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FDA Regulation of Digital Health: Software-Related Recalls Can Negatively Influence Medical Care

New York, New York, September 12, 2017—Medical software has become an increasingly critical component of health care, with the hacking of medical devices a growing concern. And yet the regulatory landscape for digital health is inconsistent and controversial. In a new study in *The Milbank Quarterly*, Jay G. Ronquillo of Western Michigan University Homer Stryker M.D. School of Medicine and Diana M. Zuckerman of the National Center for Health Research have found that software problems in medical devices are not rare and have the potential to negatively influence medical care.

In the first study to assess the impact on patient safety of the U.S. Food and Drug Administration's (FDA's) current regulatory safeguards and new legislative changes, the researchers used databases to identify all medical devices that were recalled in the U.S. from 2011 through 2015 primarily because of software defects. They counted all software-related recalls for each FDA risk category and evaluated each high-risk and moderate-risk recall of electronic medical records to determine the manufacturer, device classification, submission type, number of units, and product details.

"Our study found that millions of patients were put at risk because of flawed software," explains Diana Zuckerman, PhD, co-author of the study and president of the National Center for Health Research, a nonprofit in Washington, D.C. "Just two weeks ago, FDA recalled almost half a million pacemakers because they were found to be vulnerable to hacking. That's just the latest example of why all patients, physicians, and policymakers need to demand that health IT devices are proven to be safe."

Background

In many hospitals and other clinical settings, medical equipment and devices controlled by software have numerous essential applications, such as tracking patients' vital signs, alerting physicians to the risk of adverse drug events, and controlling the amount of medication that patients receive. In essence, the use of medical software is becoming crucial to the practice of medicine. The FDA recalls devices using a classification system based on the severity of their potential to cause harm—low, moderate, and highest risk.

Findings
- A total of 627 software devices (1.4 million units) were subject to recalls, with 12 of these devices subject to the highest-risk recalls, defined as those that can cause death or permanent harm.
- 11 of the 12 devices recalls classified as high risk had entered the market through the FDA review process that does not require evidence of safety or effectiveness, and one device had been completely exempt from regulatory review.
- The largest high-risk recall categories were anesthesiology and general hospital (such as infusion pumps) with one each in cardiovascular and neurology.
- Five electronic medical record systems were recalled for software defects classified as posing a moderate risk to patient safety, such as providing information about the wrong patient.

Regulating devices before they can be sold in the U.S. has not identified all of the software flaws that could harm patients, evidenced by the large number of patients exposed to software products later subject to high-risk and moderate-risk recalls. Without strong regulations and implementation to reinforce risk assessment and adverse event reporting, physicians and patients are likely to be at risk from medical errors and hacking caused by software-related problems in medical devices.