May 11, 2022

The Honorable Frank Pallone, Jr.
Chairman
2107 Rayburn House Office
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
1035 Longworth House Office Building
Washington, DC 20515

The Honorable Anna G. Eshoo
Chairwoman, Subcommittee on Health
272 Cannon House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member, Subcommittee on Health
2434 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, and Ranking Member Guthrie:

As organizations dedicated to the health and safety of patients, we write to express our strong support for H.R. 7253, *The Clarifying Remanufacturing to Protect Patient Safety Act*.

The legislation, introduced by Representatives Scott Peters (D-CA), John Joyce (R-PA), and Kim Schrier (D-WA), clarifies the meaning of remanufacturing, which requires registration, reporting and oversight as it relates to medical devices in order to better protect patients. In addition, this critical legislation would help educate companies and other stakeholders about what constitutes FDA-regulated remanufacturing activities.

We have concerns that so many adverse medical device events related to remanufacturing escape FDA oversight, as concluded in FDA's own 2018 report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices. These adverse events have even contributed to deaths, and like the FDA, we fear this is the result of unregulated remanufacturing activities.

While we appreciate the FDA's long standing work to clarify what are remanufacturing activities, which includes guidance issued in 2021, we believe this legislation gives the FDA additional tools to strengthen their ongoing oversight of remanufacturing.

We urge Congress to include this commonsense legislation in the MDUFA V reauthorization and pass it without delay for the benefit of not just the patients we represent, but all patients seeking healthcare in America.

Sincerely,

AliveAndKickn
AltusCampus
Avery's Hope
AZ Zebras
Center for Medicine in the Public Interest
Cervivor

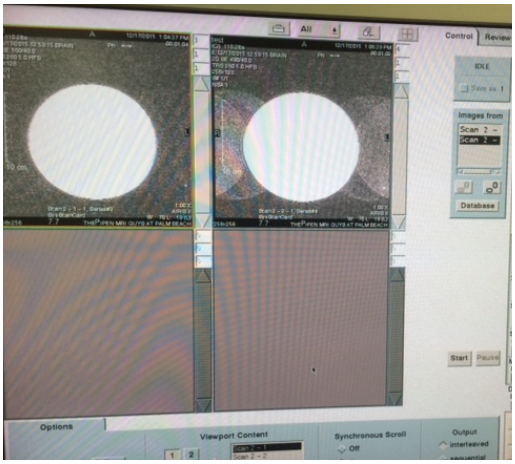
Colon Cancer Coalition
Colon Cancer Foundation
Colon Stars
Colorectal Cancer Alliance
ICAN, International Cancer Advocacy Network
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
Looms for Lupus
Lupus and Allied Diseases Association
National Scleroderma Foundation TriState Chapter
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

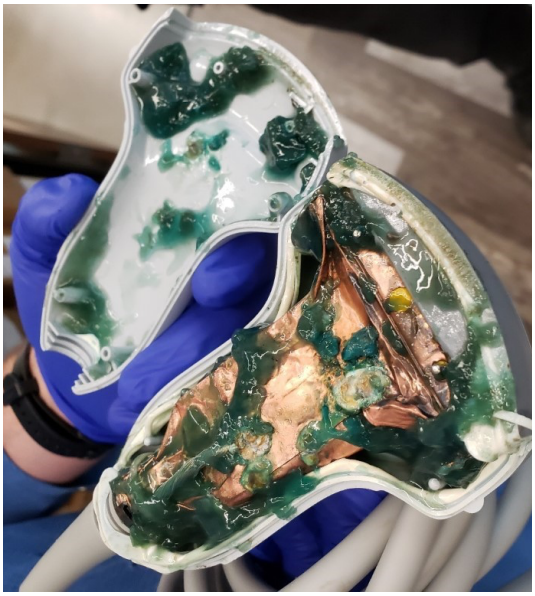
cc: Democratic Members of the Subcommittee on Health
Republican Members of the Subcommittee on Health

THE RISK: EXAMPLES OF IMPROPER REMANUFACTURING

This damaged cable was covered with plastic tubing and zip ties. This “repair” fails to meet OEM quality specifications and increases the risk of cable failure. This could result in electrical arcing causing electrocution or burns and lost signal, necessitating rescans or causing a misdiagnosis.

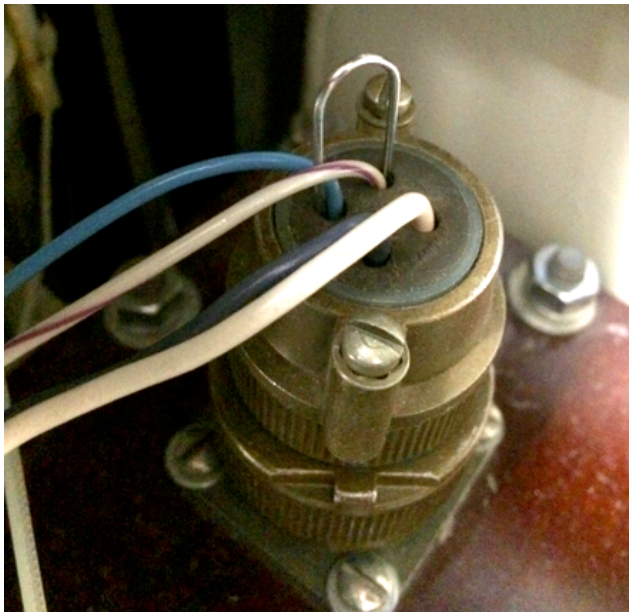
At right is an example of “ghosting” in a medical image from an MRI. In this case, remanufacturing caused electrical issues that resulted in a poor-quality image. Ghosting may require additional patient scans, delaying care or causing a misdiagnosis.





Left, a third-party business failed to properly seal this transducer after repair, allowing ultrasound gel to seep into the unit, creating potential contamination and image quality issues and risk of electrical shock for the sonographer.

On the right, a third-party used aluminum foil to shield some of an MRI system's cables in the scan room. This can present safety and electrical issues when used within the MRI filter panel that contains high voltage.



In the image at left, a paperclip has been used to override a safety interlock. This not only changes how the device functions but negates FDA-approved safety features in the original design.

Below is a side-by-side comparison of how a part should look (right) and an improperly remanufactured real world example (left). The black tape being used to hold loose wires in place on a moving part could cause the device to short circuit.