IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
GAINESVILLE DIVISION

CTD HOLDINGS, INC. Plaintiff, v. NATIONAL INSTITUTES OF HEALTH Defendant.	)	**Civil Action No. _____**

COMPLAINT

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, for injunctive and other appropriate relief. Plaintiff CTD Holdings, Inc. ("CTD") seeks the immediate processing and release of agency records it requested on October 30, 2017 from Defendant National Institutes of Health ("NIH"). CTD has yet to receive a single responsive document from NIH.

Jurisdiction and Venue

2. This Court has subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B), (a)(6)(E)(iii).

3. Venue lies in this district, where CTD has its principal place of business, under 5 U.S.C. § 552(a)(4)(B).

The Parties

4. Plaintiff CTD is a Florida corporation located in Gainesville, Florida. CTD was incorporated in 1990. It is a biotechnology company that develops cyclodextrin-based products for the treatment of diseases, specifically Niemann-Pick Type C ("NPC"), a rare and fatal genetic disease. In addition to its work developing biopharmaceuticals to treat diseases, CTD sells cyclodextrins and related products to pharmaceutical and nutritional industries for use in diagnostics and specialty drugs.

5. Defendant NIH, located in Bethesda, Maryland, is an operating division within the United States Department of Health and Human Services and is an agency within the meaning of 5 U.S.C. § 552(f)(1). NIH has possession of and control over the records responsive to Plaintiff's FOIA request. The NIH Freedom of Information Office processes FOIA requests submitted to NIH. NIH is made up of twenty-seven institutes and centers, and some of these contain offices devoted to processing FOIA requests that operate independently from the NIH Freedom of Information Office.

Factual Background

6. NPC is a genetic degenerative disorder that impacts the brain, lungs, liver, spleen, and other organs. Most cases of NPC are diagnosed in young children. NPC is extremely rare and is always fatal.

7. Since 2008, CTD has conducted a clinical development program in the United States, Brazil and Europe to study the intravenous administration of hydroxy-propyl-beta-cyclodextrin in patients with NPC. To date, CTD has devoted more than $12 million to this program.

8. CTD's clinical efforts have yielded promising results: physicians participating in CTD's program have reported improvements in fine motor skills, behavior, cognition and lung function along with decreased liver size in patients with NPC.

9. CTD is committed to transparency in its findings. As a result, CTD's program is well-known to NIH. The data generated by CTD have been presented to healthcare regulators, including the United States Food and Drug Administration ("FDA") and the Medicines and Healthcare Products Regulatory Agency in the United Kingdom. Moreover, throughout the nine years of the program, CTD has provided information regarding its research on cyclodextrins at conferences.

10. CTD recognizes that competition is natural in drug development. To that end, CTD is not alone in the effort to develop a cyclodextrin-based treatment

for NPC. In fact, global biopharmaceutical company Sucampo Pharmaceuticals, Inc. ("Sucampo"), through its subsidiary Vtesse, Inc. ("Vtesse"), also has a study underway to assess the efficacy of its own cyclodextrin-based treatment for NPC.[1]

11. NIH is made up of twenty-seven institutes and centers. These include the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD") and the National Center for Advancing Translational Sciences ("NCATS"). Congress formed NCATS with the express purpose to "advance translational sciences" by "developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities."[2] Similarly, through its extramural research programs, NICHD "funds scientists at universities and organizations" to conduct research on behalf of NIH.[3] NCATS describes its structure as one that "complements – does not compete with – the work of other research organizations."[4] This is consistent with the general practice at NIH to not use

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[1] In April 2017, Sucampo acquired Vtesse along with its signature drug, VTS-270, a cyclodextrin-based treatment for NPC.

[2] 42 U.S.C. § 287(a)(2).

[3] Discover the NICHD, NIH Publication No. 13-7976 at 3, NICHD (Dec. 2013), https://www.nichd.nih.gov/publications/pubs/Documents/Discover_the_NICHD.pdf.

[4] National Center for Advancing Translational Sciences, 2012-2013 Report at 21, NCATS (Dec. 2013), https://ncats.nih.gov/files/NCATS_2012-2013_report.pdf.

funds for research that is duplicative, redundant or that interferes with market competition.

12. It was in an effort to have a better understanding of the relationship that exists between NIH and Vtesse/Sucampo that the below FOIA requests were made.

The 2016 FOIA Request

13. On October 19, 2016, Jennifer L. Bragg, counsel for CTD ("Counsel"), submitted to the NIH Freedom of Information Office a FOIA request (the "2016 Request").[5] In the 2016 Request, Counsel requested all documents related to:

- NIH employee participation, including instances that were not part of official NIH duties, on or with Vtesse advisory committees;
- Forbes Porter and Elizabeth Ottinger's involvement as Co-Chair and Member, respectively, of Vtesse advisory committees;
- Negotiation and initiation of contractual or cooperative research and development agreement ("CRADA") relationship between NIH and Vtesse;

[5] See Exhibit 1, Letter from Counsel to NIH Freedom of Information Office (Oct. 19, 2016).

- NIH employee travel paid for by Vtesse;
- The date VTS-270 was first administered to a patient at [NIH's clinical center ("the Clinical Center")]; and
- NIH involvement with, and support of, pre-clinical work on VTS-270.

14. By letter dated October 24, 2016, a Government Information Specialist in the NCATS Freedom of Information Office – *not* the NIH Freedom of Information office where Counsel submitted the 2016 Request – acknowledged receipt of the 2016 Request and designated it as NIH Case Number 45716. The letter stated that the NIH Freedom of Information Office had forwarded the 2016 Request to the NCATS Freedom of Information Office, that the NCATS Office of Communications had begun to search for documents responsive to the 2016 Request, and that the NCATS Freedom of Information Office would "do everything possible to comply" with the 2016 Request "in a timely manner."[6]

15. By letter dated November 4, 2016, Counsel, who had not received acknowledgement of the 2016 Request from NIH, requested confirmation from the NIH Freedom of Information Office that, in addition to sending the 2016 Request to NCATS, a "comprehensive search is being conducted" within NIH. Counsel

[6] *See* Exhibit 2, Letter from Kim Minneman to Counsel (Oct. 24, 2016).

wrote that the search should comprise multiple institutes and centers within NIH, "including, but not limited to: the (i) National Institute of Child Health and Human Development; (ii) NIH Clinical Center; (iii) NIH Office of the Director; (iv) NIH Office of Extramural Research; and (v) National Cancer Institute."[7]

16. By letter dated November 7, 2016, a Government Information Specialist in the NIH Freedom of Information Office acknowledged receipt of the 2016 Request and indicated that NIH had "queried the files of the appropriate NIH offices" for responsive records. The letter stated that NIH would "do everything possible to comply" with the 2016 Request "in a timely manner."[8]

17. By telephone on November 16, 2016, Susan Cornell of the NIH Freedom of Information Office indicated to Counsel that NIH would provide documents responsive to the 2016 Request promptly and on a rolling basis.

18. More than three months after that telephone conversation, however, NIH had not corresponded with Counsel nor produced a single record in response to the 2016 Request.

19. Having received no further communications from NIH, on February 21, 2017, Counsel sent an email to a representative of the NIH Freedom

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[7] *See* Exhibit 3, Letter from Counsel to NIH Freedom of Information Office (Nov. 4, 2016).

[8] *See* Exhibit 4, Letter from Lauren Bartok to Counsel (Nov. 7, 2016).

of Information Office requesting an update regarding the status of the 2016 Request.[9]

20. By email dated February 23, 2017, a representative of the NIH Freedom of Information Office responded that NIH would release records responsive to the 2016 Request "on a rolling basis," beginning with a release of records from NCATS "in the next few weeks" to be followed by records from NICHD "in about a month."[10]

21. More than six months after NIH wrote that it would release records in a "few weeks," Counsel had not received a single record from NIH. Moreover, NIH had not communicated with Counsel whatsoever regarding the status of the 2016 Request.

22. On September 14, 2017, Counsel again sent an email to a representative of the NIH Freedom of Information Office requesting an update regarding the status of the 2016 Request.[11]

23. By email on the same date – almost eleven months after the 2016 Request and more than six months after NIH last communicated with Counsel – a representative of the NIH Freedom of Information Office responded and noted

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[9] *See* Exhibit 5, Email from Counsel to Roger Bordine (Feb. 21, 2017).

[10] *See* Exhibit 6, Email from Katherine Uhl to Counsel (Feb. 23, 2017).

[11] *See* Exhibit 7, Email from Counsel to Katherine Uhl (Sept. 14, 2017).

multiple vacancies in the NIH Freedom of Information Office which NIH was "unable to fill because of the Federal hiring freeze." The message concluded, "We are not able to complete (i.e., finalize) processing of records, which has drastically slowed down case processing. At this time we are not able to provide you with a time when you will receive your records."[12]

24. To date, more than one year after submitting the 2016 Request, Counsel has not received a single record from NIH.

The 2017 FOIA Request

25. On October 30, 2017, Counsel submitted to the NIH Freedom of Information Office a FOIA request on behalf of CTD (the "2017 Request").[13] The 2017 Request is substantially similar, but not identical, to the 2016 Request and also expands the responsiveness time frame by over one year, through October 30, 2017. Specifically, the 2017 Request is for all documents responsive to:

- NIH employee participation, including instances that were not part of official NIH duties, on or with Vtesse advisory committees;

[12] *See* Exhibit 8, Email from Stephanie Clipper to Counsel (Sept. 14, 2017).

[13] *See* Exhibit 9, Letter from Counsel to NIH Freedom of Information Office (Oct. 30, 2017).

- Forbes Porter's involvement in the Vtesse Scientific Advisory Board, including all documentation pertaining to the evaluation of the propriety of this participation from an ethics perspective, and any NIH Ethics clearance provided to Dr. Porter;
- Elizabeth Ottinger's involvement in the Vtesse Scientific Advisory Board, including all documentation pertaining to the evaluation of the propriety of this participation from an ethics perspective, and any NIH Ethics clearance provided to Dr. Ottinger;
- Negotiation and initiation of contractual or CRADA relationship between NIH and Vtesse;
- NIH employee travel paid for by Vtesse;
- The date VTS-270 was first administered to a patient at the Clinical Center; and
- NIH involvement with, and support of, pre-clinical work on VTS-270.

26. By email dated November 8, 2017, a representative of the NIH Freedom of Information Office wrote, "we will be aggregating this new request within the 45716 [2016 Request] case." In the same email, the NIH Freedom of Information Office representative wrote that records collected in response to the

2016 Request are "in the queue to be reviewed for final determination of releasability" and that "review time is much longer than normal as this office is still very short staffed due to lingering effects of the Federal Government hiring freeze."[14]

27. At the time of filing this complaint, more than *one year* after the 2016 Request, more than *eight months* after NIH represented that it would release responsive documents in a "few weeks," and more than twenty working days after CTD submitted the 2017 Request, CTD has not received *a single record* from NIH in response to the aggregated requests. NIH, moreover, has not provided a substantive determination regarding its decision whether to comply with each item in the 2017 Request or a date for the release of responsive records.

Cause of Action

Violation of the Freedom of Information Act for Wrongful Withholding of Agency Records

28. Plaintiff CTD repeats and realleges paragraphs 1–27.

29. Defendant NIH, through its acts and omissions, has wrongfully withheld agency records requested by Plaintiff CTD.

30. Plaintiff CTD has exhausted the applicable administrative remedies with respect to Defendant NIH's wrongful withholding of the requested records.

[14] *See* Exhibit 10, Email from Roger Bordine to Counsel (Nov. 8, 2017).

31. Plaintiff CTD is entitled to injunctive relief with respect to the release and disclosure of the requested records.

Requested Relief

WHEREFORE, Plaintiff CTD prays that this Court:

A. order Defendant NIH to promptly make the requested records available to Plaintiff CTD at no charge;

B. provide for expeditious proceedings in this action;

C. award Plaintiff CTD costs and reasonable fees incurred in this action under 5 U.S.C. § 552(a)(4)(E); and

D. grant such other relief as the Court may deem just and proper.

Respectfully Submitted,

Dated: November 30, 2017

s/ Erica L. Perdomo

Erica L. Perdomo
Florida Bar No. 105466
Jennifer L. Bragg (PRO HAC VICE APPLICATION TO BE FILED)
Jennifer L. Spaziano (PRO HAC VICE APPLICATION TO BE FILED)
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Avenue, NW
Washington, DC 20005
Telephone: (202) 371-7000
Facsimile: (202) 661-2393
erica.perdomo@skadden.com
jennifer.bragg@skadden.com
jen.spaziano@skadden.com

Counsel for Plaintiff CTD Holdings, Inc.