

United States Senate

WASHINGTON, DC 20510

March 3, 2011

Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW, - Room 7100
Washington, DC 20548

Dear Mr. Dodaro:

I am writing to request that the Government Accountability Office immediately launch an investigation of a pressing problem that threatens Americans' adequate access to prescription drugs.

A recent press report (attached) indicates that hospitals in Connecticut and around the country are experiencing frequent shortages of life-saving pharmaceutical products that complicate physician efforts to provide a reliable supply of medicine to patients who need it.

According to published reports, data gathered by the American Society of Health-System Pharmacists show a dramatic increase in the number of drugs that were in short supply in 2010: 148 different drugs, up substantially from 50 drugs just four years earlier.

The difficulty that hospitals encounter in securing an adequate supply of certain drugs forces doctors to ration their supply of medication, delay medical procedures, and use alternative products that may carry with them unwanted side effects or be unfamiliar to the physicians prescribing them.

I request that the GAO investigation examine the extent of hospital shortages of pharmaceutical products and the prevalence of these shortages in recent years, the impact of such shortages on patient care, possible explanations, and potential legislative or administrative approaches to addressing this problem.

Patient access to a stable and reliable source of life-saving medicine is incredibly important, and the federal government should give all due attention to efforts to address these shortages. Thank you for your attention to this request and for your continued work on behalf of the Congress and the country.

Sincerely,



Senator Richard Blumenthal

courant.com/health/connecticut/hc-ct-drug-shortage-0224-20110223,0,1855629.story

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Drug Shortages Plague Connecticut Hospitals

Scarce supplies mean substituting, rationing and borrowing

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By WILLIAM WEIR, bweir@courant.com

The Hartford Courant

5:57 PM EST, February 23, 2011

A shortage in medications has plagued hospitals in the U.S., and Connecticut health care officials say the state hasn't been spared.

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"It's pretty dramatic," said Michael W. Culligan, director of pharmacy at St. Francis Hospital and Medical Center in Hartford. "I think most of the public doesn't realize the challenge. Everybody takes these drugs for granted, but this is putting some fear into health care about what's going to happen in the future."

At any time, there are bound to be shortages of certain medications, but the number has increased significantly in the last few years. According to the American Society of Health-System Pharmacists, 148 drugs were in short supply in 2010, and 157 in 2009. (About three-fourths of these are sterile injectible drugs.) In 2006, the list of medicines in scarce supply was just under 50.

Predicting what drugs will be available from one day to the next is often guesswork.

"With the wholesaler, you'll order your drug for tomorrow and get the confirmation," said Lorraine Lee, director of pharmacy for Yale-New Haven Hospital. "You think you're going to get it, and then you don't get it."

And when hospitals don't receive a drug they've ordered, officials have to choose one of a number of options, none of them ideal. Once a drug becomes scarce, hospital officials ration it carefully, administering it only in certain cases. They might turn to an alternative drugs, perhaps one with more side effects.

"In the case of chemotherapy, for someone who's on a regimen for cancer, there might be another option

but it might not be the best option," Lee said.

If older medications are used as an alternative, Lee said, younger doctors might never have dealt with them. That means calling instructional meetings.

Connecticut hospitals have a good relationship when it comes to borrowing medications from each other. When there's a shortage all around, though, it's every hospital for itself.

"When it gets desperate, every hospital acts within its own patients' best interests, but we do everything we can to be collegial," Lee said.

It can also mean purchasing the drug from secondary suppliers, "but these companies charge more because they know they have you."

The FDA is limited in what it can do; it can't force a manufacturer to produce a certain medication. A bill introduced by U.S. Sen. Amy Klobuchar, D-Minn., and U.S. Sen. Robert P. Casey Jr., D-Pa., would at least require that manufacturers give more advance notice when it becomes apparent that a drug is likely to go into short supply. That would help, Culligan said.

"The biggest challenge about the shortage is the lack of communication we get from the drug manufacturers," he said. Knowing exactly what they'll have in supply at any one time is a "24-7 job."

"First of all, we only know about [specific shortages] when supplies are coming into the loading docks in the morning," Culligan said. "It becomes a daily communication between myself, the pharmaceutical department and the medical staff."

Michael Rubino at Hartford Hospital said the situation was particularly dire three months ago with a shortage of Lasix, a diuretic for heart patients. They got by using Bumex, a similar drug. When that started running short, the Lasix supply got replenished. Whenever an alternative is used, Rubino said, it's his department's job to make sure it gets used properly.

"You can't say that you don't have something without giving [health care workers] an alternative with an equivalent dosage," Rubino said. "It's not like a car part; you can't say 'We don't have this — wait two weeks.' That doesn't work."

For all the rationing, borrowing and substituting of drugs, Culligan said, they've managed to avert disaster. The most direct effect at St. Francis, he said, was that an elective surgery was delayed for a few hours while hospital workers obtained a necessary drug from Yale-New Haven Hospital.

But that doesn't mean there haven't been scares.

"There was an extreme shortage of propofol this past year, and for a while, it was extremely dicey," he said. "Doctors had to be very judicious in using it."

The worst part about shortages, Lee said, is that there doesn't appear to be an end anytime soon.

"It only seems to get worse," she said. "It's like a hamster on a wheel — once one drug comes back, there's another to worry about."