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June 29, 2015

Jacqueline C. Charlesworth
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United States Copyright Office
Library of Congress
101 Independence Ave. SE
Washington, DC 20559-60000

Re: Docket No. 2014-7, Exemptions to the Prohbition Against Circumvention of Technological Measures Protecting Copyrighted Works
Class 27 – Comments of Coalition of Medical Device Researchers

Dear Ms. Charlesworth,

I write on behalf of the coalition of medical device researchers (the "Coalition")[1], in response to your letter dated June 3, 2015. The Coalition is grateful for this opportunity to respond to your questions, which are answered in turn.

A. The Copyright Office Should Not Condition an Exemption on Where Researchers Decide to Share Discoveries.

You asked the Coalition how the Copyright Office should approach the question of disclosure of research, and specifically whether and how the Copyright Office could require researchers to disclose their findings to manufacturers as a condition of the exemption. Although that is usually what happens,[2] there are times where the interests of safety and security are better served by disclosing research to others. Furthermore, any limitations on how and with whom researchers can discuss their work would violate the First Amendment. The Coalition therefore requests that the Copyright Office not impose any limitations on the discussion of research as a condition of the requested exemption.

As the Coalition has noted, there is no single forum for discussion of medical device security research that best ensures public safety. Today, malformed or misconfigured code in medical devices present far greater risks than exploitable vulnerabilities,[3] and mandating the disclosure of information to a manufacturer first serves no greater safety purpose in those cases. Research is also often iterative, and a researcher may wish to discuss discoveries with a colleague first in

[1] The members of the Coalition are Hugo Campos, Jerome Radcliffe, Karen Sandler, and Benjamin West. *See* Coalition Comment, Appx. A.
[2] *See* Transcript of Hearing on Class 27 at 29–30; *see also* Coalition Reply Comment at 17–18.
[3] *See* Coalition Comment at 2–3; Transcript of Hearing on Class 27 at 25.

order to confirm, develop, or refine results.[4] A researcher may also (justifiably) believe that absent public pressure manufacturers may not respond to issues, and may therefore wish to contact the press instead.[5] They may discover something about the manufacturer's practice that requires government intervention, and therefore seek to inform the FDA, DHS, or FBI instead.[6] Finally, a researcher may determine that what they have discovered is so substantial that the public should be informed immediately so that doctors and patients can take immediate action, such as discontinuing the use of a device.[7]

Whatever the decision, it is theirs to make. The First Amendment protects the right of a speaker to decide where, to whom, and how to convey their message.[8] Any government regulation of speech because of "its message, its ideas, its subject matter, or its content" is invalid unless the government can satisfy strict scrutiny.[9] This is true whether the government decides to pursue speech through overt proscription or indirect pressure,[10] and whether the government directly prohibits the speech or instead uses it as a condition when considering whether to grant a discretionary benefit, such as the proposed exemption here.[11] Were the Copyright Office to issue a regulation targeting a specific topic of speech directly – e.g., by granting the exemption only when researchers disclose security research to manufacturers – the regulation would be presumptively unconstitutional.[12] "To deny an exemption to claimants who engage in certain forms of speech is in effect to penalize them for such speech."[13] As the Ninth Circuit put it when striking the United States Information Agency's regulations exempting audiovisual works it deemed as "educational" from foreign customs pursuant to the Beirut Agreement:

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[4] *See* Daniel Halperin et al., *Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses*, IEEE SYMPOSIUM ON SECURITY & PRIVACY 129, 142 (2008) (noting numerous people who reviewed the report prior to its publication).
[5] *See* Coalition Comment at 21; Reply Comment at 17.
[6] Both the FDA and DHS solicit such reports. *See* Coalition Reply Comment at 8.
[7] *See* Kristin Bergman, *A Target to the Heart of the First Amendment: Government Endorsement of Responsible Disclosure as Unconstitutional*, 13 NW. J. TECH. & I.P. 117, 146 (2015) (discussing a researcher's decision to tell the public first about a computer vulnerability).
[8] *See* Cohen v. California, 403 U.S. 15, 24 (1971) ("[T]he usual rule [is] that governmental bodies may not prescribe the form or content of individual expression."); U.S. West, Inc. v. FCC, 182 F.3d 1224, 1232 (10th Cir. 1999) ("Effective speech has two components: a speaker and an audience. A restriction on either of these components is a restriction on speech.").
[9] Reed v. Town of Gilbert, No. 13-502, slip op. at 6 (U.S. June 18, 2015) (quoting Police Dep't of Chicago v. Mosley, 408 U.S. 92, 95 (1972)).
[10] Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2664 (2011) ("Lawmakers may no more more silence unwanted speech by burdening its utterance than by censoring its content.").
[11] Courts refer to analysis of the latter as the "unconstitutional conditions doctrine." *See* Bd. of County Commissioners v. Umbehr, 518 U.S. 668, 674–75 (1996); *see* In re Tam, 785 F.3d 567, 577–80, *reh'g en banc granted and opinion vacated* 600 Fed. App'x 775 (Fed. Cir. 2015) (extensively reviewing the contours of the unconstitutional conditions doctrine). Exemptions to the doctrine – including when the government is funding the speech directly or making certain employment decisions – do not apply here. *See* Dep't of Texas VFW v. Texas Lottery Comm'n, 760 F.3d 427, 436 (5th Cir. 2014) (en banc) (reviewing these exceptions).
[12] *Reed*, slip op. at 6.
[13] Speiser v. Randall, 357 U.S. 513, 518 (1958).

> [B]y conditioning a valuable government benefit on the basis of speech content, the USIA forces film makers to choose between exercising their free speech and foregoing benefits . . . or curtailing the speech and obtaining the benefits. The imposition of this sort of dilemma patently transgresses the well-established principle that the government may not condition the conferral of a benefit on the relinquishment of a constitutional right.[14]

Requiring those seeking an anticircumvention exemption to disclose research to manufacturers forces them to choose between benefiting from the exemption by curtailing their right to speak to others (or their right not to speak at all[15]), or exercising their rights while foregoing the exemption. The Constitution prohibits this sort of speaker's dilemma.

Furthermore, if the exemption were to require that a researcher disclose a vulnerability *only* to a manufacturer, and not others, this would be an unconstitutional prior restraint. Restraints on publication of information "are the most serious and the least tolerable infringement on First Amendment rights."[16] They are invalid even when the government may punish the speech's eventual publication[17] – though there are hardly grounds to believe that a government would be able to punish the speech in question here.[18]

A limitation on disclosure here would also distort the public's understanding of medical device safety issues. The manufacturers themselves, as the copyright owners, would not rely on the proposed exemption, and thus would not be subject to any gag requirement it imposes. They would therefore be free to downplay, refute, or discredit any claims of device problems, while independent researchers would not be allowed to respond. Other members of the public, including doctors, patients, technicians, computer scientists, and government regulators, would be left with only one side of the story, and would be forced to make decisions without fully appreciating the risks. It is precisely this risk of interference in the marketplace of ideas that the First Amendment is designed to prevent.[19]

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[14] Bullfrog Films, Inc. v. Wick, 847 F.2d 502, 511 (9th Cir. 1988).

[15] There is a reciprocal First Amendment right not to speak. Harper & Row Publishers, Inc. v. Nation Enters., 471 U.S. 539, 559–60 (1985).

[16] Nebraska Press Ass'n v. Stuart, 427 U.S. 539, 559 (1976).

[17] CBS Inc. v. Davis, 510 U.S. 1315, 1318 (1994) (Blackmun, J., as Circuit Justice). This is true even when the limitation is temporary. *Nebraska Press Ass'n*, 427 U.S. at 560.

[18] Academics have debated whether in certain circumstances "crime-facilitating speech" could be proscribed, though they tend only to point to successful cases where speakers publish such information intending it to be used in a crime or knowing it will be. *See* Eugene Volokh, *Crime-Facilitating Speech*, 57 STAN. L. REV. 1095, 1129–30 (2005); Andrea M. Matwyshyn, *Hacking Speech: Informational Speech and the First Amendment*, 107 NW. U. L. R. 795, 799–800 (2013). These cases are easily distinguished from the research considered here. As evidenced in the initial comment, researchers usually do not publish all of the steps necessary to facilitate any action, *see* Coalition Comment at 22, the action they facilitate would only be criminal in some specific applications of this information, *see* Section B, *infra*, and it is supremely unlikely that they would publish this information with the intent that it be used in a crime. But even if it were unlawful, this still would not justify a prior restraint for the reasons noted above.

[19] *See* Sweezy v. New Hampshire, 354 U.S. 234, 261–62 (1957) ("Progress in the natural sciences is not remotely confined to findings made in the laboratory. . . . For society's good . . . inquiries into these problems, speculations about them, stimulation in others of reflection upon

No opponent to this exemption argues for this disclosure obligation, and no other area of law supports the position that the Copyright Office can impose a disclosure obligation here. The DHS states that coordinating vulnerability research with manufacturers is a "desirable goal," but is not required, and "is not always followed for a variety of reasons."[20] Where laws mandate disclosure to others, they do so in the context of businesses disclosing information about their practices to consumers, where the commercial speech doctrine tolerates greater regulation of speech.[21] Academic articles and other forms of scientific research are not commercial speech, and not subject to such greater regulation.[22] The security testing and encryption research exemptions in the DMCA similarly do not mandate disclosure of any particular content. At most, the sections allow a court to use a researcher's disclosure of information to others as an indicator to help them determine whether the person relying on the exemption is truly acting in to promote security, or is merely using that purpose as a façade to commit infringement.[23]

The decision as to where and how information related to device security should be disseminated is at heart an ethical one, and already subject to robust consideration and debate within the computer science community.[24] Ethical responsibility in speech may not be imposed by government regulation,[25] and even if it could, there is no support for the notion that disclosing to a manufacturer first would always be the ethical choice. The Copyright Office should therefore omit any disclosure obligation from this rulemaking.

B. Other Laws Exist to Regulate Actors in the Medical Device Space

Second, you asked how the proposed exemption might relate to or be limited by other federal or state laws or regulations, including the Computer Fraud and Abuse Act, and any other statutory or regulatory provisions. As the Coalition noted previously, this is an area of regulatory overlap,

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them, must be left as unfettered as possible. Political power must abstain from intrusion into this activity of freedom[.]"); *see also* Reno v. ACLU, 521 U.S. 844, 874 (1997) (noting the public's reciprocal right to receive information).

[20] *ICS-Cert Monitor* (DHS), Apr. 2015, at 7, *available at* https://ics-cert.us-cert.gov/sites/default/files/ Monitors/ICS-CERT_Monitor_Mar-Apr2015.pdf.

[21] *See, e.g.*, 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 501 (1996). Even there, however, the balance is in favor of more speech, and courts tend not to favor restrictions that limit the dissemination of "truthful, verifiable, and nonmisleading factual information." Rubin v. Coors Brewing Co., 514 U.S. 476, 483 (1995).

[22] *See, e.g.*, Oxycal Labs., Inc. v. Jeffers, 909 F. Supp. 719, 724 (S.D. Cal. 1995) (rejecting an argument that scientific literature is commercial speech).

[23] 17 U.S.C. §§ 1201(g)(3), (j)(3); *see also* H.R. CONF. REP. 105-796, at 66 (1998) ("There is no requirement that legitimate encryption researchers disseminate their findings in order to quality for the encryption research exemption in section 1201(g). Rather, the subsection describes circumstances in which dissemination, if any, would be weighed in determining eligibility.").

[24] Bergman, *supra* note 7, at 121–22; *see also* FLOYD ABRAMS, RICHARD S. SALANT LECTURE ON FREEDOM OF THE PRESS (2013), *available at* http://shorensteincenter.org/wp-content/uploads/2013/10/Salant-2013-Transcript-web.pdf (extensively reviewing when the press decides not to disclose information, even though the First Amendment allows them to do so).

[25] *See* Miami Herald Publ'g Co. v. Tornillo, 418 U.S. 241, 256 (1974).

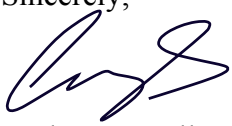
and other laws do exist to prevent unwanted actions or actors.[26] Granting an exemption here exempts researchers from 17 U.S.C. § 1201(a)(1)(A); it does not affect other laws.[27]

As noted previously, the Computer Fraud and Abuse Act ("CFAA") separately punishes those who either retrieve information from a computer or damage a computer without authorization.[28] The exemption as currently proposed requires consent from a patient if the device is used in that patient's care, in complete harmony with the CFAA. Those who seek to intrude or damage devices without authorization by the device owners will be out of compliance with both the CFAA and this exemption.

Outside of computer crimes, in the event a patient is injured through research activity, tort law would still impose liability if the researcher acted negligently, typically measured against those of a similar skill in the relevant trade.[29] Federal law also strictly regulates the marketing, sale, and distribution of medical devices, and this rulemaking does not affect these laws at all.[30] Nor would this exemption affect the additional regulations the FDA imposes on clinical research.[31] In short, as noted previously by the Coalition, what the Copyright Office decides on piracy and infringement grounds does not affect what the FDA, FCC, DHS, or other entities may decide for other reasons.[32]

The Coalition would like to thank this Office once again for their consideration of this issue. Robust medical device research is paramount to the lives of millions of people, and this exemption will help ensure that such research is allowed to continue.

Sincerely,



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[26] Coalition Reply Comment at 5, 18.
[27] *See* 17 U.S.C. § 1201(a)(1)(E).
[28] 18 U.S.C. §§ 1030(a)(2)(C), (a)(5); *see* Coalition Reply Comment at 22–23.
[29] RESTATEMENT (SECOND) OF TORTS § 299A. As the Coalition has already noted, medical device research of this sort has been conducted without significant incident for many years. Coalition Reply Comment at 3–4.
[30] *See, e.g.*, 21 U.S.C. §§ 331, 351, 352.
[31] *See, e.g.*, 21 U.S.C. § 360j(g).
[32] Coalition Reply Comment at 5.
[33] The Coalition wish to thank Cyberlaw Clinic intern Michael Rosenbloom for his assistance in drafting this letter.