A Military Exception to "Informed Consent": Doe v. Sullivan

Patrick J. Moran
COMMENT

A MILITARY EXCEPTION TO "INFORMED CONSENT": DOE v. SULLIVAN

The doctrine of informed consent preserves an individual's control over his body by protecting the right to make intelligent

1 See Eugene I. Pavalon, Human Rights and Health Care Law, 25-33 (1980). Before a treatment plan involving some risk to the patient may be initiated, the risks and alternatives must be disclosed to the patient. Id. at 25. The voluntary understanding and competent consent of the patient is required before a physician may undertake the treatment. Id. The principle of "informed consent" has been commended by legal academia as a protector of individual rights, and criticized by health professionals as a "myth" and a "fiction." See Alan Meisel, The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision Making, 1979 Wis. L. Rev. 413, 413 (1979). Critics of informed consent claim that its emphasis on individualistic values frustrates competing values. Id. at 415. Conversely, proponents contend that the doctrine protects individualism by allowing patients to determine their own destiny in medical matters. Id. at 414, 416-17.

Failure to provide adequate information generally gives rise to an action in medical negligence or in battery. See Marcus L. Plante, An Analysis of "Informed Consent", 36 Fordham L. Rev. 639, 650-56 (1969). Cases involving lack of informed consent generally sound in negligence; such claims are premised on the physician's duty of care to disclose risks, absent a justification for failing to do so, and the patient's presumed lack of consent had they been disclosed. Recent Cases, Physicians Duty to Warn of Possible Adverse Results of Proposed Treatment Depends Upon General Practice Followed By Medical Profession in the Community - Di Filippo v. Preston, 75 Harv. L. Rev. 1445, 1446-47 (1962); see Kozup v. Georgetown Univ., 851 F.2d 437, 439 (D.C. Cir. 1988); Berroyer v. Hertz, 672 F.2d 334, 342 (3d Cir. 1982); Mink v. University of Chicago, 460 F. Supp. 713, 716 (N.D. Ill. 1978). Battery claims arise from the general rule that an unauthorized touching constitutes a battery. See Mohr v. Williams, 104 N.W. 12, 13 (Minn. 1905); Union Pac. Ry. v. Botsford, 141 U.S. 250, 252 (1891) ("To compel anyone . . . to submit to the touch of a stranger . . . is an . . . assault and trespass."); Bendiburg v. Dempsey, 809 F.2d 463, 469 (11th Cir. 1990) (in absence of consent, surgery is a battery); Hernandez v. United States, 465 F. Supp. 1071, 1073 (D. Kan. 1979) (holding medical procedures performed without consent an assault and battery under federal and Kansas law); see also Plante, supra, at 657-58 (discussing battery cases).


This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment. Justice Cardozo, while on the Court of Appeals of New York, aptly described this doctrine: "Every human being of adult years and sound mind has a right to determine what shall
decisions concerning medical treatment or experiments based be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."

Id. at 2846-47 (quoting Schloendorff v. Society of New York Hosp., 105 N. E. 92, 93 (N.Y. 1914)). The right to "inviolability of his person, in other words, his right to himself," has been called a citizen's first and greatest right. Rolater v. Strain, 137 P. 96, 97 (Okla. 1913) (citations omitted). The notion that every individual has the right to possession and control of his own body without interference was firmly established at common law. See Union Pac. Ry., 141 U.S. at 251; see also Cruzan, 110 S. Ct. at 2846-47 (patients possess right to refuse medical treatment). Every part of the body is protected from intentional and unpermitted contacts, and the plaintiff need not be conscious at the time of the contact for a violation to occur. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 9, at 39-40 (5th ed. 1984). The integrity of the body is considered to be so important that, unlike in other areas of tort law, proof of harm is not necessary; the technical invasion itself warrants awarding damages to vindicate the violated right. See Mohr, 104 N.W. at 13; cf. Mason v. Wrightson, 109 A.2d 128, 130-132 (Md. 1954) (unwarranted search of criminal defendant resulted in award of nominal damages for "humiliation").

See George J. Annas, Mengele's Birthmark: The Nuremberg Code in United States Courts, 7 J. CONTEMP. HEALTH L. & POL'Y 17, 21 (1991) (Nuremberg Code, deemed most complete and authoritative statement of law of informed consent pertaining to human experimentation, requires informed, voluntary consent of research subject.) Prior to World War II, there were no recorded cases of non-therapeutic experimentation reaching the appellate courts. Id. at 22 n.16. By World War II, courts began to appreciate the value of therapeutic and non-therapeutic experimentation to the progress of medicine and required the consent of the patient. Id. at 22-23; see also Fortner v. Koch, 261 N.W. 762, 765 (Mich. 1935) (recognizing need for medical experimentation with consent of patient). The role of experimentation in the medical field became more accepted by the 1940s, and consent of the patient became essential. See Bonner v. Moran, 126 F.2d 121, 121-22 (D.C. Cir. 1941) (requiring consent of fifteen year old capable of consenting to experimental skin graft to aid cousin where parent also impliedly consented); Stammer v. Board of Regents, 39 N.E.2d 913, 914-15 (N.Y. 1942) (doctor cured facial cancer with medication invented by another patient).

As a result of the atrocities committed by Nazi physicians during World War II, the Military Tribunals at Nuremberg issued "The Nuremberg Code." See United States v. Brandt, 2 TRIAL OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNAL UNDER CONTROL COUNCIL LAW No. 10 at 181, reprinted in JAY KATZ, EXPERIMENTATION WITH HUMAN BEINGS 305-06 (1972) (setting forth ten principles stated in judgment at Nuremberg trials now known as Nuremberg Code). The first of the Code's ten points mandates complete, voluntary consent of the subject as a prerequisite to experimentation. Id. Although the Code is considered "part of international common law," United States courts have only infrequently cited it in civil cases, and have never applied it in a criminal case. See Annas, supra, at 21.

upon full disclosure of the facts and possible consequences. The underlying policy suggests that an individual’s right to balance the risks and benefits of a particular treatment should not be subordinated to societal concerns of maintaining health or advancing medical science. These larger concerns prevail, however, under

---

4 See John Norman, Note, Physicians and Surgeons: Informed Consent, 20 Okla. L. Rev. 214, 215-16 (1967). The duty of the physician is to disclose to the patient the dangers and consequences of the medical procedure of which the surgeon has knowledge. Id. at 216. The extent of this duty depends on various factors, including the “seriousness of the result,” the condition of the patient, and the “necessity of treatment.” Id. at 215-16. What began as a simple principle of law has developed into a complex doctrine. Fay A. Rozovsky, Consent to Treatment, A Practical Guide xxxi (2d ed. 1990). Today, informed consent requires that the physician provide basic information, id. at § 1.12; describe alternative choices, id. at § 1.12.2; allow a reasonable time to weigh the risks and benefits, id. at § 1.12.1; and answer patients’ questions, id. at § 1.9; see also 21 C.F.R. § 50.25 (1991) (stating elements of informed consent).

5 See Lipscomb v. Memorial Hosp., 733 F.2d 332, 336 (4th Cir. 1984) (“paramount purpose” of informed consent doctrine is “the patient’s right to determine what shall be done with his body and when”) (quoting Sard v. Hardy, 379 A.2d 1014, 1021-22 (Md. 1977)); Lambert v. Park, 597 F.2d 236, 238-39 (10th Cir. 1979) (vital social policy behind informed consent is that “a physician should be required to disclose to his patients all material risks of a proposed procedure even if other doctors in the community or specialty would not have made so full a disclosure”); Wachter v. United States, 689 F. Supp. 1420, 1423 (D. Md. 1988)(purpose of informed consent doctrine “is to assure that the patient is informed of alternative treatments”), aff’d, 877 F.2d 257 (4th Cir. 1989); see also Robert J. Levine, Ethics and Regulation of Clinical Research, ch. 5, at 70 (1981) (“[I]nformed consent is designed to uphold the ethical principles of respect for persons.”).

6 See Note, Restructuring Informed Consent: Legal Therapy for the Doctor Patient Relationship, 79 Yale L.J. 1533, 1534-35 (1970). The balancing of risks and benefits is an individual struggle; what appears to be an undue risk to one person may be seen as a benefit to another. Id. The individual, possessing much of the relevant information as to his own well-being, is in the best position to decide whether to undergo a particular treatment. See id. A more participatory approach to medical decision-making, where the patient weighs the alternative courses of action, may increase the patient’s incentive to accept treatment. Id.

7 See Meisel, supra note 1, at 423-25 (“The law often reflects a strong societal interest in promoting health at the expense of individualistic values.”). An example of the state’s use of police power to promote public health is compulsory vaccination against contagious disease. See Jacobsen v. Massachusetts, 197 U.S. 11, 21 (1905) (upholding compulsory vaccination). The exceptions to the general rule of informed consent, e.g., emergency, help balance the societal interest in health with the individual’s interest in informed decision-making. See Meisel, supra note 1, at 433.

8 See Levine, supra note 5, at 73-89 (requiring informed consent for procedures known as treatment or research). Some researchers have regarded informed consent as an obstacle to experimentation. See Milton Oppenheim, Informed Consent to Medical Treatment, 11 Clev. Marshall L. Rev. 249, 261 (1962). The countervailing policy consideration they cite is that by rendering some research more difficult or impossible, the severely ill may be denied new, effective treatments. See Robert L. Schwartz, Informed Consent to Participation in Medical Research Employing Elderly Human Subjects, 1 J. Contemp. Health L. & Pol'y 115, 117 (1985). Balancing these conflicting interests is a matter of social policy and the U.S. has leaned toward protecting the rights of autonomy over the value of research. Id. While
certain exceptions to the informed consent doctrine, for example, in emergency situations, or when the patient is incompetent.  

Federal statutes recognize the right of informed consent in all persons, both civilians and military servicemembers. One such statute, the Food, Drug and Cosmetics Act ("FDCA"), requires that consent be obtained before investigational drugs are administered to any human being. Recently, however, in Doe v. Sulli-

incidents of neglecting individual rights are remembered, such as the Nazi experiments, the effect of unrealized research is not. Id. (discussing distinction between "research" and "treatment").

See Meisel, supra note 1, at 486. There is an exception to the doctrine where circumstances indicate that full disclosure of all facts and possibilities would be unwise, for example, where the patient is unstable or depressed. See, e.g., Natanson v. Kline, 350 P.2d 1093, 1103 (Kan. 1960). A second exception is recognized where an emergency necessitates immediate action to save a patient's life and consent cannot be obtained from the patient or his legal representative. See, e.g., Franklyn v. Peabody, 228 N.W. 681, 682 (Mich. 1930) (condition not so serious an emergency to warrant exception to informed consent).

See Defense Authorization Act § 1401(c)(1), 10 U.S.C. § 980 (1988). The Defense Authorization Act prohibits the use of DOD funds for research involving human beings as experimental subjects unless the informed consent of the subject has been obtained. Id. Under the "Feres Doctrine," however, the United States is not liable under the Federal Torts Claims Act for injuries to servicemembers that arise out of or are incident to military service. 28 U.S.C. § 2680(j) (1988); see Feres v. United States, 340 U.S. 135, 146 (1950); Annas, supra note 3 at 31-32. Thus, a servicemember would be precluded from seeking monetary damages for injuries caused by involuntary submission to administration of drugs or participation in other experiments while in the military. See United States v. Stanley, 483 U.S. 669, 683-84 (1987). However, actions to halt or prevent a violation are still possible. Id.

In Stanley, the plaintiff, while a member of the armed services, had consented to take part in a test of protective clothing for chemical warfare. Id. at 671. Instead, Stanley was secretly administered lysergic acid diethylamide (LSD). Id. Hallucinations and outbreaks of violence caused by the LSD resulted in personality changes and the dissolution of his marriage. Id. The Supreme Court held that the plaintiff could not seek monetary damages for violations of his rights. Id. at 683-84. In a scathing dissent, Justice Brennan cited the Nuremberg Code and stated that the denial of money damages results in absolute immunity for federal officials who violate constitutional rights of servicemembers. Id. at 691 (Brennan, J., dissenting); see also Jaffee v. United States, 663 F.2d 1226, 1229-30, 1234-35 (3d Cir. 1981), cert. denied, 456 U.S. 972 (1982) (denying recovery to serviceman exposed to nuclear fallout from a nuclear bomb experiment).

See 21 C.F.R. § 312.34 (1991) (outlining guidelines and circumstances for implementation of Treatment IND process); Myron L. Marlin, Treatment INDs: A Faster Route To Drug Approval, 39 AM. U. L. Rev. 171 (1989). The FDCA, under a procedure known as "Treatment Use of an Investigational New Drug," or "Treatment IND," provides a new route to drug approval, wherein individuals with serious or life-threatening diseases may access experimental drugs. Id. at 172. The Treatment IND procedure facilitates the "availability of promising new drugs to desperately ill patients as early in the drug development process as possible, before general marketing begins, and [obtains] additional data on the drug's safety and effectiveness." 21 C.F.R. § 312.34 (1991).

van, the Court of Appeals for the District of Columbia Circuit upheld a Food and Drug Administration ("FDA") rule that permits the Commissioner of Food and Drugs, at the request of the Department of Defense ("DOD"), to waive this informed consent requirement in certain combat situations.14

In Sullivan, the plaintiff, Doe, a serviceman stationed in Saudi Arabia during the Desert Shield military operation, brought a class action suit on behalf of all the servicemembers stationed in the Persian Gulf region at the time.15 The DOD had anticipated the use in that conflict of chemical and biological agents by the Iraqis.16 It had identified two investigational drugs which it believed would be effective as a pretreatment administered to combat personnel to counter the effects of these agents.17 Although the two drugs had been approved by the FDA for the treatment of other illnesses, they had not been approved for use as a defense to chemical and biological warfare.18 The DOD believed that mandatory use of these drugs by combat personnel would be necessary for their survival and that obtaining informed consent during the military operation would not be practicable.19 However, no existing regulatory exception to the FDCA would allow the DOD to administer these drugs without informed consent.20 Accordingly, at the DOD's request, the FDA promulgated Rule 23(d) which allows the Commissioner of Food and Drugs to waive the informed consent requirement for the use of investigational drugs where certain battlefield or combat-related situations render consent "not feasible."21 Subsequently, pursuant to FDA Rule 23(d), the Commis-

---

13 938 F.2d 1370 (D.C. Cir. 1991)
14 Id. at 1383.
15 Id. at 1374. The serviceman's wife was also a plaintiff. Id.
16 Id. at 1371-72.
17 Id. at 1372-73.
18 Id. at 1372 n.1. Pyridostigmine bromide is approved for the treatment of myasthenia gravis, a neuromuscular disorder. The DOD proposed to administer only 15% of the average daily dosage used to treat the disorder in civilians. Id. Pentavalent botulinum toxoid vaccine is used to prevent botulism. Id. The drugs had not been approved for use as a defense to chemical or biological warfare because in order to prove the drugs' efficacy for these purposes humans would have to be exposed to the chemical or biological agents, which is considered to be too risky. Id.
19 Id. at 1373.
20 Id.; see Food and Drug Administration Rule 23(a)-(c), 21 C.F.R. § 50.23(a)-(c) (1991)(providing exceptions to requirement for informed consent).
21 Sullivan, 938 F.2d at 1373; 21 C.F.R. § 50.23(d) (1991) (Rule 23(d)) (exception from general requirement of informed consent). Rule 23(d) reads in full:
(d)(1) The Commissioner may also determine that obtaining informed consent is
sioner waived the informed consent requirement for the two drugs.\(^2\)

In order to prevent the involuntary administering of these drugs, Doe filed suit in the District Court for the District of Co-

not feasible when the Assistant Secretary of Defense (Health Affairs) requests such a determination in connection with the use of an investigational drug (including an antibiotic or biological product) in a specific protocol under an investigational new drug application (IND) sponsored by the Department of Defense (DOD). DOD's request for a determination that obtaining informed consent from military personnel is not feasible must be limited to a specific military operation involving combat or the immediate threat of combat. The request must also include a written justification supporting the conclusions of the physician(s) responsible for the medical care of the military personnel involved and the investigator(s) identified in the IND that a military combat exigency exists because of special military combat (actual or threatened) circumstances in which, in order to facilitate the accomplishment of the military mission, preservation of the health of the individual and the safety of other personnel require that a particular treatment be provided to a specified group of military personnel, without regard to what might be any individual's personal preference for no treatment or for some alternative treatment. The written request must also include a statement that a duly constituted institutional review board has reviewed and approved the use of the investigational drug without informed consent. The Commissioner may find that informed consent is not feasible only when withholding treatment would be contrary to the best interests of military personnel and there is no available satisfactory alternative therapy.

(2) In reaching a determination under paragraph (d)(1) of this section that obtaining informed consent is not feasible and withholding treatment would be contrary to the best interests of military personnel, the Commissioner will review the request submitted under paragraph (d)(1) of this section and take into account all pertinent factors, including, but not limited to:

(i) The extent and strength of the evidence of the safety and effectiveness of the investigational drug for the intended use;
(ii) The context in which the drug will be administered, e.g., whether it is intended for use in a battlefield or hospital setting or whether it will be self-administered or will be administered by a health professional;
(iii) The nature of the disease or condition for which the preventive or therapeutic treatment is intended; and
(iv) The nature of the information to be provided to the recipients of the drug concerning the potential benefits and risks of taking or not taking the drug.

(3) The Commissioner may request a recommendation from appropriate experts before reaching a determination on a request submitted under paragraph (d)(1) of this section.

(4) A determination by the Commissioner that obtaining informed consent is not feasible and withholding treatment would be contrary to the best interests of military personnel will expire at the end of one year, unless renewed at DOD's request, or when DOD informs the Commissioner that the specific military operation creating the need for the use of the investigational drug has ended, whichever is earlier. The Commissioner may also revoke this determination based on changed circumstances.

\(^{22}\) Sullivan, 938 F.2d at 1374.
lumbia seeking declaratory and injunctive relief. Doe challenged Rule 23(d) as being, on its face, outside the scope of authority granted to the FDA in the Food, Drug, and Cosmetic Act. Doe further asserted that Rule 23(d) and section 1401(c)(1) of the Defense Department Authorization Act ("DOD Act"), which prohibits the use of DOD funds for "research" on human subjects without their informed consent, could not be reconciled. Additionally, Doe claimed that forcing non-approved drugs on servicemembers without their consent violated their constitutional right to due process.

The district court granted the defendant's motion to dismiss, holding that the issue was not amenable to judicial review because it was a decision of military strategy. Nevertheless, the district court stated its belief that Rule 23(d) was within the FDA's statutory rulemaking authority, and that its application during the Persian Gulf operations did not violate the FDCA.

On appeal, the Court of Appeals for the District of Columbia Circuit affirmed, upholding the FDA's authority to promulgate Rule 23(d). Writing for the court, Judge Bader Ginsberg held that the issue was amenable to judicial review because the FDA ruling could not be considered a strategic military decision. The court of appeals found that the provision of the FDCA which dispenses with the informed consent requirement when such consent

---

24 Sullivan, 938 F.2d at 1374.
26 Sullivan, 938 F.2d at 1374-75.
27 Id. at 1375.
29 Id. at 16. The court also held that Rule 23(d) did not violate the DOD Act and that the application of the rule did not deprive the plaintiff of "liberty without due process." Id. at 14-17. The court also found that the "DOD's decision to use unapproved drugs is precisely the type of military decision that courts have repeatedly refused to second-guess." Id. at 15.
30 Sullivan, 938 F.2d at 1381. In addition, the court affirmed the district court holding that there had been no violation of the plaintiff's due process rights. Id.

In a vigorous dissent, then Circuit Judge Clarence Thomas found the issue moot as there no longer existed any case or controversy since the war had long since ended. Id. at 1384-85 (Thomas, J., dissenting). Judge Thomas noted that judicial review in this situation was only permissible where there existed a "reasonable expectation that the same complaining party [will] be subjected to the same action yet again." Id. at 1385 (Thomas, J., dissenting) (quoting Weinstein v. Bradford, 423 U.S. 147, 149 (1975)) (alteration in original). It was not reasonably likely, Judge Thomas asserted, that this same complaining party will again be personally subjected to identical FDA and DOD action. Id.
31 Id. at 1380. The court reasoned that the FDA is a non-military agency, and that the plaintiff was not challenging a military command, but rather the authority of the FDA. Id.
is "not feasible" was ambiguous and that the FDA's construction of this term in Rule 23(d) was "well within the ordinary meaning" of the words Congress used."32 Thus, following the Supreme Court's rationale in *Chevron U.S.A. v. Natural Resources Defense Council*,33 the court held that it was bound to defer to the FDA's construction.34 The court further held that the DOD Act did not restrict the authority of the FDA to promulgate Rule 23(d).35 The question whether the DOD was within its authority to administer the drugs was not addressed.36

In light of the unique demands of a military unit in combat, it is submitted that the need for a military exception to the informed consent doctrine is manifest. This Comment will discuss the nature of chemical warfare and will propose that the use of the drugs at issue was necessary to ensure not only the survival of individual servicemembers, but also that of their unit co-members. This Comment will also assert that the *Sullivan* court was correct in finding that the promulgation of Rule 23(d) was within the statutory authority of the FDA. Furthermore, it will suggest that Rule 23(d) is narrowly tailored, since it only applies to combat exigencies, and thus affords protection against abuses.

I. CHEMICAL AND BIOLOGICAL WARFARE: THE NEED FOR A MILITARY EXCEPTION TO INFORMED CONSENT

Modern chemical weapons,37 nerve agents now possessed by
Iraq and many other countries,\textsuperscript{38} cause drooling, staggering, confusion, and involuntary defecation and urination and are capable of causing death within one to fifteen minutes.\textsuperscript{39} Biological agents spread contagious diseases such as cholera and botulism among an enemy's military and populace.\textsuperscript{40} As the technology used to develop and deploy chemical and biological weapons has advanced, so have the defenses available to neutralize their effects.\textsuperscript{41} Modern protective gear,\textsuperscript{42} however, will provide adequate protection only if there is early warning of an attack\textsuperscript{43} and the amount of the agent is

\textbf{Secretary General} at 5. By the end of the war, the use of over 125,000 tons of toxic chemicals had caused 100,000 deaths and 1,200,000 other casualties. \textit{Id.} The agents used in World War I were much less toxic, and the means of dispersal were much less efficient than modern day agents and methods. \textit{Id.}

\textsuperscript{38} Speirs, supra note 37, at 191. As of 1986, France, the United States, and the Soviet Union were known to possess modern chemical weapons, and eleven countries, including Libya, China, Syria and Burma reportedly possessed them. \textit{Id.}

\textsuperscript{39} \textit{Id.} at 4. Nerve agents are stored as liquids and dispersed as either vapor or a spray of liquid droplets. \textit{Id.} The agent can penetrate the body through exposed skin or by inhalation. \textit{Id.} By reacting with enzymes, the nerve agent causes a loss of control over the nervous system and allows a rapid accumulation of powerful poisons. \textit{Id.} Respiratory lethal dosages kill in one to fifteen minutes, while death through absorption may be delayed up to two hours. \textit{Id.} Nerve agents are considered the most effective lethal chemicals used in warfare. \textit{Id.} The amount of nerve agent that would fit on the head of a pin is enough to kill one person. See Neil C. Livingstone, et al., CBW: The Poor Man's Atomic Bomb 4-5 (1984).

\textsuperscript{40} Mossby’s Medical, Nursing, and Allied Health Dictionary 164 (3d ed. 1990). Botulism is characterized by muscle weakness and paralysis, and disturbance of vision, swallowing, and speech. \textit{Id.} Two-thirds of all cases of botulism are fatal, and for those who survive, recovery is slow. \textit{Id.} Cholera is characterized by severe gastrointestinal symptoms which include diarrhea, vomiting, shock, and muscle cramps. Dorland’s Illustrated Medical Dictionary 323 (27th ed. 1988).

\textsuperscript{41} See Speirs, supra note 37, at 42-45. British soldiers responded to the first gas attacks by covering their mouths with rags. \textit{Id.} at 42. Various masks with filters were developed, but each design was soon rendered ineffective by the increasing lethality of the agents. \textit{Id.} at 44.

\textsuperscript{42} See Baker Spring, America’s Options if Iraq Uses Chemical Weapons, 1990 Heritage Found. Rep. 1, 2. U.S soldiers are equipped with a protective rubber mask, a charcoal-layered overgarment, and rubber boots and gloves. \textit{Id.} The M-17 mask used by U.S. soldiers has been heavily criticized by defense commentators while defended by the DOD. See In Need of Protection, Time, Feb. 18, 1991, at 23. A former editor of the technical journal Nuclear, Biological and Chemical Defense and Technology claims that the M-17 mask offers little protection, and that the protective suits can be penetrated by chemical agents. \textit{Id.} In fact, the currently used M-17 mask was designed in 1955, and has not “been significantly improved since.” \textit{Id.} In 1986, however, a Government Accounting Office study determined that the protection was adequate. \textit{Id.}

There has been much criticism of the protective equipment used by the U.S. military. See Ben Sherwood, Toxic Shock—Our Chemically Unready Troops, The New Republic, May 6, 1991, at 11. A 1973 Army memo listed the M-17’s design flaws, including the wearer's inability to change filters without removing the mask. \textit{Id.}

\textsuperscript{43} See Sherwood, supra note 42, at 6. United States forces in Saudi Arabia had such little confidence in their chemical warning systems that they placed chickens in boxes at the
not overwhelming. Due to these limitations in external protection, soldiers have been issued various drugs to combat internally the effects of these agents. All of these protective measures, including the use of the drugs at issue in Sullivan, are necessary to increase the survival of the unit members who depend on each other's performance.

In combat, where chemical or biological warfare is possible, allowing a soldier to refuse treatment would not only increase the probability of his own death, but may also result in the death of his comrades and the failure of the military mission. Society recognizes that civilians faced with serious physical harm have the right to refuse treatment after evaluating the risks for themselves. Soldiers who are part of an interdependent combat unit, however, cannot be allowed to chart their own course in evaluating risks at the expense of their fellow soldiers and the military objective. Just as soldiers may not decide to enter combat without a helmet or an M-16 as a matter of personal preference, they may not decline to accept medical treatment that is designed to pre-

outskirts of a base to detect chemical attacks. Id. An Army Inspector General report in 1989 warned of the weaknesses in the ability to detect an attack. Id. Once a chemical attack is detected, a soldier is expected to stop whatever he is doing and put on his protective overgarment, mask, hood, overboots, protective gloves, and individual decontamination kits with antidotes, all within eight minutes. U.S. ARMY, STP 21-1-SMCT, SOLDIERS MANUAL OF COMMON TASKS 424-28 (1987).

See Sherwood, supra note 42, at 7. A 1986 Government Accounting Office report revealed that "up to 50% of the masks currently in the field would leak if attacked with high concentrations of chemical agent." Id.

See Spiers, supra note 37, at 65-66. Each soldier is issued an injector kit, equipped with the approved drugs atropine and pralidoxime chloride, to help counter the effects of nerve gas. Id. One of the investigational drugs that the DOD received permission to use in Desert Storm, pyridostigmine bromide, was intended to be taken prior to combat to increase the effectiveness of atropine. Sullivan, 938 F.2d at 1372.

Sullivan, 938 F.2d at 1373. The DOD stated that the safety of other personnel necessitated the mandatory use of the drugs. Id. British forces are also required to take pyridostigmine pills when a chemical attack is likely. See Spiers, supra note 37, at 65.


See supra notes 4-6 and accompanying text (discussing individual right to choose treatment).

See Informed Consent for Human Drugs and Biologies; Determination That Informed Consent Is Not Feasible, 55 Fed. Reg. 52,814-15 (1990) (to be codified at 21 C.F.R. § 50.23). A letter dated October 30, 1990, from DOD's Assistant Secretary of Defense to the Department of Health and Human Services stated, "[i]f a soldier's life will be endangered by nerve gas . . . it is not acceptable from a military standpoint to defer to whatever might be a soldier's personal preference." Id.; see also Howe & Martin, supra note 47, at 23.
serve their military effectiveness. Servicemembers do not enjoy all of the rights and privileges of civilians; their individual interests are subordinated to the military mission. Moreover, the government may compel military service and the activities in which servicemembers engage are not a matter of personal choice. As the nature of war changes with increasing usage of chemical and biological weapons, the demands made on soldiers to survive must also change.

II. The Authority of the FDA to Promulgate Rule 23(d)

The FDCA permits the Secretary of Health to promulgate regulations allowing the use of non-FDA approved drugs for investigational purposes. The informed consent of those to whom these

---

50 Cf. William Winthrop, Military Law and Precedents 571-75 (2d ed. 1979) (illustrating rigid guidelines imposed on military personnel). Disobeying a lawful order is punishable as a crime under the Uniform Code of Military Justice. Id. The military crime of “misbehavior” is committed when a soldier in combat throws aside arms or willfully does “less than the utmost to combat the enemy.” Robinson O. Everett, Military Justice in the Armed Forces of the United States 50 (1956). But see George J. Annas & Michael A. Grodin, Treating the Troops: Commentary. Hastings Center Rep., March-April, 1991, at 24, 26 (arguing that administering unproven vaccines is distinguishable from requiring soldiers to wear “helmets and flak jackets” in that vaccines can cause injury in and of themselves).

One commentator has argued that “to the degree consistent with national security and military needs,” soldiers should be informed of the risks and expected benefits of the treatment; “thus, even if they are ordered to conform, their dignity as persons would be respected.” Howe & Martin, supra note 47, at 22.

51 This Comment does not address the issue of the constitutional rights of servicemembers. The Supreme Court has held that servicemembers cannot sue for damages resulting from constitutional wrongs by superiors. Chappell v. Wallace, 462 U.S. 296, 305 (1982); see also Burns v. Wilson, 346 U.S. 137, 140 (1953) (“The rights of men in the armed forces must perforce be conditioned to meet certain overriding demands of discipline and duty . . . .”).

52 Howe & Martin, supra note 47, at 23.

53 See Selective Draft Law Cases, 245 U.S. 366, 377 (1918) (consolidating six cases challenging constitutionality of draft law). The Court held that the government’s authority to compel military service was expressly granted by the Constitution in Article I, § 8, which empowers the Congress to declare war. Id. “The highest duty of the citizen is to bear arms at the call of the nation.” Id. at 388. “It is a contradiction in terms to say that the United States is a sovereign and yet lacks this power of self-defense.” Id.

54 See Burns, 346 U.S. at 140.

55 See Spiers, supra note 37, at 42-68.

56 See 21 U.S.C. § 355(i) (1988). The Act states that such regulations are within the discretion of the Secretary, who is to base any exemption on factors related to the protection of public health, including preclinical testing and the maintenance of records. Id.; see supra note 11 (discussing “Investigational New Drugs”). Clearly, the DOD viewed the use of such drugs as critical to troop survival, and the task of obtaining consent as detrimental to the troops’ best interests. See supra note 49 and accompanying text.
investigational drugs are administered is required "except where . . . [the experts administering the drug] deem it not feasible, or in their professional judgment, contrary to the best interests of [the recipient]." In Doe v. Sullivan, the plaintiff claimed that such exemptions were limited to instances in which the particular recipient of the drug is not capable of giving or withholding consent intelligently, thus rendering consent "not feasible." Prior to the promulgation of Rule 23(d), the FDA followed this interpretation and deemed informed consent "not feasible" only if communication with the subject could not be established, and if there was insufficient time to obtain consent from the subject's legal representative. Doe contended that the term "not feasible" clearly expressed the unambiguous intent of Congress to apply the exemption only in cases where the individual was incapacitated.

It is a fundamental rule of statutory construction that if congressional intent is clear, both the court and the agency involved must give effect to the "unambiguously expressed intent."

---

67 21 U.S.C. § 355(i) (1988). Although formulation of regulations exempting investigatory use of certain drugs from FDCA research requirements is a discretionary act of the Secretary, there are certain mandatory requirements attendant to their promulgation. Id. An exemption may be granted only if the sponsor of the investigation requires a certification from the medical expert using the drug that any humans being administered the drug, or their legal representative, are informed that the drug's use is investigational and unapproved. Id. The exceptions arise only if the experts deem consent "not feasible," or "contrary to the best interests of such human beings." Id. As the FDA based Rule 23(d) on the "not feasible" language, the Sullivan court did not address the "best interests" language. See Sullivan, 938 F.2d at 1382 n.17; infra note 70.

68 Sullivan, 938 F.2d at 1382. Doe claimed that the exception could not apply if the subject "has the capacity intelligently to give or withhold consent." Id.

69 Id. The rule regulating informed consent, in effect prior to Rule 23(d), supported Doe's claim. See 21 C.F.R. § 50.23(a)-(c) (1991). Under Rule 23, before informed consent may be deemed "not feasible" the investigator and a physician not participating in the investigation must certify in writing that, inter alia, the human subject is confronted by a life-threatening situation. Id. Informed consent cannot be obtained due to the subject's inability to communicate and consent cannot be obtained from the subject's legal representative because of time constraints. Id.

70 Sullivan, 938 F.2d at 1381. "Doe urged . . . that Congress spoke plainly in the FDC[A] Act and that FDA failed to give effect to the unambiguously expressed legislative intent." Id.

71 Chevron U.S.A. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984). Neither the court nor the agency may substitute its will for the "unambiguously expressed intent of Congress." Id. The courts, as final authorities on issues of statutory construction, must reject an agency's interpretation of a controlling statute if it is contrary to the statutory mandate or frustrates the intended policy of Congress. See Federal Election Comm'n v. Democratic Senatorial Campaign Comm., 454 U.S. 27, 32 (1981). When Congress uses a word "well understood," some interpretive flexibility may be permitted, but its ordinary meaning cannot be disregarded. See Social Sec. Bd. v. Nierotko, 327 U.S. 358, 369
natively, if the relevant legislative provision is silent or ambiguous with respect to the issue, then the agency need only apply a "per-
missible construction of the statute." Nowhere in the statutory language or the legislative history is the term "not feasible" de-
dined. The FDA has altered its interpretation of "not feasible" to include the urgent circumstances of imminent combat and the re-
sultant risks to the soldiers' lives. Agency regulations interpreting ambiguous statutory terms are given controlling weight unless they are arbitrary, capricious, or clearly contrary to the intent of the statute. Deference is accorded even if the agency displays "a

(1946). In Nierotko, the word at issue in the Social Security Act was "wages," used to specify which receipts were to determine taxes and benefits. Id. As Congress did not delegate to the Social Security Board the power to determine what compensation could be treated as "wages," the Court struck down the Board's regulation excluding back-pay from wages. Id. While considerable weight may be accorded an agency's interpretation, if congressional intent is clear with respect to the precise question at issue, there is no alternative but to give effect to that intention as law. See Chevron, 467 U.S. at 842-44; see also Volkswagenwerk Aktiengesellschaft v. Federal Maritime Comm'n, 390 U.S. 261, 272 (1968) (noting court does not "rubber-stamp" administrative decisions inconsistent with statutory mandate).

See Chevron, 467 U.S. at 843. In the absence of specific congressional intent on the point at issue, the court may not fill the void with its own construction. See R. Pound, THE SPIRIT OF THE COMMON LAW 174-75 (1921). The court's own construction of a statute would be permitted and necessary only in the absence of administrative interpretation. See Chevron, 467 U.S. at 844.

When the statute is ambiguous, the question for the court is limited to whether the agency's construction is permissible or "sufficiently reasonable." See Federal Election Comm'n, 454 U.S. at 39. In the absence of "a clearly enunciated legislative purpose," where an agency's interpretation is supported by a reasoned analysis, the court may uphold the regulation. Id. at 42. The court need not find that the agency's construction of the statute is one that it would have chosen if given the opportunity to do so, nor that it is the only reasonable interpretation. See Udall v. Tallman, 380 U.S. 1, 16 (1965) (quoting Unemployment Comm'n v. Aragon, 329 U.S. 143, 153 (1946)). Indeed, if the meaning of the words at issue is not clear, the administrative interpretation "becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation." See Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945).

Sullivan, 938 F.2d at 1382. The remarks by Senators Kefauver and Javits repeat the statutory language of the informed consent provision, but do not define it. Id.; 108 Cong. Rec. 22,042-43 (1962) (discussing significance of provision as a whole).

Sullivan, 938 F.2d at 1382. "Not feasible" is now interpreted by the FDA to mean "impracticable" and is thus not limited to situations in which the patient is physically incapacitated. Id. The court found the circumstances under which Rule 23(d) applied, i.e., "particularly urgent circumstances: a combat-zone setting, the safety of military personnel at that location, and the compelling need to promote success of the service members' mission," to be within the ordinary meaning of the words in the statute. Id.

See Schweiker v. Gray Panthers, 453 U.S. 34, 44 (1981). The task of the court is limited to ensuring that the interpretation is not arbitrary or capricious, or outside the statutory authority. Id.

The relationship between courts and agencies is not analogous to the relationship of appellate courts to lower courts. See generally 2 CHARLES H. KOCH JR., ADMINISTRATIVE LAW
sharp break with prior interpretations.”

AND PRACTICE § 9.5 at 93 (1985). Rather than the “clearly erroneous” standard of review applied by appellate courts to trial court rulings, the judiciary is limited to making a determination of the arbitrariness of agency action. Id. Active judicial participation in the administrative process negates the advantages of using administrative decision making, and blurs the separation of powers with respect to policy-making. Id. §§ 9.5 & 9.17. The “arbitrary and capricious” standard has developed to preserve the integrity of the administrative process by allowing a “high risk of error” to be tolerated. Id. § 9.6, at 96. Although the term “arbitrariness” is without clear meaning, it invokes a lesser degree of scrutiny than a reasonableness standard, allowing “a greater tolerance for error.” Id. at 97. To pass the reasonableness test, administrative decisions need not be uniform, but each must be “within the boundaries of sound judgment” to be upheld. Id. at 100. The standard of arbitrariness is significantly lower, as a rejected decision must be “totally intolerable [and]... outside any conceivable alternative.” Id. Federal law also directs that a reviewing court strike down any agency ruling that is “capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706 (1966); see Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 414, (1971) (setting forth classic instruction on question of arbitrariness).

An unexplained policy change by the agency has often been held to be arbitrary, and thus not deserving of the usual deference. Democratic Union Organizing Comm. Local 777, v. NLRB, 603 F.2d 862, 882 (D.C. Cir. 1979). In Local 777, the issue disputed was whether taxi drivers who leased cabs from a company were employees or independent contractors. Id. at 869. The court of appeals found that the NLRB had repeatedly reached conflicting decisions in identical cases without announcement of a “principled reason,” and refused to enforce an order of the board until it received an intelligent rationale. Id. at 882.

The leading Supreme Court case finding arbitrariness in agency action involved the National Highway Traffic Safety Administration’s (NHSTA) rescission of passive restraint requirements for automobiles. See Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 46-57 (1983). The Court recognized that judicial restraint is necessary in applying the arbitrariness test, but found no credible explanation of why the NHSTA did not pick from the various safety measure alternatives rather than disavow all new requirements. Id.

Absolute certainty of its position is not necessary on the part of the agency. See Baltimore Gas and Elec. v. Natural Resources Defense Council, Inc., 462 U.S. 87, 98-99 (1983). In Baltimore Gas a table promulgated by the Nuclear Regulatory Commission (“NRC”) to evaluate the effects of nuclear fuel cycles was challenged as not having a sufficiently certain basis. Id. at 93. The Court reasoned that the technical complexity of the topic and the in-depth rationale presented by the NRC overshadowed the absence of certainty, thus its decision was “within the bounds of reasoned decision making.” Id. The Court also stated that it would be most deferential when reviewing a scientific determination as opposed to a finding of fact. Id.

Rust v. Sullivan, 111 S. Ct. 1759, 1769 (1991). Title X of the Public Health Service Act permitted the Secretary of Health and Human Services to grant federal monetary assistance to family planning projects. Id. at 1764. Section 1008 provided that none of the funds could be used in programs where abortion was a method of birth control. Id. at 1764-65. Until recently, the department of Health and Human Services had interpreted the section to permit nondirective counselling related to abortion services. Id. at 1765. In 1988 the Department promulgated a new regulation denying Title X funds to those projects providing counselling related to abortion. Id. Relying on its rationale in Chevron U.S.A v. Natural Resources Defense Council, 467 U.S. 837 (1984), the Court held that the regulation was entitled to deference, despite the “sharp break” with prior interpretation, because, inter alia, it was supported with a reasoned analysis. Id. at 1769.
seemingly conflicting legislative policies should not be disturbed unless such action clearly appears to be outside the scope of congressional intent. It is proposed that Congress would likely approve of a rule necessary to save the lives of soldiers. Following the current standards for reviewing legislative rulings by an agency, it is suggested that the district court and the Court of Appeals of the District of Columbia correctly found the promulgation of Rule 23(d) to be within the FDA’s power.

III. The Application of Rule 23(d)

The phrase “experimental drugs and the military” conjures up images of the United States Army’s LSD tests and radiation experiments on unconsenting soldiers in the 1950s, and the barbarous experiments conducted by the Nazis on prisoners during World War II. The Defense Department Authorization Act now prohibits the use of DOD funds to perform such research on unconsenting human subjects; the plaintiff in Doe challenged the application of Rule 23(d) as violative of this act. Doe maintained that the DOD’s use of investigational drugs amounted to “research;” however, the Sullivan court never decided whether this use was “research” or “treatment.” It is submitted that Rule 23(d) is narrowly drawn to allow the administration of unapproved drugs only when it is beneficial to the recipient and not for experimentation

67 See United States v. Shimer, 367 U.S. 374, 383 (1961). In Shimer, the Serviceman’s Readjustment Act of 1944 was determined to have the purpose of enabling veterans to obtain loans with the least risk of loss upon foreclosure. Id. The plaintiff claimed that the relevant state law on deficiency judgments was applicable, while the government claimed that the Veteran Administration’s (“VA”) regulation applied. Id. at 383-85. The Court held that the administration’s policy choice was a “reasonable accommodation of [conflicting] statutory ends.” Id. at 385. There were also indications from the act itself and its legislative history that the regulation would further the intent of Congress. Id. at 386-87.

68 See Doe v. Sullivan, 756 F. Supp. 12, 15-16 (D.D.C.), aff’d, 938 F.2d 1370 (D.C. Cir. 1991). The application of Rule 23(b) during the Gulf War was moot on appeal. Sullivan, 938 F.2d at 1375; supra note 30 and accompanying text.

71 See Robert J. Levine, Treating the Troops: Commentary, HASTINGS CENTER REP., March-April, 1991, at 27. The distinction between “research” and “treatment,” the former unquestionably requiring consent under the DOD Act, is not clearly drawn. Id. (presenting several conflicting views on proper distinction). The fact that the drugs are labeled “investigational” is misleading, “many unsophisticated persons think mistakenly of the use of such drugs as research.” Id. at 28. The drugs used by the DOD during the Gulf War had, in fact, been approved at higher dosages, for other purposes. See supra note 18 and accompanying text.
or research. The procedures outlined in Rule 23(d) were created to avoid the possibility of soldiers being used as human guinea pigs. The DOD can request that the FDA Commissioner find informed consent “not feasible” only for a specific combat exigency, when “withholding treatment would be contrary to the best interests of military personnel and there is no available satisfactory alternative therapy.” In making this determination, the Commissioner must consider four factors: the context in which the drug will be administered; the nature of the information that would be provided to the recipient; the strength of the safety evidence and the effectiveness of the drug; and the nature of the disease or condition to be treated. Thus, the FDA Commissioner is a non-military reviewer, outside the DOD, that must objectively assess the benefits and risks of drug treatments and the burden of obtaining informed consent. The purpose of any application of the rule must be to treat soldiers in the best interests of their health; the Commissioner may not waive the informed consent requirement for what is essentially an experiment. Additionally, the Commissioner may revoke his determination at any time in light of changed circumstances. In Sullivan, the FDA approved the DOD’s request because the proposed mandated use of the drugs was clearly in the best interests of the soldiers and the purpose was not to experiment, but to treat inevitably deadly conditions. The policy behind Rule 23(d) is sound; it protects the best interests of soldiers in combat while simultaneously furthering the military objective.

Conclusion

The DOD is now restricted in its ability to compel servicemembers to submit to non-approved treatments by a narrowly

---

72 See supra note 21 (setting forth text of Rule 23(d) including provision that exception be applied only in “a specific military operation involving combat or the immediate threat of combat”).
74 Id. § 50.23(d)(2). The Commissioner’s review is not limited to these factors. See id.
76 See 21 C.F.R. § 50.23(d)(1) (1991); B.D. Colen, Secret Drug Testing on Soldiers in Gulf OK’d, NEWSDAY, Jan. 4, 1991, at 7. A Pentagon spokesperson objected to the critic’s labelling of the drugs as experimental since they have been successfully used to treat other conditions. Id.
77 See 21 C.F.R. § 50.23 (d)(4) (1991) (Rule 23(d)(4))
78 See Sullivan, 938 F.2d at 1374.
79 Id.; see 21 C.F.R. § 50.23(d) (1991).
drawn informed consent exception that serves the public interest by protecting servicemembers and permitting the attainment of the military objective. Rule 23(d) is a rare exception to the rule of informed consent. This exception satisfies the unique demands of a military unit in combat and warrants the authority to compel servicemembers to take certain drugs in order to protect themselves and their comrades. The rule’s strict requirements preclude experimentation on servicemembers and effectuate its vital purpose: treating servicemembers to ensure their survival on the modern battlefield.

Patrick J. Moran