

**United States Court of Appeals
FOR THE EIGHTH CIRCUIT**

Nos. 97-4157/98-2525

United States of America,

Appellant,

v.

Grand Laboratories, Inc.,
a South Dakota Corporation;
Duane C. Pankratz,

Appellees.

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* Appeals from the United States
* District Court for the Northern
* District of Iowa.
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Submitted: November 16, 1998

Filed: May 4, 1999

Before BEAM, LAY, and LOKEN, Circuit Judges.

BEAM, Circuit Judge.

The United States appeals the district court's adverse rulings arising from claims that Grand Laboratories, Inc. and Dr. Duane C. Pankratz violated the Virus-Serum-Toxin Act (the VSTA) when Dr. Pankratz switched contaminated biological product with a bogus substitute and transported the contaminated material. The district court found that Dr. Pankratz violated the VSTA, but vindicated Grand Laboratories and denied any injunction to restrain future violations of the VSTA. The district court further found that the decision of the United States Department of Agriculture (the

USDA), to deny reprocessing of the contaminated product, was arbitrary, capricious, and an abuse of discretion, and ordered reprocessing. We affirm in part and reverse in part.

I. BACKGROUND

Dr. Duane Pankratz, a doctor of veterinary medicine, is the president and owner of Grand Laboratories, Inc. (Grand Labs). Grand Labs manufactures veterinary biological products and holds a federal establishment license subjecting Grand Labs to regulation by the USDA. On June 23, 1989, Grand Labs obtained a federal license to produce a biological product called Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine (trade name—Vira Shield 5).

Between June 22 and 25, 1990, employees of Grand Labs mixed the component parts of Vira Shield 5 to create a batch called serial 45-016. Serial 45-016 was then placed in 3,896 plastic bottles. Federal law requires that each serial of the licensed product be tested for viable bacteria and fungi. See 9 C.F.R. § 113.26. Initial testing showed that serial 45-016 was contaminated. Although the alleged cost of making the serial was \$300,000, it was scheduled to be destroyed.

When informed of the test results and the serial's impending destruction, Dr. Pankratz instructed that the product not be destroyed until he gave the okay. He then produced a worthless substitute solution, poured it into plastic bottles, packed the bottles in boxes, labeled the boxes as serial 45-016, and switched the real serial with the substitute concoction. He made the switch at about 3:00 a.m. and subsequently transported the contaminated serial. Dr. Pankratz then gave the go-ahead to destroy the bogus serial 45-016. But, after discovering that the material had been tampered with, an employee of Grand Labs contacted the USDA to inform them that a contaminated product was missing. The USDA inspected the facility and could not locate the original serial 45-016. Dr. Pankratz later led the USDA inspectors to serial

45-016, which by that time was located in a van in the parking lot. It had been left unrefrigerated for some period of time.

On October 15, 1990, in an effort to remove the contaminants and thereby allow the sale of serial 45-016, Dr. Pankratz and Grand Labs submitted a request for reprocessing to the USDA. The USDA outlined what would be required to permit reprocessing: identification of the contaminants and a proposal for removing the contaminants—including harmful metabolites or toxins. Dr. Pankratz submitted several subsequent tests of the serial and presented proposals for reprocessing. After almost two years of review and subsequent testing, the USDA denied the request to reprocess. Thus, serial 45-016 has remained under quarantine at Grand Labs since October 1990.

The United States filed civil charges against Dr. Pankratz and Grand Labs in November 1991 for violations of the VSTA. Dr. Pankratz, objecting to the USDA's decision denying reprocessing, counterclaimed under the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.* After trial, the district court concluded, *inter alia*, that Dr. Pankratz was liable for shipping a contaminated biological product in violation of the VSTA, but that Grand Labs was not. The district refused to order a permanent injunction against either Dr. Pankratz or Grand Labs to prevent future violations of the VSTA. The court also concluded that serial 45-016 should not be destroyed, but instead ordered the USDA to allow reprocessing.

II. DISCUSSION

The parties have raised three primary issues on appeal: (1) the liability of Grand Labs for Dr. Pankratz's actions; (2) the USDA's denial of reprocessing; and (3) the

issuance of an injunction against Dr. Pankratz and Grand Labs.¹ We consider each separately.

A. Grand Lab's Liability

The complaint alleges that Dr. Pankratz, "acting on behalf of Grand Labs," violated the VSTA, and seeks injunctive relief against both. The district court found that Dr. Pankratz violated the VSTA, but without discussion held that Grand Labs had not. The United States contends that this is error, citing basic agency principles. Grand Labs argues that the district court did not err because all the evidence "put on by the Government to support injunctive relief related to what Dr. Pankratz did and did not do." We review this question of law de novo. See Long v. Nix, 86 F.3d 761, 764-65 (8th Cir. 1996).

Dr. Pankratz, as president and owner of Grand Labs, violated the VSTA when he transported a contaminated biological product. "The general rule is that a corporation is liable for the torts and wrongful acts of its employees acting within the scope of their authority or the course of their employment." United States v. United States Cartridge Co., 198 F.2d 456, 464 (8th Cir. 1952). This general principle of vicarious liability demands that liability be imputed to Grand Labs. Thus, the district court erred with respect to Grand Labs' liability.

B. Reprocessing

After serial 45-016 tested positive for contamination, the USDA placed it under quarantine pending final resolution of this action. Dr. Pankratz and Grand Labs then sought to reprocess the serial to allow its sale. To support the reprocessing request,

¹We have carefully reviewed the record and find no merit to arguments not discussed herein.

Grand Labs conducted several subsequent tests of the serial and alleged that the contamination shown by the initial test may have resulted from employee misconduct. However, the USDA denied the reprocessing request despite Grand Labs' evidence. The gist of the USDA's position is summarized in a letter to Dr. Pankratz that states:

The results of your latest testing do not negate the fact that the serial was found to be contaminated at the time of the initial sterility testing. Since the organism has not been identified, there is no way to determine what metabolites or toxins were produced by the contaminant.

You have not proposed an acceptable way to remove the contaminant from the serial, nor to test for possible harmful metabolites or toxins. I cannot grant an approval for your reprocessing request.

Appellant's Appendix at 79.

Dr. Pankratz and Grand Labs successfully argued to the district court that the agency's denial constituted arbitrary and capricious conduct. We, like the district court, review the agency's decision to deny reprocessing to determine if the decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Wilkins v. Secretary of the Interior, 995 F.2d 850, 852-53 (8th Cir. 1993) (quoting 5 U.S.C. § 706(2)(A)). This limited review dictates that we not substitute our judgment for that of the agency, but instead requires that we "give substantial deference to agency determinations." Downer v. United States, 97 F.3d 999, 1002 (8th Cir. 1996) (per curiam). Substantial deference is particularly appropriate where, as here, the agency's decision concerns a subject within its unique area of expertise. See id.

The dissent states that "in the interest of justice there is little to lose and everything to gain by affirming the district court" on this issue. Post at 14. This is, of course, not the proper standard of review for agency determinations. Furthermore, deference to an agency determination is all the more compelling in a case such as this,

where the district court itself concluded that "the testimony of the witnesses on both sides as to whether or not serial 45-016 was contaminated was very impressive." United States v. Grand Lab., Inc., No. C 91-4113-DEO, mem. op. at 28 (N.D. Iowa Aug. 14, 1996). The district court's statement highlights the very dilemma put before the USDA in its consideration of whether to allow reprocessing of serial 45-016—to believe the evidence supporting contamination or the evidence suggesting no contamination.

The evidence supporting contamination rests on the first test conducted by Grand Labs. The USDA's experts reviewed the test and test procedures and concluded that the results were accurate. It should also be remembered that based upon this initial test, the district court found Dr. Pankratz liable for shipment of a *contaminated* biological product, a point not challenged on appeal. In the nearly nine years since serial 45-016 was produced and over six years since the denial of reprocessing, Dr. Pankratz and Grand Labs have sought to undermine the validity of the initial test through subsequent testing and allegations of employee misconduct. Not all subsequent tests were in the administrative record, but contrary to the dissent's position, there were tests showing no contamination which were considered by the USDA in its reprocessing decision. Additionally, the USDA had evidence before it that suggested employees of Grand Labs had somehow "set-up" Dr. Pankratz. The administrative record, although not as richly developed as the trial court record, provided sufficient evidence for the USDA to make a rational reprocessing decision.

With evidence on both sides, including expert testimony, the USDA was left with the difficult decision of whether to allow or deny reprocessing. If reprocessing were allowed and any remnants of an unidentified contaminate—dead bacteria, metabolites or toxins—were not discovered and removed (a possibility since the USDA knows no way to test and remove them, and Grand Labs provided no suitable suggestions), then there would be a green light to market the product. Serial 45-016 could then be administered to thousands of head of livestock.

The other alternative was to deny reprocessing based on the initial test showing contamination and thereby err on the side of public safety.² The USDA followed their experts and chose the path of public safety. An agency making determinations that are so wrapped-up with scientific judgments must be permitted to rely upon the "reasonable opinions of its own qualified experts." Downer, 97 F.3d at 1002 (quoting Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989)).

The USDA's experts were concerned, as indicated, about unidentified contaminants in serial 45-016 as well as metabolites and toxins that the contamination may have produced. These concerns persisted throughout the reprocessing request and were not alleviated by Dr. Pankratz and Grand Labs. Thus, the reprocessing request was denied. "[E]ven if, as an original matter, a court might find contrary views more persuasive," the USDA's determination is not arbitrary, capricious, or an abuse of discretion and must be given deference. Id. (quoting Marsh, 490 U.S. at 378). Therefore, we uphold the USDA's determination on reprocessing.

C. Injunction

As noted, the complaint seeks a permanent injunction restraining Grand Labs and Dr. Pankratz from "violating the VSTA and its implementing rules and regulations including, but not limited to: . . . (3) shipping or delivering for shipment any worthless, contaminated . . . product." The United States argues that an injunction is necessary to protect the public health and safety and to prevent the likely recurrence of what was "not an isolated incident." The United States essentially seeks two injunctions: one for restraining the shipment of serial 45-016 and another for any future violation of the law. The district court denied any injunctive relief, concluding that there is little or no

²The USDA no longer authorizes reprocessing to eliminate contamination in a product. See United States Department of Agriculture, Veterinary Service Memorandum No. 880.62 (December 10, 1997).

possibility of future violations that ordinary enforcement would not adequately remedy. We review for abuse of discretion. See United States v. Green Acres Enter., Inc., 86 F.3d 130, 132 (8th Cir. 1996).

Injunctive relief is generally appropriate when there is no adequate remedy at law. See Hockenberg Equip. Co. v. Hockenberg's Equip. & Supply Co. of Des Moines, Inc., 510 N.W.2d 153, 158 (Iowa 1993). "Probably the most common method of demonstrating" that a legal remedy is inadequate is by showing that irreparable harm will result. 11A Charles Alan Wright et al., Federal Practice and Procedure § 2944, at 90 (2d ed. 1995); see also Green Acres, 86 F.3d at 132-33.

We find that shipment of serial 45-016 presents an appropriate situation for injunctive relief. Dr. Pankratz has demonstrated a willingness to circumvent established procedures and legal constraints to salvage a costly but contaminated biological product. If serial 45-016 is shipped and sold, tremendous damage could result. And since we have upheld the USDA's decision to deny reprocessing, we conclude that an injunction should issue restraining Dr. Pankratz and Grand Labs from shipment of serial 45-016.

Injunctive relief for any future violations of the law, however, presents a different analysis. The district court noted that even counsel for the United States characterized this request as essentially "a situation where the Government is seeking an injunction from the Court to require Grand to follow the law." Grand Lab., memorandum op. at 49. While there are scenarios "where Congress expressly provides for injunctive relief to prevent violations of a statute," such is not the case here. Burlington N. R.R. Co. v. Bair, 957 F.2d 599, 601 (8th Cir. 1992) (analyzing section 306 of the Railroad Revitalization and Regulatory Reform Act of 1976). Ordinary enforcement of the VSTA, although not nearly as simple as a contempt proceeding that would result from a violation of an injunction, is an adequate legal remedy. An injunction should not ordinarily issue simply because a law has been violated.

III. CONCLUSION

For the foregoing reasons we affirm in part and reverse in part the district court's judgment and remand for further proceedings consistent with this opinion.

LAY, Circuit Judge, dissenting.

The majority opinion holds that the district court erred by substituting its opinion for that of the USDA when it reversed the USDA's denial of Grand Labs' request to reprocess serial 45-016. I respectfully submit that the majority opinion reflects a basic misunderstanding of the district court's holding. The district court found that the USDA's denial of reprocessing was arbitrary and capricious because the USDA failed to review a full and fair administrative record when it decided the serial could not be retested to determine whether it could be safely marketed to the public. In so holding, the district court was simply following the Supreme Court's dictate in Florida Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985):

If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation.

Thus, it is a fundamental misconception to say that the district court substituted its own judgment for that of the USDA where the USDA's judgment was not based on consideration of all the relevant factors.

The majority's confusion probably arises from the rather unusual procedural history of this case. This action originally arose when the USDA brought a four-count civil suit against Dr. Pankratz and Grand Labs for violations of the Virus-Serum-Toxin

Act (VSTA). The defendants filed a counterclaim under the Administrative Procedure Act (APA), 5 U.S.C. §§ 551 et seq., challenging the USDA's decision to deny their requests for reprocessing of serial 45-016. The court initially granted the government's motion for summary judgment on the defendants' counterclaim and upheld the USDA's decision to deny reprocessing. The court granted the USDA's motion for summary judgment for three basic reasons. First, the USDA had explained that the contaminant discovered in the serial in the original test might have produced toxins or metabolites that could not be identified or removed. Second, the defendants had presented no evidence to indicate that the original test could be questioned. Third, the USDA showed that the product had gone unrefrigerated when Dr. Pankratz removed it, and that lack of refrigeration alone would justify the agency's denial of the reprocessing request.

The district court then proceeded to trial on the other counts. After trial, the district court found liability on only one count of the complaint (shipment of a contaminated biological product).³ The district court then reversed its earlier grant of summary judgment for the government on the counterclaim and ordered that the USDA expand its administrative record to include all relevant factors relating to the grant or denial of reprocessing. The court found that evidence disclosed at trial showed that the USDA had not considered relevant evidence that serial 45-016 was not contaminated when it made its decision to deny reprocessing.⁴ On this basis, the court ordered that

³The defendants were found not responsible for falsely labeling a biological product; for not having suitable tags or labels on a biological product; and for shipping a worthless product.

⁴The district court stated:

The USDA, as shown in the letters above, had taken a position that the first test, Exhibit A-1, of serial 45-016 showed contamination. Thereafter, they consistently held the position that no retesting could be done until such time as Grand could identify what the contaminant had been and

the case be remanded to the USDA in light of the overall record not previously considered by the USDA at the time of its original decision. The district court emphasized that the decision whether the serial would ultimately be placed on the market for sale would be made only by the USDA , but only after full and fair review testing. This appeal arises primarily from the district court's decision on this counterclaim.

It is important to set forth this procedural history because it points out that the district court was not substituting its judgment for the USDA, but rather was simply requiring a full and fair review based upon the testimonial record developed in the district court. I mention this because it is not the prerogative of the district court in reviewing agency action under the APA to make a new record and overrule the agency's decision based upon evidence that the agency has not reviewed. See Camp v. Pitts, 411 U.S. 138, 142 (1973); Wilkins v. Secretary of Interior, 995 F.2d 850, 853 (8th Cir. 1993). Contrary to the implicit holding of the majority opinion, the district court did not do this in the present case. The procedural history is also important to emphasize that the ultimate issue here is not the question of reprocessing, but whether the agency should be required to consider the entire record, including the results of current and concurrent testing, in making the ultimate decision whether the serial is safe for consumer use.

successfully demonstrate that whatever the contaminant was, it was all now removed from serial 45-016. This is an impossible position because it assumes there was contamination. Grand made tests (Exs. I-1, O-1, L-1, H-2, V-2, E-3, G-3, A-4, B-4), all of which were negative for contamination (Trial Tr. 344). None of these were part of the administrative record and therefore were never considered by the USDA.

United States v. Grand Labs., Inc., No. C91-4113-DEO, at 37 (N.D. Ia. Sept. 22, 1997)(order).

The majority opinion does not discuss the evidence the district court relied upon to conclude that its original grant of summary judgment should be vacated and that further tests should be done. I believe this evidence supported the district court's decision. The USDA based its position that serial 45-016 is contaminated solely on the results of the first sterility test performed on September 25, 1990. As the district court found, however, the testimony developed at trial casts grave doubt upon the reliability of that original test showing contamination of serial 45-016.⁵ There was testimony that

⁵The district court set out the reasons why the first test showing contamination was questionable:

“While the government would urge the Court to accept the contamination of serial 45-016 as set out in Exhibit A-1, it should be noted that Robin Moffle and Wayne Behan rushed to tell the government about that test and the moving of that serial, and acted as though they were carrying out their duty as in-house USDA representatives at Grand. (Tr. 634.) At least part of the eagerness for this conduct is that Ms. Moffle admitted that she hated Dr. Pankratz. (Tr. 357.) Thomas Miller, Grand Central Services Manager, admitted that he and Moffle agreed to lie to Dr. Pankratz about the destruction of serial 45-016. (Tr. 423.) Behan and Moffle did not report other things to the government that would have shown that there were two sides to the contamination question. They did not tell USDA officials that Dr. Pankratz had told Behan he wanted to save serial 45-016 so that it could be reprocessed. They did not reveal that Exhibit 28 showed the product 45-016 in bulk was not contaminated. The plaintiff tries to minimize this omission by saying Dr. Pankratz also did not tell the USDA about Exhibit 28. However, USDA did not ask him for test information. They were then listening to a ‘bad’ report by Moffle which left out anything favorable. (Tr. 1433.) Ms. Moffle, when asked about this, said that she forgot to tell the USDA that. Moffle and Behan further did not report that they started another sterility test in secret on October 19, 1990 on the same samples as used in the first test, and on November 2, 1990, the results showed that the product was sterile. (Ex. I-1.) After this test was completed, Ms. Moffle did not have it written up as shown in Exhibit I-1 until almost a year later, when Dr. Pankratz heard

concurrent tests were performed at Grand Labs in September, October and November which showed no contamination, and that Dr. Pankratz's employees did not report these satisfactory tests to the USDA.⁶ In fact, a second bulk sterility test was performed on the serial on September 26, 1990, the day after the initial test, and it showed no contamination. Yet the USDA was not informed of this satisfactory test. The district court also received testimony from Dr. Long, a former USDA official, that safety tests had been performed on serial 45-016 which found the serial to be free from any substance toxic enough to cause any reaction to an animal. Finally, the court found that the government failed to prove that serial 45-016 had gone unrefrigerated for any extended period of time as it had previously alleged.⁷ This evidence, however, was not in the administrative record before the USDA and was never considered by the USDA when it denied reprocessing. Therefore, the district court concluded that the USDA failed to consider important evidence to form a rational basis for its denial of Grand

about it and insisted that it be properly written up. (Tr. 610.) The defendants contend with some credence that the reason for these omissions was that they discredited and/or certainly questioned the reliability of the first test, Ex. A-1, which, of course, is the bottom line for all of this litigation.”

United States v. Grand Labs., Inc., No. C91-4113-DEO, at 30 (N.D. Ia. Sept. 22, 1997) (order) (quoting its earlier order of Aug. 14, 1996, at 55 n.13).

⁶The district court found that the employees failed to report these satisfactory test results to the USDA because they disliked Dr. Pankratz.

⁷In any event, the experts acknowledged that lack of refrigeration is relevant to the question of potency, and that upon retesting it could be determined whether lack of refrigeration had any effect on the potency of serial 45-016. Ultimately, potency may very well affect the decision whether the serial can be marketed. However, this can only be discovered upon retesting of the serial.

Labs' requests for reprocessing serial 45-016.⁸ The USDA's failure to consider this evidence justified the district court's order remanding the case to the USDA for retesting and reconsideration of serial 45-016's marketability based upon all of the relevant evidence.⁹

It may seem cavalier to say that in the interest of justice there is little to lose and everything to gain by affirming the district court. There is no question that Dr. Pankratz concealed the alleged contaminated product and substituted a bogus product in its place; his conduct clearly should not be condoned.¹⁰ However, affirming the district

⁸The district court stated:

The court finds that the agency did not fully consider several things it should have. These include but are not limited to fair consideration of the request to reprocess, that the agency ignored the regulations concerning the right of the defendants in matters involving quarantine and no-test, and acted arbitrarily and capriciously toward the legitimate requests of the defendants in that the administrative record was inadequate and there was no rational relationship between the evidence and their decision not to allow any reprocessing, and, as found here and in this court's order of August 14, 1996, serial 45-016 has not been fully and carefully tested.

United States v. Grand Labs., Inc., No. C91-4113-DEO, at 51 (N.D. Ia. Sept. 22, 1997) (order).

⁹I find it is highly significant that the district court evaluated the new evidence from 4,000 pages of testimony and considered the evidence to be such that the USDA should consider it in determining whether serial 45-016 is marketable.

¹⁰Although they do not excuse Dr. Pankratz's conduct, several facts help to explain it. It is clear from the record that Dr. Pankratz's sole motive in concealing serial 45-016 and substituting it with a bogus serial was to preserve the serial for retesting. Grand Labs had invested \$300,000 in the serial and it was the company's most important product. He had falsely been told by his employees that the USDA intended to destroy the allegedly contaminated product, and his employees had

court's order of reprocessing would not threaten the safety of animals. The district court specifically stated that it was not ordering the USDA to allow Grand Labs to market serial 45-016. Rather, it only ordered it to allow Grand Labs to spend \$40,000 of its own money to retest the serial and then submit the evidence of this retest, along with the testimony developed at trial and the satisfactory test results withheld from the USDA, for reconsideration by the USDA in light of the overall record. The bottom line is that the USDA retains the ultimate decision whether serial 45-016 may be marketed, and its decision will remain undisturbed as long as it was made based upon full and fair consideration of the record. If the government is still convinced after reprocessing that the original finding of contamination is irrevocable, it can simply deny Grand Labs the right to market the serial, and we will be back at square one. By allowing reprocessing, however, Grand Labs will be assured that the government is giving it a full and fair opportunity to urge its position that serial 45-016 is marketable.

For these reasons, I would affirm the district court. I respectfully submit that it is unreasonable to find that a district court erred by requiring an administrative agency to fully and fairly review all the evidence in making its critical decisions.

Injunctive Relief

I respectfully submit that the district court's decision denying all injunctive relief also should be upheld. The question whether a plaintiff is entitled to injunctive relief in a given case "addresses itself to the judicial discretion of the trial court," Columbia Transit Corp. v. Jones, 572 F.2d 168, 173 (8th Cir. 1978), and should be given due deference by this court. One of the requirements necessary for injunctive relief to be

concealed from the USDA tests that showed no contamination.

granted, is that the plaintiff has no adequate remedy at law. See, e.g., id. It is clear in this case that the USDA has an adequate remedy at law in the event of any future shipment of serial 45-016 or other VSTA violation by Dr. Pankratz.

Under 21 U.S.C. § 157, an adequate legal remedy exists for the USDA to enter any establishment where any virus, serum, toxin or other product used in the treatment of domestic animal is prepared, at any hour of the day or night to inspect and enforce compliance. I fail to see how an injunction in any way would create a greater deterrence from VSTA violation than does the statute itself. Furthermore, Dr. Pankratz's conduct appears to be an isolated act, and the record reveals no basis for concluding that any likelihood exists that he will ship serial 45-016 again.

For the foregoing reasons, I dissent.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.