Government Causes Generic Drug Shortage, Critics Say

By Jennifer G. Hickey

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A proposed Food and Drug Administration rule on product labeling will exacerbate shortages of generic drugs already resulting from regulations on Medicare reimbursement rates and other factors, critics charge.

Patient advocacy groups, lawmakers, and industry representatives warn that the FDA rule, which requires generic drug makers to update information on products if they become aware of new safety information, would add to the drug shortages.

Meanwhile, Roger Pilon, vice president for legal affairs at the Cato Institute, said one of the primary causes of shortages in the generic market is the government's role in regulating Medicare reimbursement rates and not allowing prices to match market demand.

"There is a problem [of generic drug shortages] because of the price controls included in the 2003 Medicare Modernization Act. When you have caps on prices, the result is you see manufacturers producing fewer drugs or getting out of the market altogether," Pilon said.

In 2011, the Government Accountability Office reported a substantial increase in the number of drug shortages since 2006, with many involving generic drugs.

According to the GAO, a total of 1,190 shortages were reported from Jan. 1, 2001, through June 20, 2011. From 2006 through 2010, the number of drug shortages increased each year, growing by more than 200 percent over that period.

The FDA rule on labeling came in response to a **2013 Supreme Court ruling** in Mutual Pharmaceutical v. Bartlett, which said generic drug makers could be sued under state law for side effects that may arise from use of their drugs.

Prior to the court ruling, the FDA prohibited generics from changing their labels. When the court said that the prohibition on label changes meant generic drug makers could not be held accountable for failure to warn against risk, the agency reconsidered that position.

The FDA contends the rule would reduce the number of shortages, but others, including the

Generic Pharmaceutical Association (GPhA), say the regulation will make matters worse.

GPhA President Ralph Neas testified at a recent hearing of the House Energy and Commerce Committee that the rule could spark a rise in generic drug prices and lead to more shortages rather than less.

Neas said FDA's proposed rule would "expose generic drug manufacturers to substantial new tort liability costs, which in turn would require them to adjust prices to stay in business, withdraw products, or decline to launch new affordable versions of brand medicines."

Neas said the "result would be **fewer generic drugs coming to market** and manufacturers withdrawing from certain high-risk markets, leading to drug shortages, the underutilization of affordable generic medicines, and ultimately increased prescription drug spending."

According to a study conducted by Matrix Global Advisors, the price tag associated with lawyers being hired by drug companies to fight product liability lawsuits could be as high as $4 billion.

On March 19, more than 15 patient and disability advocacy organizations sent a **letter to the FDA** expressing similar concerns about the proposal.

In addition to questions about whether the FDA has the legal authority to make the rule change in light of the Supreme Court's ruling, lawmakers have raised questions about the role of trial lawyers' groups in developing the regulation.

Responding to a question at a **recent hearing, Janet Woodcock**, FDA's director of the Center for Drug Evaluation and Research, acknowledged the FDA consulted with trial lawyers regarding the proposal but did not meet with physicians, pharmacists, branded drug companies, or generic drug companies.

One of the only groups the FDA met with was the **American Association for Justice**, formerly known as the Association of Trial Lawyers of America.

The AAJ, which **supports the proposed rule**, is circulating a petition to get the FDA to act quickly to push the rule through and hold generic manufacturers accountable.

The regulation is not the only action taken by the FDA that has industry representatives nervous about drug shortages.

In October 2013, the FDA required manufacturers to report to them any drugs that were actively experiencing shortages or any potential for a "meaningful disruption in supply."

A failure to adequately comply would result in the FDA's issuing a "public noncompliance letter" to the company. Critics have particular concern with a component of the rule that requires manufacturers to notify the FDA within five days of being made aware of the potential disruption or face sanctions.

In **comments submitted on Jan. 3**, the GPhA said that "reporting within a specific period of days may lead to significant over-reporting given the voluminous number of routine disruptions that occur daily and may have the unintended impact of contributing to a shortage situation."

Industry analysts attribute the drug shortages to a myriad of others factors as well, including pharmaceutical companies' opting to cease production of older, cheaper drugs in favor of newer, more profitable ones, and unanticipated production problems, such as unavailable drug components.

Robert W. Pollock, a senior adviser and outside director of the board at Lachman Consultants, said blame can be assigned to both sides of the ledger.

"When the FDA finds significant problems, they have been quick to react, but that reaction actually may be going overboard, and I would venture to say they are reacting too quickly, particularly on issues which may not have significant impact on the quality of the drugs," Pollock told Newsmax.

Steve Arnoff, deputy communications director at the GPhA, agrees that the causes are diverse, telling Newsmax that "shortages are complex and multifaceted, and different therapies face different circumstances.

"Some therapies in shortage are only made by one or two manufacturers. Others cope with unplanned disruptions in manufacturing for any variety of reasons. There is no single cause and no single solution."

As part of the 2003 Medicare legislation, a new system was implemented based on the average selling, or retail, price, called the ASP, so drug providers are reimbursed the ASP, plus a 6 percent administrative fee.

The result is that if drug prices drop too low, some manufacturers will simply stop producing the drug or switch their focus to manufacturing more profitable drugs.

Republican Rep. Bill Cassidy of Louisiana sponsored legislation in 2012 that would reverse the production decline by "pegging the reimbursement rate to a figure which accurately reflects the value of those drugs."

Cassidy, a physician himself, noted in a 2012 **Wall Street Journal editorial** that "since the reimbursement change became effective in 2005, there has been a tremendous increase in drug shortages" and "almost all drug shortages have come about after their price has plummeted, and the problem is compounded by the fact that many generics have few suppliers. For example in 2010, 90 percent of all generic injectable oncology drugs were produced by three or fewer manufacturers."

The shortages have been particularly stark with regard to cancer drugs. Research published by the American Journal of Health-System Pharmacy found shortages of oncology drugs continue to

have a significant impact on patient care.

Researchers **surveyed 358 pharmacy directors** at health systems across the United States and found that 98 percent reported at least one drug shortage during the previous 12 months, and 63 percent of respondents reported that their facility had completely run out of at least one injectable oncology drug in the past year.

As a result of the shortages, the pharmacists were forced to take corrective action: 43 percent delayed treatment and 21 percent referred patients to other providers.

Pilon said similar marketplace distortions are likely to occur under the Affordable Care Act:

"The shortage of generic drugs is a warning sign of a shortage of all medical services that we are going to see once Obamacare bites, because it wants to keep costs down but does so by restricting services."