U.S. District Court
Middle District of Florida
PLAINTIFFS EXHIBIT

Exhibit Number: Pl. 8

Case Number: 8:20-cv-01724

JEFFREY THELEN v. SOMATICS, LLC

te Identified:

From:

Richard Abrams < richard.abrams@gmail.com>

Sent:

Friday, February 05, 2010 9:29 AM

To: Cc: McDonald, William Conrad Swartz

Subject:

Re: FDA inquiry

Dear Dr. McDonald,

Dr. Swartz and I have discussed the 5 questions raised by Dr. Park and can provide the following very rough, personal estimates:

- 1. 1200-1500
- 2. We have no way of even roughly estimating this figure.
- 3. Essentially no other devices.
- 3. 0-2%
- 5. 0%

I'm not sure how useful any answers you obtain might be since there is simply no hard information available on any of these points.

Regards,

Dick Abrams

On Thu, Feb 4, 2010 at 6:00 PM, McDonald, William < wmcdona@emory.edu > wrote:

Dear Drs. Swartz and Abrams,

I am on the ECT Task Force for ECT and have been asked by the FDA to gather some basic information on devices. I have gotten some information from MECTA and want to also get information on the Thymatron. I wrote you a few weeks ago but perhaps you did not get the email. Here was the email I got from the FDA and I would appreciate any information you could provide. Thank you.

Bill McDonald, MD

JB Fuqua Professor of Psychiatry

**Emory University** 

Hi Dr. McDonald,

As you know, we are working on the ECT reclassification process at FDA. In the process of analyzing the information that has come in, a few questions arose that we did not have the answer to. We were hoping that either you or someone at APA might know the answers to these questions.

- 1. Approximately how many sites in the US do ECT?
- 2. What percentage of devices are Somatics or Mecta (estimate)?
- 3. What other devices are being used?
- 3. Estimate for percentage Medcraft?
- 5. Estimate for percentage Elcot?

Any information you may have, even if it your personal estimate, would be greatly appreciated.

Thanks very much,
Larry Park
Lawrence Park, A.M., M.D., Medical Officer
U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Division of Ophthalmic, Neurologic and ENT Devices
Office of Device Evaluation
10903 New Hampshire Avenue
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