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

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

'03 JUN 16 P3:59 0780

MEMORANDUM IN SUPPORT OF RESPONDENTS' MOTION FOR LEAVE TO AMEND THEIR ANSWER

Respondents LaHaye Center for Advanced Eye Care of Lafayette ("LaHaye Center") and Leon C. LaHaye ("Dr. LaHaye") (collectively "Respondents"), through their undersigned counsel, have moved for leave to amend Respondents' Answer for the limited purposes of responding to the United States' Motion to Amend its Complaint and to include the affirmative defense of violation of Due Process. In support thereof, Respondents state as follows:[1]

I. INTRODUCTION/FACTUAL BACKGROUND

The U.S. Food and Drug Administration ("FDA") has brought an action against Respondents under 21 U.S.C. § 333(f), which authorizes the imposition of civil money penalties

[1] In offering this motion/memorandum and in seeking to amend their initial Answer, Respondents do not waive any of their procedural or substantive rights under these proceedings.

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against persons who violate provisions of 21 U.S.C. §§ 301-97 relating to devices. Specifically, FDA has alleged that the Respondents violated several of these provisions through use of their excimer laser system. As Respondents asserted in their initial Answer, they are not subject to jurisdiction of FDA under the relevant regulations because: (1) the laser is a custom device as defined in 21 U.S.C. § 360(j)(b); (2) use of the device was within the practice of medicine and not subject to the provisions alleged to have been violated; and (3) the device was not introduced or delivered for introduction into interstate commerce. Complainants have subsequently filed an Amended Complaint. In response, Respondents now seek to amend their answer, in the interest of justice, both to address Complainants' amendments to their complaint and to assert a fundamental denial of their Constitutional rights, including their rights to Due Process of Law.

II. ARGUMENT

21 C.F.R. § 17.9(d) provides that Respondents may move to amend their answer to conform with the evidence as justice may require. Justice requires that Respondents be permitted to answer those portions of Complainants' Amended Complaint that were not included in the initial Complaint, and to which Respondents have, to date, had no chance to respond. Moreover, in light of the inability to resolve this matter informally, justice requires that Respondents be permitted to amend their complaint to challenge the fundamental violation of their Constitutional rights that will result from this proceeding, and to preserve this issue for appeal if necessary.

Due Process dictates that Respondents are entitled to adequate procedural safeguards and an impartial process. "The Due Process Clause does not create a right to win litigation; it creates a right not to lose without a fair opportunity to defend oneself." *Lane Hollow Coal Co. v. Director*, 137 F.3d 799, 807 (4th Cir. 1998). At its core, the concept of Due Process encompasses "notice and the right to a hearing appropriate to the proposed deprivation at a meaningful time and place. . . If there

has been no fair day in court, the reliability of the result is irrelevant, because a fair day in court is how we assure the reliability of results. " *Id.* at 808. These proceedings preclude any opportunity for Respondents to challenge and invalidate the underlying regulations and interpretations that serve as the basis for FDA's Complaint. Therefore, these proceedings deny Respondents the "fair day in court" to which they are entitled. Moreover, since these proceedings seek to impose a punitive penalty of $2,000,000, without permitting Respondents to fully confront and cross-examine all of their accusers and witnesses against them, and without the right to a jury of their peers, the proceedings further violate the Constitutional rights of Respondents.

Section 17.19 of 21 C.F.R. expressly denies the presiding officer in a civil money penalty proceeding the authority to find Federal statutes or regulations invalid. Therefore, the Administrative Law Judge adjudicating this proceeding must accept the validity of those regulations that Respondents are alleged to have violated. The only question the Judge is permitted to consider is whether Respondents are in violation of the regulations and statute, as interpreted by FDA. By limiting the Judge's role in this manner, however, § 17.19 effectively denies Respondents the opportunity to defend themselves fully, and violates their Constitutional rights. The Judge's inability to invalidate - either outright or in part - the regulations that form the basis of FDA's Complaint guarantees that Respondents do not have the opportunity to defend themselves or be fully heard. As such, these proceedings effectively deny Respondents the Due Process rights to which they are Constitutionally entitled.

A. Respondents Face Deprivation of Their Property Interests and Punitive Penalties

In this case, the FDA seeks to deprive Respondents of their property interest (by prohibiting Respondents' use of a custom device) and to punish Respondents by fining them $2,000,000. While Respondents contend that the Constitution guarantees them a trial by jury and

the right to fully confront and cross-examine their accusers and the witnesses against them, at a minimum, the proceeding must comport with the three-pronged test articulated by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976).

Per *Mathews,* assessing the adequacy of this administrative proceeding requires balancing: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of that interest under the required procedures and the likely reduction of that risk by requiring more or different procedures; and (3) the government's interest in using the required procedures as opposed to more or different procedures. *Mathews*, 424 U.S. at 335.

Respondents' primary defense against the FDA's allegations is that the laser at issue is a "custom device" and outside FDA's jurisdiction. In this litigation, FDA defines a custom device to not include Respondents' self-built laser, constructed from commercially and legally sold components, for use in Respondent Dr. LaHaye's practice of medicine. Respondents are prohibited from defending fully against the FDA's punitive actions and *ad hoc* litigation interpretation because to do so asks the Judge to conclude that FDA's interpretation is incorrect and effectively invalidates FDA's regulation, in violation of § 17.19. As such, Respondents are left with the impossible task of arguing that the laser in question is a custom device under FDA's litigation interpretation – an impossible task since the interpretation concludes that the laser is <u>not</u> a custom device. Without the ability to have the fact-finder consider and determine the validity of the FDA custom device regulation, Respondents are denied due process of law.

Respondents offer a defense recognized by the Supreme Court's rules of statutory and regulatory construction, based on the plain meaning of the words, that their laser is a custom device. Yet because this argument cannot be heard, they face a substantial certainty that they will be erroneously deprived of their property interest by this proceeding that seeks to penalize them

without traditional due process protections. The procedural safeguards a formal hearing appears to provide are, in fact, rendered meaningless if one of the parties to that hearing is effectively stripped of any ability to present its case fully to the presiding officer.

There are no additional administrative procedures that can be instituted to prevent this problem, until the FDA grants additional authority to the Judge to vest him with independent authority to permit a fair and full defense. As such, Respondents face as great a risk of erroneous deprivation of their interests as if they were not afforded the opportunity for a hearing at all.

B. Section 17.9 Forces the ALJ's Mind to be "Irrevocably Closed," Thereby Denying Respondents a Totally Impartial Hearing.

The Supreme Court has held that "the right to an impartial judge is an example of a constitutional right 'so basic to a fair trial that their infraction can never be treated as harmless error.'" *See., e.g. Chianelli v. EPA,* 8 Fed. Appx. 971, 980 (Fed. Cir. 2001) (*citing Chapman v. California,* 386 U.S. 18, 23 & n.8 (1966)). Typically, in the administrative context, this principle has been applied to prevent ALJ's from presiding over cases, for example, in which they have a financial interest, or where they engage in *ex parte* communications. The presumption in such cases is that decision-makers are not biased, *see Withrow v. Larkin,* 421 U.S. 35 (1975); however, courts have held that the presumption may be overcome by showing that the decision-maker's mind is "irrevocably closed." *See, e.g., NEC Corp. v. United States,* 151 F.3d 1361, 1373 (Fed. Cir. 1999) (holding that plaintiff could "prevail on its claim of prejudgment only if it can establish that the decision maker is not 'capable of judging a particular controversy fairly on the basis of its own circumstances.' This standard is met when the challenger demonstrates, for example, that the decision maker's mind is 'irrevocably closed' on a disputed issue" (internal citations omitted)). In the present case, while Respondents in no way intend to imply that the Judge harbors or exhibits any actual bias whatsoever, §17.19 forces the Judge's "mind" to be "irrevocably closed" on the custom device

defense. Therefore, the situation facing Respondents is worse than one in which the Judge harbors an actual bias, which might be overcome. Being subject to a decision-maker who is completely closed to Respondent's primary defense, without regard to the merits of Respondents' argument, deprives Respondents of the impartial decision-maker guaranteed by the Due Process clause of the Constitution.

C. **Neither Appeals From the ALJ"s Final Ruling, Nor Interlocutory Review , Protect the Respondents Constitutional Rights, Which Have Been, and Continue to Be, Violated.**

Respondent has already been unfairly penalized by FDA's punitive denial of his right to use his custom laser, FDA's allegations, and FDA's continuing prosecution seeking $2,000,000, necessitating Respondents continued funding of a legal defense in a forum where his right to due process of law is denied and his primary defense is prohibited. Respondents must be permitted to amend their answer in order to address and ultimately prevent the deprivation of Respondents' constitutional rights.

21 C.F.R. §17.18 generally prohibits interlocutory appeals from rulings of the presiding officer, and only the final decision of the Commissioner of Food and Drugs will be alleged by FDA to constitute final agency action, subject to judicial review in the courts, under § 17.51. Essentially, FDA has established a costly forum where Respondents cannot defend themselves, and seeks to force Respondents to suffer an ongoing denial of Constitutional rights, and costly deprivations of property, perhaps for years, before Respondents can present a complete defense.

As a result, Respondents must be permitted to amend their Answer to protect the Respondents from further harm resulting from the deprivation of their Constitutional rights through this administrative proceeding.

III. CONCLUSION

Inasmuch as the Administrative Law Judge in this matter is precluded under 21 C.F.R. § 17.19(c) from providing Respondents with a full and fair hearing of its defenses, justice requires that Respondents be permitted to amend their answer accordingly.

Respectfully submitted,

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