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.	)	FDA Docket No. 02H-0443

UNITED STATES' OPPOSITION TO RESPONDENTS' PROPOSED FIFTH AFFIRMATIVE DEFENSE

I. Question Presented

Respondents wish to amend their Answer to argue that the Court's inability to set aside the statutes and regulations underlying this action deprives them of their constitutional due-process rights. But for this defense to succeed, the Court would have to annul 21 C.F.R. § 17.19(c), the very provision that prohibits it from invalidating federal statutes and regulations. Further, a well-established line of decisions holds that administrative courts are an improper forum for constitutional questions. Should the Court permit respondents to add their proposed affirmative defense?

II. Argument

Respondents' motion to amend their Answer seeks to accomplish a number of objectives. First, respondents want to respond to the new allegations raised in the Government's amended

complaint. The Government, of course, has no objection to this proposal. But respondents also seek to raise as an affirmative defense the argument that, because the Court cannot invalidate the statutes and regulations underlying this action, they are denied their due-process rights. The Government opposes the addition of this affirmative defense on a number of grounds. First, granting the defense would require the court to reject 21 C.F.R. § 17.19(c) as unconstitutional. But this result is directly contrary to the provision's plain language, which precludes the Court from "find[ing] Federal statutes or regulations invalid."[1] Second, the affirmative defense turns on a constitutional argument. An established line of decisions holds that parties should not look to administrative courts to resolve constitutional questions. Finally, 21 U.S.C. § 333(f)(4) and 21 C.F.R. § 17.51 afford respondents the right of judicial review by an Article III court. Because these courts can decide constitutional questions (and, indeed, are the correct forum for doing so), respondents are not deprived of their due-process rights.

A. The Proposed Affirmative Defense Directly Contradicts 21 C.F.R. § 17.19(c).

The crux of respondents' proposed affirmative defense is that the Court's inability to nullify the Act and its implementing regulations prevents them from raising certain arguments in the underlying action. This, in turn deprives them of due-process protections. Endorsing this argument would require the Court to reject 21 C.F.R. § 17.19(c). But the plain language of that provision prohibits this very result. Accordingly, respondents are asking the Court to provide relief that it may not afford.

Moreover, respondents' due-process argument was considered, and rejected, when FDA published Section 17.19(c). The agency recognized that "the need to provide due process for

[1] 21 C.F.R. § 17.19(c)

companies and individuals from whom the Government is seeking civil money penalties" does not supercede the government's interest in moving the administrative process "with predictability and efficiency."[2]

B. An Administrative Court Is the Wrong Forum for Constitutional Challenges.

In resolving the underlying action, the Court has wide-ranging authority. But respondents' proposed affirmative defense asks the Court to venture beyond the bounds of administrative tribunals. Congress assigned original jurisdiction over constitutional questions to the federal district courts.[3] Recognizing this point, numerous courts have ruled that administrative courts may not judge the constitutional validity of the statutes and regulations before them.[4]

The Federal Circuit's decision in *Riggin v. Office of Senate Fair Employment Practices* is instructive.[5] While acknowledging that Congress may delegate to agencies the adjudicatory power over constitutional questions, the court found this jurisdiction unlikely "when the

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[2] General Comments on the Preamble, Civil Money Penalties: Biologics, Drugs, and Medical Devices, 60 Fed. Reg. 38612 (July 27, 1995)

[3] 28 U.S.C. § 1331 (2002) ("The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.")

[4] *See e.g., Buckeye Indus., Inc. v. Sec'y of Labor*, 587 F.2d 231, 235 (5th Cir. 1979) ("No administrative tribunal of the United States has the authority to declare unconstitutional the Act which it is called upon to administer"); *Papendick v. Sullivan*, 969 F.2d 298, 302 (7th Cir. 1991) (noting administrative judge's recognition of lack of jurisdiction to review constitutional claims); *Christy v. Hodel*, 857 F.2d 1324, 1327 (9th Cir. 1988) (administrative appeal denied because "Department had no jurisdiction to determine the constitutionality of federal laws or regulations"); *Simpson v. Laprade*, 248 F. Supp. 399, 401 (W.D. Va. 1965) ("in the absence of statutory authorization, an administrative agency does not have the power to determine the constitutionality of the statute it administers")

[5] 61 F.3d 1563 (Fed. Cir. 1995)

constitutional claim asks the agency to act contrary to its statutory charter."[6] Respondents ask the Court to protect their due-process rights by invalidating portions of the Act and its implementing regulations. As the *Riggin* decision makes clear, it is unlikely that Congress's intent was for the Court to so contradict FDA's statutory authority.

C. Respondents' Right To Appeal Affords Them Due-Process Protection.

Respondents premise their affirmative defense on the claim that the Court's inability to set aside the Act and its implementing regulations denies them due process. But their authority for this proposition, *Mathews v. Eldridge*,[7] belies this argument. *Mathews* makes plain that, "where, as here, the prescribed procedures . . . assure a right to an evidentiary hearing, as well as to subsequent judicial review," due process is satisfied.[8] Faced with arguments like respondents', other courts have echoed *Mathews'* holding that the right to judicial review of an agency determination sufficiently affords due process.[9]

Both the Act and the regulations governing the underlying action provide respondents the right to an evidentiary hearing and judicial review of the Court's ruling. The right to a hearing is codified at 21 U.S.C. § 333(f) and 21 C.F.R. § 17.33. The right to judicial review is set forth at

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[6] *Id.* at 1569

[7] 424 U.S. 319 (1976)

[8] *Id.* at 349

[9] *See, e.g., Fairchilds Semiconductor Corp. v. Envtl. Prot. Agency*, 984 F.2d 283, 289 (9th Cir. 1993) ("'It is sufficient [under the Due Process Clause], where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination.'") (citation omitted); *Unification Church v. United States*, 581 F.2d 870, 878 (D.C. Cir. 1978) (due process requirements met by availability of judicial review of decision of district director of Immigration and Naturalization Service); *Alberico v. United States*, 7 Cl. Ct. 165, 168 n.2 (Cl. Ct. 1984) (citing *Mathews* for proposition that due process is satisfied by right to an evidentiary hearing and judicial review).

21 U.S.C. § 333(f)(4), which provides that "[a]ny person who . . . is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order . . . ." It is further codified at 21 C.F.R. § 17.51, which provides that "[t]he final decision of the Commissioner . . . constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved. . . ." Importantly, respondents need not pay penalties assessed against them as a condition of review and they can petition to stay agency action pending review.[10] Given these safeguards, they are simply mistaken in asserting that the regulatory scheme governing the underlying action denies them due process.

* * *

Respondents' proposed affirmative defense is flawed in multiple respects. First, it asks the Court to do that which is statutorily prohibited. Second, it asks the Court to exercise authority not traditionally reserved to administrative tribunals. And finally, it is premised on respondent's incorrect assertion that the defense is necessary to preserve their due-process rights. Given these flaws, the Court should deny respondents' motion to add this affirmative defense. A proposed order is attached.

DATED: June 23, 2003

Respectfully submitted,

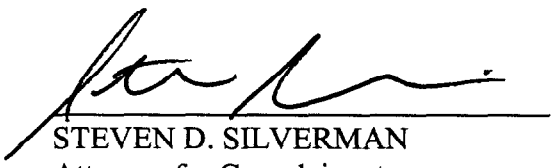
STEVEN D. SILVERMAN
Attorney for Complainant
U.S. Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-6474

[10] *Id.*

CERTIFICATE OF SERVICE

I certify under penalty of perjury that on June 23, 2003, I caused a copy of the United States' Opposition to Respondents' Proposed Fifth Affirmative Defense to be sent via first-class mail to the following:

DANIEL A. KRACOV
Attorney for Respondents
PATTON BOGGS LLP
2550 M Street, NW
Washington, DC 20037-1350
(202) 457-5623



STEVEN D. SILVERMAN
Attorney for Complainant
U.S. Food and Drug Administration
5600 Fishers Lane (GCF-1)
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D/B/A LAHAYE TOTAL EYE CARE,	)	
a corporation,	)	
and	)	
LEON C. LAHAYE,	)	
an individual.	)	

ORDER

Pending before the Court is respondents' Motion To Amend Their Answer. Having considered the arguments in support and in opposition thereto, it is ORDERED that the motion is GRANTED IN PART AND DENIED IN PART. Respondents may amend their answer to add their proposed Paragraphs 12c and 12d. Respondents' request to add their Fifth Affirmative Defense is DENIED. It is further ORDERED that counsel for respondents shall file the amended answer with FDA's Dockets Management Branch by _____, 2003.

Service of the amended answer may be made via first-class mail.

Dated: June _____, 2003

DANIEL J. DAVIDSON
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857