PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-2562

SEASIDE FARM, INC.,

Plaintiff - Appellant,

v.

UNITED STATES OF AMERICA,

Defendant - Appellee.

Appeal from the United States District Court for the District of South Carolina, at Beaufort. C. Weston Houck, Senior District Judge. (9:11-cv-01199-CWH)

Argued: October 26, 2016 Decided: December 2, 2016

Before WILKINSON, NIEMEYER, and SHEDD, Circuit Judges.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Niemeyer and Judge Shedd joined.

ARGUED: Daniel A. Speights, SPEIGHTS & RUNYAN, Hampton, South Carolina, for Appellant. Michael Shih, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. **ON BRIEF:** A. G. Solomons, III, SPEIGHTS & RUNYAN, Hampton, South Carolina, for Appellant. William B. Schultz, General Counsel, Daretia M. Hawkins, Senior Attorney, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C.; Elizabeth H. Dickinson, Chief Counsel, Michael Shane, Associate Chief Counsel for Enforcement, UNITED STATES FOOD AND DRUG ADMINISTRATION, Washington, D.C.; Benjamin C. Mizer, Principal Deputy Assistant Attorney General, Mark B. Stern, UNITED STATES DEPARTMENT OF JUSTICE, Washington,

D.C.; William N. Nettles, United States Attorney, Barbara Bowens, Assistant United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Columbia, South Carolina, for Appellee.

WILKINSON, Circuit Judge:

This case involves a Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b), 2671-2680, suit by a tomato farmer against the United States. Seaside Farm, Inc., alleges that the Food and Drug Administration negligently issued a contamination warning in response to an outbreak of Salmonella Saintpaul that devalued Seaside's crop by $15,036,293.95. The district court held that FDA was exercising a discretionary function in connection with the contamination warning and dismissed the case under 28 U.S.C. § 2680(a). That ruling was essential to protect FDA's vital role in safeguarding the public food supply, and we affirm the judgment.

I.

Salmonella Saintpaul is a rare strain of bacteria that causes moderate-to-severe illness in humans. Symptoms include fever, diarrhea, nausea, and abdominal pain. Salmonella can also enter the bloodstream and cause more serious health complications, including death. FDA consequently considers salmonella a "serious health concern." 74 Fed. Reg. 33,030, 33,031 (July 9, 2009).

A.

On May 22, 2008, the New Mexico Department of Health notified the Centers for Disease Control and Prevention that a number of local residents had been infected with Salmonella

Saintpaul. Similar reports soon arrived at CDC from Texas. After interviewing patients, CDC discovered a "strong statistical association" between the infections and eating raw tomatoes. J.A. 713. This observation was supported by a "historical association" between salmonella and tomatoes generally. J.A. 432. CDC subsequently notified FDA that tomatoes were the "leading hypothosis" for the source of the outbreak. J.A. 660.

By June 1, 2008, CDC was investigating 87 incidents of Salmonella Saintpaul across nine states. J.A. 147. FDA, including its various component parts such as the Center for Food Safety and Applied Nutrition, decided to issue an initial contamination warning to consumers in New Mexico and Texas. The contamination warning informed consumers that the outbreak was likely associated with tomatoes, but acknowledged that the exact type and the origin of the contaminated tomatoes was unknown.

By June 6, 2008, reports of Salmonella Saintpaul had risen to 145 incidents and 23 hospitalizations across sixteen states. J.A. 149. CDC notified FDA that the outbreak threatened the entire country.

On June 7, 2008, FDA issued an updated contamination warning titled, "FDA Warns Consumers Nationwide Not to Eat Certain Types of Raw Red Tomatoes." J.A. 149. The contamination warning explained the nature of Salmonella Saintpaul and specified certain types of tomato as the likely vehicles for the

bacteria. It also provided a list of countries and seven states, including South Carolina, whose tomatoes remained unassociated with the outbreak. The media, however, reported the contamination warning without mentioning that some tomatoes were not implicated. FDA officials also stressed the magnitude and national scope of the outbreak but likewise failed to mention any "safe" tomatoes.

Over the next month, CDC accumulated enough data to trace Salmonella Saintpaul to jalapeño and serrano peppers imported from Mexico. FDA withdrew the contamination warning as a result and announced that fresh tomatoes were no longer associated with the outbreak. At that point in time, Salmonella Saintpaul was linked to 1,220 infections across forty-two states and the District of Columbia. J.A. 150.

B.

Seaside harvested a crop of tomatoes in South Carolina while the Salmonella Saintpaul contamination warning was in effect. On May 18, 2011, Seaside brought suit against the United States under the FTCA alleging that FDA negligently issued the contamination warning and impaired the value of Seaside's crop by $15,036,293.95. The government claimed that the suit was barred by the FTCA provision protecting the government's exercise of discretionary functions, see 28 U.S.C. § 2680(a), and moved to dismiss the case. The district court denied the

motion as premature and ordered limited jurisdictional discovery, giving Seaside the opportunity to establish some nondiscretionary duty that FDA may have breached.

A three-year discovery fight ensued. The parties frequently disagreed over the scope of authorized inquiry, although the government ultimately produced over 12,000 pages of unredacted FDA guidance manuals, internal deliberations, daily situation reports, and confidential emails relevant to the Salmonella Saintpaul outbreak. Seaside also had the opportunity to take multiple depositions of CDC or FDA employees. Finally, the government provided an additional 13,000 pages of discovery material that was generated in a related case.

On December 15, 2015, the district court dismissed the case for lack of subject matter jurisdiction. The district court reasoned that FDA had broad discretion to warn the public about a contaminated food supply, and that Seaside failed to allege any statute, regulation, or policy that required FDA to proceed in a particular manner. The district court also acknowledged that contamination warnings implicate competing policy considerations of protecting the public from serious health risks and minimizing any adverse economic impact on associated industries. Seaside appeals.

II.

The FTCA provides a limited waiver of sovereign immunity for civil actions against the United States. 28 U.S.C. §§ 1346(b)(1), 2674. This waiver extends to certain claims resulting from "the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment." Id. § 1346(b)(1). The discretionary function exception, however, preserves sovereign immunity and insulates the government from liability for "the exercise or performance [of] a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." Id. § 2680(a). FTCA plaintiffs have the burden of showing that the discretionary function exception does not foreclose their claim. Welch v. United States, 409 F.3d 646, 651 (4th Cir. 2005); Williams v. United States, 50 F.3d 299, 304 (4th Cir. 1995).

The discretionary function exception represents "the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines), 467 U.S. 797, 808 (1984). It was meant to "protect the government from liability that would seriously handicap efficient government operations." Id. at 814

(quoting United States v. Muniz, 374 U.S. 150, 163 (1963)). Congress also wanted to "prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." Id. Consequently, federal courts lack jurisdiction over claims falling within the discretionary function exception. Holbrook v. United States, 673 F.3d 341, 345 (4th Cir. 2012); Williams, 50 F.3d at 304-05.

III.

Seaside contends the district court improperly concluded that the discretionary function exception barred its claim. Seaside also argues that it did not receive adequate discovery before the case was dismissed, and faults the district court for improperly limiting the scope of inquiry to jurisdictional issues. We shall discuss each contention in turn.

A.

Government conduct is protected by the discretionary function exception if it "involves an element of judgment or choice," and implicates "considerations of public policy." Berkovitz v. United States, 486 U.S. 531, 536-37 (1988); see United States *v.* Gaubert, 499 U.S. 315, 322-25 (1991); Varig Airlines, 467 U.S. at 813-14; Dalehite v. United States, 346 U.S. 15, 32-36 (1953). We begin by asking whether any "federal statute, regulation, or policy specifically prescribes a course

of action." Berkovitz, 486 U.S. at 536. If not, we consider generally "the nature of the actions taken and . . . whether they are susceptible to policy analysis." Gaubert, 499 U.S. at 325. The relevant inquiry is whether the decision "in an objective, or general sense, . . . is one which we would expect inherently to be grounded in considerations of policy." Baum v. United States, 986 F.2d 716, 721 (4th Cir. 1993). We do not examine, therefore, "whether policy considerations were actually contemplated in making [the] decision." Smith v. Washington Metro. Area Transit Authority, 290 F.3d 201, 208 (4th Cir. 2002) (emphasis in original). In fact, if a statute or regulation permits discretion, "it must be presumed that [decisions] are grounded in policy when exercising that discretion." Holbrook, 673 F.3d at 345 (quoting Gaubert, 499 U.S. at 324).

The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., provides that FDA may "cause to be disseminated information regarding food . . . in situations involving, in the opinion of the [Commissioner], imminent danger to health or gross deception of the consumer." Id. § 375(b) (emphasis added). A notice in the Federal Register emphasizes that "FDA's implicit or explicit authority to disseminate information under [21 U.S.C. § 375(b)] is not accompanied by any procedural requirements." 50 Fed. Reg. 43,060, 43,063 (Oct 23, 1985). The FDCA plainly delegates broad discretion, and we presume FDA is

firmly grounded in considerations of public policy when acting pursuant to that discretion.

Seaside argues in response that various FDA guidance manuals eliminate this discretion and prescribe some mandatory course of action. Seaside points to provisions that establish standard operating procedures, contamination warning protocols, "essential steps," and major considerations for emergency response activities.

It would be the rare guidance manual that did not contain some arguably mandatory language. It is our duty, however, to construe the nature of the statutory and regulatory regime as a whole. Indeed, "[t]he price of circulating internal guidance should not be an exponential increase in exposure to a tort suit." Holbrook, 673 F.3d at 347. It is questionable, moreover, whether something as informal as a guidance manual can overcome a statutory consignment of agency discretion. But even if we were to so assume, it would not aid appellant's case. For after reviewing the FDA guidance manuals, we still find the agency possesses significant discretion.

The FDA Emergency Response Plan, for example, begins with a qualification that "the nature and severity of an emergency . . . will determine . . . the specific actions . . . for each emergency." J.A. 923. It continues to explain that "the exact activities performed . . . will vary by the type and

severity of the emergency," J.A. 925, and that any given plan may "require[] significant adjustments during an incident," J.A. 926 (emphasis added). There is even an express disclaimer: "[T]hese identified steps do not comprise the entire scope of the FDA emergency response. Emergencies are unpredictable and dynamic; therefore, the Agency's strategy, while containing core activities, must be unique to each situation."[1] J.A. 925-26. Remaining provisions then speak in broad terms of what FDA "may" or "should" do, subject to the overarching nature of the emergency. See Fortney v. United States, 714 F.Supp. 207, 208 (W.D.Va. 1989) (holding that "should" is indicative of discretion), aff'd, 912 F.2d 722 (4th Cir. 1990). The FDA Emergency Response Plan thus envisions a fluid combination of variable responses and "real-time determination of the necessary course of action." J.A. 926.

The policy considerations inherent in a contamination warning are also evident. The FDCA expressly directs FDA to

[1] The core activities that comprise the FDA Emergency Response Plan, such as "Performing Initial and On-Going Planning," are all described at a high level of generality. J.A. 926. But a general directive that does not "specifically prescribe[] a course of action" likewise does not operate to restrict the exercise of agency discretion. Berkovitz, 486 U.S. at 536. Furthermore, "[t]he existence of some mandatory language does not eliminate discretion when the broader goals sought to be achieved necessarily involve an element of discretion." Holbrook, 673 F.3d at 348 (quoting Miller v. United States, 163 F.3d 591, 595 (9th Cir. 1998)).

"protect the public health by ensuring that foods are safe, wholesome, [and] sanitary." 21 U.S.C. § 393(b)(2)(A); see Gaubert, 499 U.S. at 324 ("It will most often be true that the general aims and policies of the controlling statute will be evident from its text."). As the district court rightly noted, decisions regarding contamination warnings are "grounded in the policy of protecting the public from a health risk, and reducing adverse economic impact." J.A. 1077. Discretion is necessary to evaluate available information, assess the sufficiency and reliability of evidence, resolve conflicting data, determine the overall nature of a health threat, and ultimately settle on a course of action. Both the timing and content of a contamination warning reflect this analysis. See Fisher Bros. Sales, Inc. v. United States, 46 F.3d 279 (3d Cir. 1995) (en banc). Acting too soon or waiting too late each entail profound potential consequences.

Seaside insists that there remains a genuine dispute as to whether the government ultimately executed its decision in a reasonable manner. Seaside complains that the contamination warning was overly broad, based on insufficient evidence, and wholly inadequate to notify consumers that South Carolina tomatoes remained safe for consumption. Seaside then emphasizes that no tomato in the United States ever tested positive for Salmonella Saintpaul, and that FDA actually neglected to test

sample tomatoes before issuing the contamination warning. Finally, Seaside asserts that, despite considerable evidence linking the outbreak to Mexico when the contamination warning was issued, FDA omitted that information without a defensible justification. Seaside suggests this decision was made for impermissible "political" reasons beyond the scope of FDA's discretion. Reply Br. of Appellant at 20.

Unfortunately, Seaside misunderstands the nature of the discretionary function inquiry. The decision to issue a contamination warning, especially in the middle of an escalating salmonella outbreak, clearly implicates the policy considerations which FDA was established to weigh. The FDCA even contemplates considerations regarding our commercial relationship with foreign countries. See 21 U.S.C. § 393(b)(3). Seaside fails to identify any mandatory requirements governing FDA's decision, including any directive to test sample tomatoes before issuing the contamination warning. Not only is the FDA Emergency Response Plan phrased in permissive terms, but it envisions "[i]nvestigative, laboratory, and technical/scientific staff" pursuing multiple avenues of obtaining information. J.A. 929. These would encompass, inter alia, such things as gathering field reports from state agencies, healthcare providers, and affected patients, to employing FDA's bank of pre-existing scientific knowledge about the association between

certain foods and food-borne illnesses. Whether the agency pursued its investigation, interpreted relevant evidence, or balanced policy considerations in what Seaside believes to be an optimal manner does not affect the discretionary function analysis. Seaside essentially invites us to engage in the very judicial second guessing that the discretionary function exception forbids.

We therefore conclude that the decision to issue a contamination warning "involves an element of judgment or choice," that implicates "considerations of public policy." Berkovitz, 486 U.S. at 536-37. The government rightly observes that contamination warnings -– in both timing and content -- are a prototypical discretionary function.[2]

B.

Seaside next contends it was not allowed sufficient discovery. District courts exercise broad discretion over discovery issues. Carefirst of Md., Inc. v. Carefirst Pregnancy Ctrs., Inc., 334 F.3d 390, 402-03 (4th Cir. 2003). A party is not entitled to discovery that would be futile or otherwise inadequate to establish a sufficient basis for jurisdiction. See Rich v. United States, 811 F.3d 140, 146 (4th Cir. 2015).

[2] In view of our ruling on the discretionary function exception, we have no need to address the government's contention that the contract rights exception to the FTCA likewise forecloses Seaside's claim. See 28 U.S.C. § 2680(h).

The district court was correct to recognize that the discretionary function exception is a jurisdictional threshold that must be considered before moving to the merits of an FTCA claim. Williams, 50 F.3d at 308; Smith, 290 F.3d at 211. The district court was thus well within its discretion to limit discovery to this dispositive issue. Rich, 811 F.3d at 146. Indeed, unlike in Rich, policy would be inevitably implicated in the issuance of the contamination warning and in drafting its contents. See id. at 147. Other circuits considering the discretionary function exception agree –– if they even allow discovery at all. See, e.g., Gonzalez v. United States, 814 F.3d 1022, 1031-32 (9th Cir. 2016) (refusing discovery because available agency guidelines established discretion); Baer v. United States, 722 F.3d 168, 176-77 (3d Cir. 2013) (refusing discovery because available agency guidelines did not foreclose discretion); Davila v. United States, 713 F.3d 248, 263-64 (5th Cir. 2013) (refusing discovery because the plaintiff failed to allege any "well-pleaded facts or evidence to refute the government's assertion . . . that no [nondiscretionary] policy exists"); Ignatiev v. United States, 238 F.3d 464, 467 (D.C. Cir. 2001) (remanding for limited jurisdictional discovery); In re Orthopedic Bone Screw Prod. Liability Litig., 264 F.3d 344, 365 (3d Cir. 2001), as amended (Oct. 10, 2001) (upholding limited jurisdictional discovery).

In any event, Seaside had three years of discovery. The government produced over 25,000 pages of material relevant to FDA practices and the Salmonella Saintpaul outbreak. Seaside also had the opportunity to take multiple depositions of CDC or FDA employees. This was more than adequate to determine whether FDA had some nondiscretionary duty or otherwise exercised discretion that was not susceptible to policy analysis. While Seaside expresses frustration at its inability to obtain additional information relevant to whether the contamination warning was justified, that issue is separate and distinct from the question of jurisdiction and the discretionary function exception.

Relying on Kerns v. United States, 585 F.3d 187 (4th Cir. 2009), Seaside insists that the facts necessary to determine jurisdiction are "inextricably intertwined" with the merits of the case and thus additional discovery was still necessary. See id. at 195. We disagree. Kerns, in fact, acknowledged that the discretionary function exception is a threshold issue that can be "wholly unrelated to the basis for liability under the FTCA." Id. at 196. So it is here. Whether FDA was negligent is an entirely different question from whether FDA was given the discretion to draft and issue a contamination warning, and whether exercising that discretion implicates policy considerations. While we do not suggest the agency's attempt to

warn the public of a major unfolding health crisis represented an abuse of the discretion entrusted to it, the discretionary function exception applies "whether or not the discretion involved be abused." 28 U.S.C. § 2680(a); see Gaubert, 499 U.S. at 322-25; Holbrook, 673 F.3d at 349-50.

The value of any kind of immunity, applied here as a jurisdictional bar, declines as litigation proceeds. See Mitchell v. Forsyth, 472 U.S. 511, 525-27 (1985) (explaining that qualified immunity in 42 U.S.C. § 1983 litigation "is in part an entitlement not to be forced to litigate the consequences of official conduct" and "even such pretrial matters as discovery are to be avoided if possible, as '[i]nquiries of this kind can be peculiarly disruptive of effective government'" (quoting Harlow v. Fitzgerald, 457 U.S. 800, 817 (1982)). Exposing FDA to extensive rounds of discovery on the merits would undermine the discretionary function exception and introduce the very litigation pressures Congress clearly meant to avoid. See Wu Tien Li-Shou v. United States, 777 F.3d 175, 186 (4th Cir. 2015); Holbrook, 673 F.3d at 349-50; cf. Harlow, 457 U.S. at 818 ("Until this threshold [42 U.S.C. § 1983] immunity question is resolved, discovery should not be allowed."). The district court was thus well within its discretion to order discovery in the manner that it did.

IV.

We refuse to place FDA between a rock and a hard place. On the one hand, if FDA issued a contamination warning that was even arguably overbroad, premature, or of anything less than perfect accuracy, injured companies would plague the agency with lawsuits. On the other hand, delay in issuing a contamination warning would lead to massive tort liability with respect to consumers who suffer serious or even fatal consequences that a timely warning might have averted. All this would loom if contamination warnings were not protected by the discretionary function exception.

Every public health emergency is different. There is no boilerplate warning that can account for the unknown variables of a pathogenic outbreak. There is little room for leisured hindsight when the decision is one that must be made under the pressure of events and, in many cases, on the basis of imperfect information. After three years of discovery, Seaside failed to identify any mandatory duty that FDA may have breached, or any discretionary decision that was not firmly rooted in the very policy considerations that FDA was intended to exercise. While we acknowledge and regret any financial loss Seaside may have incurred as a result of the Salmonella Saintpaul contamination warning, allowing Seaside's claim to proceed would allow the law

of tort to distort one of the most critical of governmental functions, that of safeguarding the public health and welfare.

The judgment is accordingly affirmed.

AFFIRMED