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CITIZENS COMMISSION ON HUMAN RIGHTS

UNITED STATED DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CITIZENS COMMISSION ON HUMAN RIGHTS Plaintiff, **v.** UNITED STATES FOOD AND DRUG ADMINISTRATION Defendant.	Case No. 2:18-cv-5320 **COMPLAINT FOR INJUNCTIVE RELIEF**

I. INTRODUCTION AND JURISDICTION

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552, by the Citizens Commission on Human Rights ("CCHR" or "Plaintiff") to order the production of agency records concerning communications between the Food and Drug Administration ("FDA" or "Defendant") and MECTA Corporation – a manufacturer of electroconvulsive therapy (shock treatment) devices. The FDA has improperly withheld from Plaintiff all records requested, in violation of the Freedom of Information Act.

2. Plaintiff, Citizens Commission on Human Rights, is a non-profit entity which researches and publishes information regarding psychiatric abuse. CCHR is located in Los Angeles County.

3. Defendant FDA is an agency of the United States and has possession of the documents that plaintiff seeks. The FDA does business in Los Angeles County.

4. The FDA has failed to act upon plaintiff's FOIA Request, dated June 21, 2016. The agency further failed to act upon an administrative appeal submitted on January 16, 2018. This court accordingly has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B).

FACTUAL ALLEGATIONS

5. On June 21, 2016, a simple FOIA request was submitted to the FDA seeking solely, "Copies of communications between the FDA and MECTA." (A copy is attached hereto as Exhibit A.) MECTA is a medical device manufacturer of electro-convulsive therapy devices, which are subject to the jurisdiction of the FDA.

6. One year later, on June 14, 2017, the FDA's Center for Devices and Radiological Health FOIA division responded, through Latoye Lewis, Information Specialist, requesting confirmation that CCHR still wanted the records requested. That communication, via email, stated "if you would like CDRH to continue processing your request we would need to know the type of communication records you are seeking (adverse events, compliance actions, approval correspondence, etc)."

7. Counsel responded:

> "To assist you, I also specifically want all communications relating to reclassification of ECT devices, all communications regulating them or addressing their activities, affects, failure to report adverse events, failure to report claims against them for harms caused by the device. In short, as my FOIA Request stated, I want ALL communications with MECTA. FDA will know better than I how it categorizes all of their

communications, so I have not limited the request to categories which I know."

8. Ms. Lewis responded on June 14, 2017, stating: "As your request is reaching the top of the queue, we reach out to make sure the information is still needed before we begin processing the request. Your request has not reached the top of the queue as of yet. However, I anticipate the search will begin with the next 2 to 4 weeks." No assertion was made by CDRH that this simple Request was in any way complicated or "complex." Rather, Ms. Lewis stated the search would begin in 2-4 weeks (i.e., between June 29, 2017 and July 12, 2017 because, the FOIA Request "is reaching the top of the queue.")

9. On July 11**,** 2017, CCHR queried the progress of the processing of the Request. Ms. Lewis then represented that her June 14, 2017 estimate was accurate - that the processing would begin in 2-4 weeks (from June 14, 2017).

10. However, on July 24, 2017, Ms. Lewis stated: "Your request has begun processing. In order to obtain the records being sought my office has to reach out to other component offices with CDRH to conduct the search. The search has not been completed at this time. I estimate that your request will be closed within 4 to 8 weeks.

11. On August 14, 2017, in response to a further request for an update, Ms. Lewis provided further assurances that the processing of the FOIA Request was proceeding, stating: "The time frame I recently provided you is still accurate (4 to 8 weeks). If you have any additional questions please let me know."

12. On September 21, 2017, CCHR requested a further update, given that CDRH had missed several represented target dates to complete the processing of the Request. By email dated September 27, 2017, Ms. Lewis responded to the suggestion that the FDA was intentionally delaying the request, by controverting all prior representations and stating that the FDA was removing the FOIA Request from processing it was allegedly undergoing, and placing it on a slower track:

> "The current processing time for most requests in the complex queue is 18 - 24 months. Due to the complexity of the subject matter of your request (per your email clarification on 6/14/17), your request has been placed in the complex queue for processing. Your request requires multiple offices and locations to be searched for responsive records. We are processing your request as quickly as possible. Please be advised that we process requests in a first-in, first-out manner.
>
> "There currently are 6 complex and voluminous requests ahead of your request in my queue. As of today, the estimated completion date for your request is March 31, 2018. This timing could change based on when I receive all responsive records and the volume of the records for my review."

13. Essentially the FDA email stated that rather than completing the processing it was already undergoing, as previously represented, the FDA was ceasing the processing of the Request by placing the Request into a "complex" queue, behind other requests which it viewed to be complex. Such a response manifests a lack of due diligence at best, and worse, constitutes a transparent endeavor to delay and avoid processing the Request.

14. Through counsel, CCHR accordingly wrote to the FDA and asked it to reverse this conduct, or that it would necessarily proceed with an administrative appeal. The FDA responded that such an act would cause the Request to be further delayed – thus threatening that the exercise of the right to appeal would be met with further delay as a punishment therefor.

15. No response was ever received to the FOIA Request despite the numerous promised response deadlines from the FDA set forth above. Thus, by letter dated January 16, 2018, plaintiff administratively appealed the denial of the Request. A copy of this appeal letter is attached as Exhibit B.

16. Although it has been more than 4 months since the appeal was submitted, no response was received to the Administrative Appeal.

17. Plaintiff has a right of access to the requested information under 5 U.S.C. § 552(a)(3), and there is no legal basis for defendant's denial of such access.

WHEREFORE, plaintiff requests this Court:

(1) Order defendant to provide access to the requested documents, to an including the date of the filing of this action;

(2) Expedite this proceeding as provided for in 28 U.S.C. § 1657;

(3) Award plaintiff costs and reasonable attorneys fees in this action, as provided in 5 U.S.C. § 552(a)(4)(E); and

(4) Grant such other and further relief as may deem just and proper.

Dated: June 14, 2018

Respectfully submitted,

_/s/ Kendrick Moxon_____
Kendrick Moxon
LAW OFFICE OF KENDRICK MOXON, PC
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