DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Glen R. Justice/48719-112
USP LOMPOC
U.S. Penitentiary
3901 Klein Blvd.
Lompoc, CA 93436

03-26-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2011-N-0860

Dear Dr. Justice:

This letter is to inform you that the Food and Drug Administration ("FDA" or "the Agency") is proposing to issue an order debarring you for a period of twenty five years 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 five felony counts under Federal law for conduct involving health care fraud and aiding and abetting and causing an act to be done. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On April 14, 2010, you pled guilty to five felony counts of health care fraud, aiding and abetting and causing an act to be done. On July 25, 2011, the United States District Court for the Central District of California entered judgment against you for five counts of health care fraud in violation of 18 U.S.C. § 1347, and of aiding and abetting and causing an act to be done in violation of 18 U.S.C. § 2. The underlying facts supporting this conviction are as follows.

You were a licensed physician, and owned and operated a medical practice called Pacific Coast Hematology/Oncology Medical Group, Inc. ("PCHOMG"), located in Fountain Valley, California. You enrolled as a provider with federally-funded and private health care programs.

Beginning on a date unknown, but no later than in or around 2004, and continuing through at least in or around October 2009, you devised and executed a scheme to defraud federally-funded and private health care benefit programs ("HCBPs"). As part of the scheme, you knowingly and willfully submitted, and caused to be submitted, false and fraudulent claims to HCBPs for injectable medications relating to cancer treatment. Specifically, you billed patients' HCBPs for injectable medications knowing that those medications never were provided to the patients, or you billed patients' HCBPs for more expensive injectable medications when less expensive medications were provided. You continued this despite being advised by staff not to do so and subsequent to the

execution of a search warrant at your medical practice in November 2006. As a result of your scheme to defraud, HCBPs suffered losses between $400,000 and $1,000,000.

In carrying out your scheme, acting with intent to defraud and deceive, you concealed and failed to disclose to HCBPs the true facts about your fraudulent business practices.

FDA's Finding

Section 306(b)(2)(B)(ii)(I) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act" or "the Act") (21 U.S.C. § 335a(b)(2)(B)(ii)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a felony under Federal law which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, and it finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the Act relating to drug products.

The criminal acts occurred in the course of your profession, the practice of medicine. In the course of this practice, you had legal and professional obligations to ensure that you submitted accurate medical claims for procedures you performed, as well as administering medicines that were appropriate for your patients' condition. Your convictions indicate that you knowingly and willingly disregarded your legal obligation to submit accurate medical claims for reimbursement. The fact that you billed HCBPs for different medicines than you administered to your patients and that the medicines you billed but did not administer were presumably recognized by the HCBPs as being appropriate for the patients you claimed to administer them to makes it impossible to determine whether the medicines you did administer were in fact appropriate.

The conduct that forms the basis of your conviction occurred in the course of your profession and showed disregard for the obligations of your profession and the law. In addition, injectable products are regulated by FDA as prescription drugs, and you intentionally billed for different FDA regulated drug products than what you wrote prescriptions for. Therefore, FDA has reason to believe that, if you were to provide services to a person that has an approved or pending drug application, you may violate requirements under the Act relating to drug products. Accordingly, the Agency finds that debarment is appropriate.

The maximum period of debarment for each offense under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years, and the Agency may determine whether debarment periods should run concurrently or consecutively in the case of a person debarred for multiple offenses. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors to be considered by the Agency in determining the appropriateness and length of your debarment. The factors applicable here include: (1) nature and seriousness of the offense involved, (2) nature and extent of management participation in this offense, (3) nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the Act or involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

You were convicted of five felony counts of health care fraud and aiding and abetting and causing an act to be done. As described in detail above, you stipulated in your plea agreement to knowingly and willfully devising and executing a scheme to defraud federally-funded and private health care benefit programs.

Your actions demonstrate that you were more concerned with making a profit than in taking care of the needs of your patients. Moreover, by administering less expensive medications to your patients than what you billed to HCBPs, you made it impossible to determine whether you were in fact administering the correct medications, i.e., those that were considered to be appropriate and covered by HCBPs. Therefore, your actions indicate that you did not act in the best interests of your patients. Finally, your actions have the potential for causing significant loss of public confidence in the healthcare system. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. The nature and extent of management participation in any offense involved

You owned and operated PCHOMG. In your position as owner, you prepared and submitted or caused to be submitted, false and fraudulent claims to HCBPs for medications relating to cancer treatment. You chose to engage in such criminal conduct intentionally and repeatedly. Furthermore, as a licensed physician and the owner of your own practice, you held a position of authority where your conduct served as an example for the employees of the practice. Accordingly, the Agency will consider the nature and extent of your participation as an unfavorable factor.

3. The nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health.

Rather than taking any actions to mitigate the impact of your offenses on the public, you continued your scheme over a period of years, despite being advised by your staff to desist. Accordingly, the Agency considers your failure to take effective voluntary steps to mitigate the offenses you committed to be an unfavorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B)(ii)(I) of the Act (21 U.S.C. § 335a(b)(2)(B)(ii)(I)) debarring you for a period of twenty-five years from providing services in any capacity to a person having an approved or pending drug

product application. You were convicted of five felony counts of health care fraud and aiding and abetting causing an act to be done. FDA proposes that each felony offense be accorded a debarment period of five years. In the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively (21 U.S.C. § 335a(c)(2)(A)). Given the analysis above, FDA has concluded that the unfavorable factors cumulatively far outweigh the sole favorable factor and that the five-year period of debarment for each of the five offenses of conviction need to be served consecutively, resulting in a total debarment period of twenty-five years.

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.

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.

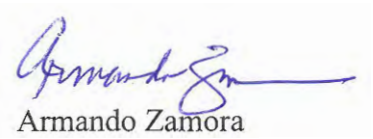
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the 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(b)(2)(B)(ii)(I) of the Act (21 U.S.C. § 335a(b)(2)(B)(ii)(I) 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-0860 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 Acting Director, Office of Enforcement within the Food and Drug Administration.

Sincerely,



Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affairs

cc:

HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Ilisa Bernstein
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi
HF-22/Matthew Warren

HFD-45/Ball, Leslie
HFD-45/Constance Lewin
HFD-45/Sherbet Samuels
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF