacists, a group that maintains a closely watched drug-shortage database, 302 drugs were in short supply as of July 31, up from 211 about a year earlier.

The new law, which among other things requires manufacturers to report anticipated shortages, is ineffective because it addresses symptoms, not the underlying economic cause. Policy makers apparently failed to ask the important question: How could this happen in a free-market economy? That would have steered them to the giant purchasing organizations that control the procurement of up to \$300 billion in drugs, devices and supplies annually for some 5,000 health care facilities. These cartels have undermined the laws of supply and demand.

Most of the drugs in short supply are sterile injectables that have been cheap mainstays for decades. They're generally administered in hospitals and outpatient clinics and sold through hospital purchasing organization contracts, not through retail pharmacies or pharmacy benefit managers.

Scarce or unavailable drugs include anesthetics, chemotherapeutic agents, [antibiotics](#), nutrients for malnourished infants, painkillers and even intravenous solutions. Physicians have been forced to improvise with less desirable or more expensive substitutes. One study

reported in an issue of The New England Journal of Medicine last December found that children with [Hodgkin's disease](#) were at greater risk of relapse because the most effective generic, mechlorethamine, wasn't available. [Propofol](#), the preferred anesthetic for many surgical procedures, is scarce because there's just one supplier of the generic in the United

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States in full production.

Improvisation has caused some patients to wake up during operations — or not at all. A March 2012 survey by the American Society of Anesthesiologists, in which about 3,000 members responded (out of around 50,000), attributed six deaths, as well as other adverse outcomes, to shortages of drugs.

A deadly outbreak of fungal [meningitis](#), which was first identified last September in Tennessee, was triggered by shortages of a [steroid](#) painkiller, prompting providers to turn to the now bankrupt New England Compounding Center, which, as a so-called compounding pharmacy, was not held by the [Food and Drug Administration](#) to the same stringent standards as regular drug manufacturers. The pharmacy's sister company, Ameridose, which has also been closed, had supply contracts with five of the largest American hospital purchasing organizations: MedAssets, Novation, Premier, HealthTrust and Amerinet. This tragedy had killed 63 and sickened 749, according to the Centers for Disease Control and Prevention.

The Government Accountability Office is investigating the role of the group purchasing organizations in the shortages and the meningitis debacle. The agency's report is expected in 2014.

The F.D.A. has permitted temporary imports, which almost surely have created shortages in other countries. That's because there is finite global manufacturing capacity; production cannot be ramped up overnight. Hospitals are rationing medications, while their pharmacists spend untold hours scrambling to find them.

The economic root cause is simple: the purchasing organizations have squeezed manufacturers' operating margins to razor-thin levels. By awarding select suppliers exclusive contracts in return for exorbitant (and undisclosed) "administrative," marketing and other fees, they have reduced the number of suppliers to just one or two for many generics. Further, they've crimped investment in maintenance and quality control, resulting in adverse F.D.A. inspections and plant closings.

This perverse system was created in 1987 when Congress enacted the [Medicare](#) anti-kickback "safe harbor," which exempted these buying organizations from criminal prosecution for accepting vendor kickbacks. Spurred by a 2002 New York Times investigation into anticompetitive purchasing group practices, Congress held several hearings to determine whether greater federal regulation was needed. Antitrust lawsuits and more government investigations and exposés followed. A study in fall 2011 issue of the Journal of Contemporary Health Law and Policy found that group purchasing organization kickbacks inflated supply costs by at least \$30 billion annually. But little has changed because of the enormous political clout of the industry's lobby, which includes the Healthcare Supply Chain Association and the American Hospital Association.

The Obama administration and Congress must protect patients by repealing the anti-kickback safe harbor and restoring free-market competition to the hospital purchasing industry.

*Margaret Clapp is a former chief pharmacy officer at Massachusetts General Hospital. Michael A. Rie is associate professor of anesthesiology at the University of Kentucky College of Medicine and co-chairman of Physicians Against Drug Shortages, where Phillip L. Zweig is the executive director.*

A version of this op-ed appears in print on September 3, 2013, on page A25 of the New York edition with the headline: How a Cabal Keeps Generics Scarce.

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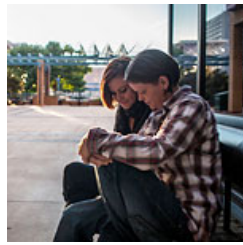
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