Ch. II-7 Drug Shortages and Patient Care

James Szalados, MD, Esq

ISSUE: Your hospital continually experiences drug shortages. Are there inherent legal risks? If so, how can you help insulate yourself from liability?

Good medical care requires that once a diagnosis is made, the appropriate treatment be instituted as expeditiously as possible. Frequently, many alternative therapies may be reasonable and appropriate; on the other hand, in some cases, there is only one best therapeutic option. Over the course of the past 15 years, there has been a steady escalation in the number of critical regional and nationwide drug shortages.

A "drug shortage" has been defined as "a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level." Providers are concerned that drug shortages may increase medical-legal liability because, in a very real sense, they are being coerced into altering their patient care plans based on administrative rather than clinical reasons.

The Drug Information Service (DIS) at the University of Utah provides comprehensive information regarding prescription drug shortages to the American Society of Health-System Pharmacists and continues to report record numbers of drug shortages, especially drugs used in Emergency Medicine, Anesthesiology, and Critical Care. DIS and FDA-acknowledged drug shortages do not fully reflect the diminished availability of drugs which are in relatively short supply and also those drugs that are either just unavailable regionally or via specific distributors. The American Hospital Association (AHA) reports that 99.5% of hospitals reported experiencing one or more drug shortage in the last six months and almost 50% of all hospitals reported shortages of 21 or more drugs; 82% of hospitals report having delayed patient treatment as a result of a drug shortages and more than 50% reported variable ability to provide patients with recommended treatments; 75% of hospitals reported implementing rationing or pharmacy-based restrictions regarding the dispensing of medications considered to be a short supply; and, most hospitals report that they are necessarily purchasing more expensive alternatives.

Types of medications in shortage range from antiepileptic drugs, cardiac arrest resuscitation medications, steroids, antibiotics, and chemotherapeutic agents through the continuum of simpler but nonetheless important additives such as sodium bicarbonate and multivitamins which are essential to the formulation of total parent nutrition and other infusions.

Published surveys of provider opinion uniformly report serious concerns regarding patient safety when those providers were faced with drug shortages. Adverse events resulting from substitution of second-tier medications may not even be easily recognized; the American Society of Anesthesiologists reported on cases where the substitution of thiopental for propofol increased the risk of laryngospasm and silent aspiration under anesthesia; events which may be otherwise attributed to faulty anesthetic technique. Drug shortages also burden hospitals and facilities with added expenses related to formulary alterations in substitutions, acquisition costs associated with out-of-network acquisition costs, and required changes in protocols, which then require changes in standard operating procedures and need for urgent provider education. In some rare cases, institutions have allegedly resorted to dispensing out-of-date medications to provide essential medications where no therapeutic alternative was available.

The root causes for drug shortages are multifactorial and include products-liability litigation against manufacturers, FDA challenges to good manufacturing practices and heightened restrictions on drug importation and reimportation, and business decisions favoring the allocation of production resources to drugs with higher returns on investment profiles.

The FDA is the agency charged with oversight of drug approval, manufacturing, and marking in the US and legislatively

derives its regulatory authority from the Food, Drug, and Cosmetic Act (FDCA). The FDCA is silent with respect to duties of pharmaceuticals manufacturers and distributors to give notice to any federal or state authority if they discontinue manufacturing a certain drug, dosage form, or if they faced either unanticipated or anticipated inability to meet either customary supply or increased demand for their drugs.

There is now some recognition that the integrity of the national pharmaceutical supply may also have National Security ramifications. Accordingly, President Obama signed Executive Order 13588 into law on October 31, 2011; the order, titled “Reducing Prescription Drug Shortages,” in conjunction with an amended Title X of the Food and Drug Administration Safety and Innovation Act of 2012 together increased industry requirements to notify the FDA of impending shortages; however, their practical effect remains to be demonstrated.

The current healthcare environment is increasingly characterized by complex regulatory mandates and heightened threat of civil, administrative, and regulatory litigation. Hospital liability for failure to have in place in adequate emergency preparedness plan was recently underscored by the $25 million 2011 class-action verdict against Tenet Healthcare Corporation for it poor response following the devastation of New Orleans by Hurricane Katrina. The Tenet Healthcare case establishes a legal “duty to plan.” A similar ethical "duty to plan” has been underscored by the Institute of Medicine in a report entitled "Crisis Standards of Care—A Systems Framework for Catastrophic Disaster Response” which systematically and methodically addresses drug shortages and other public health crises in which the demand for resources exceeds availability. The IOM framework recognizes that resource shortages and the demand for healthcare service delivery is not an “all or none” phenomenon, but rather a continuum from a conventional to contingency and, in the worst-case scenario, a crisis response effort. The Joint Commission has published Standards for Disaster Preparedness and Response and requires hospitals to develop plans in six specific focus areas including planning for self-sufficiency and maintaining care for vulnerable populations.

Negligent failure to plan is an emerging area of liability and is largely based upon foreseeability of critical events and an analysis of whether reasonable steps to eliminate or mitigate foreseeable risks of harm were taken. Increasingly therefore, the regulatory and administrative foundations to support assignment of liability for patient harm resulting from drug shortages are being laid through quasi-regulatory opinions and case law.

Provider liability for rationing and triage decisions is not well-established and traditionally providers have been accorded substantial deference by the courts when scarce resources, such as ICU beds, are allocated during emergencies. Nonetheless, it is not inconceivable that patient harm related to the non-administration of a drug, which at the time, was in short supply, might be at issue in court many years later. Providers failing to adhere to standards of care may also be at risk for a claim of patient abandonment by state regulatory bodies. Therefore, providers would be advised to carefully document the basis for their drug rationing or involuntary therapeutic substitutions whenever "drug shortages" for the basis for their therapeutic decision-making. Optimally, written records of "drug shortage" notifications would be retained and support provider decisions for drug rationing or substitution; however, in reality, this would likely be a substantial administrative burden for most busy providers and practices.

The issue of “drug shortages” once again serves to emphasize the point that planning, communication, and meticulous documentation are essential to a strong defense in the event of any allegation of negligence.