



United States Senate Committee on Health, Education, Labor, & Pensions
Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions
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Statement for the Record

Submitted by:

The Roundtable on Critical Care Policy
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Chairman Harkin and Ranking Member Enzi and other Members of the Committee, we thank you for holding this important hearing and appreciate the opportunity to submit a statement for the record.

The Roundtable on Critical Care Policy is a non-profit organization that provides a forum for the nation's leaders in critical care and public health to advance a common federal policy agenda to improve the quality, delivery and efficiency of critical care in the United States. The Roundtable brings together a broad cross-section of stakeholders, including renowned critical care clinicians, patient groups, academia, public health advocacy interests and industry.

Each year, more than five million Americans receive critical care when they are admitted into traditional, surgical, pediatric, or neo-natal intensive care units (ICUs).¹ Providers of critical care require specialized training, the care delivered in the ICU is technology-intensive, treatment is unusually complex due to what may be a patient's system—or multiple system—challenges or failures, and outcomes have life or death consequences. Approximately 540,000 individuals die each year after admission to the ICU, and almost 20 percent of all deaths in the U.S. occur during a hospitalization that involves care in the ICU.² This mortality impact is similar to heart disease or cancer.³

The lives of ICU patients depend on having access to an array of critical care medications -- drugs to regulate a patient's breathing, maintain a heart beat or prevent life-threatening infections, to name a few. Drug shortages of any of these vital medications may jeopardize health outcomes and threaten patient safety, and while we recognize the importance of access to all drugs for all patients, particularly those with terminal conditions, we wish to remind the

¹ Society of Critical Care Medicine. *Critical care statistics in the United States*.
<http://www.sccm.org/AboutSCCM/Public%20Relations/Pages/Statistics.aspx>.

² DC Angus, AE Barnato, WT Linde-Zwirble et al, "Use of Intensive care at the end of life in the United States: an epidemiologic study," *Critical Care Medicine* 32 (2004)

³ Centers for Disease Control and Prevention, National Center for Health Statistics, *Deaths and Mortality 2007*
<http://www.cdc.gov/nchs/fastats/deaths.htm>

Committee that shortages of some critical care drugs, such as those typically used to treat cardiac or respiratory arrest, may carry immediate life and death consequences.

According to a recent Roundtable on Critical Care/ Outcomes and Innovation Working Group analysis of the Food and Drug Administration's current drug shortage list, ICUs currently face shortages of at least 30 generic drugs that are commonly used to care for critically ill and injured patients (See Appendix). This includes drugs such as phenylephrine injectable and norepinephrine, which critical care providers depend on to control a patient's blood pressure; pytonadione, a medication used to control bleeding in individuals with blood clotting deficiencies; and vecuronium injectable, which relaxes a patient's throat muscles to allow for the insertion of a breathing tube.

While there are alternatives for some of these medications, many may not have acceptable substitutes in emergency situations. Furthermore, substitutions can impact other treatments and can add a layer of complexity to already difficult and life-threatening situations. For example, in some cases an alternate drug may result in less optimal outcomes, as is the case with pediatric ICUs (PICU), where fentanyl, a synthetic, generic narcotic pain-killer used to relieve pain and sedate children, was in short supply. While there are other narcotics physicians can use, none have the special attributes of fentanyl that make it a safe and key PICU medication.⁴

Moreover, medications administered frequently in the ICU often have specific protocol for usage, which covers dosing, timing and adverse effects. When a shortage forces the team to use a substitute drug, the safety and efficacy that protocol brings is lost, increasing the risk for adverse outcomes, particularly when a critical care provider has only seconds or minutes to learn about an unfamiliar substitute medication and how it is intended to be delivered.

In 2010, the Institute for Safe Medication Practices surveyed 1,800 health practitioners and found several instances in which a substitute drug or new version led to difficulties in patient care. During a shortage of propofol, for instance, health care providers reported that they had to rely on alternative sedation, which led to "problems weaning patients from a ventilator."⁵ Several examples of mis-dosing were cited due to confusion regarding the medication, including one in which a patient received an incorrect dosage of morphine and had to be transferred to critical care.⁶

Finally, shortages of these drugs have serious implications for hospital surge capacity in the event of a severe pandemic illness or a mass casualty scenario. Large stores of most of the

⁴ Christopher Johnson, MD, "The fentanyl shortage: yet another example of our vulnerable drug supply system" <http://www.chrisjohnsonmd.com/2011/10/19/the-fentanyl-shortage-yet-another-example-of-our-vulnerable-drug-supply-system/> October 19, 2011

⁵ Institute for Safe Medication Practices, "ISMP survey on drug shortages", *ISMP Medication Safety Alert!* 2010;15(15):4. <http://www.ismp.org/Newsletters/acutecare/articles/20100923.asp>

⁶ *ibid*

medications identified by the Roundtable on the FDA's drug shortage list are essential to preserving the integrity of the health care delivery system in either scenario.

As the Committee works to develop policies to stem drug shortages, the Roundtable urges Members to keep in mind the unique impact of these shortages on ICU patients – those who are critically ill and injured – and the importance of the nation's critical care providers having access to necessary medications during what may be a patient's most vulnerable time.