

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Scott S. Reuben, MD

(b) (6)

08 - 17 - 2011

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2011-N-0377

Dear Dr. Reuben:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarbing you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On January 8, 2010, you pleaded guilty to one count of Health Care Fraud. On June 24, 2010, the United States District Court for the District of Massachusetts entered judgment against you for one count of health care fraud in violation of 18 U.S.C. § 1347. The underlying facts supporting this conviction are as follows.

You were a licensed physician working as an anesthesiologist providing anesthesia services to patients in connection with surgeries, and also treating patients post-surgery in the District of Massachusetts. You also served as the chief of acute pain at a hospital in Western Massachusetts. You maintained an office at the Western Massachusetts hospital for the purpose of conducting research, and at various times your employer allowed you to spend one day a week on research rather than treating patients. Your particular interest, from a research perspective, was in post-operative multimodal analgesia therapy. You made proposals for research funding to pharmaceutical companies that manufactured drugs that you used or proposed to use in multimodal analgesia therapy. You represented to the companies that, as the principal investigator, you would be performing clinical studies with actual patients to whom you would administer the drug that was the subject of the research grant.

For many years, from at least as early as 1999, you made proposals to pharmaceutical companies and entered into contracts to perform research studies funded by the companies. You purported to perform the research called for by the contract, and published articles in various medical journals based on the purported results of the research, when in fact those studies had not been performed, and therefore the research results reported in the medical journals were false. For example, on or

about July 2005 you proposed to Pfizer, Inc. (Pfizer) to perform research on the topic of “Perioperative Administration of Celecoxib [Celebrex] as a Component of Multimodal Analgesia for Outpatient Anterior Cruciate Ligament Reconstruction Surgery.” In your proposal you indicated that you intended to include 100 patients in the study. On or about September 1, 2005, you entered into an agreement with Pfizer whereby you agreed to conduct this clinical research and in return Pfizer agreed to provide you a research grant in the amount of \$(b)(6) and sufficient supplies of the drug product and placebo to conduct the study. In 2007 you published articles about this study in the medical journal *Anesthesia & Analgesia*, claiming to have treated 200 patients achieving success with multimodal analgesia therapy. In fact, you had not enrolled any patients into the studies and the results reported were wholly made up by you and therefore false. In or about January 2007 in the District of Massachusetts, you knowingly and willfully executed a scheme and artifice to defraud a pharmaceutical company, a health care benefit program, in connection with the delivery of and payment for health care benefits, items, and services, all in violation of 18 U.S.C. § 1347. In addition, in your plea agreement you consented to be disqualified as a clinical investigator in studies related to investigational articles regulated by FDA, and were disqualified pursuant to consent agreement on April 5, 2010.¹

FDA’s Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the Act. In response to the charge of one count of health care fraud for falsifying clinical research about pain management concerning a product approved by FDA, you expressly and unequivocally admitted that you knowingly and willfully executed a scheme and artifice to defraud a pharmaceutical company, a health care benefit program, in connection with the delivery of and payment for health care benefits, items, and services, all in violation of Title 18 U.S.C. § 1347. FDA regulates clinical trials related to drug products such as those described above as part of the Agency’s regulation of drug products. FDA therefore finds that your Federal felony conviction for this violation relates to the regulation of drug products under the Act.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR Part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

¹ This proposal to debar you from providing service to a person that has an approved or pending drug product application is distinct from your previous disqualification as a clinical investigator in trials of investigational articles.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2011-N-0377 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement within the Food and Drug Administration.

Sincerely,



Armando Zamora
Acting Director
Office of Enforcement
Office of Regulatory Affairs