No. 15-5037

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

FOOD & WATER WATCH, INC., et al.,

Plaintiffs-Appellants,

v.

THOMAS J. VILSACK, SECRETARY OF AGRICULTURE, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia

RESPONSE IN OPPOSITION TO PETITION FOR REHEARING EN BANC

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General

CHANNING D. PHILLIPS
United States Attorney

MARK B. STERN
DANIEL TENNY
(202) 514-1838
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Room 7215
Washington, D.C. 20530

INTRODUCTION AND SUMMARY

This case involves a challenge to the U.S. Department of Agriculture's regulation that gives poultry slaughter establishments the option of being inspected under a new inspection system. Under the new system, employees of the slaughter establishment take on responsibility for sorting poultry (a task previously performed by federal inspectors), and thus allow federal inspectors to focus their attention on other tasks that have proven to be more effective in ensuring food safety. Analysis of data from a pilot program indicated that the new inspection system would ensure an equivalent, if not better, level of food safety than the pre-existing poultry inspection systems.

Plaintiffs disagree with the agency's analysis and assert that the new inspection system will cause poultry to be less safe. A panel of this Court held that the complaint contained insufficient allegations that the new system caused a substantial increase in the likelihood that plaintiffs would be harmed by unsafe poultry, and therefore concluded that the complaint was properly dismissed on standing grounds.

The panel's analysis was correct. The decision applied settled law to the facts of this case, and the panel's ruling presents no issue of exceptional importance warranting review by the full Court.

STATEMENT

1. Under the Poultry Products Inspection Act, 21 U.S.C. §§ 451-472, the Food Safety and Inspection Service (FSIS) places federal inspectors in poultry slaughter

establishments to ensure that poultry products are "wholesome, not adulterated, and properly marked, labeled, and packaged." *Id.* § 451. This case concerns a new inspection system that "alters the responsibilities of the FSIS inspectors and the establishment personnel." Op. 5. Under the pre-existing poultry inspection systems, federal officials were responsible for all sorting of poultry, while under the new system, "poultry establishment personnel sort the poultry carcasses and take corrective action prior to an FSIS inspection." *Id.* The new system frees federal inspectors to perform more "offline" inspection activities, in which "inspectors ensure compliance with food safety regulations, verify sanitation procedures, and collect samples for pathogen testing." *Id.* at 4.

Analysis of data from a pilot program revealed that the new inspection system "improved performance related to food safety and non-food-safety standards . . . especially in reducing pathogen levels." Op. 6 (omission in original) (quoting Proposed Rule, 77 Fed. Reg. 4408, 4421 (Jan. 27, 2012)). After performing that analysis, the agency engaged in notice-and-comment rulemaking and ultimately adopted the regulation at issue here, which gives poultry slaughter establishments the option of switching to the new inspection system (with some modifications from the version used in the pilot program). *Id.* at 7; *see* Final Rule, 79 Fed. Reg. 49,566 (Aug. 21, 2014).

2. Plaintiffs filed this lawsuit, challenging the regulation that made the new inspection system available to poultry slaughter establishments. As relevant here,

plaintiffs assert that they have standing because the individual plaintiffs, and members of the plaintiff organization, are consumers of poultry products whose health and safety will be adversely affected by the rule.

Plaintiffs moved for a preliminary injunction. After reviewing the parties' preliminary-injunction papers and conducting a hearing, the district court concluded that plaintiffs lacked standing, and dismissed the case. The court concluded that plaintiffs had not made a sufficient showing that the new "rules actually will generate any more adulterated poultry." Mem. Op. 24 [JA 595]. The court rejected as "anecdotes and speculation" plaintiffs' assertions that poultry-plant employees would not have adequate training or incentive to sort carcasses properly. *Id.* at 25-26 [JA 596-97]. And the court noted that plaintiffs "have failed to point to any scientific evidence demonstrating that the [new] rules are even incrementally more likely to produce adulterated poultry products." *Id.* at 29-30 [JA 600-01]. The district court further concluded that even if there were an increased risk that adulterated poultry products would enter the marketplace, the individual plaintiffs had not demonstrated that they would consume such adulterated poultry. *Id.* at 32-33 [JA 603-04].

3. This Court affirmed the district court's judgment. Noting that the district court had erroneously applied the summary-judgment standard in assessing whether to dismiss the case, the panel instead applied "the standard applicable pursuant to Federal Rule of Civil Procedure 12(b)(1)." Op. 10.

Turning to the substance of the standing question, the panel noted that this Court "has limited its jurisdiction over cases alleging the possibility of increased-risk-of-harm to those where the plaintiff can show '*both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account.'" Op. 12 (quoting *Public Citizen, Inc. v. National Highway Traffic Safety Admin*, 489 F.3d 1279, 1295 (D.C. Cir. 2007)) (emphasis in *Public Citizen*). The Court observed that it must be "mindful . . . that the constitutional requirement of imminence . . . necessarily compels a very strict understanding of what increases in risk and overall risk levels can count as 'substantial.'" *Id.* at 13 (omissions in original) (quoting *Public Citizen*, 489 F.3d at 1296).

The panel concluded that the plaintiffs' "complaint, as well as their various submissions in support of their motion for preliminary injunction, fails to plausibly allege that the [new poultry inspection system] taken as a whole substantially increases the risk of foodborne illness as a result of unwholesome, adulterated poultry." Op. 14. The panel noted that plaintiffs had provided "detailed allegations about how [the new system] differs from the existing poultry inspection systems," had provided descriptions of what the plaintiffs argued were "inadequacies," and had made allegations that the agency's analyses were flawed. *Id.* The Court explained, however, that "these differences and perceived flaws do not demonstrate a substantial increase in the risk of foodborne illness." *Id.* The overriding defect in plaintiffs' allegations was that plaintiffs had "focus[ed] on certain discrete aspects" of the new system that

they regarded as problematic, while making "no allegation regarding the impact of increased offline verification inspectors on the presence of adulterated, unwholesome poultry." *Id.* at 15. "Plaintiffs' failure to account for the increase in offline inspections and their attendant impact on poultry production," the panel reasoned, "prevents us from inferring that the [new system] as a whole substantially increases the risk of foodborne illness." *Id.*

Plaintiffs' anecdotal evidence "suffer[ed] from the same defect." Op. 16. Although plaintiffs submitted sworn affidavits that described in "great detail . . . the differences between the [new system] and existing poultry inspection systems," these allegations did "not allege that the risk of unwholesome, adulterated poultry is higher under the [new system] as a whole than the existing inspection systems." *Id.* at 16-17.

The panel observed that "[p]laintiffs could perhaps overcome this deficiency" if they could "plausibly allege through their use of statistics that [the new system] creates a substantial increase in the risk of foodborne illness." Op. 17. The panel noted, however, that this Court had, "in the past, refused to require a quantitative analysis in order to establish standing in increased-risk-of-harm cases," and the panel "likewise refuse[d] to hold that statistics are required for such cases." *Id.* at 18.

The panel held that plaintiffs' statistical submissions were inadequate. Plaintiffs focused their analysis on two pathogens, *Salmonella* and *Campylobacter*. Although "[p]laintiffs point[ed] to isolated statistics where [the government] found *Salmonella* rates to be 'higher' in chicken processed" in plants under the pilot program that

formed the basis for the new regulation, "the complaint does not specify how much higher the rates were." Op. 17-18. And although "selections from [a government] report . . . found under some scenarios, 'a 0.2% increase in the proportion of samples testing *Campylobacter* positive,'" the Court noted that "the same page of this report concluded that under most projected scenarios, the samples testing positive for *Salmonella* or *Campylobacter* would decrease." *Id.* at 18. And the government's "risk assessment concluded under most scenarios that annual illnesses from *Salmonella* and *Campylobacter* would remain unchanged or would decrease" under the new inspection system. *Id.* In light of these data, which are at best conflicting, "[e]ven plaintiffs' complaint acknowledges that the risk of *Campylobacter* increase is 'ambiguous.'" *Id.* (quoting Compl. ¶ 180 [JA 39]). This panel observed that "[a]n ambiguous increase in risk is hardly a substantial increase in risk." *Id.*

The panel also identified "additional problems" with plaintiffs' discussion of statistics: plaintiffs failed to account for changes to the inspection system in the final rule, and "fail[ed] to account for how increased allocations in offline inspections would impact the risk." Op. 18. "In this context," the Court concluded that "[p]laintiffs' statistics do not plausibly allege that [the new inspection system] as a whole substantially increases the risk that poultry will be contaminated with *Salmonella* or *Campylobacter* compared to the existing inspection systems." *Id.* at 18-19.

The panel explained that the plaintiffs' "avoidance" of poultry from the new system, "or alternatively the increased cost of seeking out poultry from other

sources," did not "constitute[] an injury in fact to establish standing." Op. 20. It noted the Supreme Court's observation in *Clapper v. Amnesty International USA*, 133 S. Ct. 1138 (2013), that plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." Op. 21 (quoting *Clapper*, 133 S. Ct. at 1151). That principle precluded the plaintiffs from relying on "self-inflicted injuries." *Id.* (quoting *Clapper*, 133 S. Ct. at 1152).

The panel also held that the organizational plaintiff lacked standing "to pursue its claims on its own behalf," Op. 21, and that plaintiffs did not have standing based on a procedural injury, *id.* at 25. Plaintiffs do not challenge those rulings here.

Concurring in the judgment, Judge Henderson stated that the Court "need not assess whether [plaintiffs] face a '*substantially* increased risk of harm and . . . *substantial* probability of harm.'" Henderson Op. 1 (quoting *Public Citizen*, 489 F.3d at 1295) (omission in original) (emphasis in *Public Citizen*). Judge Henderson stated that plaintiffs' "declarations make clear" that "they have the alternative of consuming [poultry inspected under the old system]—*e.g.*, by purchasing poultry from a farmers' market—and they have failed to allege that the alternative is '*not readily available at a reasonable price*.'" *Id.* (quoting *Coalition for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1281 (D.C. Cir. 2012)) (emphasis in *Coalition for Mercury-Free Drugs*).

Judge Millett issued a concurring opinion, which "join[ed] Judge Wilkins' opinion for the Court in full" and made one additional point about organizational standing (which, as noted above, is not raised here). Millett Op. 1.

ARGUMENT

The panel properly applied this Court's precedents regarding standing and pleading requirements. Plaintiffs' quarrel with the panel's application of settled law to the facts of this case is without merit, and in any event presents no issue of exceptional importance that would warrant review by the full Court.

1. Plaintiffs assert that they suffer injury-in-fact because the existence of a new poultry inspection system subjects plaintiffs to an increased risk of consuming unsafe poultry. Where, as here, "the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily substantially more difficult to establish." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992)) (quotation marks in *Defenders of Wildlife* omitted). This Court has accordingly held that a plaintiff asserting that an injury arises from inadequacy of a safety regulation must show "*both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account." *Public Citizen, Inc. v. National Highway Traffic Safety Admin.*, 489 F.3d 1279, 1295 (D.C. Cir. 2007) (emphasis in original).

In this case, any assertion that the availability of a new poultry inspection system causes plaintiffs injury would have to depend on a comparison of the safety of

poultry under the old system with the safety of poultry under the new system. The panel properly concluded that plaintiffs had "fail[ed] to allege that the [new system] as a whole will produce significantly more adulterated, unwholesome chicken compared to the existing inspection systems." Op. 14-15.

In reaching this conclusion, the panel carefully considered plaintiffs' factual submissions. The panel noted that plaintiffs' non-statistical allegations and evidence "focus[ed] on certain discrete aspects" of the new system without addressing other aspects of the system with countervailing effects. Op. 15. These allegations could not support an inference regarding the effects of the new system as a whole. *Id.*

As the panel recognized, although plaintiffs cited "isolated statistics" from government studies, they made no effort to establish that any of their hand-picked data points have statistical relevance. *See* Op. 17-18. In their petition, plaintiffs still fail to come to grips with the fact that the studies from which their data are drawn concluded that "under most projected scenarios, the samples testing positive for *Salmonella* or *Campylobacter* would decrease." *Id.* at 18. Rather than asserting that a valid statistical analysis would reach the opposite conclusion, plaintiffs continue to rely on simplistic calculations (including some new calculations performed for purposes of the rehearing petition, *see* Lovera Decl.), without asserting that they have properly controlled for variables that might have affected the results or asserting that statistical tests establish that the results are meaningful.

Plaintiffs fare no better in asserting that the panel erroneously failed "to presume that Plaintiffs will prevail on the merits of their claims when assessing standing." Pet. 5. Courts must presume that the plaintiff will succeed on the merits in the sense that a court cannot premise a lack of standing on a presumption that the party ultimately will not be entitled to relief. *See Public Citizen v. FTC*, 869 F.2d 1541, 1549 (D.C. Cir. 1989) ("[W]e cannot assume at the threshold that the FTC will prevail on the merits in order to close the courthouse door to all potential litigants."). And plaintiffs who establish that they will be subjected to a challenged policy cannot be prevented from asserting their claim on the ground that the policy is lawful and thus causes no injury. *See, e.g.*, *In re Navy Chaplaincy*, 697 F.3d 1171, 1178 (D.C. Cir. 2012). But where, as here, plaintiffs are not themselves subject to regulation, they cannot simply presume that changes to the regulatory system will injure them. Instead, they must demonstrate that the changes cause a substantial increase in their risk of injury. Otherwise, any plaintiff alleging that a regulation did not satisfy statutory requirements would have standing. *See Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002) ("Bare allegations are insufficient . . . to establish a petitioner's standing to seek judicial review of administrative action.").

Plaintiffs point to no court that has adopted their preferred approach, which would be fundamentally incompatible with the requirement that plaintiffs demonstrate injury-in-fact. Instead, they rely on cases that gave weight to congressional judgments about the importance of certain types of risks. *See Kerin v.*

Titeflex Corp., 770 F.3d 978, 982 (1st Cir. 2014); *Central Delta Water Agency v. United States*, 306 F.3d 938, 948 (9th Cir. 2002); *Baur v. Veneman*, 352 F.3d 625, 634 (2d Cir. 2003). This case does not turn on whether an increased risk of consuming adulterated poultry would be an injury-in-fact, but rather on whether the regulations caused a substantial increase in the risk of consuming adulterated poultry. Far from dispensing with this requirement, the cases on which plaintiffs rely incorporate it. *See Kerin*, 770 F.3d at 982 (recognizing that "injury may still be speculative"); *Central Delta Water Agency*, 306 F.3d at 948 (requiring "showing . . . that plaintiffs face significant risk that the crops that they have planted will not survive as a result of the Bureau's decisions to discharge water"); *Baur*, 352 F.3d at 636 (2d Cir. 2003) ("Although we conclude that Baur has asserted a type of injury . . . that is cognizable under Article III, . . . Baur must allege that he faces a direct risk of harm which rises above mere conjecture."); *Sierra Club v. U.S. EPA*, 793 F.3d 656, 664 (6th Cir. 2015) ("standing . . . turns on what reasonable inferences we can draw about redesignation's impact on [fine particulate matter]").

2. Plaintiffs argue, in the alternative, that the case should have been remanded to the district court. Pet. 13-14. Plaintiffs' assertion that they are entitled to have the district court analyze the case under the appropriate standard ignores this Court's well-established authority to "affirm on any ground properly raised." *EEOC v. Aramark Corp.*, 208 F.3d 266, 268 (D.C. Cir. 2000). Here, the panel applied the appropriate standard, on de novo review, and no remand was necessary.

Plaintiffs do not advance their argument by citing cases stating that dismissal on alternate grounds is inappropriate if plaintiffs have not had a full and fair opportunity to litigate. *See Heirs of Fruge v. Blood Services*, 506 F.2d 841, 844 n.2 (5th Cir. 1975); *Charbonnages de France v. Smith*, 597 F.2d 406, 416 n.9 (4th Cir. 1979); *Box v. A & P Tea Co.*, 772 F.2d 1372, 1376 (7th Cir. 1985); *Arlinghaus v. Ritenour*, 622 F.2d 629, 638 (2d Cir. 1980). Although the district court dismissed the case *sua sponte*, it did so only after considering the complaint, the evidence submitted in support of a preliminary-injunction motion, and full briefing on standing in the context of that motion. Plaintiffs thus had every opportunity and incentive to present their allegations, evidence, and argument in support of standing. Accordingly, plaintiffs' briefs before the panel did not argue that the district court erred by depriving plaintiffs of an opportunity to make additional allegations or introduce additional evidence, but instead argued that plaintiffs had satisfied their burden on the current record.

Plaintiffs' reliance on this Court's decision in *Haase v. Sessions*, 835 F.2d 902 (D.C. Cir. 1987), is misplaced. The Court in that case did not discuss why it remanded the matter instead of affirming the district court's judgment, but contemplated that the plaintiff would supplement the record, *see id.* at 910, and presumably remanded the case to give the plaintiff an opportunity to do so. If plaintiffs in this case believed they were entitled to supplement the record, they should have raised the issue in their briefing before the panel.

3. The panel decision does not, in any event, satisfy the criteria for rehearing en banc. Plaintiffs do not assert that this case establishes any new proposition of law. They urge, instead, that the case is of exceptional importance because it will allow the challenged regulation to remain in effect. *See* Pet. 14-15 (decision will "bar anyone from challenging the rules—even though virtually everyone consuming poultry will be exposed to this product"). On this logic, every challenge to a safety regulation would be of exceptional importance. And because, as discussed above, the cases from other circuits on which plaintiffs rely are inapposite, plaintiffs are mistaken to suggest that the panel decision conflicts with the decisions of other circuits.

Plaintiffs also argue that the Court should review the reasoning of Judge Henderson's concurring opinion, and offer supplemental declarations in support of this argument. This unorthodox procedure demonstrates at most a fact-bound quarrel with the concurrence's alternative ground for affirmance and furnishes no basis for en banc review.

CONCLUSION

For the foregoing reasons, the petition for rehearing should be denied.

Respectfully submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General

CHANNING D. PHILLIPS
United States Attorney

MARK B. STERN

s/ Daniel Tenny
DANIEL TENNY
(202) 514-1838
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Room 7215
Washington, D.C. 20530
daniel.tenny@usdoj.gov

FEBRUARY 2016

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2016, I electronically filed the foregoing with the Clerk of the Court by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

s/ Daniel Tenny
Daniel Tenny