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Breast Cancer, Drug Shortages, and the Reality of Obamacare

by Julie Gunlock
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October is National Breast Cancer month.

We can expect all the regular stories from the media: inspirational survival stories, reminders of the importance of regular screenings and early detection, etc. These predictable stories are all well and fine, but the critical issue of the day appears to be how doctors are running out of the drugs that most effectively treat breast cancer.

NPR's Morning Edition focused on that topic this morning and reported that the nationwide drug shortage is leading doctors to ration drugs -- including life saving breast cancer drugs:

> The shortages involve a wide range of medications: cancer chemotherapy agents, anesthetics, antibiotics, electrolytes needed for nutrient solutions, and dozens more. One drug currently in short supply is used in critically ill patients to bring down soaring blood pressure ... According to those who are tracking drug shortages, there have been more than delays. Some patients have died.
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> That's what the American Society of Health-System Pharmacists found when they did an anonymous survey of members. Last week the Associated Press reported that at least 15 people have died as a result of drug shortages.
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> More wrenching decisions may be just around the corner for patients with ovarian and breast cancer. A critical drug called Taxol is now on the FDA's shortage list.
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> And Mass General's pharmacists say they have less than a month's supply of Taxol on hand.

The NPR report generally blamed manufacturers for the drug shortages saying that fewer companies are making these essential drugs. But, as Cato's Walter Olsen revealed earlier this summer, the blame goes way beyond the drug companies.

> After "tainted drugs" scares a few years ago, the FDA stepped up its Good Manufacturing Practice regulations, which control the production of pharmaceuticals. In particular, it now proclaims zero tolerance, barbed by tough fines, for many technical infractions whose actual impact on patient risk is at best doubtful, and it is unafraid of shutting down production lines again and again for retooling until its regulations are satisfied to the letter. It also changes its formulation and manufacturing requirements often, with scant forgiveness for makers who have trouble retooling to the new specifications quickly.

Olsen then says that the "feds have inserted themselves into the role of central planners of drug output." John Goodman over at Health Affairs blog echoes this, saying:

> For example, a drug manufacturer must get approval for how much of a drug it plans to produce, as well as the timeframe. If a shortage develops (because, say, the FDA shuts down a competitor's plant), a drug manufacturer cannot increase its output of that drug without another round of approvals. Nor can it alter its timetable production (producing a shortage drug earlier than planned) without FDA approval. That the results might include many unpleasant surprises will surprise only those unfamiliar with the record of a century of central planning failure.

As Charlotte notedthis morning, the FDA's delays are dangerous. But what's even more terrifying is to consider how these problems will increase after Obamacare has been fully implemented.