

January 5, 2010

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket # FDA 2009-N-0392

To whom it may concern:

Disability Rights Montana is Montana's designated Protection and Advocacy system, authorized and directed by the provisions of 42 U.S.C. 10805 to advocate for and protect the civil rights of Montanans with mental illness.

I am writing to you about the proposal to bypass the safety investigation required to reclassify devices manufactured to administer electroconvulsive therapy to individuals with mental illness from Class III to Class II. We understand that the manufacturers of these devices have asked for an exception to the regulations because they can't afford to fund the scientific research to determine that the benefits of ECT outweigh its risks.

Since 1987, we and all other P&A systems making up NDRN have opposed reclassification, and we still do, because it would mean that the devices would never have to undergo the safety investigation (Pre-market Approval Application, or PMA) that is required by law for those Class III devices which predate the Medical Devices Amendments. It would effectively stamp ECT as a safe treatment (as safe as X rays) that doesn't need an investigation.

These devices have now been used on another generation of patients without having been proven safe, and without warning patients that there is no evidence of safety. Finally this year, FDA has been forced to decide whether to keep the devices in Class III and require PMAs, or to reclassify. As an initial step, it has called on the manufacturers to provide evidence of their devices' safety, but they have not done so. They are refusing to conduct clinical trials, saying they cannot afford them. But the financial interests of manufacturers must not be a basis for you, the nation's highest authority on medical matters, to reclassify ECT as a low risk treatment. There was no scientific basis for reclassification in 1987, and there is none now.

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FDA must not exempt ECT from the scientific scrutiny required of all other psychiatric and medical treatments. For the protection of future patients, keep the device in Class III and require PMAs. Only once clinical trials have been completed can FDA take responsible action on this device.

Sincerely,

DISABILITY RIGHTS MONTANA

A handwritten signature in black ink, appearing to read "Bernadette Franks-Ongoy", with a long horizontal flourish extending to the right.

Bernadette Franks-Ongoy, Executive Director

cc: Senator Max Baucus
Senator Jon Tester
Representative Dennis Rehberg