House Holds Hearing on Drug Shortages

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According to testimony given at a late September hearing held by the House Energy and Commerce Committee's Health Subcommittee, early warnings from drug companies about looming shortages of pharmaceuticals along with better manufacturing practices would help address the growing problem of drug shortages. The problem is quickly becoming a national health care crisis, as shortages of cancer, anti-infection and anesthesia drugs occur without warning when patients are in desperate need of the medications.

Subcommittee Chair Joe Pitts (R-PA) opened the hearing noting that the number of drug shortages reported to the Food and Drug Administration (FDA) increased from 61 in 2005 to 178 in 2010. In addition to cancer and anesthesia drugs, the products include "drugs needed for emergency medicine, and electrolytes needed for patients on IV feeding." A staff memo Pitts released at the hearing said that more than 240 drugs in 2010 were either in short supply or completely unavailable.

Administration witnesses Howard Koh, assistant secretary for health at the Department of Health and Human Services (HHS), and Sandra Kweder of the FDA, said that the number of drug shortages has been rising steadily over the past five years. Both Koh and Kweder suggested some remedies for the problem, but neither voiced confidence that it would be solved anytime soon because of the complex reasons for the shortages. One reason cited is that consolidation of the pharmaceutical industry has left fewer suppliers of the drugs subject to shortages, which in turn results in fewer plants being forced to make more of the drugs. With plants so busy filling orders for so many different types of drugs, they are not taking time to do needed maintenance; this leads to breakdowns in manufacturing, which ultimately cause supply problems. Other reasons included changes in inventory and distribution practices (e.g., "just in time" methods whereby hospitals save on inventory costs by ordering only small quantities of drugs, leaving providers less able to deal with shortages when they occur), shortages of underlying raw materials, and unanticipated demand.

One major reason for the shortages cited in the hearing is that manufacturers are losing interest in producing drugs that are off-patent and sold as generics at prices that leave little room for profits. This brought up a question of whether government policy is in some way interfering with the forces of supply and demand. "In our push to make products more affordable, are we tripping over ourselves?" asked Representative Tim Murphy (R-PA).

The administration officials also mentioned a disturbing aspect of the issue — development of a "gray market" in which some suppliers have been able to come up with quantities of drugs in shortage and sell them to hospitals at exorbitant prices. Some of those drugs are counterfeit, and in other cases, their quality is suspect.

As for solutions, they both said earlier warnings that manufacturers expect shortages would help. A bipartisan bill — H.R. 2445 — introduced by Representative Diana DeGette (D-CO) addresses that issue. The measure requires companies to alert the FDA when they expect shortfalls. Kweder pointed out that, when FDA does hear about a potential shortage, it is able to work with the company to solve the problem or with other manufacturers to increase their supplies of the drug. Koh added that, through this FDA drug shortages program, the agency prevented 99 drug shortages in 2011.

Witnesses representing industry included Jonathan Kafer of Teva Pharmaceuticals and Mike Alkire of Premier Healthcare Alliance. Kafer said that drug shortages are a complex and multi-stakeholder issue and that all involved must work together to resolve the issue. He called for greater communication among all the stakeholders (active ingredient suppliers, generic and brand manufacturers, wholesalers and distributors, health care providers, and government agencies), along with expedited FDA review of new manufacturing facilities and active ingredient suppliers when a drug shortage occurs. In addition, Kafer said the FDA should collaborate with the Drug Enforcement Administration (DEA) to establish a process that would streamline the DEA's quotas of active drug ingredients in response to drug shortages of controlled substances. Currently, the DEA limits the amount of active ingredients manufacturers may purchase for controlled substances.

Alkire's suggestions for dealing with drug shortages included:

- shorten the approval process for medically necessary generic drugs that appear to be in shortage;
- encourage the FDA's drug shortage program to engage members of the health care community in discussions to prioritize which drugs are critically necessary for treatment that may be at risk for shortage due to insufficient manufacturing capacity;
- create a fast-tract approval of new active pharmaceutical ingredient suppliers for medically necessary drugs in shortage;
- require manufacturers to notify the FDA of planned discontinuation or interruption in the manufacture of drugs as soon as practicable; and
- create a stakeholder committee to advise the FDA on market conditions.

Summary Judgment Granted to Hospital with No Capacity to Provide Mental Health Screening

On July 13, 2011, the U.S. District Court for the District of Nevada granted summary judgment to a hospital on a claim, brought by a patient's estate and family, alleging that the hospital violated EMTALA by unfairly neglecting to provide a mental health screening. The court held that the hospital could not be charged with discriminating against the patient under EMTALA when the hospital lacked the capacity to provide a mental health screening (Guzman-Ibarguen v. Sunrise Hospital and Medical Center, D. Nev., No. 2:10-cv-1228, 7/13/11).

The Facts

On July 25, 2008, an ambulance was dispatched to a casino responding to a report that Oscar Aniceto Mejia-Estrada was "displaying suicidal and homicidal ideation." Mejia-Estrada was transported for evaluation to the ED at the Sunrise Hospital and Medical Center in Las Vegas, Nevada. The physician examining and evaluating the patient concluded that Mejia-Estrada did not have an "acute/emergent medical condition" and was not a suicide or homicide risk. Mejia-Estrada was discharged from the Sunrise ED approximately an hour after his arrival.

Accompanied by family members, Mejia-Estrada returned to the Sunrise ED on July 27, 2008, at 12:40a.m. In 2008, Sunrise did not have licensed psychiatric beds and, since it did not provide

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psychiatric services, the hospital did not have a psychiatrist listed in the physician ED on-call roster. However, all of the Sunrise ED physicians were qualified and competent to perform a medical screening examination (MSE) to determine if an emergency medical condition related to a psychiatric condition was present.

Examined and evaluated by a triage nurse and by an ED physician, Mejia-Estrada "appeared to have altered thought processes, and reported restlessness and anxiety that was moderate in severity. He denied suicidal ideation or plan. He also appeared agitated, had hyperactive body language and respiratory distress was present." Concluding that Mejia-Estrada did not have any physical illness or injury, but based on "his chief complaints of depression and anxiety, [Mejia-Estrada] was assessed as a suicide risk." The ED physician executed a form at 2:30a.m. giving medical clearance for Mejia-Estrada to have a psychiatric evaluation and also admitting him to the hospital for appropriate medical care. Issued a hospital gown and socks, Mejia-Estrada was held in the ED discharge observation unit awaiting the requisite psychiatric evaluation from Southern Nevada Adult Mental Health to determine whether he would be admitted to their psychiatric facility. An ED nurse initiated "suicide precautions" at about 5:25a.m.

At 12:45p.m. a nurse assistant found Mejia-Estrada lying face down, unresponsive, and with a faint pulse. Security, an ED nurse and a respiratory technician were contacted. The respiratory technician examining Mejia-Estrada found two socks stuck in his mouth and throat. Efforts to revive Mejia-Estrada were unsuccessful, and Mejia-Estrada was pronounced dead at or about 1:00p.m. Decedent's heirs, including Erendira Esperanza Guzman-Ibarguen, sued Sunrise and others for an alleged EMTALA violation – failing to provide an appropriate medical screening examination – and for an alleged state medical malpractice claim. The hospital moved for summary judgment on the EMTALA claim.

The Ruling

Drawing on the United States Court of Appeals for the 9th Circuit's decision of Baker v. Adventist Health, Inc., 260 F.3d 987 (9th Cir. 2001), the federal district court wrote that "EMTALA explicitly limits the screening examination that a hospital is required to provide to one that is within the capability of the hospital's emergency department." Grounded on that appellate decision, the district court held that "[t]he record clearly establishes here that while Defendant Sunrise Hospital performed a medical screening of Mr. Mejia on July 27, 2008, it did not at that time have the capability to perform mental health screening." For that reason, the district court determined there was no genuine issue "of material fact that Sunrise Hospital violated EMTALA . . . Sunrise Hospital cannot be charged with discriminating against Mr. Mejia by failing to provide him with mental health screening where the hospital lacked the capacity to do so." Thus, the court granted summary judgment to the hospital on the EMTALA claim.

The district court also added that as made clear in the Ninth Circuit's decision in Baker, EMTALA "'. . . is not intended to create a national standard of care for hospitals or to provide a federal cause of action akin to a state law claim for medical malpractice. Indeed, EMTALA expressly contains a non-preemption provision for state remedies." Accordingly, the court added that the question as to whether Sunrise and the other named Defendants adequately discharged their duty of care to protect against Mejia-Estrada's suicide would continue as the Plaintiffs' claim of medical malpractice against Defendants since this issue is not determinative of Plaintiffs' EMTALA claim.

For the full text of the court's decision, go to http://law.justia.com/cases/federal/district-courts/nevada/nvdce/2:2010cv01228/74981/80.

EMTALA case synopsis prepared by Terri L. Nally, Principal, KAR Associates, Inc.

AAEM Opposes Proposed Changes to the Common Program Requirements

The American Academy of Emergency Medicine (AAEM) opposes the proposed changes to the Common Program Requirements that would require residents or fellows entering ACGME accredited training programs to complete prerequisite training in only ACGME or RCPSC accredited programs, and restricts graduates of AOA residency programs from serving as faculty at ACGME residency programs.

This proposed change will affect those candidates that have completed an AOA accredited internship or more extended AOA training that desire to enter ACGME accredited residency training or candidates that have completed AOA residency training who desire to enter ACGME accredited fellowship training. Considering that AOA program requirements and inspection processes are nearly parallel to ACGME standards, one would expect equivalency of graduates of ACGME/RCPSC training programs and AOA training programs. Regardless, such candidates undergo a detailed review process before selection into an ACGME program or placement on a Match List. We believe the issue of transfer between programs to be more complex in terms of equivalency of experience and we do not take a position regarding awarding credit for such circumstances.

Many emergency medicine ACGME accredited residency programs have matriculated AOA internship graduates and have found them to be of high quality and competence. Likewise, many emergency medicine ACGME accredited residency programs utilize AOA graduates as faculty and have found them to be of high quality and competence. In my own personal experience, as a faculty member at one of the few dually accredited ACGME and AOA emergency medicine training programs, I have had the opportunity to work with dozens of residents who have completed AOA accredited internships, fellows who have completed AOA accredited residencies, and attending faculty who are AOA graduates. I cannot distinguish between the AOA prepared residents, fellows, and attending faculty in terms of their skills and abilities, compared to their ACGME prepared colleagues that work with them side-by-side.

Please reconsider these proposed revisions to the Common Programs Requirements and revise them to include AOA accredited prerequisite training programs, along with ACGME and RCPSC.

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