From: Richard Abrams <richard.abrams@gmail.com>
Sent: Tuesday, June 21, 2011 1:07 PM
To: Conrad Swartz
Subject: Re: FDA ECT Advisory Panel minutes

Conrad,

Further to what our approach to FDA should be going forward (a stupid phrase now incredibly in vogue), the real question is: whom do we need to convince? The advisory panel is now totally out of the picture, and the FDA staff who presented the review to the panelists generally seemed to favor ECT (although I'd like your views on this point), so it seems we need to know who at FDA is in charge of the next step: deciding whether to downclassify to II. Presumably Dr. Eydelman has the final call on this, but she must surely receive input from other FDAers. It's often said that FDA doesn't often go against Advisory Panel recommendations, but Dr. Eydelman actively participated throughout the proceedings and could well see how divided the panelists were--there's no way she could assume a uniform view from the panel.

I think this is where Steve might provide useful input--the identification of the key players at FDA *hencеforward*.

Regards,

Dick

On Tue, Jun 21, 2011 at 1:51 PM, Conrad Swartz <cswartz@gmail.com> wrote:

Richard,

I imagine that the FDA is well aware that the ECT Advisory Panel misbehaved because the transcription immediately starts by identifying each panel member in capital letters as NONVOTING. Thus the FDA identified the panelists' inappropriate behavior in trying to register votes.

Your impressions entirely fulfill my impressions that the nonpsychiatrists behaved unprofessionally and antiscientifically. This is a close modern analogy to what Semmelweis experienced. The nonpsychiatrists turned this into a political event.

I have been wondering what we should do about this. I have an idea. We need a champion, such as a scientific writer, to expose the misperceptions and misunderstandings stated by the advisory panel. This must be someone who would not point to us, but then we have no unique insider knowledge and there will be no necessity to point to us. One such person might be the NY Times reporter. Another might be Kitty Dukakis' collaborator, Larry Tye. Ned Shorter also seems a possibility, because he is a professor of philosophy and not a psychiatrist. We could assist this writer by identifying and explaining the misperceptions and misunderstandings. What do you think of this idea?

Some relevant ideas turned up in a Medscape discussion board a few days ago. I cut and pasted the original post. The link at its bottom to the "Shrink Rap" website goes to the source. The points apply as well to ECT use as to medication use. A writer should find these concepts useful to mention in a discussion about people who propose decreased ECT availability, their statements are just more of the same old antipsychiatry religion.

Regards,
Conrad

Annoying traits of psychiatry haters...

Started By: drgrcevich, MD, Psychiatry/Mental Health, 8:40PM Jun 19, 2011

#7: The implication that all (or even the majority) of psychiatrists are purposefully evil and have mean intentions when treatment has bad outcomes.

#5.5: The implication that psychiatrists uniformly push medications on unwilling patients.

#5: Statements that someone was perfectly fine until they took psychotropic medications. People generally seek psychiatric care and medications because something is wrong.

#2: The implication that the average practicing psychiatrist had some way of personally knowing that Big Pharma manipulated research and withheld side effects and adverse effects of medications and they should have not prescribed those medications.

#1.5 Sensationalism by the media on the all of the above in an unbalanced way.

#1.25: Implications that psychiatry as a field is inflexible, finds itself above reproach and is unwilling to listen to criticism.

#1: The implied statement, "This psychiatric medication harmed me so it should be illegal for anyone else to take any psychiatric medication."

Here's the link to the post on Shrink Rap:

http://psychiatrist-blog.blogspot.com/2011/06/top-ten-or-more-things-that-annoy-me.html?

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On Tue, Jun 21, 2011 at 11:07 AM, Richard Abrams <richard.abrams@gmail.com> wrote:

Conrad,

I've just finished scrutinizing the minutes of the FDA ECT Advisory Panel, and in general, Fran Lowry's MEDSCAPE articles were accurate: all the psychiatrists came down in favor of down-classifying ECT to class II for depression, and all the neurologists and neuropsychologists supported retaining ECT in class III. The lawyer and the patient advocate members of course supported class III all the way. What is not reflected in the Lowry articles is the appalling ignorance of nearly all panel members--including the "good" ones--concerning the scientific data on ECT. Misperceptions and misunderstandings abound on nearly every page, especially concerning issues of cognitive impairment and brain damage--all of which is simply incredible to me. The FDA section head for ECT, Dr. Eydelman, was the one who mentioned the possibility of a "paper PMA", without providing any details; she also firmly reminded the panel that they were not voting on anything, but vote they all did anyway.

There's nothing I can see to do now but wait for FDA to make a decision and propose a rule on ECT device classification, and since the panel was pretty much evenly split in its recommendations, I'm not at all sure which way FDA will go. It could also easily take them months--even a year or two--before doing this, after which we would have time to respond before they actually issued a final ruling. Then, it was repeatedly stated that manufacturers would have at least 30 months to respond with a PMA if indeed one was required, so I am convinced we can go on selling Thymatrons in the US for at least another 4 years even if class III is retained and our PMA is disapproved.

I really don't think there's anything that Steve can do on our behalf until and unless FDA makes its next move--what do you think?

Regards,

Dick