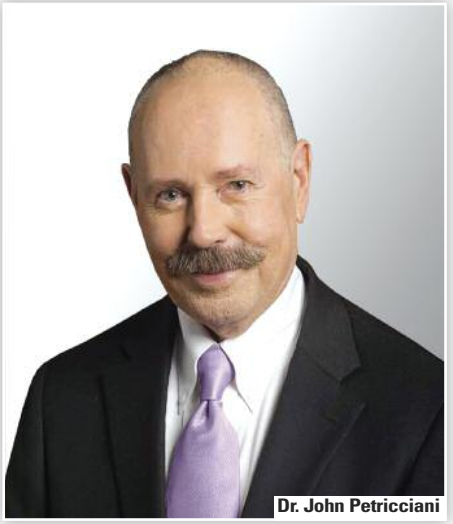
The Growing Problem of Drug Shortages

JOHN PETRICCIANI, President of the International Alliance for Biological Standardization, discusses the causes and impact of drug shortages.


Dr. John Petricciani

FDA's New Authority Over Drug Shortages

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. In the new law, Congress provided FDA with new authorities to combat shortages of drug products in the United States and imposed new requirements on manufacturers regarding early notification to the FDA of issues that could lead to a potential shortage or disruption in supply of a product.

FDASIA provides FDA with important new authorities that will help the agency combat drug shortages, including:

- Broadening the scope of the early notification requirement by requiring all manufacturers of covered drugs to notify the FDA of potential discontinuances.
- Making clear that manufacturers are required to report discontinuances to the FDA regardless of whether they intend to discontinue the product permanently or are facing only a temporary interruption of supply.
- Enabling the FDA to require, by regulation, mandatory reporting of shortages of biological products. The prior law excluded all biological products from the reporting requirements.
- Making clear that the notification requirement applies to drugs that are used in emergency care or during surgery.

Source: Food and Drug Administration

PV: *How common are drug shortages?*

PETRICCIANI: The problem of drug shortages has been growing in the United States, and the Department of Health and Human Services has been looking into this. There has been a three-fold increase in the total number of drug shortages over the six-year period from 2005 to 2010. Additionally, the number of sterile injectable doses increased dramatically in 2009 and 2010, which accounted for about 80% of the drug shortages in 2010 and 2011.

Another survey conducted by the American Hospital Association — responses from 820 community hospitals — published in 2011 found that the problem of drug shortages was prominent. Almost all of the hospitals surveyed had experienced at least one drug shortage in the previous six months. What was even more revealing is that the majority — more than 80% — of the hospitals surveyed are coping with the problem on a frequent basis. And shortages involved multiple drugs, which goes beyond this being a one-off issue.

PV: *What are the causes of drug shortages?*

PETRICCIANI: There are multiple reasons for the shortages. Some products are discontinued for any number of reasons. There are capacity issues. Another important issue is quality control. About 56% of the shortages are related to problems in quality control and manufacturing. Dr. Janet Woodcock and Marta Wosinska, both with the FDA's Center for Drug Evaluation and Research, published an article not too long ago on the issue.

They noted that the fundamental problem is the inability of the market to observe and reward quality. This lack of reward for quality can reinforce price competition and encourage manufacturers to keep costs down by minimizing quality investments. This is a very important conclusion. One way to look at this is a short-term gain versus a longer-term investment in stability.

PV: *What is the impact of drug shortages?*

PETRICCIANI: The American Hospital Association survey found that drug shortages have a direct impact on patients by causing delayed treatment in about 20% of cases and a failure to get the recommended treatment in 10% of cases. There were also some adverse events reported, although this was a small number of cases — less than 3%.

It's not just patients who are impacted by shortages. A survey by the American Society of Pharmacists showed that pharmacists were spending about nine hours per week trying to manage the problem of shortages.

PV: *How can drug shortages be addressed?*

PETRICCIANI: Because the problem of drug shortages is multifaceted, there is a need to look at the challenge broadly. Prescribers and payers should demand excellence in manufacturing. As one way of minimizing the risk of problems in manufacturing that could lead to shortages, manufacturers can help to ensure that potential problems are minimized by adopting a culture of quality in manufacturing.

The FDA's views on this provide an excellent starting point for taskforces. One taskforce is moving forward to develop and implement a strategic plan for enhancing the agency's response to preventing and mitigating drug shortages. In broad terms, the strategic plan should take into account that there are multiple causes for drug shortages. Mitigating the problem requires an evaluation of what is the root cause of any given shortage and the mechanisms that might be used to prevent future occurrences.

An educational initiative, Manufacturing Matters for Biological Medicines, is aimed at providing information about the manufacturing process for biological medicines and how the process can impact product quality and supply. PV

The TrialCard Difference

Offering a full spectrum of solutions for your brand challenges.

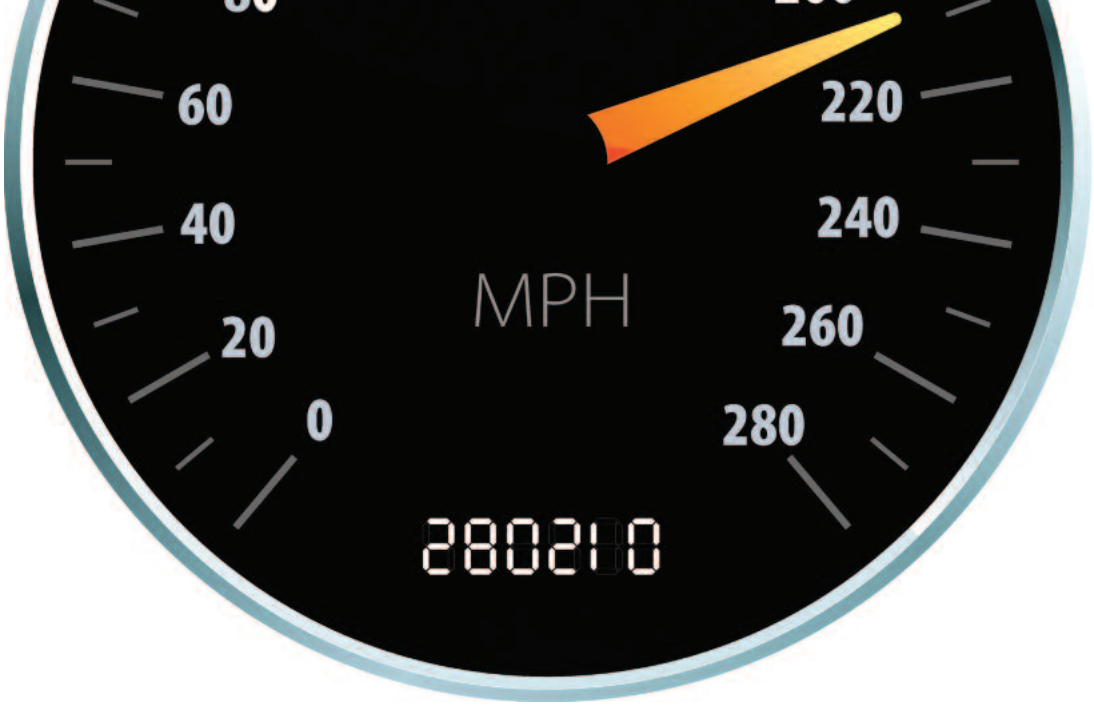
"I didn't know you guys do all that!"

- CO-PAY PROGRAMS
- BUY AND BILL PROGRAMS
- LOSS OF EXCLUSIVITY (LOE) PROGRAMS
- PATIENT ASSISTANCE PROGRAMS
- SAMPLE VOUCHER PROGRAMS
- DEBIT CARD PROGRAMS
- REBATE PROGRAMS
- PRIOR AUTH SUPPORT SERVICE PROGRAMS
- ADHERENCE/RX ABANDONMENT PROGRAMS
- Rx SAVER SOLUTION

LUMINITA RUBY
Product Manager, Endocrinology
Boston, MA.

trialcard®
Access. Acquisition. Adherence.

Call us at 1-877-343-1238 or visit trialcard.com for more information



ANALYTICS

Accelerate from product launch to peak sales.

SAS, a trusted partner to 93 of the top 100 companies in the 2010 Fortune Global 500,® delivers analytics for commercial life sciences to help you optimize resources for physicians, patients and payers. Decide with confidence.

sas.com/accelerate
for a free white paper

sas
THE POWER TO KNOW®