

FILED  
JAMES BONINI  
CLERK  
**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION** 10 DEC 10 AM 11:37

CareToLive,  
a not for profit corporation,  
6295 Emerald Parkway  
Dublin, Ohio 43016

U.S. DISTRICT COURT  
SOUTHERN DIST. OHIO  
EAST. DIV. COLUMBUS

Plaintiff,

vs.

Centers for Medicare & Medicaid Services (CMS),  
7500 Security Blvd.  
Baltimore, Maryland 21244-1850

Case No. **2:10 cv 1114**

Judge **JUDGE FROST**

**MAGISTRATE JUDGE KEMP**

Defendants.

**COMPLAINT FOR VIOLATION OF  
FREEDOM OF INFORMATION ACT**

Now comes Plaintiff CareToLive, a not for profit corporation and advocacy group organized and incorporated under the laws of and in Ohio, and hereby asserts the following causes of action against the Defendant, Centers for Medicare & Medicaid Services (CMS).

**COUNT I**

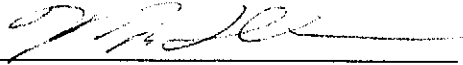
**VIOLATION OF FREEDOM OF INFORMATION ACT**

1. This Court has jurisdiction under the Freedom of Information Act (FOIA) 5 U.S.C.A. § 552.
2. Plaintiff, CareToLive (CTL), sent a proper FOIA request for documents to the Centers for Medicare & Medicaid Services (CMS) on July 6, 2010, attached hereto as "Exhibit A" and incorporate by reference thereto.

3. CTL sent a second FOIA request to CMS on July 23, 2010, attached hereto as "Exhibit B" and incorporated by reference thereto.
4. The CMS, FOIA office, confirmed receipt of the requests on August 9, 2011.
5. An inquiry from CTL to CMS on October 12, 2010 has not received a response.
6. A follow up letter seeking further information as to the status of the FOIA requests was sent by counsel on behalf and at the request of CTL on November 19, 2010 which request is attached hereto as "Exhibit C" and incorporated by reference thereto.
7. CMS has to date not responded to the November 19<sup>th</sup> inquiry from CTL counsel.
8. More than 20 business days have passed since the CTL FOIA requests were received by CMS.
9. CMS has not been responsive to requests to estimate the required time necessary to complete the FOIA or where the requests stands on the first in first out list.
10. CMS is in violation of 5 U.S.C.A. § 552.
11. The Freedom of Information Act provides that the Plaintiff is entitled to fees and costs for enforcement.

WHEREFORE, Plaintiff requests an order compelling immediate production of the requested documents as well as an award of fees and costs Plaintiff.

Respectfully submitted,



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Kerry M. Donahue (0061105)

TRIAL ATTORNEY

*BELLINGER & DONAHUE*

6295 Emerald Parkway

Dublin, Ohio 43016

Telephone: (614) 761-0402

Facsimile: (614) 789-9866

## **EXHIBIT A**

# Care To Live

a not for profit corporation

www.CareToLive.com PO Box 464 Thorofare NJ 08086-0464 info@CareToLive.com

July 6, 2010

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Freedom of Information Group  
Room N2-20-16  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

RE: FREEDOM OF INFORMATION ACT REQUEST

Dear CMS Freedom of Information Group,

Please consider this a request under the Freedom of Information Act.

We request copies of all documents relating to the decision of The Centers for Medicare and Medicaid Services to initiate a National Coverage Determination regarding the prostate cancer immunotherapeutic agent sipuleucel-T (Provenge). This request includes all documents, whether e-mails, including internal emails summarizing telephone or other conversations, letters, faxes and memoranda of telephone conversations that Dr. Louis Jacques, the director of the Coverage and Analysis Group at the Medicare Center, referred to when he said your agency heard from people in regards to Provenge. Dr. Jacques made the following statement to Matthew Herper of Forbes Magazine:

"We've been getting questions from people," says Jacques. "Well, what's up with Provenge? Is it a drug? Is it a biologic? Is it something else? Does it really work? It has been interesting to look at the evidence around it."

<http://blogs.forbes.com/sciencebiz/2010/07/why-medicare-is-reviewing-provenge/?boxes=businesschannelsections>

We request copies of all correspondence, whether electronic or otherwise, and all notes made by employees regarding all requests for inquiries, including, where available, the originating phone number where the requests were oral, or notes identifying the caller or the location of the calls and all communications then made when those inquiries were communicated to superiors within the agency. All phone logs or evidence of formal or informal inquiries or communications, internal or external, should be included.

We request all documents CMS has pertaining to the people who asked those questions as well as all other documents relating to this decision, who made the decision and include the names and organizations of all those who made the informal inquiries.

We are willing to pay all costs associated with complying with this request.

Sincerely,

Mike Kearney  
Spokesperson for CareToLive, a not for profit corporation  
E-mail: [PublicRelations@CareToLive.com](mailto:PublicRelations@CareToLive.com)  
Phone: 856-770-8540

## **EXHIBIT B**

# Care To Live

a not for profit corporation

www.CareToLive.com PO Box 464 Thorofare NJ 08086-0464 info@CareToLive.com

July 23, 2010

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Freedom of Information Group  
Room N2-20-16  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

RE: FREEDOM OF INFORMATION ACT REQUEST

Dear CMS Freedom of Information Group,

Please consider this a request under the Freedom of Information Act.

We request copies of all documents relating to the enclosed letter regarding the prostate cancer immunotherapeutic agent sipuleucel-T (Provenge) and the 27 page document entitled "Provenge PhIII Trials – The Alternative Explanation of Survival Results", which can be found here:

<http://caretolive.com/wp-content/uploads/2010/07/provenge-approval-fud.pdf>

This request includes all documents, whether it be Post Office delivered mail, e-mails, including internal e-mails summarizing telephone or other conversations, letters, faxes and memoranda of telephone conversations that were a result of the person writing the enclosed letter encouraging people as follows:

"I call upon you to read this argument and make your own independent, critical assessment of its merits. If you see the merit of the concerns it voices, I call upon you to express those views to the FDA and CMS (Leslye Fitterman, PHD; Leslye.fitterman3@cms.hhs.gov ) who have been trusted with the power of protecting the American public."

We request copies of all correspondence, whether electronic or otherwise, and all notes made by employees regarding all views expressed, including, where available, the originating phone number where the requests were oral, or notes identifying the caller or the location of the calls and all communications then made when those views were communicated to superiors within the agency. All phone logs or evidence of formal or informal discussions or communications, internal or external, should be included.

We request all documents CMS has from people who expressed their views, as well as all other documents relating to this matter, which would have commenced July 13, 2010 when the anonymous letter writer started this campaign and this would include all correspondence sent to and from Leslye Fitterman. By remaining anonymous, this letter writer has voided coverage by the CMS Privacy Policy.

Please include all electronically received information from the allegedly anonymous writer including information that might lead to the IP Address of the author when he provides the information required to post his comment. This person is not a physician and has never been threatened. He is from Wall Street and his effort was to damage the stock price for financial gain at the expense of the company and patient community.

We are willing to pay all costs associated with complying with this request.

Thanks for processing this request.

Sincerely,

          /s/          

Mike Kearney  
Spokesperson for CareToLive, a not for profit corporation  
E-mail: [PublicRelations@CareToLive.com](mailto:PublicRelations@CareToLive.com)  
Phone: 856-770-8540

## EXHIBIT C

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

November 19, 2010

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Freedom of Information Group  
Room N2-20-16  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Dear Ms. Vendetta Dutton:

Please be advised that I represent the non-profit group CareToLive (CTL). This group has sent you two Freedom of Information Act (FOIA) requests. The first once was sent on July 6, 2010. You assigned it Control # 071220107008.

A second FOIA request was sent on July 23, 2010. CTL has received no response from you on this second request so there is either no control number or the second request was combined with the first.

Please provide us with a time estimate of when we might receive the response. Assuming a first in first out what number are we currently in the line? In other words how many requests are ahead of CTL's. Also what date did the first in the current line that has not yet been responded to, arrive to the CMS office.

Thank you for your assistance in this matter.

Sincerely,



Kerry M. Donahue