United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 7, 2015 Decided January 15, 2016

No. 14-5226

R. J. REYNOLDS TOBACCO COMPANY, ET AL.,
APPELLEES

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
APPELLANTS

Appeal from the United States District Court
for the District of Columbia
(No. 1:11-cv-00440)

Mark B. Stern, Attorney, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were *Benjamin C. Mizer*, Acting Assistant Attorney General, *Ronald C. Machen, Jr.*, U.S. Attorney at the time the brief was filed, and *Alisa B. Klein* and *Patrick G. Nemeroff*, Attorneys.

Carlos T. Angulo, Andrew N. Goldfarb, Hope M. Babcock, and *Mark Greenwold* were on the brief for *amici curiae* Public Health Groups in support of appellants.

Richard M. Cooper argued the cause for appellees. With him on the brief were *Peter J. Anthony* and *Alan Mansfield*. *Laura M. Klaus* entered an appearance.

William G. Kelly, Jr. was on the brief for *amicus curiae* Center for Regulatory Effectiveness in support of appellees.

Richard A. Samp was on the brief for *amicus curiae* Washington Legal Foundation in support of appellees.

Before: MILLETT and PILLARD, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* WILLIAMS.

WILLIAMS, *Senior Circuit Judge*: With the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, § 101 (2009), Congress directed the Food and Drug Administration to establish a twelve-member Tobacco Products Scientific Advisory Committee, the duties of which included reporting on the safety of menthol cigarettes. 21 U.S.C. §§ 387g(e), 387q.[1] The Committee has now reported. While the FDA has issued a notice proposing adoption of special rules for such cigarettes, see Menthol in Cigarettes, Tobacco Products; Request for Comments, 78 Fed. Reg. 44,484 (July 24, 2013), it has not adopted a final rule. The

[1] Although the enabling statute (cited in the text below) grants the relevant authority to the Secretary of Health and Human Services, see 46 Fed. Reg. 26,052-01 (May 11, 1981); FDA Staff Manual Guide 1410.10 (May 18, 2005), the custom followed generally and in the briefs before us is to refer to the FDA where (as here) it is the acting component of that Department. See, e.g., 1 Food and Drug Administration § 4:15 (4th ed. 2015) (describing management review process for FDA rules).

plaintiffs, producers of menthol tobacco products or affiliates of such producers, claim that the FDA appointed to the Committee three members with pecuniary interests hostile to their products, in violation of relevant conflict-of-interests statutes and regulations, and that these appointments injured the plaintiffs.

Exact identification of the plaintiffs is complicated but largely irrelevant. R.J. Reynolds Tobacco Company and Lorillard Tobacco Company, together with Lorillard's parent, brought suit initially. They are now all wholly owned subsidiaries of Reynolds's parent, R. J. Reynolds Tobacco Holdings, Inc. We refer to the plaintiffs simply as plaintiffs except in describing events related only to a specific pre-merger company.

Plaintiffs allege, and in summary judgment proceedings the district court found, that three of the twelve members appointed to the Committee had unlawful conflicts of interest and that the FDA improperly failed to exclude those members or to grant conflict-of-interest waivers for them. (As we understand plaintiffs' position, they believe that a grant of waivers would have manifested acknowledgement of the conflicts of interest and thus adequately palliated their injuries. Oral Arg. Tr. at 39-40 ("[I]f they did a waiver we'd have to come up with a claim, and I don't know that we could.")) All three of the challenged members have testified in lawsuits against tobacco-product manufacturers and had pending engagements to appear as expert witnesses in future suits; two of the three had hundreds of such engagements. Their individual billings for testimony have ranged as high as $50-60,000 per case. All three have also had financial relationships with pharmaceutical companies that manufacture smoking cessation products, which compete with tobacco products.

Plaintiffs claim that the FDA's appointments of these Committee members caused them three injuries: (1) an increased risk that the FDA will regulate menthol tobacco products adversely to plaintiffs' interests; (2) access by the challenged Committee members to plaintiffs' confidential information, with a probability of their using the information to plaintiffs' detriment; and (3) the shaping of the menthol report to support the challenged members' consulting and expert witness businesses, with injuries flowing both from the report itself and from its use as support for their expert testimony and consulting. (Before the district court, plaintiff Lorillard also argued that it had been injured by a decline in its stock price, but the merged firm dropped that claim, and we do not consider it. Oral Arg. Tr. at 32.)

The district court granted summary judgment for plaintiffs and issued an order dissolving the Committee and enjoining use of the Committee's menthol report. *Lorillard, Inc. v. FDA*, 56 F. Supp. 3d 37, 56-57 (D.D.C. 2014).

We review the district court's grant of summary judgment *de novo*. *Citizens for Responsibility & Ethics in Washington v. FEC*, 711 F.3d 180, 184 (D.C. Cir. 2013). We address first—and as it proves last—the government's defense that plaintiffs lack standing. Under the familiar threefold inquiry, plaintiffs must show an injury-in-fact that is "actual or imminent, not conjectural or hypothetical," and must show causation and redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (internal citations and quotation marks omitted). At summary judgment, plaintiffs cannot rest on "'mere allegations' but must 'set forth' by affidavit or other evidence 'specific facts.'" *Id.* at 561 (quoting FED. R. CIV. P. 56(e)).

Addressing the three alleged injuries in the order already presented, we conclude that all three are too remote and uncertain, or, to put the same thing another way, insufficiently

imminent. We therefore vacate the district court's grant of summary judgment.

* * *

Risk of future FDA action. Since the FDA has not yet issued a rule, Lorillard's prospective injury from that rule remains remote. We assume without deciding that the appointment of the challenged Committee members without following statutorily mandatory conflict-of-interest waiver procedures violated a procedural right intended "to protect [plaintiffs'] concrete interests." *Lujan*, 504 U.S. at 572 n.7. A plaintiff who challenges the violation of such a right can establish standing "even though he cannot establish with any certainty that [provision of the right] will cause the [agency action] to be withheld or altered." *Id*. Although the Court did not explain the relaxation of the causation element, a failure to relax it would probably, because of the uncertain relationship between a procedural opportunity and success on the merits, eviscerate judicial enforcement of procedural mandates. In any event, despite this relaxation, the plaintiff must still demonstrate "a distinct risk to a particularized interest." *Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996) (en banc).

Although the government raised a standing and not a ripeness defense, we nonetheless treat ripeness cases as pertinent to whether the risk of injury is imminent enough. Both doctrines address the imminence issue, using the same focus on contingencies that may render the risk of harm too slight. (This is of course not to suggest that the doctrines are twins. Both have many distinctive facets, some even bearing on imminence of harm.) A claim is not adequately "ripe for adjudication," the Supreme Court has said, "if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. U.S.*, 523 U.S. 296,

300 (1998) (citations and internal quotation marks omitted). We applied this aspect of ripeness doctrine in, for example, *Atlantic States Legal Foundation v. EPA*, 325 F.3d 281, 284-85 (D.C. Cir. 2003), declining to hear a challenge to federal regulations that could adversely affect petitioners only after New York State adopted them through further notice-and-comment rulemaking. And very similar uncertainties led us to find a want of standing in *Occidental Permian Ltd. v. FERC*, 673 F.3d 1024, 1026 (D.C. Cir. 2012), where a petitioner challenged FERC's grant of authority to negotiate rates for services of an as-yet unfinished interconnection facility; uncertainties relating (for example) to whether the potentially connecting transmission lines would ever be authorized and built made the injury too remote. Compare *Chlorine Inst., Inc. v. Fed. R.R. Admin.*, 718 F.3d 922, 928-29 (D.C. Cir. 2013), where like uncertainties defeated ripeness. On the overlap of the doctrines, see generally *Louisiana Environmental Action Network v. Browner*, 87 F.3d 1379, 1383-84 (D.C. Cir. 1996).

Here, the appointment of the challenged committee members by no means rendered the risk of eventual adverse FDA action substantially probable or imminent. It remains unclear whether the FDA will issue a final rule, and what it would say. In particular, in any such rulemaking, the extent to which the FDA would be persuaded by the content of the Committee's report is quite speculative. The FDA need only "consider[]" the Committee's report, 21 U.S.C. § 387g(d)(1), along with the comments of persons responding to its notice of proposed rulemaking, *id*. § 387g(c), which of course the Administrative Procedure Act requires it to "consider[]," 5 U.S.C. § 553(c). And it is to adopt the proposed standard only if it finds, after "consider[ing] scientific evidence" on a range of issues, 21 U.S.C. § 387g(a)(3)(B)(i), that it "would be appropriate for the protection of the public health." 21 U.S.C. § 387g(d)(1)(A). If the report influences a proposed

rule to plaintiffs' detriment in the way they anticipate, they will have an opportunity to raise concerns about the report's scientific claims, including assertions of bias. Review of any claims that the (still hypothetical) rule was in excess of statutory authority or arbitrary and capricious would proceed along conventional lines. Even if we were to assume arguendo that the FDA's selection of these committee members materially increased the risk of its adoption of a rule more adverse to plaintiffs than the rule it might otherwise have adopted (or no rule at all), that would still fall short of saying that the selection rendered adoption of a more adverse rule imminent. For similar reasons, we held that plaintiffs in *Metcalf v. National Petroleum Council*, 553 F.2d 176, 184, 188 (D.C. Cir. 1977), lacked standing to challenge the composition of an advisory committee where, among other things, there was "no allegation that [the agency] took action based on" one of the committee's recommendations. Ripeness concerns underscore this point: part of the reason the injury is too remote is that, if the FDA chooses not to issue a rule, this case "may not require adjudication at all." *Friends of Keeseville, Inc. v. FERC*, 859 F.2d 230, 235 (D.C. Cir. 1988).

Plaintiffs cite our decision in *Wyoming Outdoor Council v. U.S. Forest Service*, 165 F.3d 43 (D.C. Cir. 1999), for its recognition of the general proposition that the constitutional minima of standing are somewhat relaxed when applied to procedural violations, Appellee Br. 29, a point we noted in some detail above. *Wyoming Outdoor Council* is in fact somewhat unusual in finding standing where the ultimate agency action threatening harm to plaintiffs—there, issuance of oil and gas leases—had not occurred when they brought suit. Although the lack of final leases obviously left uncertainty, we found that the Forest Service's failure to make each of the required predicate findings put plaintiffs' environmental interests "in genuine danger." *Id.* at 51.

Crucially, however, leases had been *issued* by the time of decision, *id*. at 47, and, unlike the situation as to NEPA claims in the case, the record on the issue was complete, *id*. See also *Center for Biological Diversity v. U.S. Dep't of the Interior*, 563 F.3d 466, 473, 479 (D.C. Cir. 2009) (finding standing to challenge violation of certain procedural prerequisites to approval of a leasing *program*, even though leases had not been issued). Neither of these cases is brought into play here, and accordingly we find the alleged increased risk of an FDA rule on menthol cigarettes too uncertain for standing.

Confidential information. Plaintiffs assert that they have been injured by the challenged Committee members' access to confidential information, which they could disclose to plaintiffs' competitors or could use in their expert witness work. Yet plaintiffs have not set forth by affidavit or other evidence specific facts suggesting that the challenged members have made or will make improper use of confidential information. They have only presented evidence that the Committee members received such information in the course of their time on the Committee—not that they used it the way plaintiffs fear. See, e.g., Mem. in Supp. of Defendants' Motion for Summary Judgment 11 n.5 (Doc. 65 June 21, 2013) (acknowledging that confidential information was presented to the Menthol Report writing group, of which Drs. Benowitz and Samet were members, J.A. 2436); J.A. 2545-85 (a draft chapter of the subcommittee report showing Dr. Henningfield's tracked changes and (through redactions) the presence of confidential information in the report at J.A. 2554).

There is considerable reason to believe that the challenged members will *not* disclose such information. Disclosure would subject them to criminal and civil penalties. See 18 U.S.C. § 1905 (prescribing fines and imprisonment of

up to a year); 5 C.F.R. § 2635.801(d) (incorporating 18 U.S.C. § 1905 by reference to Subpart I of the regulation; see 5 C.F.R. § 2635.902(aa)). We have rejected assertions of imminent injury where the prospective injury depends on future illegal activity, finding, for example, that a sheriff lacked standing to challenge President Obama's immigration policy partly because the plaintiff's theory depended on immigrants' committing crimes in the future. *Arpaio v. Obama*, 797 F.3d 11, 22 (D.C. Cir. 2015). More generally, we are relatively hesitant to find standing when the asserted injury "depends on the unfettered choices made by independent actors not before the courts." *Lujan*, 504 U.S. at 562 (citation and internal quotation marks omitted). Plaintiffs have not presented evidence—or at least evidence sufficient to support summary judgment—that the challenged members' access to confidential information poses an imminent risk of injury.

Shaping of the Menthol Report. Plaintiffs' evidence that they have been injured by any shaping of the report by the challenged Committee members to support their expert testimony is similarly weak. Although they note hundreds of pending tobacco cases in which the challenged Committee members are identified as prospective witnesses, Appellee Br. 6-7; J.A. 273, 278-79, they have presented no evidence on how many of the cases concern menthol tobacco products. They cite only a handful of mentions of the menthol report in challenged members' testimony and are only able to point to two cases that involved a menthol smoker. Appellee Supp. Br. 5. Moreover, their examples of such testimony do not support their contention that the shaping of the report caused any injury. For example, Dr. Henningfield, one of the challenged Committee members, mentioned the report when deposed in a case against (pre-merger) R.J. Reynolds (J.A. 2460-61), but he said that "[m]y testimony on menthol would not be different than it has been in earlier cases when menthol

has come up." J.A. 2460. Plaintiffs have not sought to refute this. Henningfield described his testimony as consistent with the report, but did not rely on it to bolster his credibility, and in fact suggested that its findings on how menthol influences the transition from use to dependence were not relevant to the plaintiff in that case, as he had allegedly become addicted to cigarettes before he started smoking menthols. J.A. 2461. Plaintiffs have also presented no facts supporting their contention that the challenged members *shaped* the report to support their testimony, or used the report's concurrence in their views to validate those views. Of course plaintiffs can press their objections to the report during cross-examination of the expert witnesses in pending cases.

Finally, the challenged members' opportunity to shape the menthol report to characterize menthol tobacco products as unsafe did not give rise to an imminent reputational injury. Plaintiffs' reliance on *Meese v. Keene*, 481 U.S. 465, 473-76 (1987), is misplaced. There a congressional statute identified certain foreign films as "political propaganda," and the Court found standing for a politician who wanted to show the films but claimed that doing so, in the face of the congressional characterization, would damage his professional reputation and impair his chances of securing reelection to the California State Senate. He backed the claim up with powerful supportive polling data. *Id.* at 472-75 & 473-74 n.7. Plaintiffs offer no comparable evidence that the Committee's report is likely to inflict such an injury on their reputations.

* * *

In sum, plaintiffs have not demonstrated that any of their three injuries is sufficiently imminent to confer standing. We therefore vacate the judgment of the district court for lack of jurisdiction and dissolve its injunction barring the use of the

menthol report and ordering the reconstitution of the Committee.

So ordered.