Profit drive leads to shortage of critical drugs, deaths in US

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Since 2006, the number of drug shortages in the United States has been steadily increasing, more than quadrupling over five years to a record 267 in 2011. Since 2010, at least 15 deaths have been linked to the shortage of critical drugs. Although largely attributed by the media to problems with drug ingredients, the source of the current crisis can be directly tied to the free-market drive for profit.

Classic sources of drug shortfalls such as the unavailability or contamination of a critical production component account for less than ten percent of the current shortage, according to the US Food and Drug Administration (FDA). In fact, the current shortage was initially provoked by a change in the way the government reimbursed doctors under Medicare, a November 3 editorial by the *New England Journal of Medicine* explained.

Of shortages in 2010, 74 percent involved what are called sterile injectable drugs (SIDs), many of which are critical anti-cancer chemotherapeutics. Since the 1970s, oncologists have supplemented their income mainly through the sale of chemotherapeutic drugs. Hospitals bought these drugs wholesale, and then doctors sold them to patients through insurance companies or Medicare at market price. Doctors were then reimbursed by Medicare for 95 percent of the drug's market price after buying drugs wholesale for 66-88 percent of this price. However, as a result of the 2003 Medicare Modernization Act, beginning in January 2005, doctors were only reimbursed by Medicare at a 6 percent markup of wholesale price.

While this did not discourage doctors from treating cancer patients with Medicare, it did have another effect. Faced with a smaller, fixed percentage reimbursement from each drug administered, many doctors simply switched to more expensive alternative drugs when it was possible for their patients. However, in many cases switching to an alternative would be inappropriate or pose a potential risk to patients, and doctors largely continued to administer drugs that they knew worked for their patients with minimal complications.

The resulting decline in demand for certain drugs caused their price to drop dramatically. For example, the cancer drug *Paclitaxel* fell in price by an order of magnitude, from $2,272 per dose to $225 per dose, over the course of a month. At the same time, the price of more expensive alternatives remained unchanged.

This fall in price did not go unnoticed by drug companies. An issue brief published on the FDA website in October notes that drugs currently in shortage are generally those that declined in price from 2006 to 2008. The authors show that drugs in shortage after 2008 showed a decline in average service volume of 6.9 percent and a decline in average price of 26.5 percent over the period of 2006 to 2008. At the same time, drugs not in shortage since 2008 showed an average increase in service volume of 11.2 percent and average price increase of 0.6 percent over the same period.

Thus, prior to the appearance of major shortages, the profitability of to-be-under-produced drugs was on the decline, likely due to some doctors switching to more expensive alternatives. In addition, the authors point out that, beginning in 2008, a large number of new SIDs became available for generic production due to the expiration of patents. Faced with products dropping in value due to decreased demand, this offered an opportunity for generic producers to increase their revenues by changing production, as drugs just coming off of patent protection are much more profitable than drugs whose price has come down after a long period of

competition on the market.

Virtually all oncological SIDs used in America are manufactured in the US, with approximately 50 percent of the market being serviced by generic drug companies. Three or fewer manufacturers produce most of the oncological SIDs administered by doctors in the US. These companies do not maintain extra, unused production capacity, and as a result the production of new products requires the retirement or reduced production of older drugs.

However, newer and more profitable drugs are not necessarily replacements for the older medicines on which doctors and patients depend. As most SIDs are produced by less than a handful of companies, the uncoordinated decision to reduce or discontinue production of less profitable drugs by one or a few companies had an enormous effect, resulting in shortages of critical drugs.

In response to the crisis, the Obama administration has called only for “greater transparency” by drug companies, in order to supposedly raise public awareness of future shortages. No resources have been made available to directly address the shortage, either by purchasing needed drugs from abroad or by investing in increased domestic production. In line with so-called health care reform the administration will take no measures that cut across the profit interests and monopoly of the pharmaceutical giants, insurance companies and hospital corporations.

The requirements of drug manufacturing make changing production lines from one type of drug to another extremely expensive. Thus, drug companies’ decisions to change production will only be remedied by their increasing capacity.

Supporters of the drug industry insist that rising prices due to the shortage will incentivize drug manufacturers to improve production capacity by updating or building new facilities and thus make up for the shortage. This will, of course, mean even bigger profits. Increased capacity cannot be brought online, however, for several more years. In the meantime, shortages of critical medicines will persist, with tragic results for doctors, patients, and families across the country.

This crisis underscores the need for the nationalization of the drug monopolies and the establishment of a socialist health care system.