March 2, 2007

Department of Health and Human Services
Michelle Johnson-Lancaster
IBC Coordinator
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Ms. Johnson-Lancaster,

I am responding to your correspondence of February 20, 2007 regarding a complaint lodged by the Sunshine Project. Specifically, it appears that the Sunshine Project alleges that Third Wave has been unresponsive to its request for IBC meeting minutes ranging from May 1, 2003 through to the present.

As indicated by Section I-B of NIH's Guidelines for Research Involving Recombinant DNA Molecules, Recombinant Molecules are defined as:

> (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
>
> Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines*.
>
> Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transportation itself contains recombinant DNA.

Third Wave has explained to the Sunshine Project on multiple occasions that we have no grants that involve recombinant DNA molecules as defined by above NIH guidelines for the requested timeframe (please see the attached correspondence dated Jan. 28, 2004 and Oct. 11, 2006). In fact, the only grant that may even be responsive is Grant no. 2R44 GMØ64317-02 ("Genetic Profiles for

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Perioperative Applications"), which does not involve Recombinant Molecules as defined above. Therefore, it is Third Wave's understanding that it is not subject to the NIH's requirement to supply the information requested by the Sunshine Project.

Please do not hesitate to contact me with any questions or comments.

Sincerely,

Cindy S. Ahn
Vice President and General Counsel
Third Wave Technologies, Inc.
Tel (608) 204-2949
Fax (608) 663-4049
cahn@twt.com

Cc: Lana Skirboll, Ph.D., Director, NIH Office of Science Policy
Valerie Bonham, J.D., Office of General Counsel, NIH
Norka Ruiz Bravo, Ph.D., NIH Deputy Director of Extramural Research
Joseph Ellis, Acting Director, NIH Office of Policy for Extramural Research Administration
Allan C. Shipp, Director of Outreach, NIH Office of Biotechnology Activities
Edward Hammond, Director, Sunshine Project

THIRD WAVE
TECHNOLOGIES

February 4, 2004

Edward H. Hammond
Director
The Sunshine Project
101 West 6th Street
Suite 607
Austin, TX 78701

By fax: (512) 494-0545

RE: letter dated 28 January 2004

Dear Mr. Hammond,

Third Wave Technologies is not currently performing NIH funded research involving recombinant DNA molecules as defined in the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section I-B. Therefore, in compliance with Sections I-D-1 and I-D-2 of the NIH Guidelines, Third Wave Technologies is not obligated to supply the information you requested.

If you have additional questions regarding this matter please feel free to contact me at (608) 663-7082 or by e-mail at *sday@twt.com*.

Sincerely,

Stephen P. Day, Ph.D.
Director, Medical Affairs

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THIRD WAVE TECHNOLOGIES

November 2, 2006

Edward H. Hammond
Director
The Sunshine Project
1920 Stuart St.
Berkeley, CA 94703

By fax: (512) 494-0545

RE: letter dated 11 October 2006

Dear Mr. Hammond,

As stated in my letter of February 4, 2004, Third Wave Technologies is not currently performing NIH funded research involving recombinant DNA molecules as defined in the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section I-B. That section of the Guidelines defines recombinant DNA as follows:

"Section I-B. Definition of Recombinant DNA Molecules

In the context of the *NIH Guidelines*, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines*.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transposon itself contains recombinant DNA."

http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_lnk_2002z.pdf

Therefore, in compliance with Sections I-D-1 and I-D-2 of the NIH Guidelines, Third Wave Technologies is not obligated to supply the information you requested.

If you have additional questions regarding this matter please feel free to contact me at (608) 663-7082 or by e-mail at sday@twt.com or Third Wave Technologies Vice President and General Counsel, Cindy Ahn at (608) 273-8933, extension 2949 or by e-mail at cahn@twt.com .

Sincerely,

Stephen P. Day, Ph.D.
Director, Medical Affairs

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