No. 11-1454

# In the Supreme Court of the United States

HOLISTIC CANDLERS AND CONSUMERS ASSOCIATION, ET AL., PETITIONERS

*v.*

FOOD AND DRUG ADMINISTRATION, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

**BRIEF FOR THE RESPONDENTS IN OPPOSITION**

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## QUESTION PRESENTED

Whether warning letters sent by the Food and Drug Administration—which identify possible violations of federal law and ask for corrective action from the recipients, but have no legal consequences—constitute "final agency action" subject to judicial review under the Administrative Procedure Act.

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### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 36-47) is reported at 664 F.3d 940. The opinion of the district court (Pet. App. 48-64) is reported at 770 F. Supp. 2d 156.

### JURISDICTION

The judgment of the court of appeals was entered on January 3, 2012. The petition for a writ of certiorari was filed on April 2, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

### STATEMENT

Petitioners sell or advocate the use of "ear candles" to treat a variety of ailments. Ear candles are hollow cones made from fabric soaked in beeswax or paraffin, which are placed into the ear and set on fire with an

open flame. The Food and Drug Administration (FDA) sent warning letters to five of the petitioners here, stating that, based on the information available to the agency, petitioners' products were medical devices subject to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, and that petitioners' products are adulterated and misbranded medical devices under the FDCA. The letters requested petitioners to take corrective measures and informed them that failure to do so could result in enforcement action by the agency. Dkt. 7 Ex. B (warning letters). Petitioners sued FDA under the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.*, raising constitutional and statutory challenges to the warning letters. The district court dismissed the complaint, Pet. App. 48-64, and the court of appeals affirmed, *id.* at 36-47, holding that petitioners lack a cause of action under the APA because the warning letters do not constitute final agency action.

1. a. The FDCA defines a medical "device" as

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> * * *
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon be-

> ing metabolized for the achievement of its primary intended purposes.

21 U.S.C. 321(h). Depending on a medical device's classification, the device's manufacturer may be required to notify FDA prior to introducing the device into interstate commerce, 21 U.S.C. 360(k), and may also be required to obtain FDA's approval of the device, 21 U.S.C. 360e. A failure to comply with those provisions renders the device, respectively, misbranded (21 U.S.C. 352(*o*)) or adulterated (21 U.S.C. 351(f)) in violation of the FDCA. A device is also misbranded in violation of the FDCA if, *inter alia*, the device's labeling is false or misleading (21 U.S.C. 352(a)), the device's labeling lacks adequate directions for safe use of the device (21 U.S.C. 352(f)(1)), or the device is dangerous to health when used in the manner directed in its labeling (21 U.S.C. 352(j)).

With respect to the classification of a device, and the resulting regulatory obligations of the device's manufacturer, the FDCA establishes three classes, based on the degree of regulation necessary to reasonably assure the safety and effectiveness of a device. See 21 U.S.C. 360c(a). Class I devices, which are subject to the least extensive regulation, are those for which the "general controls" provided by the FDCA are sufficient to provide a reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(A).[1] Class II devices are those for which general controls alone would be insufficient to as-

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[1] General controls include, *inter alia*, prohibitions on adulteration (21 U.S.C. 351) and misbranding (21 U.S.C. 352), as well as requirements that device manufacturers register with the FDA (21 U.S.C. 360) and maintain such records as the agency may require to assure a device's safety and effectiveness (21 U.S.C. 360i). See 21 U.S.C. 360c(a)(1)(A).

sure safety and effectiveness, but "special controls" in conjunction with the general controls would provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(B).[2] Many class I devices, and certain class II devices, are exempt from the notification provision of 21 U.S.C. 360(k). See 21 U.S.C. 360(*l*).

Class III devices are those that present a potentially unreasonable risk of illness or injury for which general controls and special controls are insufficient to provide reasonable assurance of the device's safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). Because of their risks, class III devices, unlike class I and II devices, generally must be approved by FDA before introduction into interstate commerce. See 21 U.S.C. 360c(a)(1)(C), 360e.

FDA must classify all medical devices that were in interstate commerce before the 1976 amendments to the FDCA regulating medical devices. See 21 U.S.C. 360c(a) and (b)(1). Devices first introduced into interstate commerce after the 1976 amendments, including those that are the same type as a pre-amendment device, are classified by statute as class III devices. See 21 U.S.C. 360c(f)(1)-(3). That classification stands unless FDA either (1) finds that the device is "substantially equivalent" to a pre-amendment device of the same type that has not yet been classified or that has been classified in class I or II, or (2) reclassifies (on its own motion or on a proper petition) the device into class I or II. *Ibid.*

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[2] Special controls include performance standards, postmarket surveillance, patient registries, guidelines, or other actions FDA determines are necessary to provide assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(B).

Of relevance here, FDA has not issued an order finding ear candles "substantially equivalent" to a legally marketed device. Nor has FDA reclassified ear candles as class I or II. Accordingly, ear candles first marketed after the 1976 amendments—including, it appears, those marketed by petitioners—are class III devices. See 21 U.S.C. 360c(f)(1)-(3).

b. If FDA believes that a person is violating the FDCA, the agency may issue a warning letter giving the person an opportunity to take voluntary corrective measures before the agency pursues enforcement action. Warning letters are "the agency's principal means of achieving prompt voluntary compliance with the [FDCA]." FDA, *Regulatory Procedures Manual*, 4-1-1 (July 2012), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf. A warning letter is "informal and advisory"; it "communicates the agency's position on a matter" but "does not commit FDA to taking enforcement action." *Ibid.*

2. On February 17, 2010, FDA issued warning letters to fifteen manufacturers and distributors of ear candles, including five of the petitioners here. The letters stated that petitioners' ear candles appeared to be "devices" under the FDCA. See Pet. App. 38-39; Dkt. 7 Ex. B (warning letters); see also 21 U.S.C. 321(h)(2) and (3). FDA notified the manufacturers that it considered their products to be adulterated and misbranded. Pet. App. 38. In particular, the letters advised, "[b]ased on the labeling * * * , it appears your ear candles are intended to mitigate [a variety of medical disorders]," yet "you have not obtained marketing approval or clearance before you began offering your product for sale." *Ibid.* (quoting Feb. 17, 2010, letter from FDA to petitioner

Harmony Cone). FDA further noted that it "ha[d] received medical device reports consistent with the danger to health posed by your device[s,] . . . including reports involving ruptured tympanic membranes and burns." *Id.* at 38-39.

The warning letters referred the manufacturers to FDA's website for information about how to obtain approval. Pet. App. 51. The letters further stated that the manufacturers "should take prompt action" to comply with the FDCA and "request[ed] that [the manufacturers] immediately cease marketing, promoting and distributing * * * ear candles," noting that failure to do so "may result in regulatory action being initiated by [FDA] without further notice." Dkt. 7 Ex. B at 3.[3] Finally, the letters asked each manufacturer to "[p]lease let [FDA] know in writing what steps [it] ha[s] taken" in response and to "explain how [the manufacturer] plan[ned] to prevent" future violations of the FDCA. *Ibid.* Although one petitioner provided a written response to FDA, no petitioner presented FDA with proposed labeling disclaimers or disclosures for FDA's evaluation. Pet. App. 51-52.

3. Petitioners sued FDA in district court under the APA, alleging that the warning letters violated the First, Ninth, Tenth, and Fourteenth Amendments to the Constitution, and seeking injunctive relief staying FDA's determination that petitioners' ear candles are unapproved medical devices and a declaration voiding FDA's determination. Pet. App. 48.

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[3] Petitioners inaccurately describe the letters as "instruct[ing]" the manufacturers, Pet. 11, in the form of "a cease and desist order," Pet. 18, to stop marketing, promoting, and distributing ear candles. The letters do not use that, or any other, commandatory language.

The APA authorizes judicial review only for "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. To satisfy the finality requirement of the APA, "the [administrative] action must mark the 'consummation' of the agency's decisionmaking process * * * [and] must not be of a merely tentative or interlocutory nature." *Bennett* v. *Spear*, 520 U.S. 154, 177-178 (1997) (citation omitted). Additionally, the action "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.* at 178 (citation omitted). A claim "is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas* v. *United States*, 523 U.S. 296, 300 (1998) (internal quotation marks and citation omitted).

Applying those principles, the district court dismissed petitioners' complaint on several alternative grounds. Pet. App. 48-64. As relevant here, the court concluded that petitioners' claims were not subject to review because the warning letters did not constitute final agency action. *Id.* at 57. The district court explained that the "text of the Warning Letters plainly contradicts [petitioners'] claim of finality" in that the letters are "not final demands, but rather intermediate requests for voluntary compliance." *Id.* at 57-58. The court added that this conclusion was confirmed by "FDA policy," which "is clear: Warning Letters are informal, advisory, and * * * [do] not commit FDA to taking enforcement action." *Id.* at 58.

4. The court of appeals affirmed. Pet. App. 36-47. The court of appeals agreed with the district court that the warning letters did not constitute final agency ac-

tion, and it therefore concluded petitioners had no cause of action under the APA. The court of appeals explained that "FDA's warning letters fail to satisfy either condition [of *Bennett's* two-part finality test]: they neither mark the consummation of the agency's decisionmaking process nor determine [petitioners'] legal rights or obligations." *Id.* at 42. The court emphasized the "informal and advisory" nature of the warning letters, as well as the fact that FDA had made clear "that it would await [petitioner's] responses before taking any final regulatory action." *Id.* at 43, 47.

**ARGUMENT**

The decision of the court of appeals that the warning letters are not final agency action subject to judicial review is correct and does not conflict with any decision of this Court or any other court of appeals. Further review is not warranted.

1. The court of appeals correctly held that FDA warning letters do not constitute final agency action and therefore are not subject to judicial review under the APA. The finality requirement in 5 U.S.C. 704 reflects the strong interest in postponing judicial review when an agency's position is, as here, still tentative. "Judicial review at that stage improperly intrudes into the agency's decisionmaking process," and it "squanders judicial resources since the challenging party still enjoys an opportunity to convince the agency to change its mind." *Ciba-Geigy Corp.* v. *EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986). Indeed, "[i]t conserves both judicial and administrative resources to allow the required agency deliberative process to take place before judicial review is undertaken." *Reliable Automatic Sprinkler Co.* v. *CPSC*, 324 F.3d 726, 733 (D.C. Cir. 2003).

In general, "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* v. *Spear*, 520 U.S. 154, 177-178 (1997) (citations omitted). The court of appeals correctly determined that FDA warning letters do not satisfy either condition.

In *Bennett*, this Court addressed a Fish and Wildlife Service biological opinion outlining for the Bureau of Reclamation measures that should be taken to avoid jeopardy to an endangered species. 520 U.S. at 158. The Court concluded that the biological opinion was final agency action because the Bureau had agreed to be bound by that opinion's directive in operating an irrigation project, see *id.* at 159, and because the opinion altered the legal regime by affecting when the Bureau could lawfully "take" an endangered species, *id.* at 178. As a result, the opinion letter had "direct and appreciable legal consequences" for those with interests in the project's water, and therefore constituted final agency action subject to judicial review under the APA. *Ibid.*

By contrast, the warning letters here did not mark the consummation of FDA's decisionmaking process. As FDA has explained, warning letters give "firms an opportunity to take voluntary and prompt corrective action before [FDA] initiates an enforcement action." *Regulatory Procedures Manual* 4-1-1. An enforce ment action—typically a seizure or an injunction—is not inevitable, and indeed, most warning letters do not result in enforcement action. See FDA, *Enforcement Statistics Summary Fiscal Year 2011* (report-

ing 1720 Warning Letters, but only 15 seizures and 16 injunctions), http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM285781.pdf. Violations identified in warning letters "*may* lead to enforcement action if not promptly and adequately corrected." *Regulatory Procedures Manual* 4-1-1 (emphasis added). Consistent with the *Regulatory Procedures Manual*, the warning letters at issue here stated that "FDA will evaluate the information you submit and decide whether your product may be legally marketed." Pet. App. 43 (quoting FDA warning letter) (emphasis and internal quotation marks omitted). Relatedly, the warning letters were not based on a formal and complete administrative record. At this stage, FDA's statement that petitioners violated the FDCA was not "final and binding" on the agency or petitioners but rather remained "tentative [and] interlocutory [in] nature." *Bennett*, 520 U.S. at 178.

Petitioners repeatedly refer (Pet. 11-12, 14, 20, 23, 24, 31, 32, 34) to oral statements by an FDA official—a deputy director of the Office of Compliance of FDA's Center for Devices and Radiological Health—made at a March 2010 meeting, as evidence of the finality of FDA's determination that the manufacturers' products are devices. Those statements are not final agency actions, most obviously because, as the court of appeals explained, a "statement or advice given by an FDA 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." Pet. App. 46-47 (quoting 21 C.F.R. 10.85(k)).

Nor did the warning letters finally determine the "rights or obligations" of petitioners with regard to the distribution of ear candles, or trigger "direct and appre-

ciable legal consequences." *Bennett*, 520 U.S. at 178. Rather, the letters "request[ed]" that petitioners "take prompt action to correct [the identified] deviations" from the FDCA, and cautioned that "[f]ailure to promptly correct these deviations may result in regulatory action." Pet. App. 39. The letters served only to communicate FDA's position with regard to ear candles, and to warn recipients about the possibility of future enforcement action. See *Regulatory Procedures Manual* 4-1-1. The letters nonetheless remained "informal and advisory" and "[did] not commit FDA to taking enforcement action." *Ibid.*

Nor do petitioners identify any consequence of the letters themselves—such as the effect on the Bureau of Reclamation's operations in *Bennett* or the potential for increased sanctions against the petitioner in *Sackett* v. *EPA*, 132 S. Ct. 1367, 1370, 1371, 1372 & n.2 (2012)—as distinguished from the fact that the letters articulate the agency's tentative view of the present state of affairs. Indeed, FDA made clear, both in the warning letters and at the March 2010 meeting, that it would await petitioners' responses before "evaluat[ing]" those responses and "mak[ing] decisions." Pet. App. 47.[4]

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[4] Petitioners also contend that the issues they raise are ripe for review See Pet. 15-26 (citing, *inter alia*, *Abbott Labs.* v. *Gardner*, 387 U.S. 136 (1967)). The court of appeals explained that its conclusion that the warning letters do not constitute final agency action reviewable under the APA made it unnecessary for it to consider whether the case was ripe for judicial review. Pet. App. 42 n.4. In any event, under *Abbott Laboratories*, 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." 387 U.S. at 149. As the court of appeals noted, an issue is not "fit if it does not involve final agency action." Pet. App. 42 n.4.

2. Petitioners do not contend that the decision below conflicts with the decision of any other court of appeals. The D.C. Circuit itself has consistently held that agency letters similar to FDA warning letters do not represent final agency action subject to judicial review. See Pet. App. 44-45; see also *Independent Equip. Dealers Ass'n* v. *EPA*, 372 F.3d 420, 427 (2004) (Roberts, J.); *Reliable Automatic Sprinkler*, 324 F.3d at 732; *AT&T* v. *EEOC*, 270 F.3d 973, 975 (2001); *American Fed'n of Gov't Emps.* v. *O'Connor*, 747 F.2d 748, 752-753 (1984), cert. denied, 474 U.S. 909 (1985).

Other circuits have likewise held that FDA warning letters are not subject to judicial review. See, *e.g.*, *Cody Labs., Inc.* v. *Sebelius*, 446 Fed. Appx. 964, 969 (10th Cir. 2011) ("[E]very court to consider the question has held that an FDA warning letter does not constitute 'final agency action.'"); *Dietary Supplemental Coal., Inc.* v. *Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) ("We have held that [FDA] regulatory letters do not constitute final agency action.") (citing *Biotics Research Corp.* v. *Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983)), cert. denied, 508 U.S. 906 (1993).

3. Petitioners contend that the decision below conflicts with this Court's recent decision in *Sackett*, *supra*. That case involved an Environmental Protection Agency (EPA) compliance order issued pursuant to the Clean Water Act (CWA). The CWA prohibits "the discharge of any pollutant by any person" into "navigable waters" without a permit. 33 U.S.C. 1311, 1344. If EPA determines that a person has violated that restriction, EPA may either issue a compliance order requiring the person to comply with the restriction, or it may initiate a civil enforcement action. 33 U.S.C. 1319(a)(3). The resulting civil penalty may not "exceed [$37,500] per day

for each violation," 33 U.S.C. 1319(d), but "when the EPA prevails against any person who has been issued a compliance order but has failed to comply, that amount is increased up to $75,000—up to $37,500 for the statutory violation and up to an additional $37,500 for violating the compliance order." *Sackett*, 132 S. Ct. at 1370. In *Sackett* itself, EPA had issued a compliance order finding that the Sacketts' residential lot contained navigable waters, concluding that the Sacketts had violated the CWA by placing fill material on the property, and directing the Sacketts immediately to restore the property pursuant to an EPA plan. *Id.* at 1370-1371. When the Sacketts requested a formal hearing to challenge the order, EPA denied their request. *Id.* at 1371.

This Court held that EPA's compliance order constituted final agency action and that the Sacketts could obtain immediate judicial review of it. The Court determined that the compliance order had "all of the hallmarks of APA finality" because it determined the Sacketts' rights and obligations "to 'restore' their property according to an agency-approved Restoration Work Plan, and [to] give the EPA access to their property." *Sackett*, 132 S. Ct. at 1371-1372. Moreover, legal consequences "flow[ed] from" the issuance of the order because it "expose[d] the Sacketts to double penalties in a future enforcement proceeding," and the order "mark[ed] the 'consummation' of the agency's decisionmaking process" inasmuch as the "Findings and Conclusions" contained in the compliance order "were not subject to further agency review." *Ibid.* (citing *Bennett*, 520 U.S. at 178) (internal quotation marks omitted).

Petitioners argue that the EPA compliance order in *Sackett* is "strikingly similar to the warning letters of [FDA] in this case." Pet. 16. That is incorrect. Contra-

ry to petitioners' assertion (see Pet. 18), FDA warning letters do not manifest the same "hallmarks of APA finality," 132 S. Ct. at 1371, as the EPA compliance order in *Sackett*. Unlike that order, FDA warning letters trigger no legal consequences and are subject to further agency "evaluat[ion]" based on the recipient's response. See Pet. App. 47. Such letters do not trigger any enlarged exposure to penalties for noncompliance with the FDCA, nor does their issuance preclude further agency consideration or review. Rather, the letters state FDA's position on the facts available to it, encourage voluntary compliance with the FDCA, and alert the recipient of possible enforcement action by the FDA. If and when an enforcement action is brought, the agency's claim is not that the recipient has "violated" the warning letter, but rather that it has violated the underlying requirements of the FDCA.

In a further contrast to *Sackett*, where the petitioners' request for a hearing was denied, see 132 S. Ct. at 1371, petitioners here could have pursued formal administrative avenues that could have prompted final agency action for purposes of judicial review (subject, of course, to other doctrines that might preclude judicial review in a particular case). In particular, petitioners could have challenged FDA's view that ear candles are medical devices by filing a citizen petition under 21 C.F.R. 10.30, or petitioners could have presented proposed labeling to FDA with disclaimers and disclosures for their products, as FDA suggested in its warning letters. But aside from one petitioner's submission of a procedurally defective and abandoned citizen petition, see Dkt. 10 at 7 n.6, petitioners took no such steps.

**CONCLUSION**

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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