

Short Comment Regarding a Proposed Exemption Under 17 U.S.C. 1201

Item 1. Commenter Information

The Medical Device Innovation, Safety and Security Consortium (MDISS) is a non-profit public-private-partnership established to accelerate the improvement of the security profile our nation's biomedical devices and associated networks. Membership includes medical device manufacturers, healthcare delivery organizations, other technology companies, cybersecurity companies, etc. MDISS collaborates closely with government agencies and other non-profit entities including but not limited to the FDA, NIST, NCCOE, Center for Internet Security, NHISAC, and university researchers. Contact: Dale Nordenberg, MD, dalenordenberg@mdiss.org, 917-767-1491

Item 2. Proposed Class Addressed

Proposed Class 25: Software—Security Research

Item 3. Statement Regarding Proposed Exemption

At this time, MDISS is not able to support the proposed **COALITION OF MEDICAL DEVICE RESEARCHERS FOR EXEMPTION TO PROHIBITION ON CIRCUMVENTION OF COPYRIGHT PROTECTION SYSTEMS FOR ACCESS CONTROL TECHNOLOGIES** Docket No. 2014-07.

+MDISS agrees that the cybersecurity of connected medical devices is critical for patient safety and privacy.

+MDISS supports the need of patients to have access to, and ultimate control of, their healthcare data but there is no evidence that 'hacking' and reverse engineering a device to obtain patient data will help and not harm patients. Who will certify the data is not corrupted? Will that data be available and trusted to be integrated with the patient's broader healthcare record? Will each person/patient understand all such issues before they make a request for such action?

+HIPAA regulation. It's not clear that HIPAA supports the access to PHI proposed in this petition.

+MDISS believes that it is critical that the USA provide a robust environment for medical innovation and the commercialization of this innovation for patients. It's not evident that research requires the bypassing of intellectual property protections. This may adversely impact innovation incentives for universities and companies that create this IP for patients.

+MDISS has concerns about the ambiguity of the term 'researcher'. The healthcare system is highly regulated to protect patients. Medical devices, hospitals, care providers, medications, etc. are all regulated to help ensure patient safety, privacy and healthcare rights. Will all 'researchers' have the necessary domain expertise to responsibly and safely hack a patient's device and associated data?

+MDISS is very supportive of medical device research. There are many mechanisms that will support in-depth research opportunities while ensuring patient safety, and these may be encouraged or mandated through regulatory and policy processes.

+MDISS also questions if a patient's desire to hack a device is sufficient cause to provide such permission in this highly regulated environment. What is the role of the provider who prescribed the device? Should a patient deviate from the dosing directions of medications?

PRIVACY ACT ADVISORY STATEMENT Required by the Privacy Act of 1974 (P.L. 93-579)

The authority for requesting this information is 17 U.S.C. §§ 1201(a)(1) and 705. Furnishing the requested information is voluntary. The principal use of the requested information is publication on the Copyright Office website and use by Copyright Office staff for purposes of the rulemaking proceeding conducted under 17 U.S.C. § 1201(a)(1). NOTE: No other advisory statement will be given in connection with this submission. Please keep this statement and refer to it if we communicate with you regarding this submission.