United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 17, 2011 Decided January 3, 2012

No. 11-5118

HOLISTIC CANDLERS AND CONSUMERS ASSOCIATION, ET AL.,
APPELLANTS

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:10-cv-00582)

James S. Turner argued the cause and filed the briefs for appellants.

Andrew E. Clark, Senior Litigation Counsel, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Tony West*, Assistant Attorney General, U.S. Department of Justice, *William B. Schultz*, Acting General Counsel, U.S. Department of Health and Human Services, and *Eric M. Blumberg*, Deputy Chief Counsel. *Robert E. Kopp*, Attorney, U.S. Department of Justice, entered an appearance.

Before: TATEL and GARLAND, *Circuit Judges*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* GARLAND.

GARLAND, *Circuit Judge*: Ear candles are hollow tubes made of fabric soaked in beeswax or paraffin; a user places one end in his ear and sets the other on fire with an open flame. The appellants are manufacturers, distributors, and users of ear candles, along with organizations that advocate the use of holistic health remedies like ear candles. Their lawsuit challenges warning letters the Food and Drug Administration (FDA) issued to several of the appellant manufacturers, advising that the agency considered their candles to be adulterated and misbranded medical devices. The district court dismissed the appellants' complaint on the ground, among others, that the warning letters did not constitute "final agency action" subject to judicial review under the Administrative Procedure Act. We agree and affirm the dismissal of the complaint.

I

In February 2010, FDA issued "Warning Letters" to fifteen manufacturers and distributors of ear candles, including several of the appellants. A typical warning letter advised the recipient that FDA considered its candles to be adulterated and misbranded medical devices because "[b]ased on the labeling . . . , it appears your ear candles are intended to mitigate or treat allergies, headaches, colds, flu, sinus congestion, sore throat, ear infections" and a variety of other medical disorders, yet "you have not obtained marketing approval or clearance before you began offering your product for sale." Letter from FDA to Harmony Cone (Feb. 17, 2010) (J.A. 42-43) [hereinafter FDA Warning Letter]; *see* Letter from FDA to King Cone Int'l (Feb. 17, 2010) (J.A. 45) (stating that the manufacturer's website contains claims that the "device is intended to relieve," inter alia, "vision disorders[,] . . . depression, and attention deficit disorder"); *see also* J.A. 47, 49 (warning letters to other

manufacturers).[1] FDA further noted that it "has received medical device reports consistent with the danger to health posed by your device[s,] . . . including reports involving ruptured tympanic membranes and burns." FDA Warning Letter (J.A. 43). The letters advised the appellants to "take prompt action to correct [the identified] deviations" from the Food, Drug, and Cosmetic Act (FDCA). *Id.* (citing, inter alia, 21 U.S.C. §§ 321(h), 351(f)(1)(B), 352(a), 352(f)(1), 352(j)). They also "request[ed]" that the appellants cease marketing, promoting, and distributing ear candles and "correct the problem," and warned that "[f]ailure to promptly correct these deviations may result in regulatory action." *Id.*

On March 26, 2010, after receiving such a letter, representatives of one of the appellant companies met with FDA officials. According to the appellants, at the meeting an FDA agent reiterated the agency's position that ear candles are medical devices, and the then-Deputy Director for Regulatory Affairs asserted that FDA did not intend to approve ear candles for use in the market. *See* Certification in Support of Compl. ¶¶ 4-5. Even so, the Deputy Director concluded the meeting by telling the representatives that "we look forward to your response[,] . . . and we will evaluate that response and make decisions on what we are going to do, going forward." *Id.* ¶ 4. The company never responded and never submitted the information required to seek approval or clearance for its ear candles.

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[1]The appellants dispute that ear candles are medical devices, averring that "[p]roperly made Holistic Candles are a natural holistic modality . . . used for and intended to be used for relaxation, comfort, reduction of stress and for the natural furtherance of the well-being of the user." Compl. ¶ 19.

Instead, the appellants filed this lawsuit. Their complaint alleges, among other things, that FDA's warning letters, coupled with the statements made by FDA officials during the March 2010 meeting, are contrary to the FDCA and violate the First Amendment.[2] "Plaintiffs have a right to bring this action pursuant to the Administrative Procedure[] Act," the complaint states, "because . . . FDA [has] engaged in final agency actions that 'are contrary to law.'" Compl. ¶ 10.

The district court dismissed the appellants' suit on several grounds, including that the appellants lack standing and that the warning letters do not constitute final agency action. *Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 160-62 (D.D.C. 2011). Because standing is a "threshold jurisdictional question," we must address it first. *Byrd v. EPA*, 174 F.3d 239, 243 (D.C. Cir. 1999). FDA argues that the appellants lack standing because the letters "do not impose any requirements on the recipients," FDA Br. 14, and hence have not caused them the "injury in fact" required to establish standing, *id.* at 17. *See Bennett v. Spear*, 520 U.S. 154, 167 (1997). "In analyzing whether [a plaintiff] has standing at the dismissal stage," however, "we must assume that [the plaintiff] states a valid legal claim and 'must accept the factual allegations in the complaint as true.'" *Info. Handling Servs., Inc. v. Def. Automated Printing Servs.*, 338 F.3d 1024, 1029 (D.C. Cir. 2003) (internal citation omitted). The appellants here claim that the warning letters announce "FDA's determination that ear candles are, per se, unapproved Medical Devices and cannot be sold in the United States," Compl. ¶ 17, which "effectively outlaw[s] the manufacture" of ear candles, *id.* ¶ 3. If the appellants are right that FDA's actions outlaw the manufacture of ear candles, there is no doubt that the appellants that

[2]These are the only allegations that the appellants have raised on appeal and are the only ones that we address in this opinion.

manufacture such devices have suffered the requisite "injury in fact." *See Bennett*, 520 U.S. at 167-68.[3]

Although the appellants have standing, we conclude that they cannot satisfy another requirement for maintaining this suit: a cause of action. The appellants' claims all rely upon the Administrative Procedure Act (APA), 5 U.S.C. §§ 701 *et seq*., to provide a cause of action. Compl. ¶ 10; *see Trudeau v. FTC*, 456 F.3d 178, 185 (D.C. Cir. 2006). The APA, however, only provides a right to judicial review of "*final* agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704 (emphasis added); *see Trudeau*, 456 F.3d at 185 ("'If there was no final agency action . . . , there is no doubt that appellant would lack a cause of action under the APA.'" (quoting *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003))). "As a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the consummation of the agency's decisionmaking process -- it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 177-78 (internal citations and quotation marks omitted); *see AT&T Co. v. EEOC*, 270 F.3d 973, 975 (D.C. Cir. 2001). FDA's warning letters fail to satisfy either condition: they neither mark the consummation of the agency's decisionmaking process nor determine the appellants' legal rights or obligations.[4]

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[3]In light of this conclusion, we need not consider the standing of the remaining appellants. *See, e.g.*, *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1232 (D.C. Cir. 1996).

[4]Because we affirm on this ground, we do not address the additional grounds for dismissal offered by the district court. In

The letters plainly do not mark the consummation of FDA's decisionmaking. The FDA Regulatory Procedures Manual describes FDA warning letters as giving "firms an opportunity to take voluntary and prompt corrective action *before* it initiates an enforcement action." FDA Manual, § 4-1-1 (emphasis added). The Manual states that the violations for which warning letters are issued "*may* lead to enforcement action if not promptly and adequately corrected," not that they inevitably will. *Id.* (emphasis added).

Consistent with this description, the warning letters at issue here advise the recipients that "it *appears* your ear candles are intended to mitigate or treat" the listed disorders, explain where to get the "information you need to submit in order to obtain approval or clearance for your device," and state that "FDA *will evaluate* the information you submit and decide whether your product may be legally marketed." FDA Warning Letter (J.A. 42-43) (emphasis added). They further state that "failure to promptly correct these deviations *may* result in regulatory action being initiated." *Id.* (J.A. 43) (emphasis added). According to the letters, such regulatory actions "include, but are not limited

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particular, although the parties focus considerable attention on whether the case is ripe for judicial review, our conclusion that the warning letters do not constitute final agency action makes it unnecessary for us to consider the remainder of the ripeness inquiry. To determine whether a dispute is ripe, a reviewing court must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). Although both the fitness and hardship prongs encompass a number of considerations, a dispute is not ripe if it is not fit, *see Natural Res. Def. Council, Inc. v. U.S. Nuclear Regulatory Comm'n*, 680 F.2d 810, 817 n.19 (D.C. Cir. 1982), and (at least in an APA case) it is not fit if it does not involve final agency action, *see Natural Res. Def. Council v. EPA*, 643 F.3d 311, 319 (D.C. Cir. 2011) (citing *Abbott Labs.*, 387 U.S. at 149).

to seizure, injunction, and/or civil monetary penalties." *Id.* No such actions have been taken against the appellants to date.

Nor do the letters represent a decision determining rights or obligations, or one from which legal consequences flow. The FDA Manual explains that "[a] Warning Letter is the agency's principal means of achieving prompt *voluntary* compliance with the Federal Food, Drug and Cosmetic Act." FDA Manual, § 4-1-1 (emphasis added). Although a warning letter "communicates the agency's position on a matter," it is only "informal and advisory" and "does not commit FDA to taking enforcement action." *Id.* Indeed, the Manual states that, "[d]espite the significance of the violations [for which a warning letter may be issued], there are some circumstances that may preclude the agency from taking any further enforcement action following the issuance of a Warning Letter." *Id.* In short, an FDA warning letter compels action by neither the recipient nor the agency.

Once again, the letters at issue here are consistent with the Manual's description. The letters tell the manufacturers that they "*should* take prompt action to correct" the identified deviations, "*request*[]" that they cease marketing, promoting, and distributing ear candles, and state that "[f]ailure to promptly correct these deviations *may* result in regulatory action being initiated." FDA Warning Letter (J.A. 43) (emphasis added). It is plain, therefore, that "[n]o legal consequences flow from the agency's conduct to date, for there has been no order compelling [the appellants] to do anything." *Reliable Automatic Sprinkler*, 324 F.3d at 732.[5]

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[5]The appellants fear that if they cannot challenge the letters now, they may ultimately have to expend resources defending themselves in an enforcement action later. But the law is clear that "practical consequences, such as the threat of having to defend [oneself] in an

Accordingly, like other agency advice letters that we have reviewed over the years, FDA warning letters do not represent final agency action subject to judicial review.[6] *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986), cited by the appellants, is not to the contrary. In that case, the court determined that letters EPA sent to manufacturers were final

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administrative hearing should the agency actually decide to pursue enforcement, are insufficient to bring an agency's conduct under our purview." *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004) (internal quotation marks omitted); *see FTC v. Standard Oil of Cal.*, 449 U.S. 232, 244 (1980); *Reliable Automatic Sprinkler*, 324 F.3d at 732.

[6]*See Indep. Equip. Dealers*, 372 F.3d at 427 (holding that an EPA advice letter that "had no binding effect whatsoever -- not on the agency and not on the regulated community" -- was not final agency action); *Reliable Automatic Sprinkler*, 324 F.3d at 731-32 (ruling that a Consumer Product Safety Commission letter, stating that agency officials intended to make a preliminary determination that a company's products presented a substantial product hazard and requesting "voluntary corrective action" from the company, did not constitute final agency action); *AT&T*, 270 F.3d at 974-76 (holding that EEOC Letters of Determination, "stating that in [the Commission's] view [the plaintiff] had unlawfully discriminated," did not constitute final agency action); *Fla. Power & Light Co. v. EPA*, 145 F.3d 1414, 1419-20 (D.C. Cir. 1998) (ruling that EPA letters that, "without more, have no binding effect" on the plaintiff, are not "final regulations" under the Resource Conservation and Recovery Act of 1976); *id.* at 1419 (noting with approval a Ninth Circuit decision holding that an "agency letter alleging statutory violations and warning of possible injunctive and civil penalty remedies did not constitute final agency action" (citing *Air Cal. v. DOT*, 654 F.2d 616, 620-21 (9th Cir. 1981))); *see also Standard Oil*, 449 U.S. at 241-43 (holding that an FTC complaint, averring that the agency had "reason to believe" the plaintiffs had committed statutory violations, was not final agency action subject to immediate judicial review).

because they expressed EPA's "unequivocal position" that it could require labeling changes on a registered pesticide without first following the cancellation procedures prescribed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136d(b). *Ciba-Geigy*, 801 F.2d at 435-36; *see Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1136-37 (D.C. Cir. 2010). By contrast, FDA expresses no such position, unequivocal or otherwise, regarding its authority to regulate ear candles without taking further administrative action. To the contrary, it acknowledges that, for example, it may "only ban devices after going through a formal process that it has not undertaken here." FDA Br. 19-20 (citing 21 U.S.C. § 360f). Moreover, unlike EPA, which "gave no indication that [its position was] subject to further agency consideration or possible modification," *Ciba-Geigy*, 801 F.2d at 437, FDA advised the appellant manufacturers to submit further information, which it said it would "evaluate" and use to "decide whether [their] product[s] may be legally marketed," FDA Warning Letter (J.A. 43).

In support of their claim of finality, the appellants also point to language on FDA's website and to the March 2010 meeting in which agency officials allegedly stated that FDA would never approve ear candles. FDA's web page concerning ear candles lists a variety of actions taken by the agency in the past, including the issuance of warning letters, under a general heading entitled "[e]nforcement." *See* FDA Consumer Update, Don't Get Burned: Stay Away From Ear Candles (Feb. 18, 2010), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm200277.htm. Such a generic heading, however, is insufficient to transform advisory letters into final agency action.[7] Similarly, a "statement or advice given by an FDA

[7]It also "does not follow from the fact that [FDA] has brought administrative proceedings against other manufacturers that the agency will use its resources to proceed against" the appellants. *Reliable Automatic Sprinkler*, 324 F.3d at 733.

employee orally . . . is an informal communication that . . . does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed." 21 C.F.R. § 10.85(k); *see id.* § 10.65(a); *cf. AT&T*, 270 F.3d at 975 (noting that agency action is not final when the "agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party"). Moreover, FDA made clear in the March 2010 meeting, as it had in the warning letters, that it would await the appellants' responses before taking any final regulatory action. *See* Certification in Support of Compl. ¶ 4 ("[W]e look forward to your response[,] . . . and we will evaluate that response and make decisions."). In short, neither FDA's website nor the March 2010 meeting supplies the finality that the warning letters lack.

II

Because the February 2010 warning letters, even as supplemented by FDA's website and the appellants' conversations with FDA officials, do not constitute final agency action, the appellants' complaint is not cognizable under the APA and must be dismissed for failure to state a claim. The district court's order granting FDA's motion to dismiss is therefore

affirmed.