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Ms. Jaqueline C. Charlesworth
General Counsel and Assoicate Register of Copyrights
United States Copyright Office, Library of Congress
101 Independence Ave. SE
Washington DC, 20559

Re: Docket No. 2014-7, Response to FDA letter concerning Proposed Class 27

Dear Ms. Charlesworth,

On behalf of the coalition of medical device researchers in this proceeding (the "Coalition," see Coalition Comment at App'x A), I write to briefly respond to the letter dated August 18, 2015 from Mr. Bakul Patel, Associate Director for Digital Health and the Center for Devices and Radiological Health at the FDA, which your office posted on its website on September 9.

The Coalition has no objection to the two recommendations made by the FDA at the close of Mr. Patel's letter, which the Coalition understands to mean:

1. *Nothing in this rule affects any present or future regulation by the FDA, including rules as to the marketing and sale of medical devices.* The Coalition has already stated as much in this proceeding. *See* Reply Comment at 22–23; Coalition Letter of June 29, 2015 at 4–5.

2. *The rule should require researchers to follow institutional review boards and other FDA regulations when conducting clinical trials.* Again, nothing the Copyright Office does in this proceeding will alter FDA requirements, and therefore any reliance on the exemption in the course of research and development for clinical trials will still be subject to the numerous regulations in that space, including requirements imposed by the FDA concerning institutional review boards. In any event, the Coalition is primarily concerned with access to software and data on devices that are already approved and in use or no longer in use. No member of the Coalition is seeking this exemption in order to conduct clinical trials. *See generally* Comment, App'x C–F.

The Coalition notes that the FDA repeatedly stresses concerns related to the marketing and sale of devices, citing numerous regulations that apply when a person is selling or marketing medical devices. These concerns, however valid, are not implicated by the work of the members of the Coalition, who do not modify the software of devices being used in patient care and do not sell or market devices after they have been modified. *See* 1201 Rulemaking Process Public Roundtable Transcript, May 29, 2015, at 16. Should a member of the Coalition or any other person relying on

this exemption "step[] into the role of a device manufacturer," Patel letter at 3, he or she would, of course, be obligated to follow the laws and regulations mentioned by the FDA.

To the extent Mr. Patel's letter raises other concerns about the exemption, the Coalition feels as though they have been addressed completely by its prior submissions.

Thank you very much, and let me know if you have any questions.

Sincerely,

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cc: Mr. Bakul Patel, Center for Devices and Radiological Health, FDA
Ms. Laura Moy, Open Technology Institute, New America Foundation
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