

# ZUCKERMAN SPAEDER LLP

ATTORNEYS AT LAW

1201 CONNECTICUT AVENUE, N W  
WASHINGTON, D C 20036-2638  
(202) 778-1800  
FACSIMILE (202) 822-8106

WILLIAM B SCHULTZ  
(202) 778-1820  
WSCHULTZ@ZUCKERMAN.COM

October 24, 2002

Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

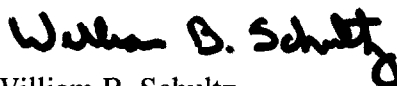
Re: Petition to Post Statement in Response to Warning Letter on FDA Website

Dear Sir or Madam:

Please find enclosed a Petition on behalf of Dr. Frank I. Marcus regarding posting Dr. Marcus's response to an FDA warning letter on FDA's website. Please call me at the telephone number above if you have any questions concerning this Petition.

Thank you for your assistance to this matter.

Sincerely yours,



William B. Schultz  
Attorney for Petitioner Frank I. Marcus

Enclosure

cc: Joseph M. Sheehan, Director, Regulatory Staff, Center for Review and Radiological Health  
Les Weinstein, Ombudsman, Center for Devices and Radiological Health  
Steven H. Unger, Director, Office of the Ombudsman  
Daniel Troy, Chief Counsel  
William K. Hubbard, Senior Associate Commissioner

**FOOD AND DRUG ADMINISTRATION**

10/23/02 11:50:23 AM

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**Petition to Post Statement in** )  
**Response to Warning Letter on** )  
**FDA Website** )  
\_\_\_\_\_ )

**Docket No.** \_\_\_\_\_

**Submitted on Behalf of Dr. Frank I. Marcus**

**October 24, 2002**

**CITIZEN PETITION TO POST STATEMENT IN RESPONSE  
TO WARNING LETTER ON FDA WEBSITE**

Pursuant to 21 C.F.R. § 10.30, Dr. Frank I. Marcus petitions the Food and Drug Administration to post on its website Dr. Marcus's response to the April 27, 2001 Warning Letter issued by the Agency to Dr. Peter Likins, President, University of Arizona. The Warning Letter has been posted on FDA's website for more than a year and contains a number of serious allegations concerning Dr. Marcus. Many of these allegations were addressed in a letter of response sent by the University to the Food and Drug Administration, but due to miscommunications within FDA, the University's letter was not reviewed prior to the issuance of the Warning Letter. Considerations of fundamental fairness require that the Food and Drug Administration exercise its discretion to post Dr. Marcus's response on its website.

**A. Action Requested**

Petitioner requests that the Food and Drug Administration immediately post his response to the FDA's Warning Letter on its website for as long as the April 27, 2001 Warning Letter is posted. The statement in response is attached to this petition.

**B. Statement of Grounds**

Petitioner is a Professor Emeritus at the University of Arizona and has been a member in good standing of the University faculty since January 1969. He founded the Section of Cardiology and was the chief of cardiology at the University Medical Center. He is a clinical cardiologist with special training in cardiology and electrophysiology, has published 250 scientific articles in peer reviewed medical journals, and has contributed 52 book chapters. He is on the Editorial Board of nine cardiology journals and regularly reviews scientific articles for approximately 15 journals. His appointments in scientific societies include past President of the Association of the University Cardiologists. He was also a member of the Board of Trustees of the American College of Cardiology and was founder and first President of the Arizona Chapter of American College of Cardiology. He has participated in many clinical trials in which data obtained by him and his staff have been submitted to the FDA and has never had any challenge to the veracity of this data.

Until 1997, Dr. Marcus had not conducted animal studies for submission to the FDA in support of an application to market a medical device or drug. In 1997, Bard Electrophysiology, Inc. asked him to evaluate a new electrophysiology catheter that subsequently was approved and is being now marketed under the name "Stinger Catheter." The purpose of the study was to obtain his judgment concerning the handling characteristics of this catheter when inserted and guided to the heart of an anesthetized dog. In addition, Dr. Marcus recorded electrical signals from the various cardiac chambers of the dog heart to evaluate the clarity of these signals and to compare them with similar data obtained from a catheter that had been FDA-approved and was

being manufactured by another company. Radiofrequency energy was delivered to the catheter tip, and after a suitable time the animals were sacrificed and the lesions were evaluated pathologically. The study was conducted in 1997. The catheter received approval in part from the data submitted from the study in which he participated.

Prior to initiation of the study, Bard agreed in writing to serve as the quality assurance unit for this study. The audit conducted by Bard personnel on May 14, 1997 indicated that Bard personnel deemed the site to have sufficient training, resources and expertise to adequately conduct the study. The study records provided to FDA on October 6, 2000 demonstrate that every attempt was made to insure Good Laboratory Practices compliance throughout the duration of the study from April 1997 to issuance of the final report in November 1997.

The Warning Letter contains numerous statements concerning Dr. Marcus's cooperation with the inspection and his compliance with FDA's regulations, including that Dr. Marcus did not maintain control of the study and that he did not cooperate with the inspection. These are serious allegations, and Dr. Marcus's response is contained in the attached statement that he seeks to post on FDA's website. FDA has ample legal authority to do so.

Under the Electronic FOIA Amendments of 1996, 104 P.L. 231, codified as part of the FOIA 5 U.S.C. §552, FDA is required to make certain documents available in its electronic reading room. It has complied with the requirements of this law by placing many documents generated by the agency, including the Warning Letter issued to the University of Arizona, on its website.

Petitioner is not raising a question about whether FDA has complied with the 1996 Act. The April 27, 2001 Warning Letter posted on the FDA Website, however, contains statements about Dr. Marcus's professional conduct and has injured his reputation. The FDA should give Dr. Marcus an opportunity to put these statements in context by permitting him to post his response to these statements in the Agency's electronic reading room. In this way, when a member of the public searches for the University of Arizona or for Dr. Marcus's name, that person will have the opportunity to read Dr. Marcus's response in conjunction with the Warning Letter. This request is fully consistent with the goals of the FOIA and with the Electronic FOIA Amendments of 1996, and the FDA has discretion to grant it. *See* United States Department of Justice, "What You Will Find in the FOIA Reading Rooms," available at [http://www.usdoj.gov/04foia/04\\_2\\_1.html](http://www.usdoj.gov/04foia/04_2_1.html) ('[W]hile the FOIA requires that DOJ make . . . four categories of records available in its reading rooms, each component may at its discretion include other types of records') (last accessed on October 10, 2002). *See also* United States Department of Justice, FOIA Update, Vol. XVIII, No.1, "Amendment Implementation Questions" (Winter 1997) (noting Agency flexibility to make records available under Electronic FOIA Amendments), available at [http://www.usdoj.gov/oip/foia\\_updates/Vol\\_XVIII\\_1/page3.htm](http://www.usdoj.gov/oip/foia_updates/Vol_XVIII_1/page3.htm)."

Petitioner believes that FDA should adopt a policy that would give every person mentioned in a warning letter the opportunity to respond. Regardless of whether the Agency decides to permit all persons mentioned in warning letters posted on the Agency's website an opportunity to respond, however, there are several aspects of petitioner's request that justify exercise of FDA's discretion here. First, even though the Warning Letter was issued to the

University of Arizona, the Warning Letter arose out of an inspection of nonclinical laboratory studies for which petitioner was the study director. Thus, the Warning Letter directly involves petitioner's conduct. Second, FDA officials did not forward the University of Arizona's response to FDA's initial inspection report (dated January 30, 2001) from the FDA District Office to Office of Compliance, Center for Devices and Radiological Health, in time for the University's response to be taken into account in drafting the Warning Letter (issued April 27, 2001). Third, it has been more than 18 months since the Warning Letter was issued, and the FDA has not reinspected the facilities at the University to determine whether they are now in compliance. Even though he has no control over either the obligations of the University to institute changes required by FDA or over FDA's decision as to when to perform another inspection of University facilities, during this time, Dr. Marcus has had to live under the cloud of the Warning Letter.

### **C. Conclusion**

For the foregoing reasons, the FDA should *immediately* post on its website the attached response to its April 27, 2001 Warning Letter to the University of Arizona. Due to the sensitive nature of this matter, its continuing affect on petitioner, and the straightforward nature of petitioner's request, we request an expedited and prompt decision on this petition.

### **D. Environmental Impact**

This petition qualifies for categorical exclusion under 21 C.F.R. §§ 25.15 and 25.30. The action requested in this petition will not have any impact on the quality of the human environment.

### **E. Certification**

The undersigned certifies that, to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



William B. Schultz  
Zuckerman Spaeder LLP  
1201 Connecticut Avenue NW  
Washington, DC 20036  
(202) 778-1820

Attorney for Petitioner Frank I. Marcus

STATEMENT OF DR. FRANK I. MARCUS IN RESPONSE TO WARNING LETTER  
ISSUED TO THE UNIVERSITY OF ARIZONA, DATED APRIL 27, 2001

This statement is a response to the information contained in the Warning Letter issued by the Food and Drug Administration to Dr. Peter Linkins, President, University of Arizona, dated April 27, 2001. The letter grew out of an inspection carried out at the University of Arizona from September 18-22 and October 3-6, 2000, which related to a study that I had performed in 1997 for Bard Electrophysiology, Inc., Boston, MA.

I have written this response because the letter accuses me of poor record keeping, of mismanagement and of refusing to provide records to the FDA inspectors. *I am responding as an individual and not for the University of Arizona.*

First, I would like to provide information concerning my background. I am a Professor Emeritus at the University of Arizona and have been a member in good standing of the University faculty since January 1969. I am a clinical cardiologist with special training in cardiology and electrophysiology, and I founded the Section of Cardiology and was the chief of cardiology at the University Medical Center. I have published 250 scientific articles in peer reviewed medical journals and have contributed 52 book chapters. I am on the Editorial Board of nine cardiology journals and regularly review scientific articles for about 15 journals. My appointments in scientific societies include past President of the Association of the University Cardiologists. I was a member of the Board of Trustees of the American College of Cardiology and was founder and first President of the Arizona Chapter of American College of Cardiology. I have participated in many clinical trials in which data obtained by me and my staff have been submitted to the FDA and have never had any challenge to the veracity of this data.

Until 1997, I had not conducted animal studies for submission to the FDA in support of an application to market a medical device or drug. In 1997, Bard Electrophysiology, Inc. asked me to evaluate a new electrophysiology catheter that subsequently was approved by FDA and is now being marketed under the name "Stinger Catheter". The purpose of the study was to obtain my judgment concerning the handling characteristics of this catheter when inserted and guided to the heart of an anesthetized dog. In addition, I agreed to record electrical signals from the various cardiac chambers of the dogs heart to evaluate the clarity of these signals and to compare them with similar data obtained from a catheter that was FDA-approved and manufactured by another company. Radiofrequency energy was delivered to the catheter tip, and after a suitable time the animals were sacrificed and the lesions were evaluated pathologically. The study was conducted in 1997. The catheter received approval in part from the data submitted from the study in which I participated.

Prior to initiation of the study, Bard agreed in writing to serve as the quality assurance unit for this study. The audit conducted by Bard personnel on May 14, 1997, indicated that Bard personnel deemed the site to have sufficient training, resources and expertise to adequately conduct the study. The study records provided to FDA on October 6, 2000, demonstrate that every attempt was made to insure Good Laboratory Practices ("GLP") compliance throughout the duration of the study from April 1997 to issuance of the final report in November 1997.

In the Warning Letter, there are repeated statements that I refused to provide records to the FDA inspector. I respectfully disagree. Not all the records required to be maintained under FDA's Good Laboratory Practice regulations were available at the site. However, I provided the inspector with all of the records in my possession. I informed the inspector that I had moved my offices in October 1999 and that it had been necessary to discard numerous records in order to find sufficient room in my new facility. At no time was any record in my possession or control withheld from the inspector, nor was the inspector ever denied access to any person in the area of the facility. *All of the records which I was not able to produce were available from BARD.*

With regard to the request for records, when the FDA inspector called me from Los Angeles on September 22<sup>nd</sup> to inform me that she would be coming to Tucson on September 25<sup>th</sup> to begin the inspection, she made no specific request regarding material to be reviewed. Within the first day or two after she had arrived, it became apparent to me that the inspector was seeking access to records in Bard's possession, and I contacted Mr. Matt Nowland, in Bard's regulatory affairs office. Since I was not certain as to the extent and details of the information that the inspector wanted, Mr. Nowland placed several calls to the Tucson FDA office to ascertain what records the inspector sought in addition to the records that were in my position and that I had made available to the inspector. Mr. Nowland later informed me that he had never received any response from the inspector. On October 5, 2000, Mr. Nowland participated in a conference call with the inspector and myself at which time it was learned from the inspector which additional records were sought. Mr. Nowland provided a complete set of duplicate records on October 6, 2000. The FDA inspectors also requested records of all animal studies I had done in the previous three years. These were unrelated to the Bard study and the request was not specifically related to the FDA or any FDA-regulated product. The attorney representing the University of Arizona determined that these records were confidential and not accessible to outside parties, including the FDA. *All records related to the Bard GLP study were made available to the FDA.*

The above information addresses the major accusations in the Warning Letter directed towards me. There were a number of other allegations that were answered in the response letter sent to the FDA by the University of Arizona to correct the misunderstandings or wrongful allegations directed against me. I would like to focus on one item of importance from that letter.

The Warning Letter also stated that I did not demonstrate control of the study, that I did not compile the data report, and that I was not the author of the final report submitted to the FDA. The inspector at the FDA office had stated that there were at least five examples of wording differences between Bard's premarket approval submission and the report signed by me. When I asked to see the differences in wording so that I could verify that there were indeed differences, the inspector refused this request and, therefore, I could not comment on any alleged differences in the wording. When I again asked the inspector on October 22, 2000, to provide me with examples of the differences, it was stated that this could not be done until the inspection was completed and the report was made. It seems unlikely to me that there were such differences. Bard personnel collected the data, served as the quality assurance unit, verified it and compiled a report in collaboration with me, as evidenced by my signature on the final report. The inspector was able to review drafts that were in my possession for this current inspection. Further, data collected by the University of Arizona personnel were submitted to the inspector and these notes and reports were prepared and finalized for my signature. It continues

to be my belief that the exact same document as was signed by the study personnel, Mr. Ian McCurry and myself was included in the PMA. Therefore, I never was able to identify any differences.

In conclusion, I submit that there have been many unfounded and inaccurate allegations made regarding my activities and participation in the Bard Electrophysiology study.