[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 07-14309

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
OCT 7, 2008
THOMAS K. KAHN
CLERK

D.C. Docket Nos. 05-02083 CV-GET-1
06-00406-CV-GET

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

versus

LESTER M. CRAWFORD, D.V.M., Ph.D.,
as Commissioner of the United States Food and Drug Administration,
UNITED STATES FOOD AND DRUG ADMINISTRATION,
MICHAEL O. LEAVITT, as Secretary of the
Department of Health and Human Services,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
ACTING COMMISSIONER ANDREW C. VON ESCHENBACH, M.D.,

Defendants-Appellees.

No. 07-14312

D.C. Docket Nos. 06-00406 CV-GET-1
05-02083-CV-GET

UNITED STATES OF AMERICA,

Plaintiff-Third Party Defendant-Appellee,

versus

18 CASES, MORE OR LESS, OF AN ARTICLE OF FOOD, EACH CASE CONTAINING 120/100 TABLET BOTTLES LABELED IN PART Lipodrene Dietary Supplement 100 ct. Sida Cordifolia (leaves) (25 mg ephedrine group alkaloids) Lot 05121004 Manufactured for Hi-Tech Pharmaceuticals, Inc., Norcross, GA, et al.,

Defendants,

HI-TECH PHARMACEUTICALS, INC.,

Claimant-Third Party Plaintiff-Appellant.

Appeals from the United States District Court
for the Northern District of Georgia

(October 7, 2008)

Before WILSON, PRYOR and COX, Circuit Judges.

PER CURIAM:

We consider in this appeal whether 21 U.S.C. § 342(f)(1)'s de novo provision impacts the evidentiary weight to be given to Food and Drug Administration (FDA) regulations. Section 342(f)(1)'s de novo provision provides that a reviewing court

shall decide any issue in an adulterated dietary supplement proceeding de novo. The issue is whether a FDA regulation which declares that dietary supplements containing ephedrine alkaloids are adulterated is sufficient proof of adulteration, or is more evidence needed under § 342(f)(1)'s de novo provision? Because FDA regulations have the force and effect of law, we conclude that the no other evidence is needed. We affirm.

I. BACKGROUND

Hi-Tech Pharmaceuticals, Inc. manufactured, marketed, distributed, and sold dietary supplements containing ephedrine alkaloids. In June 1997, the United States FDA proposed a rule regarding products containing certain levels of ephedrine alkaloids. The FDA received thousands of comments and considered voluminous evidence about the risks of ephedrine alkaloids. Then, six and a half years later, in February 2004, the FDA issued the "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk" (the "Final Rule"). The Final Rule states:

> Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are

> adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

21 C.F.R. 119.1.

The Final Rule was enacted under the Dietary Supplement Health Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325 (1994), amending the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301-399. Under the FDCA, "adulterated" describes a product that "presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling," or if the labeling does not discuss it, "under ordinary conditions of use[.]" 21 U.S.C. § 342(f)(1)(A).

The Final Rule became effective on April 12, 2004. Its effect was to ban the sale and distribution of all dietary supplements containing ephedrine alkaloids and to make those products subject to seizure and condemnation by the government. On February 23, 2006, United States Marshals entered Hi-Tech's premises and seized some dietary supplement products and ingredients found there. Hi-Tech concedes that the seized products and ingredients contain ephedrine alkaloids.

II. PROCEDURAL HISTORY

Prior to the seizure, Hi-Tech filed a declaratory relief action seeking relief from enforcement of the Final Rule on the ground that the FDA had not complied with the

Administrative Procedures Act (APA) in promulgating the Final Rule ("the APA action"). The United States filed a separate action for forfeiture of dietary supplement products and ingredients containing ephedrine alkaloids ("the enforcement action"). After the property was seized, Hi-Tech filed a statement of interest and a third-party complaint in the enforcement action. The district court consolidated the APA action and the enforcement action.

On cross-motions for summary judgment, the district court denied Hi-Tech's motion and granted summary judgment to the FDA and the United States, finding that all required administrative procedures were followed and that the seizure was proper because the seized property was adulterated. *See Hi-Tech Pharm., Inc. v. Crawford*, 505 F. Supp. 2d 1341 (N.D. Ga. 2007). Hi-tech appeals.

III. STANDARD OF REVIEW

This court reviews a district court's grant of summary judgment de novo, applying the same legal standards used by the district court. *See, e.g.*, *Hilburn v. Murata Elecs. N. Am., Inc.*, 181 F.3d 1220, 1225 (11th Cir.1999). Summary judgment is appropriate where "'there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.'" *Wooden v. Bd. of*

Regents of the Univ. Sys. of Ga., 247 F.3d 1262, 1271 (11th Cir.2001) (quoting Fed. R. Civ. P. 56(c)).

IV. ISSUE ON APPEAL

Hi-Tech raises several issues on appeal, but only one merits discussion.[1] Hi-Tech contends that the district court erroneously relied on the Final Rule to find that Hi-Tech's dietary supplements were adulterated and, therefore, properly seized. Hi-Tech argues that, in an enforcement proceeding under the statute, the Government may not rely on the Final Rule to meet its burden to prove that a product is adulterated. The Government must instead, Hi-Tech argues, present additional evidence to the district court to prove, by a preponderance of the evidence, that the product is adulterated.

In making this argument, Hi-Tech relies on the language of 21 U.S.C. § 342(f)(1), which states the conditions under which a dietary supplement or ingredient shall be deemed to be adulterated. In this case, the Government relied on 21 U.S.C. § 342(f)(1)(A), which states that a dietary supplement will be deemed adulterated if

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[1]Hi-Tech's other arguments on appeal are meritless. Hi-Tech contends that: (1) during the administrative process, the FDA did not provide adequate notice that the Final Rule might ban ephedrine alkaloids completely; (2) the Final Rule is not a logical outgrowth of the regulation originally proposed by the FDA; and (3) the FDA's use of a risk-benefit analysis to determine whether a dietary supplement poses an "unreasonable risk" is contrary to congressional intent and unreasonable itself. We find these arguments meritless for the reasons stated by the district court. *See Hi-Tech Pharm.*, 505 F. Supp. 2d at 1351-1353.

it "presents a significant or unreasonable risk of illness or injury under . . . conditions of use recommended or suggested in labeling, or . . . if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use[.]" *Id.* Later, the statute that applies to enforcement proceedings states, "In any proceeding under [21 U.S.C. § 342(f)(1)], the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis." 21 U.S.C. § 342(f)(1).

Hi-Tech focuses on the use of the term de novo in the last sentence of 21 U.S.C. § 342(f)(1) and argues that it requires a district court to hear original evidence on the question of adulteration, even where the FDA has conducted an administrative rulemaking process and promulgated a valid rule declaring the product adulterated.

V. DISCUSSION

As a general matter, FDA regulations like the Final Rule, which have been issued after proper administrative process, have the force and effect of law. *See Abbott Labs v. Gardner*, 387 U.S. 136, 151-53, 87 S. Ct. 1507, 1517-18 (1967) (stating that a final FDA regulation, if within the agency's authority, has the status of law). It is for this reason that violation of such regulations may "carry heavy criminal and civil sanctions," such as forfeiture. 387 U.S. at 152, 87 S. Ct. at 1517.

The question posed in this appeal is whether the de novo language in the last sentence of 21 U.S.C. § 342(f)(1) somehow transforms the Final Rule into something other than a regulation with the force of law. In other words, did Congress act to diminish the effect of the FDA regulations regarding adulterated dietary supplements by using the term de novo in the last sentence of the statute?

As the parties recognize, the meaning of the de novo language in the last sentence of 21 U.S.C. § 342(f)(1) in an enforcement action is an issue of first impression in the federal appellate courts. Two courts of appeals have held that the provision applies only in enforcement proceedings, not in actions brought solely under the APA.[2] But no court has decided how the provision operates in an enforcement action such as this one, where the FDA has promulgated a regulation declaring a product adulterated.

Because there are no court decisions answering this question, the district court turned to legislative history in an effort to determine the intent of Congress. The Senate Report states:

> Section 4 of the bill adds two new provisions to the Federal Food, Drug and Cosmetic Act to provide further power to the Food and Drug Administration to proceed where the safety of a dietary supplement

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[2] *See NVE, Inc. v. Dep't of Health and Human Servs.*, 436 F.3d 182, 192 (3d Cir. 2006); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1037 (10th Cir. 2006).

> poses risks to consumers. First section 4 provides new power to the FDA to declare a dietary supplement adulterated through rulemaking. FDA may use this power where it is determined that a dietary supplement presents a "substantial and unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling."

S. Rep. No. 103-410, at 35 (1994) (emphasis added). The Report also explains that the section was intended "to codify current law that the government bear the burden of proving dietary supplements adulterated." *Id.* at 36. The Report further states, "The government must produce the preponderance of the evidence as to the harmful effects from the dietary supplement . . . ." *Id.* And, the Report cites *United States v. 71/55 Gallon Drums of Stuffed Green Olives*, 790 F. Supp. 1379 (N.D. Ill. 1992), a case where there was no FDA regulation declaring the food at issue adulterated, in support of its statements regarding the burden of proof. Thus, the legislative history clearly states that the government has the burden of proof in an enforcement proceeding. However, it provides no guidance as to whether and how an FDA-promulgated regulation declaring a product adulterated may be used as evidence in such a proceeding.

On appeal, Hi-Tech concedes, and we agree, that the de novo language in the statute does not prevent the Government from using the Final Rule as evidence of adulteration in an enforcement proceeding. What Hi-Tech argues is that the Final

Rule alone cannot be sufficient evidence of adulteration and that the Government must present the district court with some additional proof that the product subject to forfeiture "presents a significant or unreasonable risk of illness or injury" under recommended or ordinary conditions of use in order to satisfy its burden. 21 U.S.C. § 342(f)(1)(A).

We disagree. The statute does not say that the applicability of a regulation promulgated by an executive agency, through an extensive administrative procedure, cannot be sufficient proof of adulteration. And the legislative history does not so indicate. Indeed, that history suggests the opposite: that the statute empowers the FDA to settle the issue of adulteration through rulemaking and that additional proof to a court will not be necessary. *See* S. Rep. No. 103-410, at 35.

Having considered the text of the statute and its legislative history, we conclude that Congress used the term de novo to indicate that the Government had the burden of proof, by preponderance of the evidence, that a dietary supplement "presents a significant or unreasonable risk of illness or injury" under recommended or ordinary conditions of use. 21 U.S.C. § 342(f)(1)(A). In the absence of a regulation like the Final Rule, the Government would have to carry its burden by submitting evidence of the risks of illness or injury under the recommended or

ordinary conditions of use. *See e.g., 71/55 Gallon Drums of Stuffed Green Olives*, 790 F. Supp. 1379. But, as here, where the FDA has already considered evidence of the risks, benefits and uses of a product; proposed a regulation addressing the product; issued notice of the proposed regulation; considered comments on that regulation and evidence relevant to that regulation over a considerable period of time; and promulgated a valid Final Rule, it is sufficient for the Government to present evidence that: (1) the regulation exists and (2) it applies to the product that is the subject of the enforcement action. We do not read the statute to require more.

VI. CONCLUSION

Because the parties agree that the Final Rule applies to the seized property, no genuine issue of material fact exists. The district court properly granted summary judgment for the Government.

AFFIRMED.