

PRESS RELEASE

U.S. Law Allowing Use of Unproven Brain Devices in “Orphan” Neuropsychiatric Disorders Needs to Be Strengthened, a Team of International Experts Says

Bad Neuenahr-Ahrweiler, 7 February 2011. – Warning that patients could be at risk, an interdisciplinary group of multinational investigators is calling on the U.S. Congress and federal regulators to tighten a law that permits use of brain devices to treat rare neuropsychiatric disorders without supporting clinical trials or stringent patient oversight.

In the February issue of the American journal “Health Affairs”, the members of a project by the Europäische Akademie GmbH come to the conclusion that the U.S. Food and Drug Administration’s (FDA) Humanitarian Device Exemption (HDE) regulation should be revised so that uses of such devices in neuropsychiatric patients meet the highest standards of clinical research, patient safety and research integrity. The authors voice concern that the humanitarian approval allows device manufacturers to seek a “simpler, cheaper and faster approval process” while depriving “patients of the rigorous trial that the severity and complexity of their condition warrants, as well as hampering scientific discovery.” They make the case for revision by examining how the law was used to approve deep brain stimulation (DBS) in patients with treatment-resistant obsessive-compulsive disorder (OCD), which they argue is not a rare disorder.

The researchers say such misuse of the law could open the door to a number of other inappropriate applications of what was intended to be compassionate legislation designed for orphan disorders that affect only a few thousand Americans a year. “We believe there needs to be more careful regulation of the use of the Humanitarian Device Exemption in psychiatric patients,” says lead author Dr. Joseph Fins, Professor of Medicine, Professor of Public Health and Professor of Medicine in Psychiatry at Weill Cornell Medical College in New York City.

The U.S. Congress established the HDE in the Safe Medical Devices Act of 1990. The law sought to help bring novel devices to the market to treat uncommon conditions that otherwise might not attract the attention of device manufacturers. If the FDA’s Center for Devices and Radiological Health approves an HDE, as requested by a manufacturer, that device can be marketed without evidence of effectiveness. Clinicians go through their local institutional review board for approval to use the device, but patients do not sign a research informed consent document and may not clearly understand that the device to be used has not been evaluated for clinical benefit, the authors say. This can confuse

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patients and foster a therapeutic misconception about an experimental intervention, especially when device manufacturers market the device as a new therapy.

The authors are not advocating for elimination of the HDE, but are calling for more careful regulation of its use in psychiatric research so that critical safety information is not side-stepped. They suggest that in approving such future applications, the FDA should make sure the disorder in question is indeed rare. But they also suggest that device manufacturers be required to collect safety data and place it in a central repository, as well as develop a plan to monitor safety data.

The commentary's contributing authors are members of the Europäische Akademie's project group "Deep Brain Stimulation in Psychiatry. Guidance for Responsible Research and Application" which is funded by the Volkswagen Foundation (Germany). Some of the authors, who have expertise in psychiatry, neurosurgery, neuropsychology, philosophy, ethics and the law, have disclosed potential conflicts of interest in the study manuscript.

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Publication:

Joseph J. Fins, Helen S. Mayberg, Bart Nuttin, Cynthia S. Kubu, Thorsten Galert, Volker Sturm, Katja Stoppenbrink, Reinhard Merkel, Thomas E. Schlaepfer: **Misuse Of The FDA's Humanitarian Device Exemption In Deep Brain Stimulation For Obsessive-Compulsive Disorder**, *Health Affairs*, February 2011, vol. 30 no. 2, 302–311

The study can be found at the Health Affairs website:

<http://content.healthaffairs.org/content/30/2/302.abstract>

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