DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John D. Noonan, MD
17 Mason Lane
Slingerlands, NY 12159-3616

11-30-2010

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0300

Dear Dr. Noonan:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of four 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 misdemeanor under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act), and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. This letter also offers you an opportunity to request a hearing on this proposal, and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On August 11, 2009, you entered a plea of guilty to a one-count information charging you with misdemeanor misbranding of a drug. On February 19, 2010, judgment was entered against you in the United States District Court for the Northern District of New York for misdemeanor misbranding a drug, in violation of 21 U.S.C. 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. 2. The underlying facts supporting this conviction are as follows.

The Plastic Surgery Group, LLP, (TPSG) is a limited liability partnership whose members consist of professional corporations. You were the principal of one such professional corporation. TPSG provides a number of plastic surgery treatments to patients, including Botulinum Toxin Type A injections. Prior to 2009, BOTOX®/BOTOX® Cosmetic, a product manufactured by Allergan, Inc., was the only Botulinum Toxin Type A product licensed by FDA for use in humans for any indication, including for the temporary improvement in appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity, commonly described as the treatment of facial wrinkles.[2]

[2] On July 31, 2009, FDA approved a supplemental application to the license for BOTOX®/BOTOX® Cosmetic, which in relevant part changed the proper name of the biological product from Botulinum Toxin Type A to onabotulinumtoxin A. See Letter fr. FDA to Allergan Inc. (July 31, 2009), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/103000s5209s5210ltr.pdf. This nonproprietary name change is not material to these purposes, and for the sake of consistency with the related criminal proceedings, the product will continue to be referred to in this letter as Botulinum Toxin Type A.

Beginning in or about January 2004, Dr. William F. DeLuca, Jr., the principal of another TPSG partner corporation and a physician in the practice, authorized TPSG's supervisory nurse to order and obtain at least 31 vials of what was represented to be Botulinum Toxin A distributed by Toxin Research International, Inc. (TRI) in Arizona (TRI-toxin). On or about this time, TPSG stopped purchasing BOTOX®/BOTOX® Cosmetic[3] and began exclusively purchasing for use in its practice TRI-toxin, which has never been licensed or approved by the FDA for any use.

From approximately February 2004 to December 2004, you injected approximately 10 patients seeking treatment for severe glabellar lines with TRI-toxin having offered it for sale as BOTOX®/BOTOX® Cosmetic.

You pleaded guilty to one count of misbranding, admitting that on or about November 2, 2004, in the Northern District of New York, you misbranded or caused the misbranding of a drug, namely TRI-toxin, while it was held for sale and after shipment in interstate commerce, in that you, in connection with the injection of a patient, offered the TRI-toxin for sale to a patient under the name of another drug, namely BOTOX®/BOTOX® Cosmetic, in violation of Title 21 U.S.C. 331(k), 352(i)(3), 333(a)(1), and 18 U.S.C. 2.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. You misbranded or caused the misbranding of a drug in violation of the Act, namely, by offering a drug that had not been approved for use, TRI-toxin, for sale to patients under the name of another drug that is approved, namely BOTOX®/BOTOX® Cosmetic, and then injecting the unapproved drug into patients in your clinic. FDA finds that this type of conduct, which served as a basis for your conviction, undermines the process for the regulation of drugs because the misbranding of drugs is prohibited by the Act.

The maximum period of debarment under section 306(b)(2)(B)(i)(I) of the Act is five years. 21 U.S.C. 335a(c)(2)(A)(iii). Section 306(c)(3) of the Act (21 U.S.C. 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of management participation in this offense; (3) the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved; and (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

[3] Although it is likely that TPSG used product labeled BOTOX® Cosmetic rather than product labeled BOTOX®, it is not clear from the criminal proceedings which product TPSG actually used. This difference is not relevant for these purposes because the products are identical with the exception of different labeling. For the sake of consistency with the related criminal proceedings, the product used will continue to be referred to in this letter as BOTOX®/BOTOX® Cosmetic.

FDA regulates the manufacture and distribution of drugs in the United States. FDA also regulates the manufacture and distribution of biological products, which includes toxins like Botulinum Toxin

Type A. As noted above, only one Botulinum Toxin Type A product was licensed by FDA prior to 2009. FDA licensed BOTOX® in 1991, and approved a supplement for the indication of treatment of glabellar lines in 2002. Products for this latter indication are marketed and labeled as BOTOX® Cosmetic. TRI-toxin has never been licensed or approved by FDA for any use. In your plea agreement, you admitted to the misbranding of a drug.[4] Specifically, you admitted to administering or causing the administration of a misbranded drug, namely TRI-toxin, to patients on at least 10 occasions under the name of BOTOX®/BOTOX® Cosmetic.

FDA finds that your conduct created a risk of injury to consumers due to the use of an unapproved drug, undermined the Agency's oversight of an approved drug product by representing that you used the approved drug while actually substituting an unapproved drug in its place, and seriously undermined the integrity of the Agency's regulation of drug products. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. Nature and extent of management participation

In determining the appropriate period of debarment, FDA also shall consider the nature and extent of your management participation in the offense, and whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense. You were a principal of a corporation that is a partner of TPSG. On August 11, 2009, TPSG pleaded guilty to one felony count of misbranding of a drug. You injected approximately 10 patients seeking treatment for facial wrinkles with the unapproved TRI-toxin representing it to be BOTOX®/BOTOX® Cosmetic from about February 2004 to December 2004. You and six other defendants, including four other treating physicians, a supervisory nurse, and the practice administrator, pleaded guilty to misbranding TRI-toxin as BOTOX®/BOTOX® Cosmetic. The foregoing indicate that in your position of authority as a principal in a TPSG partner corporation, you participated in the group's unlawful conduct of administering this unapproved drug on multiple occasions to patients who thought they were receiving BOTOX®/BOTOX® Cosmetic. Accordingly, the Agency will consider this as an unfavorable factor.

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

FDA next will consider the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including, among other things, full cooperation with any investigations (including extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. In the sentencing memorandum filed on behalf of TPSG in the criminal misbranding matter, it is indicated that the practice took certain steps to mitigate the impact of its criminal activity of which you were a part. Specifically, the memorandum indicates that TPSG ceased administering TRI-toxin when it discovered in December 2004 that TRI-Toxin was an unapproved biological product, and that all

[4] FDA licensed BOTOX®/BOTOX® Cosmetic pursuant to the Agency's authority set forth in Section 351(a) of the Public Health Service Act (PHSA), 42 U.S.C. 262(a). The misbranding provisions of the Act apply to products licensed under the PHSA. See 42 U.S.C. 262(j) ("[t]he Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) applies to a biological product subject to regulation under this section").

monies paid by patients for the procedures during which TRI-toxin was used is being returned. TPSG Sent. Mem. at 5, 9, *U.S. v. TPSG*, Crim. Action No. 09-0411 (N.D.N.Y Jan. 25, 2009). The memorandum also indicates that you brought to the attention of the practice a problem with TRI-toxin in another jurisdiction, and that it was this notice that caused TPSG to cease using the unapproved drug. *Id.* at 5. The Agency will consider this as a favorable 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.

Weighing all factors, the Agency has determined that the facts supporting the unfavorable factors outweigh those in support of the favorable factors, and therefore warrant the imposition of a four-year permissible debarment in this case. You were a principal in the partner corporation of a practice that engaged in a pervasive practice of injecting patients with an unapproved drug while representing that the patients were receiving a well-known FDA-approved drug. During the period of February to December 2004, approximately 150 TPSG patients were injected with TRI-toxin believing that they were receiving BOTOX®/BOTOX® Cosmetic. You injected approximately 10 of those patients with the unapproved drug. The nature and seriousness of the conduct underlying your conviction warrant a four-year period of debarment.

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) of the Act (21 U.S.C. 335a(b)(2)(B)) debarring you for a period of four years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of misbranding a drug, a Federal misdemeanor offense under the Act. As explained above, this offense relates to the regulation of drug products under the Act. Furthermore, the conduct that served as the basis for this conviction undermines the process for the regulation of drugs. Based on the factors discussed above, FDA proposes a four-year debarment period.

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) of the Act (21 U.S.C. 335a(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. FDA-2010-N-0300 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.

You also may notify the Secretary that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) (21 U.S.C. 335a(c)(2)(B)).

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,

Howard R. Sklamberg, Esq.
Director
Office of Enforcement
Office of Regulatory Affairs

cc:
HF-3/Daniel J. Davidson
HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-7/ Nancy Boocker
HFD-300/ Deborah Autor
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-600/ Gary Buehler
HFC-2/ Michael Verdi

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

HFA-305 (Docket No. FDA-2010-N-0300)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFM-100
HFC-200/CF