



NOV 26 2002

CERTIFIED MAIL
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Bruce I. Diamond, Ph.D., EF388009
Atlanta Transitional Center
332 Ponce de Leon Avenue
Atlanta, GA 30308

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 00N-1531

Dear Dr. Diamond:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debaring you for 10 years from providing services in any capacity to a person that has an approved or pending drug product application. The FDA bases this proposal on a finding that:

(1) you were convicted of misdemeanors and felonies under Georgia State law for theft, written false statements, bribery, and violation of the Georgia Controlled Substances Act; and (2) you were a material participant in offenses for which another person is being debarred. This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Debarment

On December 16, 1997, the Superior Court for the County of Richmond, State of Georgia, accepted your plea of guilty and entered judgment against you for 53 counts of criminal offenses committed in violation of the Official Code of Georgia, Annotated (O.C.G.A.) as follows: 16 counts of theft by taking (O.C.G.A. section 16-8-2), 10 counts of theft of services (O.C.G.A. section 16-8-5), 2 counts of written false statements (O.C.G.A. section 16-10-20), 8 counts of acquisition of a controlled substance by misrepresentation (O.C.G.A. section 16-13-43), 8 counts of prescribing dangerous drugs (O.C.G.A. section 16-13-78.1), 7 counts of prescribing controlled substances (O.C.G.A. section 16-13-41(f)), 1 count of practicing medicine without a license (O.C.G.A. section 43-34-26), and 1 count of bribery (O.C.G.A. section 16-10-2). The underlying facts supporting this conviction are as follows:

You were a professor on the faculty of the Medical College of Georgia (MCG), a unit of the Board of Regents of the University System of Georgia. Richard Borison, M.D., Ph.D., was the chairman of the Department of Psychiatry and Health Behavior at MCG.

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From 1988 to 1996, you and Dr. Borison used your positions as faculty members of MCG to defraud the MCG of an amount in excess of \$10 million in clinical research funds. You and Dr. Borison, on your own authority, contracted with numerous pharmaceutical companies to conduct clinical studies on various drugs for treating Alzheimer's disease, schizophrenia, anxiety, and depression. Under the terms of your employment, however, you were required to obtain approval from the MCG for any pharmaceutical research. MCG policies also required that funding for all research performed under the auspices of the college be paid to the MCG Research Institute, Inc., a research-facilitating entity of the medical college. You diverted the funds paid by study sponsors into private for-profit business entities owned or controlled by you and Dr. Borison rather than to MCG or the Board of Regents, as required by law.

To assist in perpetrating the fraud, you fostered the appearance that the study research was conducted under the auspices of the MCG. The research was conducted at state owned property (the MCG and the Georgia Regional Hospital), at other facilities such as the Veterans Administration Hospital using state employees, or at private office space leased by you and Dr. Borison. To assist in the conduct of the clinical research testing, you and Dr. Borison used the services of full-time MCG employees during their regular working hours to help in recruiting study subjects and in conducting the studies. You used these MCG employees for your own financial gain without approval of the MCG and without compensating the Board of Regents of the University System of Georgia. Moreover, some of the employees you used to help you in carrying out the clinical studies were not qualified or properly trained to conduct medical procedures on human subjects. To conceal the thefts, you, among other things, made false statements orally and in writing to departments and agencies of the State of Georgia about your involvement in clinical study research at MCG.

In addition, you, a non-physician and not authorized by law to dispense or prescribe medicine, frequently prescribed controlled substances and dangerous drugs to patients, employees, and yourself by signing Dr. Borison's name on prescriptions.

On one occasion, to conceal your illegal activities, you and Dr. Borison paid money to an MCG employee to obtain her cooperation and silence regarding the attempted suicide of a study subject who was enrolled in one of your clinical research studies.

A 172-count indictment was returned against you in February 1997. You agreed to plead guilty to 53 counts of theft, making false statements, bribery, and violation of the Georgia Controlled Substances Act. On December 16, 1997, the Superior Court for the County of Richmond, State of Georgia convicted and sentenced you for the offenses.

FDA's Findings

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)) permits the FDA to debar an individual if FDA finds that the

individual has been convicted of a felony that involves, among other things, bribery, fraud, false statements, or racketeering, and the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under the Act relating to drug products. Your felony conviction under Georgia state law was for defrauding the MCG of over \$10 million paid by pharmaceutical companies for the conduct of clinical studies on human subjects, making written false statements, bribing an employee, acquiring controlled substances, prescribing dangerous drugs and controlled substances, and practicing medicine without a license. Your actions at MCG demonstrate a pattern of conduct sufficient to find that there is reason to believe you may violate requirements relating to drug products again.

In the alternative, section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits the FDA to debar an individual if it finds that the individual has been convicted of a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the Act and that the conduct undermines the process for the regulation of drugs. Your felony conviction under O.C.G.A. § 16-10-2 was for bribing an employee to conceal information about the attempted suicide of a subject in a clinical study, an offense related to the development or approval of any drug product. This conduct undermines the process for the regulation of drugs. Your felony conviction under O.C.G.A. § 16-13-41-(f) was for illegal conduct relating to the regulation of controlled substances. You, while not being a registered practitioner who was licensed or otherwise authorized by the state of Georgia to prescribe controlled substances, prescribed chloral hydrate, a Schedule IV controlled substance under the Act, to several individuals. This conduct, illegally prescribing controlled substances, undermines the process for the regulation of drug products.

Section 306(b)(2)(B)(iii) of the Act (21 U.S.C. 335a(b)(2)(B)(iii)) permits the FDA to debar an individual who materially participated in acts that were the basis for a conviction of another person for an offense under section 306(a)(2) or section 306(b)(2)(B)(i) or (ii) of the Act, if FDA finds 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 the Act relating to drug products. The Agency is in the process of debaring Richard Borison under section 306(b)(2)(B)(i)(I) or 306(b)(2)(B)(ii) of the Act. Your conviction for theft, bribery, false statements, and violations of the Georgia Controlled Substances Act is based, in part, on evidence of illegal conduct by you and Richard Borison, showing that you were a partner with Borison in planning and carrying out criminal activities which were the basis of Dr. Borison's conviction obtained by the State of Georgia. FDA finds that your participation in criminal activities with Richard Borison at MCG also demonstrates a pattern of conduct sufficient to find that there is reason to believe you may violate requirements under the Act relating to drug products.

Under section 306(l)(2) of the Act, permissive debarment may be applied when an individual is convicted within the 5 years preceding this notice. You were convicted in December 1997 less than 5 years ago. The Agency may debar you for up to 5 years for each offense, and can determine whether the debarment period for multiple offenses shall run concurrently or consecutively (section 306(c)(2)(A) of the Act) (21 U.S.C. 335a(c)(2)(A)). A person debarred for multiple offenses means a person debarred for two or more offenses described in section 306(a) or (b)(2).

FDA finds that you have committed two offenses for which you may be permissively debarred: (1) under section 306(b)(2)(B)(ii), you are eligible based upon your conviction under Georgia State law for theft, bribery, false statements, and violation of the Georgia Controlled Substances Act, and (2) under section 306(b)(2)(B)(iii), you are eligible because of your involvement as a material participant in Dr. Borison's offense, as described above.

Section 306(c)(3) of the Act provides six factors for consideration in determining the appropriateness of and the period of permissive debarment for an individual (21 U.S.C. 335a(c)(3)). These are as follows:

- (A) the nature and seriousness of the offense involved,
- (B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,
- (C) 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,
- (D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,
- (E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and,
- (F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

The Agency considers that four of these factors are applicable for consideration:

1. The nature and seriousness of the offense involved (Factor A)

You were convicted of 53 criminal counts of theft by taking, theft of services, written false statements, acquisition of controlled substances by misrepresentation, prescribing dangerous drugs and controlled substances, practicing medicine without a license, and bribery. Your conviction was based primarily on your actions related to the conduct of clinical study research involving drugs, such as olanzapine, tacrine hydrochloride, and venlafaxine hydrochloride, indicated for conditions such as Alzheimer's disease, depression, schizophrenia, and other mental disorders.

The Agency finds that your conduct created a risk of injury to consumers (1) by routinely prescribing drugs to subjects when you had no training or authority to prescribe drugs, and (2) by routinely directing employees who were inadequately trained to conduct medical procedures on study subjects. Accordingly, the Agency will consider the nature and seriousness of your conduct as an unfavorable factor.

2. The nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense (Factor B)

You participated in the planning of, directed, and initiated the conduct underlying your conviction. You and your partner, Dr. Borison, developed and carried out a scheme to conduct clinical drug study research on human subjects purportedly under the auspices of the MCG, but diverted the funds paid by the drug companies for the research from the MCG into private for-profit entities controlled or owned by you and Dr. Borison. To assist in carrying out your scheme, you directed other MCG employees to recruit subjects and to participate in the conduct of the clinical studies. 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 (Factor C)

The Agency is aware that you were willing to testify as a witness for the State of Georgia, although the State did not call you. While the agency generally would consider this to be a

favorable factor, you did not promptly disclose to appropriate authorities all wrongdoing. Furthermore, your conduct was performed primarily in exchange for financial gain, since you were a partner with Dr. Borison in diverting for yourselves clinical study funds that legally belonged to the MCG. The Agency also finds that you displayed a wanton disregard for the public health by bribing an employee to obtain her silence and cooperation about the attempted suicide of a subject enrolled in one of the clinical research studies. Accordingly, the Agency considers the nature and extent of your mitigation an unfavorable factor.

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

The Agency is unaware of any prior convictions.

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, debarring you from providing services in any capacity to a person that has an approved or pending drug product application for 2 periods of 5 years, to run consecutively. You were convicted of 53 counts of theft, false statements and writings, bribery, and violations of the Georgia Controlled Substances Act, which includes felonies described in section 306(b)(2)(B)(i) and (ii). You were also a material participant qualifying for debarment under section 306(b)(2)(B)(iii) for the conviction and debarment of Richard Borison. The Agency proposes a 5-year debarment period for each offense, 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 formal evidentiary hearings as applied to debarments 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 a waiver of your right to a hearing. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue the 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

Bruce I. Diamond
Docket No. 00N-1531

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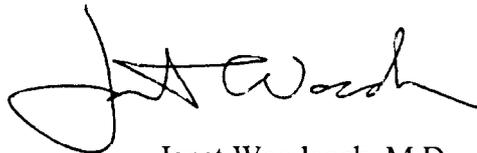
information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

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 and your actions as a material participant subject 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. 00N-1531 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You must file four copies of all submissions under 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 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,

A handwritten signature in black ink, appearing to read "Janet Woodcock". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research