

February 9, 2022

Honorable Michelle Mussman
Illinois House of Representatives
257-S Stratton Office Building
Springfield, IL 62706

SUBJECT: "Right to Repair"

Dear Honorable Michelle Mussman:

As organizations dedicated to the health and safety of patients, we write to express our strong opposition to any "right to repair" legislation that would promote the substitution of highly qualified and certified repair operations with operations who aren't required to undergo training or adhere to quality-management protocols required by the U.S. Food and Drug Administration (FDA). This kind of legislation would put patients at risk of adverse events and potential harm.

Patients deserve dependable, quality care that utilizes the best equipment, medicines and trained medical professionals. The Digital Fair Repair Act, HB 3061, has us concerned. With the inclusion of FDA regulated devices, we worry this legislation, if it becomes law, would unnecessarily expose patients to new and unnecessary health risks.

Compelling original equipment manufacturers (OEMs) to share proprietary servicing information with independent repair organizations (ISOs) that are not required to adhere to the same strict FDA requirements as device manufacturers makes medical devices more vulnerable to malfunction and cyber hacks, which in turn can lead to harm to the patient, device user, and technician or increase the likelihood of inaccuracies and missed diagnoses.

Given the sophistication and technology powering these machines, it's no surprise that medical device servicing and repair is complex. Repairs to any kind of modern technology brings its own complexities and training requirements and creates a variety of different risks when done incorrectly. For medical devices, if repairs are done incorrectly, patients can be directly endangered, care delayed, or diagnoses missed. That's why the FDA regulates some servicers to follow quality-management processes, meet minimum training requirements and report incidents to enhance patient and user safety. ISOs, however, aren't held to any regulatory standards or reporting requirements. An open-ended medical device "right to repair" law that forces the transfer of intellectual property to companies with little to no accountability makes this lack of oversight even more problematic.

The patients we represent frequently encounter complex medical devices during their care- from CT scanners that emit radiation or sensitive infusion pumps that dose pharmaceutical therapies. These individuals don't choose to depend on these medical devices for their health, but they deserve the peace of mind that comes with knowing their device has been maintained on par with rigorous FDA standards.

Thank you for considering our community's perspective and we urge you to oppose any legislative efforts to increase patients' risk by forcing manufacturers to make public their service materials to unregulated, unaccountable service technician businesses.

Sincerely,

AliveAndKickn
AltusCampus
Center for Medicine in the Public Interest
Cervivor
Colon Cancer Coalition
Colon Cancer Foundation
Colon Stars
Colorectal Cancer Alliance
ICAN, International Cancer Advocacy Network

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
 Looms for Lupus
 Lupus and Allied Diseases Association
 Navigations SoC
 One Cancer Place
 Patients Rising Now
 People with Empathy
 RetireSafe
 S.H.O.U.T. International
 Say YES to Hope
 Support Fibromyalgia Network
 The Blue Hat Foundation
 The Colon Club
 U.S. Pain Foundation

