NEWS RELEASE

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**Gaps in Recalls of Home-Use Medical Devices   
Top ECRI’s Hazards List for 2023**

*ECRI’s report warns of potential safety risks with 10 health technologies, including single-use products, medication cabinets, cybersecurity of cloud-based systems, and ventilator disinfection*

**PLYMOUTH MEETING, PA—**ECRI, the most trusted voice in healthcare, names gaps with recalls of home-use medical devices as the nation’s most pressing health technology safety issue for 2023.

Recall notices for home-use products often do not reach users, placing patients at serious risk of harm, according to the independent nonprofit safety leader in its just-released Top 10 Health Technology Hazards report.

As the home healthcare trend accelerates, ECRI is concerned about home care patients not receiving safety notices that warn of problems with the medical devices they are using. Device manufacturers seldom have direct communication with home care patients, and healthcare providers may not proactively contact patients about recalls. Patients with affected products may learn about a recall long after it was issued, and potentially from an unreliable source.

“Even if patients do receive notifications, the language may be jargon-heavy and perplexing, and patients may have difficulty determining whether their device is affected or what to do about it,” cautions Marcus Schabacker, MD, PhD, president and CEO of ECRI. “Without clear, understandable information about a product recall, patients cannot accurately assess the health risks and may harm themselves by continuing to use an unsafe device, or by inappropriately stopping use of a device.”

One example is the recall of continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines. The recall was initiated in June 2021 and affected 5.5 million devices; however, several months elapsed before some patients became aware of the recall. Moreover, because of the language used in the recall notice, patients were confused about whether to continue to use the device and what actions they needed to take.

For 2023, ECRI's report includes a series of challenges to industry, urging manufacturers to pursue device or process improvements that could mitigate—or even eliminate—some of the hazards included on the list. With healthcare facilities understaffed and healthcare workers overstressed, it's more important than ever that technologies be designed in ways that ensure their safe use.

“Reducing preventable harm requires more than just vigilance on the part of technology managers and device users. The medical device industry also has a role to play,” says Schabacker.

The 10 topics on ECRI’s 2023 hazards list are listed below in rank order:

1. **Gaps in** **Recalls for At-Home Medical Devices** cause patient confusion and harm

2. Growing number of **Defective Single-Use Medical Devices** puts patients at risk

3. Inappropriate use of **Automated Dispensing Cabinet Overrides** can result in medication errors

4. **Undetected Venous Needle Dislodgement** or access-bloodline separation during hemodialysis can lead to death

5. Failure to manage **Cybersecurity Risks Associated with Cloud-Based Clinical Systems** can result in care disruptions

6. **Inflatable Pressure Infusers** can deliver fatal air emboli from IV solution bags

7. Confusion surrounding **Ventilator Cleaning and Disinfection** requirements can lead to cross-contamination

8. Common misconceptions about **Electrosurgery** can lead to serious burns

9. Overuse of **Cardiac Telemetry** can lead to clinician cognitive overload and missed critical events

10. **Underreporting Device-Related Issues** may risk recurrence

Now in its 16th year, ECRI’s annual report identifies health technology concerns that warrant attention by patients, healthcare leaders, and industry. ECRI’s team of biomedical engineers, clinicians, and healthcare management experts follows a rigorous review process to select topics for the annual list, drawing insight from incident investigations, reporting databases, and independent medical device testing.

The full Top 10 Health Technology Hazards report, accessible to ECRI members, provides detailed steps that organizations can proactively take to prevent adverse incidents. An executive brief version is available for complimentary download at www.ecri.org/2023hazards.

On February 1, ECRI is presenting a live lab webcast, [Home-Use Device Recalls: What You Need to Know to Mitigate Risk and Protect Patients](https://www.ecri.org/events/home-use-device-recalls-what-you-need-to-know-to-mitigate-risk-and-protect/), to provide additional information about this year’s number one hazard.

To learn more, visit [www.ecri.org](http://www.ecri.org), call (610) 825-6000, ext. 5891, or email [clientservices@ecri.org](mailto:clientservices@ecri.org).

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**About ECRI**

ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on technology evaluation and safety, ECRI is respected and trusted by healthcare leaders and agencies worldwide. Over the past fifty-five years, ECRI has built its reputation on integrity and disciplined rigor, with an unwavering commitment to independence and strict conflict-of-interest rules. ECRI is the only organization worldwide to conduct independent medical device evaluations, with labs located in North America and Asia Pacific. ECRI is designated an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality. ECRI and the Institute for Safe Medication Practices PSO is a federally certified Patient Safety Organization as designated by the U.S. Department of Health and Human Services. The Institute for Safe Medication Practices (ISMP) formally became an ECRI Affiliate in 2020. Marcus Schabacker, MD, PhD, President and CEO of ECRI, was awarded 2021 Healthcare Leader by the Philadelphia Business Journal. Visit us at www.ecri.org.