Written by **Beverly K. Eakman** on June 3, 2011

Got Meds? Not Necessarily, Say U.S. Hospitals

Over the Memorial Day weekend, while many were getting their first taste of summer — ergo, not reading the news — it was reported that U.S. hospitals were experiencing shortages of both common and specialized drugs, so much so that they are looking for substitutes and combing the globe for overseas suppliers. An Associated Press story announced that some "89 drug shortages occurred in the first three months of this year, according to the University of Utah's Drug Information Service (UUDIC)…which tracks shortages for the American Society of Health-System Pharmacies."

Turns out, this is not a new problem. According to Linda S. Tyler, Pharm. D., FASHP, Pharmacy Manager, Drug Information Services, University of Utah Hospitals and Clinics, the first drug shortages in the United States occurred in 1996, during the Clinton Administration, when data collection on the topic began. At the time, there were only five drugs affected, but that number rose swiftly to 20 drugs between 1997 and 2000, according to UUDIC tracking. In 2001 the number of shortages grew to 120, most of which were resolved by the following year because they didn't rise to the level of adversely affecting hospitals and patient care. Today, that has changed.

Shortages are not only inconvenient, but expensive. Tyler wrote that "[c]hanges in drug supply can alter the way medications are prepared in the pharmacy, the way they are administered to patients, and, in some cases, whether patients receive medications at all." She estimates that "many organizations spend between one-half and three full-time equivalent (FTE) personnel on the management of drug shortages. These extra FTEs spend their time investigating the reason for the shortage, finding alternative agents, working with wholesalers, finding alternative suppliers, compounding a replacement product internally, or communicating with other practitioners."

The knee-jerk public response to this news is along the lines of: Do we make anything in this country anymore? Is there anything that is not still outsourced, imported, or subject to rationing?

The real factors are more complicated, and more disturbing. In 2003, Tyler categorized several reasons for shortages, summed up as regulatory issues (7 percent), product discontinuation (20 percent), raw materials issues (8 percent), manufacturing problems (28 percent), and supply-and-demand (10 percent). In her updated publication, Tyler notes that this leaves some 27 percent of shortages unexplained. Deeper, more hidden, reasons include "Grey" Market Vendors, Prime Vendors and Just-in-time Vendors, Industry Consolidations, Market Shifts, Manufacturer Rationing, Restricted Distribution, Manufacturer Discontinuation — and the fact that sometimes drug companies are loathe to reveal the details of shortages for fear of a public, legal or other backlash.

Most of these categories appear to be self-explanatory, although the motives pretty much revolve around demand (read: *money*). Thus persons with legitimate, but rare, disorders who rely on particular

drugs may find their doctors hard-pressed to locate a new source or alternative (the National Association for Rare Disorders helps), while well-hyped, trendy complaints (like attention-deficit "disorder" and depression) see a new pill on the market several times a year. War is certainly a factor, when soldiers require an unexpectedly large quantity of a certain product, creating temporary shortages in the U.S.

But "grey market vendors" are more troublesome. Tyler explains that "the profitability of [certain] pharmaceuticals attracts vendors who [then] create artificial shortages by selectively purchasing excessive quantities of products, … thereby depleting the available stock. These vendors then re-sell the products back to the users at inflated prices."

"Prime Vendors and Just-in-Time Inventories" are another development that makes for concern. Tyler explains:

> The increased use of prime vendors may have contributed to the drug shortage situation by reducing the amount of product available in the supply chain. It is no longer easy to weather shortages by relying on stockpiled inventories because both wholesalers and health systems maintain minimum levels of stock. As a result, manufacturer supply issues are transmitted directly to the user without the benefit of an inventory buffer, thereby increasing the number of short-term shortages that may impact [larger] institutions.

The practice of maintaining minimum supply levels could be disastrous, especially as we contemplate bio- and chemical weapon attacks, not to mention out-sized, super-toxic strains of E. coli that have now killed some 18 Europeans and sickened 1,600 via an unknown, salad-vegetable-borne contaminant. Persons who get any E. coli infection can suffer horribly (somewhat reminiscent of Hemorrhagic Fever (Ebola)/Renal Syndrome [HFRS]), as this one attacks the kidneys, too, and is apparently drug-resistant.

Furthermore, many of the drugs that are ubiquitous and easy to get are also the most misleading (e.g., Exedrin Migraine and Extra Strength Exedrin contain identical ingredients, including the percentages of each compound; Eli Lilly's antidepressant Prozac gets only a new color (pink) and a new name (Sarafem) for treatment of so-called premenstrual dysphoric disorder (PMDD), dubbed a mental illness in women.

Warehousing medicines are not in the same category as warehousing books. A case can be made for no longer warehousing books, as computerized printing and the Internet have made doing so unnecessary, given easy on-demand operations. Warehousing medicines, however, is critical, even as a stop-gap measure until a better drug can be researched.

Moreover, the medical and pharmaceutical community may need to work to get a handle on the supply-and-demand problem quickly, giving the heave-ho to misrepresented drugs and quick approval and distribution for critical ones, including those for rare diseases. Shortages are not an option.

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