

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074  
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<http://oversight.house.gov>

June 28, 2016

The Honorable Sylvia Matthews Burwell  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Madam Secretary:

On December 29, 2015, the Food and Drug Administration (FDA) released the Proposed Order, “Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episodes in Patients 18 years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses.”<sup>1</sup> While we are encouraged the FDA is working to development new and innovative ways to address the nation’s growing mental health problems, we have questions about the proposed order.

The proposed order relates to electroconvulsive therapy (ETC) devices that are used to “apply a brief intense electrical current to the head in order to induce a generalized seizure.”<sup>2</sup> The order proposes that ECT devices intended for treating major depressive disorder or bipolar disorder in adults who are treatment resistant or require a rapid response be reclassified from Class III to Class II under the Federal Food, Drug, and Cosmetic Act. Since Class II devices do not need to have premarket approval before their use there is a question of whether this change will lead to increased use of ETC devices. While you note that the FDA has concluded that ECT “demonstrated effectiveness in the acute phase (less than 3 months after treatment)” there were nonetheless “various scientific opinions regarding the long-term effectiveness of ECT for the treatment of depression....”<sup>3</sup>

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<sup>1</sup> Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episodes in Patients 18 years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses, 80 Fed. Reg. 249, 81223 (Dec. 29, 2015) (to be codified at 21 CFR 882).

<sup>2</sup> *Id.* at 81226.

<sup>3</sup> *Id.* at 81227.

The FDA has also identified a number of “Risks to Health” from the use of ECT devices.<sup>4</sup> These include adverse reactions to anesthetic agents used during these procedures, cardiovascular complications, cognition and memory impairment, death, dental trauma, manic symptoms, physical trauma, prolonged seizures, pulmonary complications, and worsening of psychiatric symptoms.<sup>5</sup> The order also notes there was insufficient clinical data to support effectiveness of ECT use for conditions like bipolar mania, schizophrenia, and catatonia.<sup>6</sup> Yet, the order does conclude that the potential benefits of ECT outweigh the risks.<sup>7</sup>

The order also proposes “Special Controls” to provide reasonable assurances of safety and effectiveness.<sup>8</sup> These controls include disclosure of precautions and warnings, device use instructions, and appropriate labeling.

Given the complexity of this issue and your admission that the long term effectiveness of these devices remains debated, we hope that you will be able to provide the Committee with more information on the FDA’s proposed order before it becomes finalized.

Please provide answers to these questions no later than July 12, 2016:

1. The Proposed Order states that while ECT may be appropriate for treatment in the acute phase, there are differing opinions on the long-term effectiveness of the treatment. Will the FDA be issuing strict instructions on how long providers or patients may utilize these devices? And if not, how does the FDA propose to monitor the longer term use of these products?
2. The Proposed Order repeatedly states that this is for treatment of patients “18 years of age and older.” What are the known dangers of using such treatments on individuals younger than 18 and how will the FDA monitor whether providers are utilizing treatment for minors?
3. The special controls in the Proposed Order discuss how proper labeling will help disclose the risks of ECT use to users and patients. Will this labeling be required in a way that guarantees the patient will see it? How will the FDA ensure that users are having frank and easy to understand conversations with patients about the risks of ECT use?
4. What health programs utilizing federal tax dollars currently (or will in the future) reimburse for the use of ETC services? Provide a list of those programs and the amount spent annually for the last five years.

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<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 81228.

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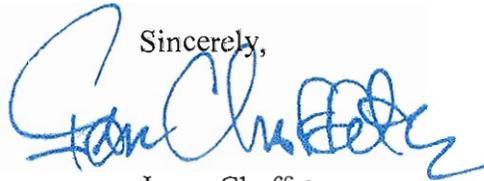
5. What data does the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, or FDA collect on the number of patients utilizing ECT? Describe how information on patient population or use is tracked if at all, and provide the underlying data.

The Committee on Oversight and Government Reform is the principal oversight committee of the House of Representatives and may at “any time” investigate “any matter” as set forth in House Rule X.

When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information about responding to the Committee’s request.

If you have questions about this request, please contact the Committee staff at (202) 225-5074. Thank you for your attention to this matter.

Sincerely,



Jason Chaffetz  
Chairman

Enclosure

cc: The Honorable Elijah E. Cummings, Ranking Member

## Responding to Committee Document Requests

1. In complying with this request, you are required to produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.
2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic format should also be organized, identified, and indexed electronically.
5. Electronic document productions should be prepared according to the following standards:
  - (a) The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
  - (b) Document numbers in the load file should match document Bates numbers and TIF file names.
  - (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
  - (d) All electronic documents produced to the Committee should include the following fields of metadata specific to each document:  
  
BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH,  
PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE,  
SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM,  
CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE,  
DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,  
INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION,  
BEGATTACH.
6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.
8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.
9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.
10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.
11. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
13. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
14. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.
15. Unless otherwise specified, the time period covered by this request is from January 1, 2009 to the present.
16. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.
17. All documents shall be Bates-stamped sequentially and produced sequentially.
18. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

### **Definitions**

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, or otherwise.
3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
4. The terms “person” or “persons” mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.
6. The term “referring or relating,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.
7. The term “employee” means agent, borrowed employee, casual employee, consultant, contractor, de facto employee, independent contractor, joint adventurer, loaned employee, part-time employee, permanent employee, provisional employee, subcontractor, or any other type of service provider.