

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

Item 1. Commenter Information

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Item 2. Proposed Class Addressed

Proposed Class 27: Software – networked medical devices

Item 3. Statement Regarding Proposed Exemption

According to the CDC, nearly 10% of Americans have some form of diabetes, an autoimmune disorder wherein your body destroys the parts of your pancreas that regulate blood glucose. In the past decade of my life, I have come to know and care about not one, not two, but five people with type 1 diabetes, a form of diabetes currently considered to be largely genetic, and for which we do not know of any prevention or cure. 3 million Americans have type 1 diabetes.

Before the 1920s, a diagnosis of type 1 diabetes was a death sentence. Today, we mitigate the effects of this disease by having the patient manually regulate their blood glucose level, using a combination of two tools: a blood glucose meter and injectable insulin (the hormone produced by the pancreas that triggers the movement of glucose from the blood to cells).

In order to better mimic the natural pancreas, many patients (including now all five of the people I know particularly well with this disease) have come to use an "insulin pump", which continuously injects insulin into the bloodstream over a long period of time. These pumps are expensive, and are often attached to blood glucose meters, with which they communicate.

Over the past five years, most of these devices have been equipped with Bluetooth, and now can communicate with a computer to transfer their information history into databases that can be used to provide statistics on how well the patient is progressing. This can be invaluable to the patient's adaptation to the disease. However, this software is often an "afterthought".

Even more bothersome, the content is a silo, separated from information obtained from unrelated devices that would inherently be developed by other manufacturers. It would be very useful to be able to aggregate and correlate this information in order to build reports.

Sometimes, even simple things can be very relevant: being able to see your child's glucose level as measured by a continuous glucose monitor right on the screen of your cell phone. This is something that is very easy to do, and does not have any medical consequence (as might a closed-loop glucose delivery system, the "holy grail" of this kind of hacking), but is something that becomes a transformative work from the perspective of these closed devices.

<http://www.wired.com/2014/12/diabetes-patients-hacking-together-diy-bionic-pancreases/>