

POLITICO

Gray market threatens drug supply

By: **Brett Norman**

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Shortages in critical drugs have tripled in the past five years, killing some patients, delaying surgeries and disrupting chemotherapy treatments at hospitals around the country.

There are several causes, and they're all complicated: The Food and Drug Administration doesn't have enough resources to enforce strict regulations; there are manufacturing disruptions in aging facilities; and slim profit margins may discourage production in the first place.

But whatever the explanation for the shortage itself, one universally acknowledged result — on top of the danger to patients — has been a proliferating “gray market” of secondary prescription drug dealers charging hospitals huge markups for scarce supplies.

And pressure is building to answer the question: Who has the authority to do anything about it?

Sen. Richard Blumenthal (D-Conn.), a member of a working group on drug shortages at the Health, Education, Labor and Pensions Committee, said the complexity of the problem means that multiple agencies may have roles to play, “which could be part of the problem.”

“It's not only a safety and manufacturing issue. which involves the FDA. but also a

market-pricing and fair-trade issue that could involve other agencies,” Blumenthal said. “One of the front-burner questions that we're trying to address is who should be held accountable, and it's a matter of considerable urgency and impatience to us.”

The Government Accountability Office is

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researching a report on the drug shortage issue now, he said.

A survey this summer by the Institute for Safe Medication Practices “generated hundreds of comments from respondents who feel unsupported by regulatory agencies that have not stepped in to control the gray market ... and outraged by the price gouging that accompanies the sale of these vital medications,” according to a summary.

Fifty-six percent of about 550 hospitals that answered the survey reported daily solicitations by gray-market vendors. A separate survey this summer by Premier, an alliance of hospitals that does group purchasing and performance improvement, examined more than 1,742 such offers to acute-care hospitals that averaged a 650 percent markup over standard contract prices.

Though most states have price-gouging laws for products such as gasoline to protect consumers from profiteering in the wake of a natural disaster, few have any addressing prescription drugs. There’s no federal law addressing drug price-gouging, either.

“Nobody has presented FDA with the hammer of Thor to fix the shortage problem itself,” said Susan Winckler, a senior adviser at Leavitt Partners, while moderating a panel at an all-day FDA workshop on drug shortages last week. Instead, it will take cooperation among multiple agencies at the federal and state level, she said.

The bulk of the critical shortages are among generic drugs, especially so-called sterile injectables like chemotherapies and anesthesia. These are usually older workhorse drugs that must meet special requirements for sterile manufacturing and handling. Some must remain refrigerated so they don’t become ineffective. That’s of particular concern in the gray market, in

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which some drugs have been diverted from the mainstream distribution network and later sold at often exorbitant rates.

When the FDA learns about a gray-market offer from a suspect vendor, the complaint is referred to the Office of Criminal Investigation, says Valerie Jensen, associate director of the agency's drug shortage program.

The agency can investigate whether the drugs have been stored and handled properly, but "the buying and selling practice is not regulated by FDA, the pricing is not regulated by FDA," Jensen said. "We know it's a problem, and we know that that needs to be handled."

But by whom?

Some stakeholders at the FDA workshop suggested the FTC could intervene. But Mitch Katz, a spokesman for the agency, said the lack of federal law against price-gouging means gray-market activity was not its responsibility.

The Drug Enforcement Administration already plays a role by setting production quotas for controlled drugs, and it's responsible for adjusting those quotas based on demand or manufacturing disruptions.

Prescription wholesalers, on the other hand, are licensed by pharmacy boards at the state level, and the requirements vary. Some require facility inspections and others do not, said Joseph Hill, federal legislative director of the American Society of Health-

System Pharmacists, one of the sponsors of a drug shortage summit convened by stakeholders last year.

Lawmakers and physician and hospital groups said their primary concern is the root causes of the drug shortage problem, because if the drugs were readily available at low prices, the gray market would

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disappear.

But one of the first steps legislators are taking to address the issue could inadvertently give an edge to gray marketeers.

Bills have been introduced in the House and the Senate that would require manufacturers to notify the FDA six months in advance of an anticipated shortage. Shortages stem from quality control issues, manufacturing upgrades or the loss of a source of an active ingredient in a drug, among other reasons.

So far this year, based on voluntary notifications from manufacturers, FDA has successfully expedited the regulatory reviews to keep the drug companies in production and avert 99 looming shortages.

The idea is that, if all companies were required to report expected shortfalls of critical medicines, the FDA could prevent or mitigate even more.

The flip side, however, is that making that information public creates opportunities for gray marketeers to hoard supplies of a given drug, accelerate the shortage and then capitalize on it.

“It is complicated,” said Ralph Neas, a longtime advocate of liberal causes who became president of the Generic Pharmaceutical Association last month.

GPhA, among other key stakeholders, supports the creation of a formal reporting

system, but Neas said it needs to be designed with care.

“The way the gray market acts now is very entrepreneurial. If I inform the FDA, and it’s some sort of public database, [the gray market] could create shortages. When that information should become public, and how, are all key questions.”

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So far this year, the University of Utah Drug Information Service, which tracks shortages, has reported 210 of them, just short of the record 211 registered in 2010.

That's up from roughly 70 five years ago, and the number has shot up despite ramped-up efforts by the FDA's drug shortage office, which has a full-time staff of four coordinators who work with experts throughout the agency to expedite the reviews that keep manufacturers supplied and operating.

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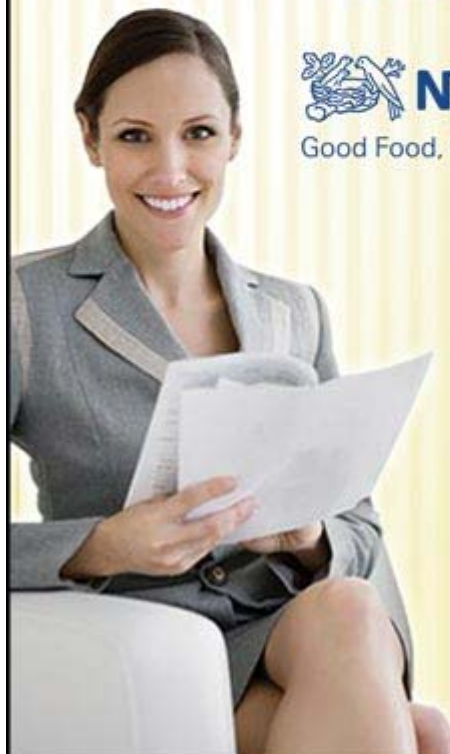
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