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Food and Drug Administration
Rockville MD 20857

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Eduardo Caro Acevedo, MD
P.O. Box 1618
Guaynabo, Puerto Rico 00970

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 01N-0541

Dear Dr. Caro:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debaring you for a period of 5 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 a felony under Federal law for engaging in a conspiracy to defraud the United States and that you have violated requirements relating to drug products. This letter also offers you an opportunity for a hearing on this proposal.

Conduct Related to Debarment

On February 16, 2001, the United States District Court for the District of Puerto Rico accepted your plea of guilty to one count of conspiracy to offer and pay kickbacks in relation to the referral of Medicare beneficiaries to a durable medical equipment company, in violation of the Medicare antikickback law (42 U.S.C. 1320a-7b), and in violation of 18 U.S.C. 371. The court sentenced you to 2 years probation for the offense. The underlying facts supporting this felony conviction are as follows:

You were a physician authorized to practice medicine in Puerto Rico as a Medicare provider. As a Medicare provider, you were authorized to prescribe, among other things, durable medical equipment to Medicare beneficiaries.

Efrain Sierra-Pujols was the owner of Efrain Sierra, Inc. (Sierra), located in Levittown, Puerto Rico. Sierra was authorized to sell durable medical equipment to Medicare beneficiaries. To increase the volume of Medicare claims to his company, Efrain Sierra-Pujols offered and paid money to you to unlawfully induce you to refer patients to Sierra's Medicare business.

You received money in return for referring patients to Sierra's business for the furnishing of durable medical equipment and services payable under the Medicare program. You received cash payments, the specific amount depending on the value of the service or equipment that you referred to Sierra. The unlawful kickback payments made to you allowed Sierra to improperly invoice Medicare for approximately \$11,940.

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In addition, you have demonstrated a pattern of conduct sufficient to find reason to believe that you may violate requirements relating to drug products. In July 2002, you were issued a Notice of Disqualification to Receive Investigational New Drugs. This action was based upon repeated and deliberate submissions of false information to drug sponsors in required reports for studies of investigational new drugs (INDs) that are subject to section 505 of the Federal Food, Drug and Cosmetic Act. In 1997, you repeatedly and deliberately failed to comply with regulations governing the conduct of clinical investigators and the use of INDs in following two protocols sponsored by Daiichi Pharmaceutical Corporation. Among other things, you submitted false information in required reports, deviated from protocols, maintained inaccurate and inadequate study records, failed to report adverse events, were cited for inadequate accountability of study medications, failed to obtain adequate institutional review board approval, and failed to obtain proper consent from study subjects or their legally authorized representatives. As a result, you no longer are entitled to receive investigational new drugs.

FDA's Finding

Section 306(b)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(b)(2)(B)(ii)) allows the FDA to permissively debar an individual if FDA finds, based on convictions and other information, that the individual has:

- “demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products,” and the individual was “convicted of a conspiracy to commit, or aiding or abetting,” a felony which involves, inter alia, fraud.

Based on your numerous violations of requirements relating to INDs, you have demonstrated a pattern of conduct sufficient to find that you may violate requirements under the Act relating to drug products.

Further, you were convicted of a felony under 18 U.S.C. 371 for engaging in a criminal conspiracy to defraud the government by offering and paying kickbacks in relation to the referral of Medicare beneficiaries to a durable medical equipment company, in violation of the Medicare antikickback law. To prevent fraud and abuse in the Medicare program, Congress prohibited certain improper practices, including the solicitation or receipt of kickbacks, bribes or other unlawful remuneration in return for referring patients to a health care provider for services covered by Medicare. Accordingly, the Agency finds that you are eligible for permissive debarment.

Under section 306(c)(2)(A)(iii) of the Act, the period of a debarment proposed under section (b)(2) shall not be more than 5 years. Under section 306(l)(2) of the Act, permissive debarment may be applied when an individual acted or was convicted within the 5 years preceding initiation

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of an Agency action proposed under section 306(b). You were convicted in February 2001, less than five years ago.

Section 306(c)(3) of the Act provides several factors for consideration in determining the appropriateness of and the period of permissive debarment. The factors applicable here include: (1) nature and seriousness of the offense involved, (2) nature and extent of management participation in any offenses, (3) nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions involving matters within the jurisdiction of the FDA.

1. Nature and seriousness of the offense involved.

You knowingly and willfully received remuneration for referring an individual to a person for the furnishing of items for which payment may be made under the Medicare Part B program. Your participation in this conspiracy defrauded the Medicare system by contributing to the unnecessary expenditure of taxpayer dollars, excluding potential competing suppliers from the system, misdirecting program funds, and creating incentives to order more supplies than needed.

Although your conduct, clearly in violation of the Medicare antikickback law, may not directly have compromised the integrity of the drug approval or regulatory processes, your activity in connection with your disqualification to receive INDs did. Your conduct directly created a risk to patients enrolled in the protocols and undermined the determination of safety, effectiveness, and quality of the drug that the two protocols were designed to assess. Accordingly, the Agency considers the nature and seriousness of your conduct as an unfavorable factor in determining the length of your debarment.

2. Nature and extent of management participation in any offense.

As a Medicare provider, you were in a position of authority to plan, direct, or initiate the criminal conspiracy to receive kickbacks in relation to the referral of Medicare beneficiaries to a durable medical equipment company. As a physician, you used your position to refer patients to Sierra for personal financial gain and abused your position of public trust in a manner that significantly affected your role as a clinical investigator. Moreover, you were in a position of direct authority when you repeatedly and deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of INDs. Therefore, the Agency considers the nature and extent of your participation as an unfavorable factor.

3. Nature and extent of voluntary steps to mitigate the impact on the public.

It appears that you fully disclosed all wrongdoing to the authorities in your plea agreement in connection with Medicare antikickback laws. In addition, according to CDER's records, other than the 1997 studies for which you were disqualified from receiving INDs, you have not been

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involved in any other IND studies since 1994 and you have been ineligible to receive INDs since 2002. Accordingly, the Agency will consider the nature and extent of mitigation as a favorable factor.

4. Prior convictions.

The Agency is unaware of any additional criminal convictions. However, your disqualification to receive INDs is additional evidence of the type of behavior that the Agency considers as an unfavorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, the FDA proposes to issue an order under section 306(b)(2)(B) of the Act debaring you from providing services in any capacity to a person that has an approved or pending drug product application for a period of 5 years. Your repeated and deliberate failure to comply with regulations governing the conduct of clinical investigators and the use of INDs in the context of two separate protocols demonstrates a pattern of conduct sufficient to satisfy the requirement for permissive debarment. Further, you were convicted of one count of engaging in criminal conspiracy to offer and pay kickbacks in relation to the referral of Medicare beneficiaries to a durable medical equipment company in violation of the Medicare antikickback law, a felony involving fraud, as described in section 306(b)(2)(B)(ii). The Agency proposes a 5-year debarment period for the offenses based on the factors discussed above.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given notice of an opportunity for 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: (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, the Agency 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

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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 this conviction subjects you to debarment under section 306(b)(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. 01N-0541 and sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 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 the Federal Food, Drug, and Cosmetic Act (sec. 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.34).

Sincerely yours,



Steven K. Galson, M.D., M.P.H.
Acting Director
Center for Drug Evaluation and Research

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