

Timeline for Dr. Maha Hussain

This is an approximate, and brief, timeline of what Dr. Maha Hussain was up to, beginning in and around 2005, up until the time when Dendreon was sent a CR Letter, which she adamantly fought for, while Novacea received almost \$500 million from Schering-Plough. Note: She is a Consultant on the Advisory Board of Novacea Inc.

This timeline is only as accurate as the data gathered and it is presented for all to draw their own conclusions.

September 14, 2005

By Peggy Peck, Senior Editor, MedPage Today

<http://www.medpagetoday.com/Gastroenterology/PancreaticDiseases/tb/1730>

One of the three-panel members who voted against Tarceva, Bruce Cheson, M.D., of Georgetown University said after the vote that the Tarceva benefit did not outweigh its risks. But other panelists, including **Maha Hussain, M.D.**, of the University of Michigan in Ann Arbor **said that even slight benefits are significant in "a tough disease."**

April 19, 2006

10 months prior to Dr. Hussain signing her Dendreon conflict of interest waiver saying her husband handles all their investments, she was able to list all of her conflicts of interest on the Sprycel waiver.

Dr. Hussain has been asked to participate in all official matters regarding New Drug Application (NDA) 21-986, proposed trade name Sprycel (dasatinib) tablets (BMS-354825), sponsored by Bristol Myers Squibb, with the proposed indications for (1) treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia with resistance to prior therapy including imatinib, and (2) the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy.

Dr. Hussain has advised the Food and Drug Administration (FDA) that she has financial interests that could potentially be affected by her participation in the matter described above. Dr. Hussain owns stock in P -I I I, - , and -I. All companies involved with competing products to Sprycel (Dasatinib).

Looks like her husband, Dr. Salam Jafar Hussain, wasn't managing the portfolio and Maha actually knew her holdings.

(The timeline is continued on the next page)

April 20, 2006

The Prostate Cancer Foundation **2005 Annual Report** lists the following:

PCF's Therapy Consortium Clinical Investigators with pictures:

Dr. David Argus (ProQuest Scientific Advisory Board)

Dr. Michael Carducci

Dr. Eric Small

Dr. Philip Kantoff

Dr. Mario Eisenberger

Dr. Maha Hussain

Dr. Christopher Logothetis

Dr. William Nelson (ProQuest Scientific Advisory Board)

Dr. Kenneth Pienta

Dr. Howard Scher (ProQuest Scientific Advisory Board)

Dr. George Wilding

June 2, 2006

Committee: Oncologic Drugs Advisory Committee

I acknowledge that contingent upon public disclosure of the financial interest listed below, related to new drug application (NDA) 21-986, proposed trade name Sprycel (dasatinib) tablets (BMS-354825), sponsored by Bristol Myers Squibb, with the proposed indications for (1) treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia with resistance to prior therapy including imatinib, and (2) the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy, I am eligible to receive waivers under 18 U.S.C. §208 (b)(3) and 21 U.S.C. §355 (n)(4).

Type of Interest Nature Magnitude

Stock 2 competing firms Valued at less than \$5,001 per firm.

Stock 2 competing firms Valued between \$5,001 and \$25,000 per firm.

Stock 2 competing firms Valued between \$25,001 and \$50,000 per firm.

I hereby request that FDA make this information publicly available on my behalf. I understand that without public disclosure of this interest the waiver is not valid.

(The timeline is continued on the next page)

August 24, 2006

PSA predicts treatment success in advanced prostate cancer

Study led by U-M investigator finds patients with lower PSA levels 7 months after therapy lived longer

Results of the study appear in the Aug. 20 issue of the Journal of Clinical Oncology.

“Our analysis showed that a low or undetectable PSA after seven months of androgen deprivation therapy is a powerful predictor of risk of death in patients with new metastatic prostate cancer. This could allow oncologists to identify patients who are unlikely to do well with this treatment long before they develop clinical signs of treatment resistance,” says lead study author Maha Hussain, M.D., professor of internal medicine at the U-M Medical School.

Dr. Hussain is also a member of the Oncologic Drug Advisory Committee (ODAC) of the FDA and a member of the Michigan Cancer Consortium Advisory Committee on Prostate Cancer.

In addition, Urologic Oncology Program investigators participate in the Prostate Cancer Foundation's Clinical Research Consortium. The consortium ensures that leading cancer centers maintain a robust infrastructure for conducting prostate cancer clinical trials. The U-M Comprehensive Cancer Center is one of eight leading prostate cancer programs that form the consortium. Together, these institutions collaborate to rapidly and efficiently develop promising prostate cancer therapies. **To date, Prostate Cancer Foundation has provided more than \$17 million to this effort.** More information on this and other initiatives can be found on their www.prostatecancerfoundation.org.

http://www.cancer.med.umich.edu/cancertreat/urologiconcology/research_discovery_progress.shtml

October 2006

Release Date

Sponsored by InforMEDical Communications, Inc.

Expiration Date: September 2008

Maha Hussain:

-Abbott: research support

-Bristol-Myers Squibb: research funding

-Centocor: consultant/advisory board

-Elan: consultant/advisory board

-Merck: research funding

-**Novacea: advisory board, consultant**

-Pfizer: consultant/advisory board, research funding; sanofi-aventis: research funding.

(The timeline is continued on the next page)

December 04, 2006

Date Updated

Content provided by Revolution Health Group

Dr. Hussain's research efforts are focused on the development of therapies for patients with bladder and prostate cancer. She currently serves as principal investigator of five ongoing investigator-initiated national and international multicenter clinical trials that she designed. She is also a Fellow of the American College of Physicians.

December 4, 2006 Disclosures:

Grants/Research Support: Sanofi-Aventis SA, Bristol-Myers Squibb Company, Abbott Laboratories, Merck & Co. Inc., Willex AG, PharmaMar SA, Pfizer Inc.

Consultant Advisory Board: Novacea Inc., Chiron Corporation, Bristol-Myers Squibb Company, Eli Lilly and Company, Centocor Inc., Pfizer Inc., Elan Pharmaceuticals Inc.

January 24, 2007

Faculty: Hussain, Maha

Employment or Leadership: N/A

Consultant or Advisory Role: Oncogenix; Lilly; Elan

Stock Ownership: N/A

Honoraria Research: Oncogenix; Elan; Lilly

Funding: Merck

February 2, 2007

(Modified February 5, 2007)

Congressionally Directed Medical Research Programs: Partnering For A Cure

The FY05 Clinical Consortium Award supports the creation of a major multi-institutional clinical trial resource to facilitate rapid execution of novel clinical trials. The goal is to speed the implementation of clinical trials with novel therapeutics that ultimately will decrease the impact of the disease. **Dr. Howard Scher of Memorial Sloan-Kettering Cancer Center is leading this multi-institutional consortium.**

Participating clinical sites and **lead investigators are:**

-Dr. Tomasz Beer, Oregon Health and Science University

-Dr. Michael Carducci, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

-Dr. Maha Hussain, University of Michigan Comprehensive Cancer Center

-Dr. Philip Kantoff, Dana-Farber Cancer Institute

-Dr. Paul Matthews, The University of Texas M.D. Anderson Cancer Center

-Dr. Eric Small, University of California, San Francisco Comprehensive Cancer Center

-Dr. George Wilding, University of Wisconsin, Comprehensive Cancer Center

(The timeline is continued on the next page)

February 26, 2007

Dr. Hussain, an employee of the FDA, signs her waiver for her conflicts of interest.

<http://www.fda.gov/OHRMS/DOCKETS/AC/07/waivers/2007-4291-w-03-Hussain-208.pdf>

March 26, 2007

Published in the Bernstein Report:

FDA has granted a waiver to Maha Hussain, a professor at the University of Michigan Health System, who will participate as a voting consultant to the committee.

The waiver document notes that Hussain “has a national reputation in the fields of cancer research and clinical care for advanced genitourinary cancers” and is a member of FDA’s Oncology Drugs Advisory Committee (ODAC).

“There is a critical need on the Committee for clinical care expertise in the treatment of advanced, metastatic prostate cancer patients who don’t respond to standard treatment,” according to the waiver. It also asserts that her “clinical trial expertise will contribute to the Committee’s discussion of appropriate patient populations and study end points.”

The waiver notes that Hussain is the principal investigator on a research contract awarded by a competing company for a product that is not related to Provenge. Under the draft guidance this probably would not be considered a conflict. However, the fact that her husband owns stock in three competing companies, valued at \$15,000-\$300,000, would at minimum prevent her from voting. If the total value of the stock exceeds \$50,000, Hussain wouldn’t even be at the table if the new policy were in effect.

March 29, 2007

Dr. Richard Pazdur was seen passing notes during lunch to Dr. Maha Hussain. Dr. Hussain is a sitting ODAC panel member and is serving as that advisory panel’s interim chairperson.

After lunch, Dr. Hussain tried to control the floor as she wanted to influence others in regards to Provenge’s efficacy. She got her facts mixed up and she showed she was on a mission, no doubt for Dr. Pazdur.

April 26, 2007 12:08 PM ET

Matthew Herper of Forbes.com writes this about Dr. Hussain after her letter to the FDA started appearing on the internet:

Hussain's opinion may carry particular weight because she heads the FDA panel that normally deliberates over cancer drugs. In a regulatory twist, Provenge was reviewed by a separate committee, charged with analyzing cellular, tissue and gene therapies. (Provenge therapy consists of specially treated immune system cells.)

April 27, 2007

Dr. Hussain’s letter to the FDA published in The Cancer Letter and on the internet for all the world to see. Not sure when it first appeared on the internet. It is interesting that Matt Herper of Forbes.com was already working on an article about it to be published at 12:08 PM ET on the 26th.

(The timeline is continued on the next page)

May 8, 2007

Dendreon receives Complete Response Letter from FDA For ProvengR Biologics License Application. This letter delays approval of Proveng.

May 30, 2007

Evelyn M. Rusli of Forbes.com wrote:

On Tuesday, **Novacea** was just another young biotech, with a modest market capitalization of \$187.8 million.

That all changed on Wednesday, when the drug maker announced it had signed a deal worth over \$500 million with pharma juggernaut Schering-Plough.

Under the agreement, the companies will jointly develop and market **Novacea's Asentar, a promising prostate cancer drug in late-stage clinical trials.**