

ORIGINAL



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:)
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POM Wonderful, LLC *et al.*)
)
)
)
_____)

Docket No. 9344

NON-PARTIES JOHNS HOPKINS UNIVERSITY AND MICHAEL A. CARDUCCI
M.D.'S MOTION FOR *IN CAMERA* TREATMENT

Non-Parties Johns Hopkins University ("JHU") and Professor Michael A. Carducci, M.D. ("Dr. Carducci"), by and through their undersigned counsel and pursuant to 16 C.F.R. § 3.45 (b), hereby move for *in camera* treatment of certain documents to be specified below. In support of this Motion, JHU and Dr. Carducci respectfully refer to and incorporate the Affidavit of Michael A. Carducci, M.D. ("Carducci Aff.") submitted herewith and Exhibit A attached thereto, and further state:

1. The Commission has notified JHU and Dr. Carducci of the Commission's intention to offer the documents and materials attached as Exhibit A to the Carducci Affidavit as evidence at the May 24, 2011 Administrative Hearing in the captioned matter. Under the Commission rules, documents may be granted *in camera* treatment where their disclosure will "likely result in a clearly defined, serious injury" to the person or entity whose records are involved.
2. As discussed in greater detail in the Carducci Affidavit submitted in support of this Motion, JHU and Dr. Carducci have identified and are requesting *in camera* treatment for those specific materials described in the Affidavit which contain confidential and sensitive data and information that if publicly disclosed at this time will compromise the likelihood that research and study results will be accepted for publication in a scientific or medical journal (hereafter "Sensitive Research Data"). If the research and study results are rendered unpublishable because of public disclosure of Sensitive Research Data now, JHU and Dr. Carducci will be seriously injured.

3. Counsel for JHU and counsel for POM Wonderful have conferred, and JHU understands that POM Wonderful will be moving for continued protection and *in camera* treatment for additional documents listed on Exhibit A to the Carducci Aff. By not moving in their own right for protection of these materials, JHU and Dr. Carducci expressly do not waive confidentiality with respect to these additional documents listed on Exhibit A, nor do the University and Dr. Carducci tacitly or implicitly agree that such materials should be made public.

WHEREFORE, for the reasons set forth above as well as in the Affidavit of Michael A. Carducci filed concurrently with this Motion, Johns Hopkins University and Dr. Michael A. Carducci respectfully request that the Sensitive Research Data specified and referenced in the aforementioned Affidavit receive *in camera* treatment for a period of not less than two (2) years.

Dated: April 20, 2011

Respectfully submitted,



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Michael A. Carducci

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AFFIDAVIT OF MICHAEL A. CARDUCCI, M.D.

1. I am over the age of eighteen and competent to testify.
2. I am a Professor of Oncology and Urology in the Johns Hopkins University School of Medicine ("Johns Hopkins" or "the University").
3. I have over twenty years of experience in the practice of medicine and I am knowledgeable with respect to the medical, scientific and academic standards governing confidentiality and sensitivity of unpublished research data and pre-publication research reports and analyses.
4. I make this Affidavit on the basis of my professional experience as well as my personal knowledge with respect to the study entitled "Safety and Efficacy of POMx in Men with Prostate Cancer: An 18-Month, Randomized, Double-Blind, Dose-Finding Study of the Effects of Two (2) Doses of Pomegranate Juice Extract Capsules (1 or 3 capsules/day) on Rising Prostate Specific Antigen Levels in Men Following Initial Therapy for Prostate Cancer (hereafter the "Study"). I served as Lead Principal Investigator for the Study.
5. Attached to this Affidavit as Exhibit A is the list of documents I understand that Counsel for the Federal Trade Commission ("FTC") intends to offer into evidence in the May 24, 2011 administrative trial in the captioned matter. For ease of reference, University

counsel has numbered these documents from 1 to 30 on the left hand margin of the list.

For the sake of clarity, I shall also reference the FTC Bates labeling for the documents I describe below.

6. Based on my understanding of the relevant scientific, medical and academic principles, the following documents should remain confidential and should be subject to protection from public disclosure:

Item 22:

9/4/2009 Email Chain (H. Liker, M. Carducci et al re: POM interim analysis (MCARDUCCI-009479 – 009488) (Carducci Deposition Exhibit 17)

Item 23:

9/15/2009 Email Chain (M. Carducci, L. Tuan, P. Wozniak, H. Liker) re POM Interim analysis-Carducci (MCARDUCCI-009496 – 009497) (Carducci Deposition Exhibit 18)

Item 26:

5/28/2010 Email from P. Wozniak to M. Carducci, H. Liker, B. Gillespie et al re: POM Wonderful PSADT (MCARDUCCI – 012008 – 012021) (Carducci Deposition Exhibit 20)

Item 28:

POM Wonderful Company Protocol: 2007-001 6/4/2010 Clinical/Statistical Report (MCARDUCCI-012598 – 014133)

Item 30:

FTC Deposition of Michael Carducci and deposition exhibits 12/13/10. To the extent that they are included anew in this "catch all" deposition exhibit item, I reiterate my desire for confidentiality and protection of Items 22, 23, 26 and 28, and add the following:

1/7/2010 Email B. Gillespie to M. Carducci (Carducci Deposition Exhibit 19) (MCARDUCCI 009982)

8/4/10 Study Data Tables (Carducci Deposition Exhibit 8) (DKESSLER 0000031 – 36)

7. If the Court fails to preserve and protect the confidentiality of the above-listed documents, and if these documents are therefore made public before the Study results and the complete analysis and evaluation of the same is submitted to and accepted and published by a scientific or medical journal, both the University and I are likely to suffer

serious injury. First, it is not usual or typical in medical and scientific practice to publish interim data or analyses, just as authors are not typically compelled to make rough drafts public. Moreover, "pre-publication" of the final Study results is very likely to impact and jeopardize the willingness of a journal to publish the Study. Medical and scientific journals do not typically publish studies that are already in the public domain.

8. I expect that the final Study results and analysis will be published in a journal in the early part of 2012. Timing of disclosure is therefore the primary issue. The University's request that these materials remain confidential will protect the opportunity to publish, avoid the injury to me and the University, and make it more likely that the broader scientific and medical community and the public at large will have access to the Study results and the work through a widely available published journal.

I solemnly affirm under the penalties of perjury and upon personal knowledge that the contents of the foregoing Affidavit are true.

April 20, 2011
Date



Michael A. Carducci, M.D.

Exhibit A

Item	Depo. Ex #	Description	Beginning Bates #	Ending Bates #
1	3	Dr. Carducci's Curriculum Vitae	MCARDUCCI-003172	MCARDUCCI-003230
2	21	<i>Protocol for A Randomized, Placebo-Controlled, Pre-Surgical Study of the Effects of Pomegranate Pills in Men with Prostate Cancer Prior to Radical Prostatectomy</i>	MCARDUCCI-003527	MCARDUCCI-003572
3		<i>Research Agreement between JHU and POM Wonderful</i>	MCARDUCCI-003586	MCARDUCCI-003647
4	6	<i>Protocol v. 3 for Safety and Efficiency of POMx in Men with Prostate Cancer:</i>	MCARDUCCI-004364	MCARDUCCI-004417
5		<i>Protocol v. 2 for Safety and Efficiency of POMx in Men with Prostate Cancer:</i>	MCARDUCCI-006381	MCARDUCCI-006434
6	4	<i>Confidentiality Agreement between POM Wonderful and Dr. Carducci</i>	MCARDUCCI-007138	MCARDUCCI-007141
7	28	Email from B. Gillespie to M. Carducci	MCARDUCCI-008164	MCARDUCCI-008165
8	11	Email from J. Walczak to M. Carducci	MCARDUCCI-008341	MCARDUCCI-008341
9	13	Email from L. Wallace to M. Carducci	MCARDUCCI-008402	MCARDUCCI-008403
10	22	Email from A. Pantuck to M. Carducci et al	MCARDUCCI-008441	MCARDUCCI-008441
11	12	Email from S. Tate to M. Carducci	MCARDUCCI-008469	MCARDUCCI-008469
12		Email from J. Walczak to H. Liker	MCARDUCCI-008568	MCARDUCCI-008569
13		Email from H. Liker to M. Carducci et al	MCARDUCCI-008573	MCARDUCCI-008575
14		Email from M. Dreher to M. Carducci et al	MCARDUCCI-008576	MCARDUCCI-008582
15	16	Email from H. Liker to M. Carducci	MCARDUCCI-008949	MCARDUCCI-008950
16	23	Email from D. Ford to M. Carducci	MCARDUCCI-009092	MCARDUCCI-009092
17	24	Email from M. Tupper to M. Carducci	MCARDUCCI-009201	MCARDUCCI-009203
18	25	Email from H. Liker to M. Carducci	MCARDUCCI-009205	MCARDUCCI-009205
19	26	Email from D. Ford to M. Carducci	MCARDUCCI-009212	MCARDUCCI-009212
20	27	Email from H. Liker to M. Carducci	MCARDUCCI-009358	MCARDUCCI-009364
21		Letter from POM Wonderful to FDA	MCARDUCCI-009359	MCARDUCCI-009364
22	17	Email from L. Tuan-Wallace to S. King	MCARDUCCI-009479	MCARDUCCI-009488
23	18	Email from P Wozniak to M. Carducci	MCARDUCCI-009496	MCARDUCCI-009497
24		Email from B. Gillespie to M. Carducci	MCARDUCCI-009965	MCARDUCCI-009965
25		Email from B. Gillespie to M. Carducci	MCARDUCCI-009965	MCARDUCCI-009965
26	20	Email from P Wozniak to M. Carducci	MCARDUCCI-012008	MCARDUCCI-012021
27	5	Supplemental Interrogatory responses from JHU	MCARDUCCI-012069	MCARDUCCI-012071
28		POM Wonderful Company Protocol: 2007-001 Clinical/Statistical Report	MCARDUCCI-012598	MCARDUCCI-014133
29	15	Email from J. Walczak to M. Carducci	MCARDUCCI-015336	MCARDUCCI-015354
30		FIC Deposition of M. Carducci and deposition exhibits		
30	19	Email from B. Gillespie to M. Carducci		
30	14	Email from M. Carducci to J Walczak		
30	10	Email from Y. Xiaobu		
30	9	Email from H. Liker to M. Carducci		
30	8	Clinical/Statistical Report		
30	7	Abstract Submitted to: ASCO Genitourinary Cancer Symposium		

Certificate of Service

I hereby certify that a copy of the pleadings attached hereto was sent to the following individuals via U.S. First Class Postage Prepaid Mail to:

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ORDER

The Non-Parties Johns Hopkins University and Michael A. Carducci M.D.'s Motion For
In Camera Treatment is hereby _____ this _____ Day of _____
_____, 2011.

Judge