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Food and Drug Administration

RE: Docket No. 2014-N-1210 "Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treamtent-Resistant or Require a Rapid Response; Effective Date of Requiremnt for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses

AND

Docket No. FDA-2014-D-1318 for "Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and FDA Staff"

By now you will have seen some of the efforts I have been involved with in attempting to prevent FDA from being able to down-classify the shock device from a Class III experimental device that has never been tested for safety or efficacy (in part because it is seen as unethical to potentially subject humans to being lab rats) and has been shown to be ineffective, with 'Sham-ECT' (or shock treatment that is given to people who think they are getting shock treatment but are really only getting anesthesia and drugs—anesthesia and drugs, by the way, all of which have inherent risks and potential death as consequences—real ECT does no 'better' than Sham-ECT.

The American Psychiatric Association is crediting people like me of stopping the industry from being able to down-classify the shock device over the decades. They have a campaign to respond to FDA that urges psychiatrists to ignore "antipsychiatry" and ultimately, "patients" and carves itself out as a trade organization 'protecting' its psychiatrists' interests. While the FDA has attempted to cut out a swath of the human body that is made to sound as if small, but actually is representative of millions of people. The FDA proposed rule suggests shock treatment is 'safe enough' for people who are said to be "treatment-resistant" or "require a rapid response" of shock treatment because they were said to be having a "Severe Major Depressive Episode" as part of unproven "illnesses" which have no biological evidence for existing—"Depressive Disorder" and "Bipolar Disorder". The FDA is specific, for those "18 Years of Age and Older" so you would think that children and adolescents—minors—would be protected from shock treatment. Nonetheless, in the American Academy of Child and Adolescent Psychiatry's response to the FDA, the child psychiatrist trade organization arguesd it should be able to be used for a host of minors who have been assigned psychiatric or developmental disabilities. Oh and get this, for those who have been so poisoned by the drugs that they

have Neuroleptic Malignant Stimulation which they refer to as NMS—to maybe have others forget that their drugs cause Neuroleptic Malignant Stimulation and when the children do not perform as they want and are "treatment-resistant" in this situation, where the drugs are not 'working'—they now argue the child psychiatrists ought to be able to use it, basically, however they want. Remember FDA, you say that they can use it for this and ultimately, they can call anything "X" since there are not actual legitimate tests.

NIMH suppression of truth and public censoring of truth and questions for the truth is a whole other issue. I have photo evidence of this published.

In research I have done, there is literally an argument, for example to stay away from the terminology of psychosurgery because of its deep connections to the horrors of lobotomy that were exposed. The term argued for use, "neurosurgery for psychiatric disorders", which you can be sure, the new packaging of "electrical stimulation" promoted by translational research.

NIMH suppression of truth and public censoring of truth and questions for the truth is a whole other issue. I have photo evidence of this published.
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The rise and protection of people like Lisanby is of question in an official complain that was made to the FDA Ombudsman Office and Obmudsman for Neurological Devices, as is organized psychiatry's trade organizations being held responsible for their false statements of safety and efficacy of shock treatment. NIMH and Lisanby must be questioned.

Do not be fooled, "require rapid response" is a euphemism for forced treatment.

This may all seem like a lot, but we have spelled it out in both the petition and the complaint. I wrote them with the input of anyone who called in to a weekly teleconference that was coordinated by MindFreedom International

In the time you have allotted for the comment period, I cannot even tell you how much has happened in the 90 days since FDA published the proposed rule. I have talked with hundreds of people (and about a hundred people regularly through Social Media and other avenues). People who identify as survivors of shock treatment—or who are trying to survive—do not see what FDA is doing as a good idea. Some are outright surprised that FDA is moving to down-classify the shock device to a Class II device and most believe the shock device should be banned. Those who have trouble with the government banning things think that it must not be able to be used under the assumption that it is a 'medical device'.

I occasionally here reports from people—or more-often, second-hand, of a brief euphoric high that some people get from the head injury that they suffer. However, this 'acute' non-permanent high quickly dissipates as the brain (and moreover, the person's experiences) remain the same although many acknowledge some kind of dramatic personality changes, like passions deadened and anger and tolerance for others minimized. This, and, minus perhaps, exact memory of any number of things past, and inability to process and/or remember things in the present, or to develop memories, (which is why the maintenance). Repeatedly having electricity shot through one's brain adds up. The way shock treatment works is by damaging the brain.

I am not part of a trade organization. The complaint and petition was written via participation in 10 national teleconferences coordinated by MindFreedom International—an organization that is basically an entirely volunteer organization. We are just getting to a point of where we are able to get the word out to people who are typically very hard to reach: people who are or who have been in a position to be subjected to shock treatment. We need more time to adequately respond.

FDA must hold hearings. The new information that has been supplied by our petition and complaint (and the new information from the 2010-2011 FDA processes that has been ignored by FDA in this process) must be addressed.

People say, it is someone's mistake to make—but if people are not being adequately informed not only of the potential "unknown" benefits for why subjected to shock—and are not informed of the long list of known consequences that hold high risks—and people are somehow not sucked out of the medical model of psychiatry that has surrounded them and ill-informed of the lack of actual scientific-evidence of psychiatry—then sure, it is someone's mistake to make—but do not call it medicine.

I submitted 674 individual comments that came in on the petition that we set up, directly to FDA-2014-N-2010. There may by under 10 submissions that are replacements of data entry mistakes. I should have had FDA-2014-D-1318 listed on each, but at the time, I did not realize how long it would take to input each individual response to the docket.

I want to underscore that as of 10:48PM 3/28/16 the petition itself has the support of 1,950 people.

As an ally, I testified at on behalf of more than 80 people at the January 27 – 28, 2011 FDA hearings, many who are (and sadly, since have passed), were shock survivors. Our petition displayed video of these hearings, and people who are shock survivors talking afterwards about how they felt heard by the panel, but were still concerned of what FDA would do—if FDA would take the panels recommendations. The panels' decisions now, of course, disregarded and for those panel members I was able to reach, two seemed to be not willing to speak up because of lack of information and time to digest it; one said flat

out no comment on FDA proceedings, and one, I thought maybe would have spoken out, but to my knowledge, has not. This could change, perhaps with time, of course, there's also that new law that allows for the FDA to just propose a rule and order it so. I, and those who I am working with toward reaching your senses, find this process entirely unacceptable for our government to operate this way.

FDA must hold public accessible hearings about down-classifying the shock device.

FDA must give us time to reach those people who are most vulnerable to being subjected to shock treatment—people in institutions, adult homes, group homes, who not only may not have access to the internet and technologies—but are often barred from communication with the larger world, as they languish in these institutions.

Following the, 2011 hearings, FDA waited years to respond to the calls of people who are shock survivors.

FDA can easily extend this, minimally to May 4, 2016 which would have been 90 business days, counting holidays and weekends, from when the proposal was released during the holiday season—December 29, 2016—when only a dedicated few were paying attention. Despite our immediate response we are just now getting the word to people.

We need more time to adequately present the information—the new information—we have obtained about shock treatment throughout these processes.

From the conclusion of complaint:

In short, our public complaint requests that the FDA Ombudsman Office intervene on all thirteen major issues we take with the processes FDA used/is using concerning this attempt to down-classify the shock device. Our overall requests are:

First, we do not want the shock device down-classified for any reason, but particularly the fraudulent reason that it is 'safe enough' for people who are 'depressed' 'bipolar', 'treatment-resistant' or 'require rapid response';

Second, we want FDA to hold public accessible hearings based on the balance of this new information prior to approving the proposed rule and draft guidance;

Third, we want a complete moratorium on all shock treatment until these issues are resolved; and

Fourth, we want all of the issues publicly asserted in this complaint addressed.

Here are the materials I discussed:

You can see 1950+ people who signed the petition to say #FDAStopTheShockDevice here:
https://www.change.org/p/fda-stop-fda-from-down-classifying-the-shock-device-to-a-class-ii-device-stop-shock-treatment;

You can read the full 47-page public complaint here:
http://laurentenney.us/files/113651456.pdf.

You can download the full 47-page public complaint here:
http://laurentenney.us/public-complaint-to-fda-ombudsman-shock-device.html.

NIMH Deletes and Blocks Truth During Public Q&A about Shock Treatment on Facebook
http://www.citizensdemandingjustice.org/2016/03/nimh-deletes-and-block-truth-during.html

Thousands Are Having ShockTreatment For Breakfast #FDAStopTheShockDevice
http://www.citizensdemandingjustice.org/2016/03/thousands-are-having-shock-treatment.html
(this includes video of Sue Clark-Wittenburg (1955-2015) who was a leader of the move to ban shock).

Here is a video I made of the 2011 hearings that includes interviews of people who are shock survivors
https://www.youtube.com/watch?v=tQ4vKpJo2KA

Testimony from 2011 Hearings:
my testimony representing over 80 people who are shock survivors at 2011 Hearings:
http://psychcentral.com/lib/lauren-tenney-on-ect/

The dispute over informed consent at the 2011hearings Lisanby v. Tenney:
http://psychcentral.com/lib/informed-consent-for-ect/

The Opal Project 2010 Comments to FDA Docket on Shock Device
http://laurentenney.us/files/113669923.pdf

You can read my previous blogs about the FDAs 2015/2016 attempts at down-classification of the shock device here:
Shock Devices Safe as Eyeglasses? 89 Days to Say No.
http://www.madinamerica.com/2015/12/shock-device-safe-as-eyeglasses-89-days-to-say-no.

40 Days to Tell #FDAStopTheShockDevice
http://www.madinamerica.com/2016/02/40-days-to-tell-the-fdastoptheshockdevice.

This was published prior to the FDA releasing the proposed rule:
Electroshocking Veterans and Their Fetuses
http://www.madinamerica.com/2015/11/electroshocking-us-veterans-and-their-fetuses

With the Public Defrauded, the Illegitimacy of Forced Psychiatry Crystalizes
http://www.madinamerica.com/2015/06/with-a-public-defrauded-illegitimacy-of-forced-psychiatry-crystalizes/

Online Radio
You can also listen to multiple episodes of Talk with Tenney that focus on Shock Treatment as Crime Against Humanity and more recent ones that are specific to the FDA here:

www.blogtalkradio.com/TalkWithTenney

Talk with Tenney: Electroshock: A Crime Against Humanity June 4, 2014
http://www.blogtalkradio.com/talkwithtenney/2014/06/05/talk-with-tenney-electroshock-a-crime-against-humanity

Talk with Tenney: Electroshock and Informed Consent and Litigation Strategies June 11, 2014
http://www.blogtalkradio.com/talkwithtenney/2014/06/12/talk-with-tenney-electroshock-informed-consent-and-litigation-strategies

Talk with Tenney: Shock Survivors To David Healy: Defend Stance on Shock (ECT) June 17, 2014
http://www.blogtalkradio.com/talkwithtenney/2015/06/18/talk-with-tenney-shock-survivors-to-david-healy-defend-stance-on-shock-ect

Talk with Tenney: David Healy You Promote This? Life After Electroshock July 22, 2015
http://www.blogtalkradio.com/talkwithtenney/2015/07/23/talk-with-tenney-david-healy-you-promote-this-life-after-electroshock

Talk with Tenney: Special Electroshock: Cognitive Impairments and Rehabilitation September 30, 2015
http://www.blogtalkradio.com/talkwithtenney/2015/10/01/talk-with-tenney-special-electroshock-cognitive-impairments-and-rehabilitation

Talk with Tenney: FOIA: Evidence of VAMCs Electroshock Veterans and Other Disgusting Acts November 11, 2015
http://www.blogtalkradio.com/talkwithtenney/2015/11/12/talk-with-tenney-foia-evidence-of-vamcs-electroshocking-veterans-and-other-dis

T**alk with Tenney: Special Reading of Shock FDA Reclassification December 29, 2015**
http://www.blogtalkradio.com/talkwithtenney/2015/12/29/talk-with-tenney-special-reading-of-shock-fda-reclassification-document

Talk with Tenney: Special: Tell the FDA No to Reclassifying the Shock Device December 30, 2015
http://www.blogtalkradio.com/talkwithtenney/2015/12/31/talk-with-tenney-special-tell-the-fda-no-to-reclassifying-the-shock-device

Talk with Tenney: Special: Electroshock and Suicide; Cure or Cause? January 6, 2016
http://www.blogtalkradio.com/talkwithtenney/2016/01/07/talk-with-tenney-special-electroshock-and-suicide-cure-or-cause

Talk with Tenney: Special: 13 Days Left to Say #FDAStopTheShockDevice March 15, 2016
http://www.blogtalkradio.com/talkwithtenney/2016/03/16/talk-with-tenney-special-13-days-left-to-say-fdastoptheshockdevice

Talk with Tenney: Comment on Complaint: FDA Ombuds Office #FDAStopTheShockDevice March 17, 2016
http://www.blogtalkradio.com/talkwithtenney/2016/03/18/talk-with-tenney-comment-on-complaint-fda-ombuds-office-fdastoptheshockdevice

Talk with Tenney: Special Update on #FDAStopTheShockDevice Campaign March 22, 2016
http://www.blogtalkradio.com/talkwithtenney/2016/03/23/talk-with-tenney-special-update-on-fdastoptheshockdevice-campaign

INFORMATION THAT FDA MUST ADDRESS:

- **the results of the Survivor Survey**
  www.ectjustice.com;
- **Aftershock: Life After ECT**
  https://aftershocklifeafterect.wordpress.com/2016/02/09/a-collection-of-ect-statistics
- **The Law Project for Psychiatric Rights research collection page concerning shock treatment**
  http://psychrights.org/research/Digest/Electroshock/electroshock.htm
- **The Coalition for the Abolition of Electroshock in Texas**
  www.endofshock.com
- **From the Files of Leonard Roy Frank on Electroshock**

http://psychiatrized.org/LeonardRoyFrank/FromTheFilesOfLeonardRoyFrank.htm#Electroshock_

- **Peter Breggin, M.D.'s The Dangers of Electroconvulsive Therapy**
  http://www.breggin.com/index.php?option=com_content&task=view&id=40
- Peter Breggin M.D.'s ECT Resources Center
  http://www.ectresources.org/
- **Mad in America's ECT Archives**
  http://www.madinamerica.com/category/ect/
- **MindFreedom International's Electroshock Page**
  http://www.mindfreedom.org/kb/mental-health-abuse/electroshock/electroshock-info
- **Linda Andre's (2009) Doctors of Deception: What They Don't Want You to Know About Shock Treatment**
  http://rutgerspress.rutgers.edu/product/Doctors-of-Deception,4419.aspx
- **Bonnie Burstow's *Psychiatry and the Business of Madness: An Ethical and Epistemological Accounting* (especially concerning debunking claims of reducing** suicide). *http://www.palgrave.com/fr/book/9781137503831*

framed by:
Paula Joan Caplan's *The Say You're Crazy: How the Worlds Most Powerful Psychiatrists Decide Who Is Crazy* (especially for debunking the idea of a) psychiatric assignment and b) "treatment-resistance"
https://books.google.com/books?id=X4CNx3EiGJUC&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false

I am sure you agree, with the wealth of information that is here, that having the benefit of better organizing our position for the FDA to not down-classify the shock device for any reason, but especially a fraudulent reason, makes immediate sense.

I will continue to collect information from people. Our petition remains active. I look forward to your response.

Thank you for your time and attention.

Sincerely,

Lauren J. Tenney

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