



IN MY VIEW

HOW PPTA DEALT WITH SHORTAGES

IN SEPTEMBER 2011 FDA (CDER) organized a public Workshop to address drug shortages in the United States of America. Many speakers voiced their concern about drug shortages, especially in the areas of anesthetics, parenteral food, cancer treatments and antibiotics. Late October, President Obama signed an Executive Order to double the number of FDA staff working on this important issue.

I remember as if it were yesterday the enormous attention we got from patients, treaters, congress and media when there was a shortage of immune globulins in the late 90's. I had just moved to the United States and suddenly I learned firsthand what it is to be in the middle of congressional and media attention. My introduction to the United States was being interviewed by Mike Wallace on *60 Minutes*, being interviewed by the *New York Times* and CNN, and not to forget the 2 Congressional Hearings in 1998. By the way, the second Hearing in September 1998 was relatively short because it was the day that Ken Starr published the "Lewinsky Report" which seemed to be far more important for the House of Representatives than our issues.

During the FDA Workshop we heard several statements that demonstrate the outrage by many participants: "Drug shortage situation is unacceptable.... Cannot believe this is happening in America... Action is needed now..." Drug shortage is a public health problem and responsibility of everyone in the room..."The situation calls for real-time, bi-directional communication on supply between manufacturers and FDA/ stakeholders..."

It sounded very similar to the comments that we heard in the late nineties and were the basis for the Advisory Committee on Blood Safety and Availability (ACBSA) to develop their recommendation to develop a program that collects and disseminates standardized information on supply, with involvement of the trade association and preferably on a monthly basis.

PPTA made a statement at the FDA Workshop to explain the history of our data system and its utility to patients, regulators and other stakeholders. Notably, while many workshop participants focused on the problems associated with drug shortages, PPTA's presentation was the only one that described a concrete, time-tested plan of action. Stakeholders like patient groups and FDA (CDER) have repeatedly stated their appreciation for the system developed by PPTA. Like any system that was developed over a decade ago, it is always necessary to look at it and see whether improvements can be made. That speaks for itself. But we should never forget that having data available whenever there are questions about a potential shortage is a fundamental tool to clarify any concern that may exist. Over the years we have learned that and were always able to respond in a responsible manner to stakeholders.

We received many compliments over the years about our system and we are thankful for that. I hope that our system will maintain its importance and can be a model for other sectors of the pharmaceutical industry that are currently facing similar problem. 