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In re: Notice of Inquiry on Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 79 Fed. Reg. 55,687 (Sept. 17, 2014). Exception for Class 27.

I am currently a Medical Device Researcher working directly with medical device manufacturers to test the security of medical devices through my employer. Under normal circumstances, I'm a proponent of allowing security researchers to test devices. Independent researchers conducting research on their own time have made many significant security findings. But with medical devices, the circumstances are different.

When security issues are discovered in medical devices, it could result the device having to go through recertification with the FDA. That process could take months to years to complete while the vulnerability in the device remains. While Google has a 60 day notice period once they notify a vendor of a security bug, a medical device manufacturer can't *patch* their software or hardware in the same way Google, Microsoft, or Adobe can.

While the vulnerability remains unpatched but out in the public, it may cause patients to decide against an appropriate therapy because of an increased fear of malicious use. In this scenario, the risk-benefit calculation typically made between a doctor and patient based solely on the medical risks and medical benefits is changed by the security researcher.

Medical device benefits are evaluated by the FDA prior to medical device approval against the known risks such as infection. The manufacturer must balance all identified risks with the benefits and determine if the overall risk profile is acceptable or not. This process is required by the FDA and has recently made advances to incorporate malicious use alongside the other risks. The change to the risk management process gives the FDA a complete picture of the risks, which allows them to evaluate the overall safety and efficacy of a medical product.

For these reasons, I encourage you not to allow an exception for medical device research.