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

In the matter of LAHAYE CENTER FOR ADVANCED EYE CARE OF LAFAYETTE, D/B/A LAHAYE TOTAL EYE CARE, a corporation, and LEON C. LAHAYE, an individual.	AMENDED ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTIES FDA Docket No. 02H-0443

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. §§ 301-97. The Act authorizes the imposition of civil money penalties against persons who violate any of its provision relating to devices.[1] Pursuant to 5 U.S.C. § 554 and 21 U.S.C. § 333(f)(3)(A), an opportunity for a 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

[1] 21 U.S.C. § 333(f). The term "devices" is defined at 21 U.S.C. § 321(h).

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AAMD1

Food and Drugs under 21 C.F.R. § 5.10(a). FDA has personal jurisdiction over the LaHaye Center for Advanced Eye Care of Lafayette, d/b/a LaHaye Total Eye Care ("LaHaye Center"), and Leon C. LaHaye (collectively, "Respondents") 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.

RESPONDENTS

3. The LaHaye Center is, and at all relevant times was, a corporation organized and existing under the laws of the State of Louisiana. It operates five offices in southwestern Louisiana and its principal place of business is located at 201 Rue Iberville, Lafayette, Louisiana 70508.

4. Leon C. LaHaye, an ophthalmologist, is, and at all relevant times was, the owner, sole officer, and president of the LaHaye Center. He is also its medical director. LaHaye has authority over all aspects of the LaHaye Center. He makes business decisions on its behalf, supervises its medical and support staff, and has the power to hire and fire employees.

BACKGROUND

5. The Act requires an approved application for premarket approval as a condition for the use or introduction into commerce of a Class III medical device.[2] The Act exempts from this requirement a device covered by an approved application for an investigational device exemption ("IDE"). The purpose of the IDE is to permit unapproved devices to be used in investigational

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

studies on humans, to determine their safety and efficacy.[3] 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 and applicable FDA regulations (21 C.F.R. § 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 study (21 C.F.R. §§ 812.100, 812.150). An investigator also may not, before receiving FDA approval, obtain a subject's consent or begin the study (21 C.F.R. § 812.110(a)).

6. LaHaye uses lasers in his practice to correct nearsightedness, farsightedness, and astigmatism.

7. In 1995, LaHaye built his own excimer laser system, later dubbed by him the "LAHayeSER." The LAHayeSER was not FDA approved, as required by 21 U.S.C. § 360e. LaHaye nevertheless immediately began using it to treat patients.[4]

8. In February of 1997, LaHaye applied for an IDE in connection with his laser. FDA conditionally approved the IDE in late March of 1997, requiring him to correct certain deficiencies in the IDE application and to obtain Institutional Review Board ("IRB") approval before beginning the study. LaHaye acted as the study sponsor and an investigator.

9. Pursuant to the IDE, Respondents conducted trials under two protocols over the next four years. The conditions of approval of the first protocol ("P1") permitted clinical trials to treat

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[3] 21 U.S.C. § 360j(g)(1)

[4] The laser falls within the definition of "device" set forth at 21 U.S.C. § 321(h). Under 21 U.S.C. § 360c, it is considered a Class III investigational device. Certain of the laser's components traveled in interstate commerce.

up to 754 eyes, within a defined range, to correct nearsightedness and related astigmatism.[5] Contrary to the conditions of approval, Respondents treated more than 110 subjects before receiving IRB clearance. P1 allowed Respondents to provide enhanced treatment to these 110 subjects, in addition to the authorized 754 eyes.

10. The second protocol ("P2") applied a vision correction methodology different than P1 (spherical ablation replacing non-spherical ablation). Under this protocol, FDA authorized Respondents to correct nearsightedness, again within a defined range, in the primary eye of 50 subjects. Respondents were not permitted to correct astigmatism or to use the laser on more than one eye per subject.

11. In October of 1997, after inspecting their treatment facility, FDA sent Respondents a Warning Letter admonishing them to conduct their study according to the IDE and the conditions of the two protocols. Respondents replied by letter, assuring FDA of their intention to comply with the requirements governing the study.

VIOLATIONS

12. Despite Respondents' promise, from late October of 1997 through mid-March of 2001, they repeatedly violated 21 U.S.C. §§ 331(q)(1) and (2) and the regulations implementing 21 U.S.C. § 360j(g).[6] Their violations took myriad forms, including the following:

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[5] Specifically, P1 authorized Respondents to correct myopia (nearsightedness) of -1 to -22 diopters with up to -7 diopters of astigmatism using LASIK non-spherical ablation.

[6] Exhibit A to this complaint identifies by initials and subject number the 175 individuals whose treatment exceeded the limits of the two protocols, thereby violating the IDE. The exhibit also contains data reflecting the manner in which Respondents' vision correction procedures violated the protocols under which they were performed.

a. Respondents treated more than 30 subjects beyond the number approved for P1 and more than 130 subjects beyond the number approved for P2. This violates 21 C.F.R. § 812.110(a) because Respondents permitted these additional subjects to participate in the studies before obtaining IRB and FDA approval;

b. For more than 141 subjects, Respondents ignored the parameters approved for P2 by treating nearsightedness beyond the permitted range, astigmatism, and both eyes of some subjects. Respondents thereby violated 21 C.F.R. § 812.110(b), which requires investigators to "conduct an investigation in accordance with . . . the investigational plan and any conditions of approval imposed by . . . FDA";[7]

c. As set out in sub-paragraphs 12.a and b, Respondents treated numerous subjects beyond the numbers permitted by the IDE and treated conditions falling outside of the IDE's parameters. Under 21 C.F.R. § 812.35, a study sponsor may not change an investigational plan (*e.g.*, by adding subjects and expanding the study parameters) before submitting a supplemental amendment and obtaining FDA and, where appropriate, IRB approval. Respondents breached this requirement; and

d. Respondents did not prepare and submit complete, accurate, and timely reports concerning the studies conducted under the two protocols. For example, in many reports,

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[7] The total number of violations identified in sub-paragraphs 12.a and b (at least 300) greatly exceeds the 175 violations for which FDA seeks civil money penalties. That is because, for virtually all of the 175 subjects identified in Exhibit A, Respondents violated multiple regulatory requirements. For example, in treating subject GM (the first subject listed in Exhibit A), Respondents exceeded the number of subjects approved by P2 (the controlling protocol), improperly treated both of the subject's eyes, and provided treatment beyond P2's parameters. Because of the sheer volume of Respondents' violations, FDA believes that a charge of 1 violation per subject is sufficient.

Respondents fail to list all subjects treated with the investigational laser. Other reports list one of the subject's eyes as having been treated when, in fact, Respondents treated both eyes. Respondents also attribute procedures to an FDA-approved laser that actually were performed with the experimental laser. This practice took place at the direction of LaHaye, who ordered a key employee (on peril of losing her job) to misrepresent the laser used to perform the procedures. Respondents' conduct violates 21 C.F.R. § 812.140(a)(3), which requires investigators to record the exposure of each subject to the investigational device, including the date and time of each use. Respondents conduct also violates 21 C.F.R. § 812.150, which compels investigators "to prepare and submit . . . complete, accurate, and timely reports." Respondents' conduct further violates 21 U.S.C. § 331(q)(2), which prohibits the "submission of any report that is required by or under the Act that is false or misleading in any material respect."

AMOUNT OF PENALTY

13. Complainant seeks to assess against the LaHaye Center a civil penalty in the amount of $15,000 for each of at least 175 violations of 21 U.S.C. §§ 331(q)(1) and (2). Pursuant to 21 U.S.C. § 333(f)(1)(A), the penalty is capped at $1 million.

14. Complainant seeks to assess against Leon LaHaye a civil penalty in the amount of $15,000 for each of at least 175 violations of 21 U.S.C. §§ 331(q)(1) and (2). Pursuant to Section 21 U.S.C. § 333(f)(1)(A), the penalty is capped at $1 million.

INSTRUCTIONS FOR FILING AN ANSWER AND OBTAINING A HEARING

15. Respondents have 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, each respondent must file an answer, pursuant to 21 C.F.R. § 17.9, with the Dockets Management Branch (HFA-305), Food

and Drug Administration, Room 1-23, 5630 Fishers Lane, Rockville, MD 20857, within 30 days of the date of service of this Complaint. The failure by either respondent to file an answer within 30 days of service of the Complaint may result in the imposition of the proposed penalty and assessment against that respondent, as provided by 21 C.F.R. § 17.11. Each Respondent may retain counsel for representation in conjunction with this proceeding.

16. Pursuant to 21 C.F.R. § 17.9, Respondents' answers, if filed, must admit or deny each of the allegations made in this Complaint and must include the following: all defenses on which Respondents intend to rely; all reasons (if any) why Respondents contend that the penalty and assessment should be less than the amount requested by this Complaint; and the name, address, and telephone number of Respondents' counsel (if any).

PRAYER FOR RELIEF

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

1. The Presiding Officer enter a finding that each of the allegations in this Complaint is true;

2. The Presiding Officer enter a finding that Respondents each violated 21 U.S.C. §§ 331(q)(1) and (2) on at least 175 occasions by failing to comply with the requirements prescribed under 21 U.S.C. § 360j(g) and the accompanying regulations set forth at 21 C.F.R. Part 812.

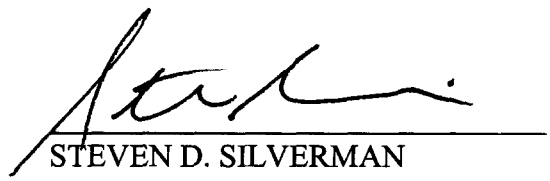
3. The Presiding Officer enter a finding that each and every affirmative defense presented by Respondents is not meritorious;

4. The Presiding Officer enter a finding that Respondents are liable for civil penalties pursuant to 21 U.S.C. § 333(f); and

5. The Presiding Officer enter a finding that the appropriate amount of the civil penalties for which Respondents are liable, considering all mitigating or aggravating factors including the nature, circumstances, extent, and gravity of the violations; Respondents' ability to pay a penalty; the effect on their ability to continue to do business; their prior violations; their degree of culpability; and such other matters as justice may require, is $1 million per Respondent.

DATED: June 23, 2003

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify under penalty of perjury that on June 23, 2003, I caused a copy of the United States' Amended Administrative Complaint for Civil Money Penalties to be sent via first-class mail to the following:

DANIEL A. KRACOV
Attorney for Respondents
PATTON BOGGS LLP
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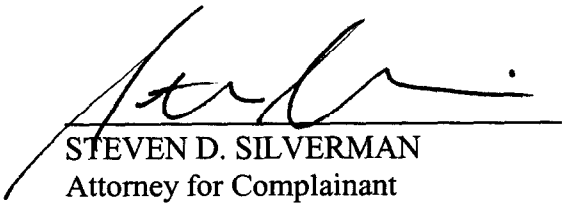

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