UNITED STATES, Appellee

v.

Andrew J. KISALA, Specialist
U.S. Army, Appellant

No. 04-0246

Crim. App. No. 20000930

United States Court of Appeals for the Armed Forces

Argued December 8, 2005

Decided September 27, 2006

GIERKE, C.J., delivered the opinion of the Court, in which CRAWFORD, EFFRON, BAKER, and ERDMANN, JJ., joined.

Counsel

For Appellant: Captain Todd N. George (argued); Colonel Mark Cremin, Colonel Robert D. Teetsel, Lieutenant Colonel Mark Tellitocci, Major Sean S. Park, and Captain Jeremy W. Robinson (on brief).

For Appellee: Captain Michael C. Friess (argued); Colonel Lauren B. Lecker, Colonel Steven T. Salata, Lieutenant Colonel Margaret B. Baines, Lieutenant Colonel Theresa A. Gallagher, Lieutenant Colonel Mark L. Johnson, Major Natalie A. Kolb, Captain Mark J. Hamel, and Captain Edward E. Wiggers (on brief).

Amicus Curiae: Lieutenant Brian L. Mizer, JAGC, USN, and Captain Pamela A. Holden, JAGC, USN, for the United States Navy-Marine Corps Appellate Defense Division (on brief).

Military Judge: Patrick J. Parrish

Chief Judge GIERKE delivered the opinion of the Court.

Appellant was convicted, contrary to his pleas, of willfully disobeying a lawful order of his superior commissioned officer to receive an anthrax vaccination.[1] Appellant has challenged the lawfulness of the order. We hold that Appellant has not rebutted the presumption that the order was lawful. In particular, Appellant has not demonstrated that the order relied improperly upon interpretations by the Food and Drug Administration (FDA) of the long-standing approved license to administer this specific Vaccine.[2]

I. FACTS

Appellant's Battalion Commander issued a direct order to Appellant on August 24, 2000, in the presence of the sergeant major, the company commander, and the first sergeant, to receive the anthrax vaccination by the close of business that day. Due to the limited availability of the Vaccine at Fort Bragg at the time, there was difficulty locating a clinic where Appellant would be able to receive the inoculation. A clinic with the Vaccine was not located until after 1600 hours on August 24, 2000. Because it would have been difficult to transport Appellant to the clinic in time to receive the shot prior to the

[1] Appellant's offense was a violation of Article 90, Uniform Code of Military Justice (UCMJ), 10 U.S.C. § 890 (2000).
[2] Anthrax Vaccine Adsorbed is the vaccine that was the subject of this order. Although it is commonly referred to as "AVA," this opinion refers to it as the "Vaccine."

termination of routine clinic hours, the battalion commander and the company commander extended the time for Appellant to comply with the order to August 25, 2000.

On the morning of August 25, 2000, the company commander issued Appellant a written counseling statement reiterating the battalion commander's order to receive the anthrax vaccination prior to 1700 hours on August 25, 2000. Appellant signed this statement thereby acknowledging his understanding of the order. At the time of the counseling statement, Appellant was told that the Vaccine was available and that the company commander was willing and able to take Appellant to the clinic to receive the Vaccine.

Appellant refused to receive the Vaccine and was charged with willfully disobeying the lawful order of a superior commissioned officer in violation of Article 90, UCMJ. Contrary to his pleas, Appellant was convicted of this offense (with the date August 25, 2000, substituted for August 24, 2000). The military judge sentenced Appellant to be reduced to pay grade E-1, confined for thirty days and to be discharged from the service with a bad-conduct discharge. The convening authority approved the sentence as adjudged. The United States Army Court

of Criminal Appeals affirmed the findings and sentence as approved.[3]

This Court granted review of the following issue:

> WHETHER THE ORDER THAT APPELLANT SUBMIT TO AN ANTHRAX VACCINATION ON AUGUST 24, 2000, WAS A LAWFUL ORDER UNDER THE CIRCUMSTANCES AT THAT TIME.[4]

II. DISCUSSION

Long ago this Court recognized the foundational principle of military discipline: "Fundamental to an effective armed force is the obligation of obedience to lawful orders."[5] Reflecting the authority of this principle, an order is presumed to be lawful, and a subordinate disobeys an order at his own peril.[6] However, a servicemember may challenge the lawfulness of

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[3] United States v. Kisala, No. Army 20000930 (A. Ct. Crim. Dec. 22, 2003).

[4] United States v. Kisala, 60 M.J. 128 (C.A.A.F. 2004).

[5] Lee v. Pearson, 18 C.M.A. 545, 546, 40 C.M.R. 257, 258 (1969) (quoting United States v. Noyd, 18 C.M.A. 483, 491, 40 C.M.R. 195, 203 (1969)). Indeed, a professional military institution could not otherwise function without a service member having a duty to obey lawful orders.

[6] Manual for Courts-Martial, United States pt. IV, para. 14.c.(2)(a)(i) (2005 ed.)(MCM), states:

> An order requiring the performance of a military duty or act may be inferred to be lawful and it is disobeyed at the peril of the subordinate. This inference does not apply to a patently illegal order, such as one that directs the commission of a crime.

See also United States v. New, 55 M.J. 95, 108 (C.A.A.F. 2001); United States v. Hughey, 46 M.J. 152, 154 (C.A.A.F. 1997); United States v. Nieves, 44 M.J. 96, 98 (C.A.A.F. 1996); United States v. Womack, 29 M.J. 88, 90 (C.M.A. 1989); Unger v. Ziemniak, 27 M.J. 349, 359 (C.M.A. 1989); Nico Keijzer, Military Obedience 97-98, 155-71 (1978); William Winthrop, Military Law

an order at the time it is given or in later disciplinary proceedings.[7]

This Court has outlined the essential attributes of a lawful order that sustain the presumption of lawfulness to include: "(1) issuance by competent authority –- a person authorized by applicable law to give such an order; (2) communication of words that express a specific mandate to do or not do a specific act; and (3) relationship of the mandate to a military duty."[8] In light of the presumption of lawfulness, long-standing principles of military justice place the burden of rebutting this presumption on the accused.[9]

In this case, Appellant is attempting to overcome this presumption of the lawfulness of the order to receive the Vaccine. Appellant's assertion that the order was unlawful has two components. First, Appellant claims that the Vaccine is an investigational new drug or a drug unapproved for its applied use as a vaccine against inhalation anthrax. Second, Appellant

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and Precedents 575-76 (2d ed. 1920 reprint); see generally William C. De Hart, Observations on Military Law and the Constitution and Practice of Courts-Martial 165-66 (1946).

[7] This opinion, while relying on the presumption of lawfulness, is not inconsistent with R.C.M. 916(d) under which, "It is a defense to any offense that the accused was acting pursuant to orders unless the accused knew the orders to be unlawful or a person of ordinary sense and understanding would have known the orders to be unlawful."

[8] United States v. Deisher, 61 M.J. 313, 317 (C.A.A.F. 2005); MCM pt. IV, para. 14.c.(2)(a)(ii)-(iii), para. 14.c.(2)(d); see also Noyd, 18 C.M.A. at 489, 40 C.M.R. at 201 (presenting examples of when an order may be unlawful).

[9] United States v. Hughey, 46 M.J. 152, 154 (C.A.A.F. 1997).

claims that the order to receive this investigational new drug violated federal law and was therefore unlawful.[10]

[10] Appellant asserts that 10 U.S.C. § 1107 (2000), and Exec. Order 13,139, 64 Fed. Reg. 54,175 (Oct. 5, 1999), confer upon him a right to refuse the order to receive the Vaccine. The relevant portions of these two authorities appear below.

10 U.S.C. § 1107:

> (a)(1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an investigational new drug or a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in subsection (d)
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> . . . .
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> (d) Content of notice. The notice required under subsection (a)(1) shall include the following: (1) clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use. (2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered. (3) Information regarding the possible side effects . . . . (4) Such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed.

Exec. Order 13,139:

> Sec. 3. Informed Consent Requirement and Waiver Provision. (a) Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DOD) must obtain informed consent from each individual . . . .
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> Sec. 6. (a) This order applies to the consideration and Presidential approval of a waiver of informed consent under 10 U.S.C. § 1107 and does not apply to other FDA regulations.
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> (b) This order is intended only to improve the internal management of the Federal Government. Nothing contained in this order shall create any right or benefit, substantive

We conclude that Appellant's argument fails with regard to both components and address them in turn.

APPELLANT'S ASSERTION THAT THE VACCINE WAS AN INVESTIGATIONAL NEW DRUG OR DRUG UNAPPROVED FOR ITS APPLIED USE

To support his argument, Appellant made several allegations regarding the status of the Vaccine. Appellant first asserts that the Food and Drug Administration initiated an investigation into the Vaccine but never issued a final rule approving use of the Vaccine to protect against inhalation anthrax. Second, Appellant asserts that the Vaccine's manufacturer, working in conjunction with the Department of Defense (DoD), filed an investigational new drug application in 1996.[11] According to Appellant, this application proposed to conduct investigations that would support specifically adding "inhalation anthrax" to the Vaccine label.

Appellant also asserts that the Vaccine was and is an investigational new drug unapproved for its applied use -- to protect against inhalation anthrax. In support of this

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> or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

[11] The Michigan Department of Public Health (MDPH) filed an Investigational New Drug Application in 1996. "The manufacturer's stated purpose for filing the application was 'to conduct clinical investigations designed to investigate changes in the approved labeling for the licensed product. The potential labeling would affect the specific clinical indication, route and vaccination schedule for AVA.'" Doe v. Rumsfeld, 297 F. Supp. 2d 119, 132 (D.D.C. 2003) (quoting letter from MDPH to Dr. Kathryn C. Zoon (Oct. 20, 1996)).

argument, Appellant relies on two successive and related federal district court opinions that issued first a temporary and then a permanent injunction preventing the DoD from subjecting military personnel to involuntary anthrax vaccinations absent informed consent or a presidential waiver.[12]

The federal district court's evaluation of the civil remedies differs from our evaluation of the criminal charges that arise in the military context of Appellant's willful disobedience of a presumed lawful order. The linchpin of this case is the presumed legality of the military order to receive the Vaccine. The district court opinions neither recognize nor address this critical presumption.

Additionally, on appeal from this decision, the United States Court of Appeals for the District of Columbia Circuit noted that the parties "still dispute whether [the Vaccine]'s original 1970 license takes it outside the definition of a 'drug unapproved for its applied use' within the meaning of 10 U.S.C. § 1107(g)(2)."[13] In noting this disagreement of the parties, the court expressly declined to resolve that issue because it would have no impact on the litigants in the case. Moreover, the D.C. Circuit highlighted that the injunction issued by the district

[12] Doe, 297 F. Supp. 2d at 135; Doe v. Rumsfeld, 341 F. Supp. 2d 1, 15-16 (D.D.C. 2004).
[13] Doe v. Rumsfeld, 172 Fed. Appx 327, 328 (D.C. Cir. 2006), No. 04-5440, 2006 U.S. App. LEXIS 3275, at *3 (D.C. Cir. Feb. 9, 2006).

court in 2004, by its own terms, remained in effect until the FDA classified the Vaccine as safe and effective for its intended use. The D.C. Circuit also noted that after the district court issued the permanent injunction, the FDA issued a classification on December 19, 2005.[14] Therefore, once this classification was issued, the injunction was dissolved.

As stated above, there is a presumption that orders are lawful.[15] Under this presumption, the servicemember challenging the order bears the burden of demonstrating the illegality. Where, as here, we are faced with an order based upon a rule promulgated by an agency outside the normal purview of our Court, we should treat the agency's administrative determinations with considerable deference.[16] Given this degree of deference to the determinations of the FDA, the burden on the servicemember challenging the rule is particularly high.

The National Institutes of Health (NIH) licensed the Vaccine for use against anthrax in 1970.[17] In 1972, the authority to

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[14] Doe, 172 Fed. Appx at 328; 2006 U.S. App. LEXIS 3275, at *2
[15] See supra note 6.
[16] Cf. Auer v. Robbins, 519 U.S. 452, 461 (1997) (an agency's interpretation of its own regulation is entitled to deference); Udall v. Tallman, 380 U.S. 1, 16 (1964) ("[T]his Court shows great deference to the interpretation given the statute by the [ ] agency . . . . When the construction of an administrative regulation rather than a statute is in issue, deference is even more clearly in order.").
[17] 36 Fed. Reg. 8704-05 (May 11, 1971), see also Hearing to Review the Dep't of Defense Anthrax Vaccine Immunization Program Before the S. Comm. on Armed Services, 106th Cong. 9 (2000)

license biological drugs shifted to the FDA.[18] The licenses for drugs approved by the NIH remained effective unless and until the FDA actively decided to suspend or revoke the license.[19] The Vaccine's license has never been suspended or revoked. Additionally, Appellant has not shown that the license was erroneously granted. He has, therefore, not overcome the presumption that the order to receive the Vaccine was lawful.

In 1973 the FDA established a two-stage process for reviewing biological products licensed prior to July 1, 1972.[20] This two-stage process was composed of an advisory review panel, and a request for "data and views."[21]

In accordance with this review, the FDA directed an independent panel of nongovernmental scientists and medical personnel to review the safety and labeling of biological products that had been licensed prior to July 1, 1972.[22] According to 21 C.F.R. 601.25, the panel was: "(1) to evaluate the safety and effectiveness of biological products for which a license has been issued . . . (2) to review the labeling of such biological products, and (3) to advise [the FDA Commissioner] on

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(written statement of FDA), available at http://armed-services.senate.gov/statemnt/2000/000413fd.pdf.

[18] See Press Release, FDA Issues Final Rule and Final Order Regarding Safety and Efficacy of Certain Licensed Biological Products Including Anthrax Vaccine, (Dec. 30, 2003).

[19] 21 C.F.R. § 601.4 (2004); 21 C.F.R. § 601.4 (1977).

[20] 21 C.F.R. § 601.25 (1974).

[21] Id. § 601.25(a), (b).

[22] Id. § 601.25(a).

which of the biological products under review are safe, effective, and not misbranded."[23]

The Vaccine was included in this review of all biological products licensed prior to July 1972. The expert panel recommended that the Vaccine, originally licensed in 1970, be classified as a Category I product.[24] This classification indicates that the Vaccine was safe and effective as labeled. The panel recommended that the Vaccine continue to be licensed on the basis of the evidence of its safety and effectiveness.[25]

As required by 21 C.F.R. § 601.25, the proposed rule required public comment, and the FDA received four total comments, none of which addressed the Vaccine.[26]

In 1996, the Vaccine's manufacturer submitted an investigational new drug application to the FDA.[27] The application identified three areas in which the current anthrax license could be modified: (1) the labeling of the Vaccine, (2) the administration method, and (3) the dosage.[28] It is important

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[23] Id.
[24] 50 Fed. Reg. 51,002-03, 51,058-59, (Dec. 13, 1985).
[25] Id. at 51,059.
[26] See 70 Fed. Reg. 75,180, 75,182 (Dec. 19, 2005).
[27] See supra note 11.
[28] See Doe, 297 F. Supp. 2d at 132 (citing letter from MDPH to Dr. Kathryn C. Zoon (Oct. 20, 1996)). The introductory statements to the 1996 Investigational New Drug (IND) application likewise provided that "the ultimate purpose of the IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule." Doe, 297 F. Supp. 2d at 132 (quoting introductory statement to the IND application (Sept. 20, 1996)).

to note that this application is limited to the three listed purposes and had no effect on the original license of the Vaccine or its subsequent recognition as safe and effective.

The licensing history reflects that the Vaccine has been licensed as approved for anthrax inoculation since 1970[29] without interruption, revocation, or suspension. Moreover, the agency approval has been reaffirmed as recently as December 19, 2005.[30]

Therefore, based on the high degree of deference we give to the FDA determination that served as the basis for the order, and in light of Appellant's failure to demonstrate that the 1970 license was incorrect, modified, or withdrawn, we conclude that Appellant has not carried his burden of demonstrating that the FDA's classification was erroneous.

Because Appellant has not established that the Vaccine is an investigational new drug or a drug unapproved for its applied use, the notice requirements of 10 U.S.C. § 1107,[31] are not implicated by the order to receive the Vaccine. Additionally, Exec. Order 13,139, directing that DoD obtain informed consent from each individual to whom an investigational new drug is to be administered unless the Secretary of Defense can justify a

[29] 36 Fed. Reg. 8704.
[30] 70 Fed. Reg. 75,180, 75,182.
[31] 10 U.S.C. § 1107(a).

need for a waiver of informed consent from the President,[32] is not implicated by the order to receive the Vaccine.

Therefore, we conclude that the Vaccine is not an investigational drug that would implicate 10 U.S.C. § 1107 or Exec. Order 13,139. Accordingly, Appellant has failed to overcome the presumption of the lawfulness of the orders.

III. DECISION

The decision of the United States Army Court of Criminal Appeals is affirmed.

[32] Exec. Order 13,139, 64 Fed. Reg. 54,175.