



**From:** Emma Watson  
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**Subject:** Support for medical device exemption in HB 4562

Novocure supports the inclusion of a medical device exemption in HB 4562. Medical devices are often highly complex machines that are engineered to operate in a specific manner to ensure safety and functionality. These life-saving devices should only be serviced by regulated technicians with specific training.

Medical devices face substantial regulatory scrutiny from the Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act ("FFDCA"). Congress has continued to expand and amend the FFDCA to ensure continued access to complex medical devices which place the priority on patient safety and product effectiveness.

Right to repair legislation without an exemption for medical devices would allow third-party independent service providers (ISOs) to modify and repair intricate devices in a manner that may not be consistent with how devices are intended to operate. ISOs are not held to the same regulatory standards as original equipment manufacturers, opening the possibility of repairs that jeopardize patient safety and device efficacy.

Right to repair legislation should include an exemption for FDA regulated medical devices to ensure that device functionality, patient safety, and manufacturer integrity are maintained as per the original FDA approval. Otherwise, the devices may not function as intended which could irreparably harm patients or harm the effectiveness of these life saving devices. Novocure supports the inclusion of a medical device exemption in HB 4562, which strengthens the bill's consumer protections.

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