

Exhibit A

Declaration of Frederick J. Sadler

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

CARETOLIVE,)	
a not-for-profit corp.,)	
)	Civil No. 2:08-CV-00005
Plaintiff,)	
)	JUDGE FROST
v.)	
)	MAGISTRATE JUDGE KING
U.S. FOOD and DRUG)	
ADMINISTRATION,)	
)	
Defendant.)	

DECLARATION OF FREDERICK J. SADLER

I, Frederick J. Sadler, declare as follows:

1. I am the Director of the Division of Freedom of Information (“DFOI”), Office of Management Programs, United States Food and Drug Administration (“FDA”), located in Rockville, Maryland. I have held this position since March 2007. I previously served as the Denials and Appeals Officer in the DFOI Office from July 2000 to December 2006. From December 2006 until March 2007, I served as the Acting Director of DFOI.

2. In my capacity as Director of DFOI, my duties and responsibilities include supervising the office in the receipt and certain aspects of the processing of requests for FDA records under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552.

3. The statements made in this declaration are based upon my personal knowledge, information made known to me in my official capacity, and information available to me in my official capacity and about which I have become knowledgeable.

4. I submit this declaration in support of the government’s motion for a stay of proceedings in the above-captioned matter. The purpose of this declaration is to set forth DFOI’s

actions with respect to the FOIA request that is the subject of the Complaint in this case.

5. FDA received 18,865 FOIA requests in calendar year 2006 and 11,400 FOIA requests in calendar year 2007. FDA processed 15,742 FOIA requests in calendar year 2006 and 17,295 FOIA requests in 2007.

REQUEST PROCESSING BY DFOI

6. Under FDA's regulations at 21 C.F.R. § 20.40(a), all requests for FDA records must be made in writing to the Freedom of Information Staff at FDA, which is currently known as "DFOI", in the Office of Management Programs.

7. FDA has created an electronic tracking system, the Agency Information Management Systems ("AIMS"), to store and track requests for documents submitted pursuant to FOIA. The AIMS tracking system debuted in January 2006. As of January 2006, when a FOIA request is received by DFOI, a Freedom of Information technician ("FOI technician") on my staff scans the request into a PDF format, logs and uploads the request into AIMS, and assigns the request a reference number. The reference number is four digits reflecting the calendar year in which the request was received (i.e., 2005, 2006, 2007) followed by a number reflecting the number of FOIA requests received by DFOI to date during that particular calendar year.

8. Because of FDA's size and the vast number of documents generated in the course of agency business, FDA has created a decentralized FOI process. Accordingly, after the FOI technician receives, scans, and logs an incoming request, he or she directs AIMS to forward, or "route," the request to the FDA office(s) which, based on a preliminary review of the request, is (are) most likely to possess responsive records ("the action office(s)"). The routing of a particular request through AIMS to the appropriate action office(s) takes place following receipt

and logging. I am available to consult with the FOI technicians in the event that the routing of a particular request is not clear from the text of the request.

9. Under the AIMS system, once a FOIA request is logged in, the AIMS system automatically sends a letter to the requester acknowledging FDA's receipt of the request ("the acknowledgment letter"). The acknowledgment letter is sent by U.S. mail and leaves DFOI's office within one business day after the request is logged into AIMS. The acknowledgment letter also notifies the requester that FDA will respond to the request as soon as possible, and invites the requester to contact FDA at a designated phone number and address if the requester has any questions related to the request.

CHRONOLOGY OF EVENTS

10. On September 11, 2007, DFOI received a FOIA request from Bellinger & Donahue, dated August 15, 2007.¹ Consistent with DFOI practice, an FOI technician logged the request into AIMS, and assigned it reference number 2007-8316, reflecting that it was the 8316th FOIA request that FDA received in 2007. (See Letter from Bellinger & Donahue to FDA, dated August 15, 2007, with stamped reference number 2007-8316, attached as Exhibit 1).

11. On September 11, 2007, FDA sent plaintiff an acknowledgment letter with respect to this FOIA request. (Letter from Shera S. Behram to Bellinger & Donahue dated September 11, 2007, attached as Exhibit 2).

12. DFOI forwarded Plaintiff's request to the Access Litigation and Freedom of

¹ The delay between the date of Bellinger & Donahue's letter and receipt by DFOI occurred because the requester improperly sent the request to the agency's Cincinnati district office rather than to DFOI. Per 21 CFR 20.40(a), all FOIA requests must be received in DFOI in order to be logged and processed. The request was ultimately forwarded from the Cincinnati district office to DFOI on or around September 11, 2007.

Information Branch of FDA's Center for Biologics Evaluation and Research ("CBER") on September 14, 2007. DFOI referred Plaintiff's request to CBER because the request sought documents relating to Provenge, an unapproved biological product regulated by CBER. Thus, CBER was most likely to have responsive documents. CBER responded and released on November 6, 2007, 31 pages of records to Bellinger & Donahue.

13. DFOI also forwarded Plaintiff's request to the Office of the Executive Secretariat in FDA's Office of the Commissioner ("OC"). DFOI did so because the request sought agency correspondence. The Office of the Executive Secretariat maintains certain agency correspondence in its files. OC responded, through DFOI, on January 24, 2008, indicating that no responsive records had been located. (Letter from Theola Myo Khin to Kerry Donahue, dated January 24, 2008, attached as Exhibit 3).

14. On October 10, 2007, DFOI forwarded Plaintiff's request to the Division of Information Disclosure Policy ("DIDP") in FDA's Center for Drug Evaluation and Research ("CDER"). DFOI did so because, after consultation with CBER, it appeared that CDER was also likely to have records relating to Provenge.

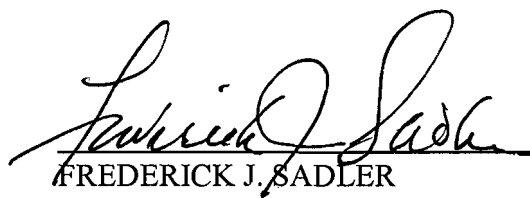
15. On January 2, 2008, Plaintiff filed the Complaint in this case.

16. Plaintiff's FOIA request is still pending at CDER and will be processed when it rises to the top of DIDP's Complex Track. This process is explained in detail in the declaration of Nancy Sager, also filed in support of the government's motion for a stay.

17. FDA takes its responsibilities in the administration of its FOIA program very seriously. In fiscal year 2007, FDA spent 14 million dollars and 93 staff years (i.e., the equivalent of 93 full-time employees) responding to FOIA requests. Despite this financial and

personnel commitment, FDA is not able to process all of the FOIA requests it receives within the statutory timeframes.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

A handwritten signature in black ink, appearing to read "Frederick J. Sadler", written over a horizontal line.

FREDERICK J. SADLER
Director
Division of Freedom of Information
Office of Management Programs
Food and Drug Administration
U.S. Department of Health and Human Services

Executed on February 12, 2008, in Rockville, Maryland.

Scott P. Bellinger
Kerry M. Donahue*
*Also admitted in Florida

BELLINGER & DONAHUE
Attorneys At Law

6295 Emerald Parkway
Dublin, Ohio 43016
Office 614-761-0402
Fax 614-789-9866

August 15, 2007

RE: CareToLive v. FDA, Southern District of Ohio, case no. 2:07 CV 729

Brenda S. Zimmer
FDA
6751 Steger Dr.
Cincinnati, Ohio 45237-3097

2007-8316
RECEIVED
SEP 11 2007

Dear Brenda S. Zimmer,

Please consider this a request under the Freedom of Information Act. **FDA DFOI (HF-85)**

We request the following:

- 1) A copy of all letters written to the FDA (or prepared by the FDA) and purported to be from Dr. Scher, Dr. Hussain and Doctor Fleming in between March 29th 2007 and April 30th of 2007, regarding the BLA submitted for Provenge also known as Sipuleucel-T including the envelope or other means of communication whereby the FDA received such letters and a copy of any record of those letters then being disclosed to any media or other persons or specifically a publication called "The Cancer Letter", including the means of communication to the Cancer Letter of the Scher, Hussain and Fleming letters from the FDA or its employees to outside persons, publications or companies.

We are willing to pay the cost.

115013

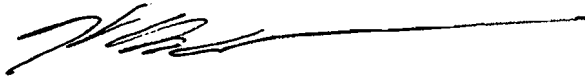


- 2 -

August 15, 2007

Please call if you have questions about this request. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Kerry Donahue", written over a horizontal line.

Kerry Donahue



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

BELLINGER & DONAHUE ATTY
KERRY DONAHUE
6295 EMERALD PKY
DUBLIN OH 43016 US

09/11/2007

In Reply refer to:
2007-8316

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

PROVENGE (SIPULEUCEL-T) - LTRS 3/29/07-4/30/07

We will respond as soon as possible and may charge you a fee for processing your request. If you have any questions about your request, please call Shera S. Behram, Information Technician, at (301) 827-6552 or write to us at:

Food and Drug Administration
Division of Freedom of Information
5600 Fishers Lane, HFI-35
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.

Sincerely,

Shera S. Behram,
Information Technician,





DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

KERRY DONAHUE
BELLINGER & DONAHUE ATTY
6295 EMERALD PKY
DUBLIN OH 43016 USA

01/24/2008
In Reply refer to:
2007-8316

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

PROVENGE (SIPULEUCEL-T) - LTRS 3/29/07-4/30/07

The Office of the Executive Secretary, Office of the Commissioner, Food and Drug Administration has received your Freedom of Information Act request. After a diligent search, this office has not located any responsive records. Other agency components may respond to your request under separate cover.

The following charges for this request to date may be included in a monthly invoice:

Reproduction	Search	Review	Fiche	Other	Total
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Reproduction=\$3.10	Search=\$404.75	Review=\$0.00	Fiche=\$0.00	Other=\$0.00	Total=\$407.85
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All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane (Room 6-30)
Rockville, MD 20857

Sincerely Yours,

Theola Myo Khin
Freedom of Information Specialist

Enclosures:
if indicated

