United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 20, 2009 Decided September 29, 2009

No. 08-5117

THOMAS REMPFER, U.S. AIR FORCE, ET AL.,
APPELLANTS

v.

JOSHUA M. SHARFSTEIN, MD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:06-cv-02131-RMC)

John J. Michels Jr. argued the cause for appellants. With him on the briefs was *Mark S. Zaid*.

Melissa N. Patterson, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Michael F. Hertz*, Acting Assistant Attorney General, *Jeffrey A. Taylor*, U.S. Attorney, and *Mark B. Stern*, Attorney. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Before: HENDERSON, TATEL, and GARLAND, *Circuit Judges*.

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

GARLAND, *Circuit Judge*: Pursuant to the Department of Defense's Anthrax Vaccine Immunization Program, members of the armed forces may be ordered to submit to inoculation against anthrax disease. Eight servicemembers brought suit in district court to challenge the Food and Drug Administration's approval of the anthrax vaccine and to enjoin the Defense Department from administering it. The district court dismissed three counts of the complaint on the merits and dismissed a fourth count because the plaintiffs lack standing to make it. We affirm.

I

Anthrax is an acute bacterial disease caused by infection with spores of Bacillus anthracis. It can be contracted through three routes of exposure: by skin contact (cutaneously), by inhalation, and by ingestion. From 1954-1959, a clinical study led by Dr. Philip Brachman tested an anthrax vaccine produced by the Department of Defense (DOD). *See* Philip S. Brachman et al., *Field Evaluation of a Human Anthrax Vaccine*, 52 AM. J. PUB. HEALTH 632 (1962) [hereinafter Brachman Study]. Dr. Brachman studied 1249 textile workers exposed to imported goat hair, dividing the population into a vaccine group, a placebo group, and an observational (no treatment) group. *Id.* at 634, 638.[1] During the study, 26 cases of anthrax occurred: 21

[1]As the FDA explained: The Brachman Study's "selected population was at risk because the mill workers routinely handled anthrax-infected animal materials. Prior to vaccination, the yearly average number of human anthrax infections among workers in these mills was 1.2 cases per every 100 employees." Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order, 70 Fed. Reg. 75,180, 75,186 (Dec. 19, 2005). By the mid-1980s, this industrial setting was

contracted cutaneously and 5 by inhalation. *Id.* at 638. Three of the cutaneous cases occurred in the vaccine group; the remainder, and all inhalation cases, occurred in the placebo and observational groups. *Id.* The study calculated that the vaccine was 92.5 percent effective (lower 95 percent confidence limit = 65 percent). *Id.* at 644. The study noted, however, that the small number of inhalation cases "makes the data less significant in showing effectiveness of the vaccine" with respect to that "form of the disease." *Id.* at 643.

DOD subsequently contracted with Merck, Sharpe, & Dohme to develop a new version of the vaccine for large-scale production. *See* Food and Drug Administration (FDA), Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order, 70 Fed. Reg. 75,180, 75,192 (Dec. 19, 2005) [hereinafter 2005 Final Order]. Later, it entered into a similar contract with the Michigan Department of Public Health (MDPH), the relevant division of which is now operated by the BioPort Corporation. *Id.* at 75,181, 75,182, 75,192, 75,197. MDPH/BioPort produced and continues to produce the current generation of the vaccine, known as Anthrax Vaccine Adsorbed (AVA). *Id.* at 75,192.

"vanishing, precluding any further clinical studies." Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002, 51,058 (Dec. 13, 1985). Today, "due to the significant health risks associated with exposure to anthrax spores, it would not be ethical to actively expose human study subjects to B. anthracis spores in order to assess the effectiveness of an anthrax vaccine in a controlled clinical trial. Furthermore, naturally occurring anthrax is now so rare that a field study of vaccine effectiveness is no longer feasible in the United States." 70 Fed. Reg. at 75,192.

Prior to 1972, the National Institutes of Health (NIH) was the agency responsible for the licensing of biological products. *See* 2005 Final Order, 70 Fed. Reg. at 75,181. In 1970, NIH issued a license for AVA. As labeled, the vaccine was to be administered in a six-shot sequence, with specified intervals between each inoculation. *Id.* at 75,184.

In 1972, responsibility for licensing biological products was transferred from NIH to the FDA. *Id.* at 75,181. The FDA then issued procedures for determining that products previously licensed by NIH "are safe, effective, and not misbranded." Procedures for Review of Safety, Effectiveness and Labeling, 38 Fed. Reg. 4319, 4321 (Feb. 13, 1973) (codified as amended at 21 C.F.R. § 601.25). Under those procedures, the FDA appoints an independent advisory panel to report on covered products. *See* 21 C.F.R. § 601.25(a), (e). After reviewing the panel's recommendations, the FDA makes its own determination, which it publishes as a proposed order along with the panel's report. *See id.* § 601.25(f). After receiving and reviewing comments, the FDA publishes a final order. *See id.* § 601.25(g).

In 1973, the FDA announced that advisory panels would review the safety and effectiveness of several vaccines previously licensed by NIH, including AVA. Biological Products; Bacterial Vaccines and Toxoids with Standards of Potency, Single or in Combination; Safety, Effectiveness and Labeling Review; Request for Data Information, 38 Fed. Reg. 5358 (Feb. 28, 1973). In 1980, an advisory panel submitted a report finding that the "best evidence for the efficacy of anthrax vaccine comes from [the] placebo-controlled field trial conducted by Brachman." Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002, 51,058 (Dec. 13, 1985). Although the panel concluded that "inhalation anthrax occurred too infrequently [in the Brachman Study] to assess the protective effect of vaccine

against this form of the disease," it recommended categorizing AVA as "safe and effective under the limited circumstances for which [it] is employed." *Id.* at 51,058, 51,059. In 1985, the FDA issued a proposed order classifying AVA as "safe and effective and not misbranded," *id.* at 51,104, but it did not issue a final order, *see* 2005 Final Order, 70 Fed. Reg. at 75,182.

In 1998, DOD implemented the Anthrax Vaccine Immunization Program (AVIP), which subjected members of the Armed Forces at risk of anthrax exposure to mandatory administration of AVA. *See id.* at 75,183. Thereafter, Congress directed DOD to support an independent examination of AVA by the Institute of Medicine of the National Academy of Sciences. *Id.*; *see* H.R. Rep. No. 106-371, at 256 (1999) (Conf. Rep.). A committee convened by the Institute conducted the study, examined "all available data," and concluded that, "[a]s indicated by evidence from studies in both humans and animals, . . . AVA, as licensed, is an effective vaccine to protect humans against anthrax, including inhalational anthrax." COMM. TO ASSESS THE SAFETY AND EFFICACY OF THE ANTHRAX VACCINE, INSTITUTE OF MEDICINE, THE ANTHRAX VACCINE: IS IT SAFE? DOES IT WORK? 1-2 (2002) (J.A. 140-41) [hereinafter Institute of Medicine Report].

Meanwhile, in July 2000, a shortage of the vaccine resulted in a temporary suspension of DOD's vaccination program, causing servicemembers who had begun the six-dose regimen to miss scheduled shots. First Am. Compl. ¶¶ 58, 59, 61; *Rempfer v. Von Eschenbach*, 535 F. Supp. 2d 99, 111 (D.D.C. 2008). According to the plaintiffs, when the suspension ended in 2002, DOD announced that personnel whose vaccination series had been interrupted would not repeat any doses already received but would instead continue with the next dose in the series. First Am. Compl. ¶¶ 63-64.

Six servicemembers sought to enjoin the vaccination program in 2003. *Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 123, 130 (D.D.C. 2003). Although they did not dispute that AVA had been approved as safe and effective against cutaneous anthrax, they argued that it was not a licensed vaccine for inhalational anthrax. *Id.* As a consequence, they maintained, 10 U.S.C. § 1107(f)(1) barred administration of the vaccine without either informed consent or a Presidential waiver.[2]

Finding a likelihood of success on this claim, the district court issued the requested preliminary injunction in December 2003. *Doe*, 297 F. Supp. 2d at 135. Days later, the FDA finalized the order it had proposed in 1985, but revised it to specify that AVA was safe and effective "independent of the route of exposure." Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255, 260, 257-59 (Jan. 5, 2004). The district court vacated that order for failure to comply with the notice-and-comment requirements

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[2]The statute provides:

> In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President. The President may grant such a waiver only if the President determines, in writing, that obtaining consent is not in the interests of national security.

10 U.S.C. § 1107(f)(1).

of the Administrative Procedure Act (APA), 5 U.S.C. § 553. *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004). The court then issued a permanent injunction -- "unless and until FDA follows the correct procedures to certify AVA" as safe and effective -- against "involuntary anthrax vaccinations absent informed consent or a Presidential waiver." *Id.* at 16. The government filed an appeal in this court.

In December 2004, the FDA issued a new proposed order for comment. Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 78,281 (Dec. 29, 2004). After reviewing the comments, the FDA issued a new final order on December 19, 2005, again classifying AVA as safe and effective in the prevention of anthrax regardless of the route of exposure. 2005 Final Order, 70 Fed. Reg. 75,180. In February 2006, a panel of this court concluded that, because issuance of the new order caused the permanent injunction to dissolve "[b]y its own terms," the government's appeal was moot. *Doe v. Rumsfeld*, 172 Fed. Appx. 327, 328 (D.C. Cir. 2006). In October 2006, DOD announced resumption of the mandatory immunization program. First Am. Compl. ¶ 48.

Thereafter, the plaintiffs in the case now before us -- eight servicemembers subject to mandatory inoculation orders -- initiated new proceedings in the district court challenging the FDA's 2005 final order. First Am. Compl. ¶¶ 1-8. They also sought to enjoin DOD from deviating from the recommended six-shot schedule for servicemembers whose vaccinations DOD had suspended between 2000 and 2002. The plaintiffs alleged that any such deviation would violate 10 U.S.C. § 1107(f)(1). *Id.* ¶¶ 102-12; *see supra* note 2. The district court resolved the only issue raised by the plaintiffs' three claims against the FDA -- whether the agency's reliance on the Brachman Study to establish the vaccine's effectiveness against anthrax was

arbitrary or capricious under the APA -- in favor of the agency. *Rempfer*, 535 F. Supp. 2d 99. It also dismissed the plaintiffs' claim against DOD for lack of standing based on the plaintiffs' failure to allege that they had been or would be subjected to off-schedule inoculations. *Id.*

We review the district court's APA ruling de novo, "as if the agency's decision 'had been appealed to this court directly.'" *Gerber v. Norton*, 294 F.3d 173, 178 (D.C. Cir. 2002) (quoting *Dr. Pepper/Seven-Up Cos. v. FTC*, 991 F.2d 859, 862 (D.C. Cir. 1993)). We also review de novo the district court's dismissal of the claim against DOD for lack of standing. *Muir v. Navy Fed. Credit Union*, 529 F.3d 1100, 1105 (D.C. Cir. 2008).

II

The plaintiffs' principal challenge is to the FDA's determination that the anthrax vaccine is effective.[3] More specifically, they fault the FDA's reliance on the Brachman Study in making that determination. They argue that reliance on that study was improper because: 1) it cannot support a finding of effectiveness against anthrax contracted by inhalation; and 2) it cannot support a finding of effectiveness for the current generation of the anthrax vaccine. The plaintiffs do not contest the vaccine's safety.

We will consider both arguments, but first pause to correct the plaintiffs' misperception regarding the nature of the district

[3]"Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological or other effect of the biological product, when used under adequate directions, for use and warnings against unsafe use, will serve a clinically significant function in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 C.F.R. § 601.25(d)(2).

court's review, and of ours, under the APA. The plaintiffs repeatedly insist that the district court was obliged to deny the government's motion to dismiss because they had raised genuine issues of material fact and hence were entitled to discovery to flesh out their claims. But "when a party seeks review of agency action under the APA [before a district court], the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "The entire case on review is a question of law," and the "complaint, properly read, actually presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Marshall County Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).[4] Consequently, challengers are "not . . . ordinarily entitled to augment the agency's record with either discovery or testimony presented in the district court," and there is "no inherent barrier to reaching the merits" at the motion to dismiss stage. *Id.* Our review, like that of the district court, is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously. *See* 5 U.S.C. § 706.

A

The plaintiffs first object that, because the Brachman Study included few cases of anthrax contracted by inhalation, it cannot support a conclusion of effectiveness against that route of exposure. We grant the plaintiffs' premise but disagree with their conclusion.

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[4]*See Am. Bioscience*, 269 F.3d at 1083 (noting that, "when reviewing agency action[,] the question of whether the agency acted in an arbitrary and capricious manner is a legal one which the district court can resolve on the agency record, regardless of whether it is presented in the context of a motion for judgment on the pleadings or in a motion for summary judgment").

The FDA does not dispute that, if "the cases of inhalation anthrax reported in the course of the Brachman study [are] analyzed separately, [they] are too few to support a meaningful statistical conclusion." 2005 Final Order, 70 Fed. Reg. at 75,183. But this simply directs us to the underlying issue: should "inhalational anthrax" be analyzed separately? That question cannot, as appellants assume, be answered as an abstract question of statistical method. Rather, it must be answered as a matter of scientific judgment. To illustrate: if the *route*-of-exposure distinction were replaced with a *time*-of-exposure distinction, no one would insist that "morning anthrax" must be analyzed separately from "afternoon anthrax." Yet categorizing cases by time seems arbitrary not because time of exposure is any less measurable a distinction than route of exposure, but because time seems unlikely -- as a scientific matter -- to be relevant to vaccine effectiveness.

Of course, in comparison to time of exposure, it is not as self-evident that route of exposure is unlikely to be relevant. After all, Dr. Brachman did flag the route-of-exposure distinction half a century ago. Moreover, the FDA agrees that, as a general matter, "the route of exposure to an infectious agent may potentially have an impact on the effectiveness of a vaccine." *Id.* at 75,187.

But in the case of the anthrax vaccine, the FDA's scientific judgment is that route of exposure is not relevant to the vaccine's effectiveness. The reason, the agency explains, is as follows:

> With regard to the known pathophysiology of anthrax, the signs and symptoms of disease arise due to the production of toxins by anthrax bacteria growing within the infected individual. The toxins produced by anthrax bacteria do not vary based on the route of

> exposure. The antibodies produced in response to vaccination contribute to the protection of the vaccinated individual by neutralizing the activities of those toxins. *Thus, AVA elicits an antibody response to disrupt the cytotoxic effects of toxins produced by anthrax bacteria, regardless of the route of infection.*

2005 Final Order, 70 Fed. Reg. at 75,187 (emphasis added). In other words, AVA responds to anthrax in the same way regardless of how the disease enters the body. Thus, for purposes of establishing AVA's effectiveness, the inhalational versus cutaneous distinction is one without a difference, and there is no need to treat them separately in interpreting the Brachman Study. This, the FDA explains, is why it disagrees with the 1980 advisory panel's statement that inhalation anthrax occurred too infrequently in the Brachman Study to provide a basis for assessing the efficacy of AVA against that form of the disease. *Id.* at 75,183; *see* 38 Fed. Reg. at 4321 (stating that "the report of each panel is advisory to the Commissioner, who has the final authority to accept or to reject the conclusions and recommendations of the panel").

As the FDA further notes, its judgment in this respect is in accord with the report of the committee of experts charged by the Institute of Medicine with conducting an independent review. 2005 Final Order, 70 Fed. Reg. at 75,183. The committee found that "laboratory experiments indicate that AVA provides effective protection against inhalational challenge in rabbits and macaques, the animal models in which the disease is most reflective of the disease in humans." Institute of Medicine Report, at 10. And the committee concluded that, "[a]s indicated by evidence from studies in both humans and animals, . . . AVA, as licensed, is an effective

vaccine to protect humans against anthrax, including inhalational anthrax." *Id.* at 2.[5]

At bottom, the plaintiffs' claim that the Brachman Study establishes nothing in regard to "inhalational anthrax" relies on the proposition that route of exposure is scientifically relevant. But the FDA's contrary determination is a scientific judgment within its "area of expertise," the kind of judgment to which this court gives a "high level of deference." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995); *see Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998). Moreover, as the plaintiffs themselves concede, there is no scientific evidence in the administrative record to contradict that judgment. *See* Oral Argument Recording at 35:03.[6] In the

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[5]The FDA found additional support for the effectiveness of the vaccine in epidemiological data "on the occurrence of anthrax disease in at-risk industrial settings collected by the [Centers for Disease Control and Prevention] and summarized for the years 1962 to 1974." 2005 Final Order, 70 Fed. Reg. at 75,183. The FDA noted that unvaccinated persons within the at-risk populations had been infected by anthrax during that period, but that "no cases have occurred in fully vaccinated subjects while the risk of infection has continued." *Id.*

[6]At oral argument, plaintiffs' counsel pointed to one piece of evidence purportedly contradicting the FDA's judgment -- a declaration the plaintiffs filed in the district court. *See* J.A. 212. The declaration was not submitted to the FDA during the administrative proceedings and was not mentioned in the plaintiffs' appellate briefs. It is therefore outside the scope of our review on two accounts. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971) (holding that review is generally limited to the "record that was before the [agency] at the time [it] made [its] decision"); *Ark Las Vegas Rest. Corp. v. NLRB*, 334 F.3d 99, 108 n.4 (D.C. Cir. 2003) (holding that arguments raised for the first time at oral argument are waived).

absence of such evidence, we must defer to the FDA's judgment that AVA is effective regardless of the route of exposure.

B

The plaintiffs' other principal contention is that, because the Brachman Study used an earlier generation of the anthrax vaccine, it cannot establish the effectiveness of the current version. We again grant the premise but reject the conclusion.

The fact that manufacturing changes occur during the course of vaccine production is not unique to AVA, and the FDA has an established protocol for analyzing such changes: "[A] manufacturer may make manufacturing changes in a product without performing additional clinical studies to demonstrate the safety and effectiveness of the similar product if data regarding the manufacturing changes support the conclusion that the versions are comparable." 2005 Final Order, 70 Fed. Reg. at 75,184. The plaintiffs maintain that "there is no evidence within the Administrative Record that the FDA *ever* compared the different anthrax vaccines and efficacy data to reach the conclusion that the vaccines are comparable." Appellants' Br. 43. But that is simply incorrect, because the FDA did make the requisite comparability determination.

As the FDA explained in its 2005 Final Order, it "reviewed the historical development of AVA and conclude[d] that DOD directed the development of the vaccine, including its formulation and manufacturing process, from the vaccine used in the Brachman study . . . to the vaccine that was ultimately licensed and manufactured by BioPort." 2005 Final Order, 70 Fed. Reg. at 75,184. "All three versions of anthrax vaccine," the agency determined, "were tested in animals and demonstrated to protect test animals . . . against challenge with virulent [anthrax] spores." *Id.* In addition, "clinical data comparing the safety and

immunogenicity of [AVA] with [the DOD] vaccine . . . reveal that the serological responses to [AVA] and [the DOD] vaccine were similar with respect to peak antibody response and seropositivity." *Id.* That is, human blood serum showed similar antibody production in response to the different versions of the vaccine. *Id.* at 75,184, 75,192-93. The FDA also found that the two versions were "comparable in their ability to protect test animals." *Id.* at 75,184. On this basis, the agency concluded that the two vaccines were comparable and that the Brachman Study could therefore be used to approve AVA. *Id.*

Once again, we are presented with a scientific judgment by the FDA to which we owe considerable deference. And once again, the plaintiffs fail to proffer any scientific evidence to rebut it. Our conclusion must therefore be the same as above: the FDA did not act arbitrarily or capriciously in resting a finding of effectiveness on the results of the Brachman Study.[7]

III

Finally, we address the plaintiffs' claim that DOD is subjecting military personnel to mandatory immunization on an unapproved schedule of inoculations. The district court dismissed this claim on the ground that the plaintiffs lack standing to raise it. "To establish constitutional standing, a plaintiff must show an injury in fact that is fairly traceable to the challenged conduct and that will likely be redressed by a

[7]Scattered throughout the plaintiffs' briefs are a number of additional arguments criticizing the Brachman Study. Because those arguments are raised "only summarily, without explanation or reasoning," they are waived. *City of Waukesha v. EPA*, 320 F.3d 228, 251 n.22 (D.C. Cir. 2003). In any event, we agree with the carefully considered opinion of the district court that those additional challenges lack merit. *See Rempfer*, 535 F. Supp. 2d at 108-11.

favorable decision on the merits." *Muir*, 529 F.3d at 1105 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). The district court concluded that the plaintiffs have not alleged the constitutionally requisite injury in fact, and we agree.

The plaintiffs' complaint alleges that DOD began its program of mandatory inoculation in 1998, suspended it for some period during 2000-02 due to a supply shortage, and then resumed the program without correcting for the interruption in the recommended six-shot dosage schedule. First Am. Compl. ¶¶ 10, 58-64. The plaintiffs do not allege that servicemembers who were or will be inoculated for the first time under the post-2002 regime will have their inoculations interrupted and restarted off schedule. Nor do they claim that DOD is otherwise stopping and restarting the shot sequences. Rather, they allege that "'[p]ersonnel whose vaccination series *was interrupted during the p[re]vious AVIP slowdown* . . . . will just continue with the next dose in the series.'" First Am. Compl. ¶ 63 (emphasis added) (quoting an Air Force statement).

As the district court noted, the plaintiffs have "not alleged that they themselves have been, or imminently will be, subjected to such [an interrupted] vaccination schedule." *Rempfer*, 535 F. Supp. 2d at 111. The complaint does not allege that the inoculation sequence of any of the plaintiffs was actually interrupted by the 2000-02 AVIP suspension. Nor have the plaintiffs filed an affidavit to that effect. At oral argument, the plaintiffs insisted that they are under no obligation to make such an allegation. *See* Oral Argument Recording at 15:35-48.

The plaintiffs are wrong. "[I]t is the burden of the party who seeks the exercise of jurisdiction in his favor clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute." *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (internal quotations and

citations omitted). Thus, the plaintiffs "must 'allege . . . facts essential to show jurisdiction. If [they] fai[l] to make the necessary allegations, [they have] no standing.'" *Id.* (quoting *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936)) (alterations and omissions in original). Plaintiffs have failed to make the necessary allegation here, and they therefore lack standing to raise this challenge.

IV

For the foregoing reasons, the judgment of the district court is

Affirmed.