



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

March 9, 2005

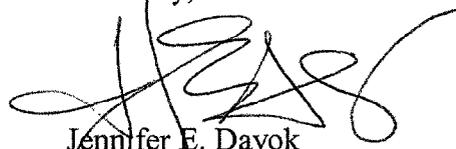
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: In the Matter of Gerald Dorros, M.D.

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and two copies of an Administrative Complaint for Civil Money Penalties, which is the first filing in this matter. Because the parties have already agreed to settle this matter, also enclosed please find an original and two copies of a fully-executed Settlement Agreement for entry by the Administrative Law Judge. If you have any questions, please call me at (301) 827-5523. Thank you.

Sincerely,



Jennifer E. Dayok
Associate Chief Counsel
for Enforcement

Enclosure

cc w/encl.:

Hon. Daniel J. Davidson, A.L.J.
Corey B. Rubenstein
Stacy Gerber Ward

2005 H-0099

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UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of)	
)	ADMINISTRATIVE COMPLAINT
GERALD DORROS, M.D.,)	FOR CIVIL MONEY PENALTIES
)	
an individual.)	FDA Docket No. <u>2005H-0099</u>
)	
)	

Complainant, the Center for Devices and Radiological Health, U.S. Food and Drug Administration ("FDA"), U.S. Department of Health and Human Services, alleges as follows:

INTRODUCTION

1. FDA brings this action under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301, et seq. The Act authorizes the imposition of civil money penalties against persons who violate any of its provisions relating to devices.¹ 21 U.S.C. § 333(f). Pursuant to 5 U.S.C. § 554 and 21 U.S.C. § 333(f)(3)(A), an opportunity for hearing must precede the imposition of money penalties.

JURISDICTION

2. The Secretary of Health and Human Services has subject matter jurisdiction over this action pursuant to 21 U.S.C. § 333(f) and has delegated his functions to the Commissioner of Food and Drugs. 21 U.S.C. § 5.10(a). FDA has personal jurisdiction over Gerald Dorros, M.D. (hereinafter "Dorros" or "Respondent") pursuant to 21 U.S.C. § 333(f). Pursuant to 5 U.S.C §§ 554 and 556, 21 U.S.C. § 333(f)(3)(A), and the implementing regulations at 21 C.F.R. Part

¹ The term "devices" is defined at 21 U.S.C. § 321(h).

17, an administrative law judge appointed pursuant to 5 U.S.C. § 3105 has the authority to conduct a civil money penalty hearing and assess a civil penalty.

RESPONDENT

3. Dorros is, and at all relevant times was, a medical doctor licensed to practice medicine in the State of Wisconsin and elsewhere.

BACKGROUND

4. Generally, the Act requires an approved application for premarket approval ("PMA") before a Class III medical device can be introduced into interstate commerce.² 21 U.S.C. § 360e. Unless it meets an exemption under law, a Class III device that is required to, but does not, have in effect an approved PMA is adulterated. 21 U.S.C. § 351(f)(1)(B). The Act exempts from this requirement a device covered by an approved application for investigational device exemption ("IDE"). 21 U.S.C. § 360j(g)(1). The purpose of the IDE is to permit unapproved devices to be used in investigational studies on humans, to determine whether they are safe and effective. Regulations promulgated at 21 C.F.R. Part 812 establish strict conditions under which those studies may occur. For example, the investigation must be conducted according to the investigational plan--which must include, among other things, the specific intended use of the device, the objectives of the investigation, a written protocol describing the methodology to be used, and analysis of the protocol demonstrating that the investigation is scientifically sound--and applicable FDA regulations. 21 C.F.R. §§ 812.25(a), 812.110(b). Further, an investigator must obtain informed consent from each subject on whom the device will be used and submit complete, accurate, and timely reports of the investigation. 21 C.F.R. §§ 812.100, 812.150. A sponsor or investigator cannot begin an investigation or any part of an investigation until both

² The three medical device classifications are set forth at 21 U.S.C. § 360c.

FDA and an investigational review board ("IRB") have approved the IDE application relating to that investigation or part of investigation. 21 C.F.R. §§ 812.42, 812.110(a).

5. Dorros, a cardiologist, imported some stent-graft devices, without an approved PMA or exemption under law, into the United States and used them to repair human aortic aneurysms, which are dilations of the wall of the aorta that cause that artery to be weakened and susceptible to rupturing. These devices, which were Class III medical devices required to have an approved PMA or be subject to some exemption from the PMA requirement, were manufactured in Argentina by Latecba, S.A. Dorros used the devices in investigational procedures, during which he would insert the device through an artery in the patient's leg and guide it through the body with a catheter and wires to the aortic aneurysm. Dorros performed two types of aneurysm repairs with the Latecba devices. If the aneurysm was above the diaphragm, Dorros performed a thoracic aortic aneurysm repair ("TAA"). If it was below the diaphragm, he performed an abdominal aortic aneurysm repair ("AAA").

6. In 1996, Dorros submitted an IDE application to FDA (a pre-IDE had been submitted in 1995) requesting approval to import the Latecba device as part of a clinical investigation to repair AAAs only. In January 1997, Dorros received final IDE approval to import and use the Latecba devices to perform a limited number of AAAs under the conditions set forth in the investigational plan and FDA regulations.

7. Despite the limited nature of the IDE approval, Dorros imported the Latecba devices from Argentina and used some of them in unauthorized TAA procedures. From January 1997 to March 2000, Dorros performed at least eight TAAs with unapproved Latecba devices in violation of the investigational plan and FDA regulations. Included in these procedures were TAA's

performed at St. Luke's Medical Center in Milwaukee, Wisconsin on patient M.A. on or about August 23, 1999 and patient V.M. on or about February 23, 2000.

VIOLATIONS

8. Respondent repeatedly violated 21 U.S.C. § 331(a) by causing the introduction into interstate commerce of adulterated devices, including the two devices he imported to perform the unapproved TAA procedures referenced in paragraph 7 above.

AMOUNT OF PENALTY

9. Complainant seeks to assess against Respondent a civil penalty in the amount of \$15,000 for each of the two violations of 21 U.S.C. § 331(a) referenced in paragraphs 8 and 9 above, for a total penalty of \$30,000.

INSTRUCTIONS FOR FILING AN ANSWER AND OBTAINING A HEARING

10. Respondent has a right to a hearing under 21 U.S.C. § 333(f). Applicable regulations are set forth at 21 C.F.R. Part 17. To obtain a hearing, Respondent must file an answer, pursuant to 21 C.F.R. § 17.9, with the Division of Dockets Management (HFA-305), Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852, within 30 days of the date of service of this Complaint. The failure by Respondent to file an answer within 30 days of service of this Complaint may result in the imposition of the proposed penalty and assessment against Respondent, as provided by 21 C.F.R. § 17.11. Respondent may retain counsel for representation in conjunction with this proceeding.

11. Pursuant to 21 C.F.R. § 17.9, Respondent's answers, if filed, must admit or deny each of the allegations made in this Complaint and must include the following: all defenses on which Respondent intends to rely; all reasons (if any) why Respondent contends that the penalty and

assessment should be less than the amount requested by this Complaint; the name, address, and telephone number of Respondent's counsel (if any).

PRAYER FOR RELIEF

Based on the violations described in this Complaint, Complainant prays that The Presiding Officer:

1. Enter a finding that each of the allegations in this Complaint is true;
2. Enter a finding that Respondent violated 21 U.S.C. § 331(a) on at least two occasions by introducing into interstate commerce adulterated devices;
3. Enter a finding that each and every affirmative defense presented by Respondent is not meritorious;
4. Enter a finding that Respondent is liable for civil penalties pursuant to 21 U.S.C. § 333(f); and
5. Enter a finding that the appropriate amount of the civil penalties for which Respondent is liable, considering all mitigating and aggravating factors including the nature, circumstances, extent, and gravity of the violations; Respondent's ability to pay a penalty; the effect on his ability to continue to do business; his prior violations; his degree of culpability; and such other matters as justice may require, is \$30,000.

DATED: 3/9/05

Respectfully submitted,



JENNIFER E. DAYOK
Attorney for Complainant
U.S. Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5523

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of)
GERALD DORROS, M.D.,) ADMINISTRATIVE COMPLAINT
an individual.) FOR CIVIL MONEY PENALTIES
)
)
) FDA Docket No. _____
)
)

SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT is made this _____ day of _____, 2005, by and between Complainant Food and Drug Administration ("FDA") Center for Devices and Radiological Health ("CDRH") and Respondent Gerald Dorros, M.D. ("Dorros").

WHEREAS, CDRH filed an administrative complaint for civil money penalties against Dorros, a copy of which is attached hereto and incorporated herein, alleging that Dorros violated 21 U.S.C. § 331(a) on at least two occasions by introducing into interstate commerce devices that were adulterated within the meaning of 21 U.S.C. 351(f)(1)(B) in that they were Class III devices that were required to, but did not, have in effect an approved PMA, nor were they subject to an exemption from the PMA requirement;

WHEREAS, FDA and Dorros have engaged in discussions directed to the resolution of this civil money penalties action;

WHEREAS, these discussions have resulted in compromise and settlement, as set forth herein, and FDA and Dorros, without admitting or denying the allegations in the Complaint, hereby agree to the following:

1. The Secretary of Health and Human Services has subject matter jurisdiction over this action pursuant to 21 U.S.C. § 333(f) and has delegated his functions to the Commissioner of Food and Drugs under 21 U.S.C. § 5.10(a). FDA has personal jurisdiction over Respondent Dorros pursuant to 21 U.S.C. § 333(f). Pursuant to 5 U.S.C §§ 554 and 556, 21 U.S.C. § 333(f)(3)(A), and the implementing regulations at 21 C.F.R. Part 17, an administrative law judge appointed according to 5 U.S.C. § 3105 has the authority to conduct a civil money penalty hearing and assess a civil penalty.

2. This Settlement Agreement is being executed contemporaneously with a misdemeanor criminal plea agreement and civil settlement between Dorros and the United States. In remedy of the alleged violations, Dorros agrees to pay a civil money penalty of \$30,000. This amount shall be due and payable no later than 10 days from the date of the sentencing pursuant to the contemporaneous criminal misdemeanor plea.

3. All parties waive any right to a hearing under 21 U.S.C. § 333(f), and any other right that they may have to contest or appeal the imposition or amount of civil money penalties herein assessed.

4. In the event that Respondent fails to make timely payment of the amount specified in this Settlement Agreement, interest shall automatically accrue on all unpaid amounts at the rate of 15% *per annum*, compounded daily, commencing on the date that payment is due.

Complainant may proceed against Respondent for collection of any and all amounts owed by Respondent, including any unpaid balance and interest.

5. If Complainant is required to take administrative or judicial action to enforce this Settlement Agreement, Respondent shall be liable for Complainant's costs of such action, including reasonable attorney fees.

6. Complainant and Respondent shall bear their own costs, including attorney fees, relating to the action underlying this Settlement Agreement.

7. The administrative law judge shall retain jurisdiction of this action until the full amount of the penalty due herein and any interest, if accrued, are paid. Upon final payment of such amounts, Complainant shall file a Joint Stipulation for Dismissal with Prejudice with the administrative law judge.

8. This Settlement Agreement fully resolves and settles all claims in the Administrative Complaint for Civil Money Penalties against Respondent Gerald Dorros, M.D., and any and all claims or actions which could be initiated by FDA or brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or regulations promulgated thereunder related to the facts circumstances, events, medical procedures, or violations alleged in the Complaint to the extent that such claims or actions or potential claims or actions are based on facts, circumstances, events, or violations that predate the filing of the Complaint. Specifically reserved and excluded from the scope and terms of this Settlement Agreement as to any entity or person (including Dorros) are any criminal liability or any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

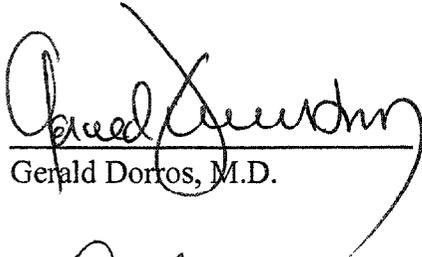
IT IS SO ORDERED:

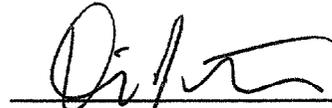
Dated this ____ day of _____, 2005.

DANIEL J. DAVIDSON
Administrative Law Judge

For Respondent:

Gerald Dorros, M.D.


Gerald Dorros, M.D.

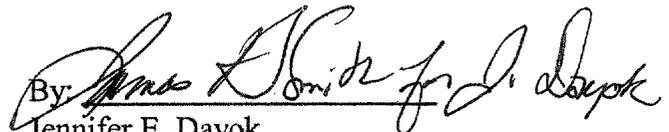

David Stetler *3/1/05*
Corey Rubenstein
Stetler and Duffy
Counsel for Gerald Dorros, M.D.

For Complainant:

Center for Devices and Radiological
Health


DANIEL G. SCHULTZ
Director, Complainant CDRH

GERALD F. MASOUDI
Acting Chief Counsel

By: 
Jennifer E. Dayok
Attorney for Complainant CDRH
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(301) 827-5523

CERTIFICATE OF SERVICE

I hereby certify that, on this 9th day of March, 2005, I have caused a copy of the foregoing Administrative Complaint for Civil Money Penalties and Settlement Agreement to be served on Gerald Dorros, M.D., by United States certified mail, return receipt requested, via his counsel at the following address:

Corey B. Rubenstein
Stetler & Duffy, Ltd.
Suite 1200, 11 South LaSalle St.
Chicago, IL 60603

A handwritten signature in black ink, appearing to read 'JENNIFER DAYOK', written over a horizontal line.

JENNIFER DAYOK
Attorney for Complainant
5600 Fishers Lane (GCF-1)
Rockville, MD 20857