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EMERGING MILITARY TECHNOLOGIES: BALANCING MEDICAL ETHICS AND NATIONAL SECURITY

*Efthimios Parasidis*¹

This article, prepared for the CETMONS-Frederick K. Cox International Law Center's symposium, International Regulation of Emerging Military Technologies, examines the law and ethics of emerging biomedical innovations. In addition to unpacking the legal regime that governs the military biomedical complex, I discuss the ethics and regulation of human subjects research, the overlap between military law and military medicine, and the socio-medical implications of the current framework.

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I. INTRODUCTION

The twenty-first century is quickly taking shape as the age of the biomedical military. As the U.S. Department of Defense (DoD) candidly states, one of its primary goals is to exploit the life sciences to create soldiers with superior physical, physiological, and cognitive abilities.² Projects include: (1) developing drugs that can reduce fear, increase aggressiveness, or keep individuals awake and alert for up to seven days straight; (2) genetically engineering the human immune system so that it is able to recognize and adapt to any pathogen; (3) creating implantable electrodes that permit human-to-human and human-to-computer communication via thought alone; and (4) establishing human-to-computer interfaces that are able to detect a person's neurological state and release neurochemicals that can combat fatigue, enhance mood, suppress or improve memory, or facilitate learning.³

Emerging biomedical technologies are creating new paradigms for reevaluating the law and ethics governing the practice of medicine and medical research. Although the motto of the American military physician is to "conserve the fighting force," an integral component of military research concerns physical and cognitive enhancements that endeavor to augment human faculties. While biomedical enhancements have yet to be used on a widespread basis in the theater of war, it may just be a matter of time before enhancements are integrated into military missions. Not only must policy-makers and the military consider the practical implications of enhanced warfighters, a more fundamental question that must be addressed is who should be responsible for balancing national security priorities with medical, social, and ethical concerns.

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2. TONY TETHER, DEF. ADVANCED RES. PROJECTS AGENCY, STATEMENT TO THE SUBCOMM. ON TERRORISM, UNCONVENTIONAL THREATS AND CAPABILITIES 11 (2003).
 3. For project details, see Catherine L. Annas & George J. Annas, *Enhancing the Fighting Force: Medical Research on American Soldiers*, 25 J. CONTEMP. HEALTH L. & POL'Y. 283, 283-308 (2009); Michael N. Tennison & Jonathan D. Moreno, *Neuroscience, Ethics, and National Security: The State of the Art*, 10 PLOS BIOLOGY, no. 3, Mar. 2012 at 1; JONATHAN D. MORENO, *Juicing the Brain*, 17 SCIENTIFIC AM. MIND, no. 17, Dec. 2006, at 66-73; Hannah Hoag, *Neuroengineering: Remote Control*, NATURE, June 19, 2003, at 796-798; Michael H. Bonnet et al., *The Use of Stimulants to Modify Performance During Sleep Loss: A Review by the Sleep Deprivation and Stimulant Task Force of the American Academy of Sleep Medicine*, 29 SLEEP 1163, 1176-1180 (2005).

As with civilian legal doctrine, military law recognizes a distinction between the practice of medicine and medical research. With respect to the former, military law dictates that the DoD can mandate that service members comply with an order to be administered treatment of an FDA-approved medical product that the DoD determines is in the best interest of an individual service member or a military mission.⁴ One recent example is the smallpox vaccine mandate that was promulgated in 2002. Although smallpox was eradicated in nature in 1980, many countries have access to the smallpox virus via laboratory stockpiles.⁵ After 9/11, the DoD feared that smallpox would be used against U.S. troops as a biological weapon, and thus DoD determined that the smallpox vaccine was needed as prophylaxis.⁶ In turn, DoD administered the vaccine to thousands of service members. Although smallpox was not used against U.S. troops, many service members suffered vaccine-related adverse health effects, including serious and unanticipated cardiac adverse events.⁷ Notably, since DoD deemed administration of the smallpox vaccine to be a requirement of service, pursuant to military law, a service member who refused the vaccine was subject to court-martial and severe punitive measures, such as docked pay and dishonorable discharge.

With respect to military medical research, federal regulations and DoD guidelines provide safeguards for military personnel who take part in biomedical research conducted or sponsored by the military. In part, these protections aim to ensure that service members are not coerced or compelled into serving as research subjects.⁸ At the same

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4. Efthimios Parasidis, *Justice and Beneficence in Military Medicine and Research*, 73 OHIO ST. L.J. 723, 726 (2012).
 5. Naomi Seiler, Holly Taylor, & Ruth Faden, *Legal and Ethical Considerations in Government Compensation Plans: A Case Study of Smallpox Immunization*, 1 IND. HEALTH L. REV. 3, 5 (2004).
 6. Bryant J. Webber et al., *Spread of Vaccinia Virus Through Shaving During Military Training, Joint base San Antonio–Lackland, TX, June 2014*, MED. SURVEILLANCE MONTHLY REP., Aug. 2014, at 2, 2.
 7. See, e.g., Seiler, Taylor & Faden, *supra* note 4, at 12-13. As will be discussed in this article, in addition to the smallpox vaccine, mandatory prophylaxis for anticipated chemical or biological warfare has also included administration of the anthrax vaccine, pyridostigmine bromide (PB), and the botulinum toxoid (BT) vaccine. See generally, John D. Grabenstein et al., *Immunization to Protect the U.S. Armed Forces: Heritage, Current Practice, Prospects* 28 EPIDEM. REV. 3 (2006) (reviewing the historical practice and scope of military immunizations).
 8. The regulations were enacted, in part, in response to research conducted by the military during the twentieth century. The studies—which includes mustard gas experiments, radiation experiments, and experiments with LSD and other psychotropic drugs—are well documented. See, e.g., Parasidis, *supra* note 3, at 724.

time, however, there are exceptions to the regulations that allow the DoD to mandate that non-FDA-approved products be administered to service members.⁹ When this occurs, the line between research and practice is blurred, and it becomes unclear whether, and to what extent, protections governing research involving human subjects apply.

The military's emerging focus on biomedical products and human enhancements complicates the legal and bioethical issues that are raised by the coalescence of military medicine and military research. For example, in the context of emerging biomedical technologies, it is unclear what risk-benefit profile is acceptable during battle, and whether that standard should change in times of peace, or when war is imminent. It is also unclear to what extent risk-related information must be provided to service members, and whether they should be afforded the opportunity to opt out of treatment with enhancements or experimental products. Importantly, should a product- or research-related adverse event occur, injured service members do not have the full spectrum of legal remedies available to them as civilians do.

II. A TANGLED WEB OF LAWS AND REGULATIONS GOVERNS MILITARY MEDICINE AND RESEARCH

A. The Development of Federal Guidelines in the United States

Federal regulations governing research on human subjects are a relatively recent construct. Although medical research in the U.S. dates back to the beginning of the republic, a federal framework governing human subjects research was first established in 1974 following “a series of highly publicized abuses” at the hands of government researchers and physicians.¹⁰ The 1974 guidelines established a system that centered on utilization of institutional review boards (IRBs) to review research protocols.¹¹ Five years later,

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9. 10 U.S.C. § 1107 (1998) (codifying notice of use of an investigational new drug or a drug unapproved for its applied use).
 10. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. No. 143, 44512 (July 26, 2011) (to be codified at 45 C.F.R. 46, 160 & 164). The abuses are well documented, and include the Tuskegee Syphilis Study, as well as experiments conducted at Willowbrook State Hospital and the Brooklyn Jewish Chronic Disease Hospital. *See, e.g.*, JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* (1982); Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CTR. REPORT 21 (1978); Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966); CARL COLEMAN ET AL., *ETHICS AND REGULATION OF RESEARCH ON HUMAN SUBJECTS* 37–44 (2003).
 11. Although the federal guidelines have since expanded, IRBs continue play an integral role in the oversight of research involving human subjects.

the National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research (the “National Commission”) published the Belmont Report, which identified fundamental ethical principles that should govern research involving human subjects.¹² A series of amendments to the federal regulations followed, culminating, in 1991, with the publication of the Common Rule.¹³

The Common Rule sets forth guidelines that apply to government-funded research with human subjects.¹⁴ Under the Common Rule, there are three primary mechanisms for protecting research subjects: informed consent, review by an IRB, and institutional assurances of compliance with federal policies.¹⁵ Among its provisions, the Common Rule requires that risks to research subjects are minimized, and that risks are reasonable in relation to the anticipated benefits.¹⁶ The Common Rule also provides additional protections for “vulnerable populations,” which are defined as populations that are subject to coercion or undue influence. Currently, these subpopulations include pregnant women, children, human fetuses and neonates, and prisoners.¹⁷ The supplemental protections include procedural guidelines addressing membership on IRBs that review research protocols involving vulnerable populations, as well as substantive guidelines that IRBs must consider in reviewing and monitoring the research.¹⁸

In 2011, the U.S. government published an Advanced Notice of Proposed Rulemaking, which highlighted the drastic change in the research landscape since the time the Common Rule was adopted and the need for amendments to the law to account for these changes. In calling for amendments to the Common Rule, the U.S. Department of Health and Human Service (HHS) and the Office of Human Research

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12. Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report Of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979).
 13. Protection of Human Subjects, 45 C.F.R. §46 (2014) (original version at 56 Fed. Reg. 28,002 (1991)).
 14. Many institutions voluntarily adopt the Common Rule requirements for all research involving human subjects, though the federal requirements only mandate that, for non-government funded research, the institution commit to complying with general principles of human subjects research as, for instance, outlined in the Belmont Report. *See id.*; COLEMAN ET AL., *supra* note 9, at 107.
 15. 45 C.F.R. §§ 46.101–46.124.
 16. *Id.*
 17. 45 C.F.R. §§ 46.201–46.409.
 18. *See* 45 C.F.R. § 46.201–46.505.

Protection (OHRP) emphasized the fact that the law has “not kept pace with the evolving human research enterprise,” and highlighted areas, including “advanced technologies” and “genomics,” where this has been the case.¹⁹ To date, however, no amendments to the Common Rule have been enacted.

B. The Framework Governing Military Personnel

The DoD has adopted the Common Rule,²⁰ and Executive Order 12333 mandates that the Central Intelligence Agency (CIA) comply with the guidelines outlined in the Common Rule.²¹ In addition, DoD Directives provide additional safeguards for service members who are solicited for, or enrolled in, clinical trials that are conducted or sponsored by the government.²² At the same time, however, a number of laws and regulations provide exceptions that negate many of the protections. The following is a snapshot of the tangled web of laws and regulations that apply to military personnel:

•DoD Directive 3216.02, issued November 8, 2011, defines a key triggering term for Common Rule protections—“research involving human subjects”—to exclude: (1) “activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs”; and (2) activities related to an “operational test and evaluation” (OTE) project.²³ Under 10 U.S.C. § 139, an OTE project is a “field test, under realistic combat conditions, of any item (or key component of) weapons, equipment, or munitions for the purpose of determining the effectiveness and suitability of the

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19. 76 Fed. Reg. 44,512; *see generally*, OFC. HUM. RES. PROT., <http://www.hhs.gov/ohrp/> (last visited November 22, 2014) (OHRP is the division within HHS that “provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported” by HHS).
 20. Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003, 28,012 (June 18, 1991) (to be codified at 32 C.F.R. pt. 219).
 21. Exec. Order No. 12,333, 3 C.F.R. 1981 Comp., p. 200 (1981), *reprinted as amended in* 3 U.S.C. 2008 Comp., p. 1064 (2008) (“No agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject’s informed consent shall be documented as required by those guidelines.”).
 22. *See, e.g.*, U.S. Dep’t of Def., Instru’n No. 3216.02 (Nov. 8, 2011), *available at* <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.
 23. *Id.*

weapons, equipment, or munitions for use in combat by typical military users.”²⁴

- The Project BioShield Act of 2004 creates the Emergency Use Authorization (EUA) process, which provides the FDA the authority to grant the DoD permission to use a medical product for off-label or investigational purposes during a declared emergency.²⁵ Although an EUA may be issued for both civilian and military populations, only military personnel are subject to forced use.²⁶

- Under 10 U.S.C. § 1107(f), for members of the armed forces, the President of the U.S. can issue an informed consent waiver for off-label or investigational use of a medical product so long as the use is “in connection with the member’s participation in a particular military operation.”²⁷

- 10 U.S.C. § 980 grants the DoD the authority to issue an informed consent waiver if a research project aims to “advance the development of a medical product necessary to the armed forces” and “may directly benefit the subject.”²⁸ The statute does not describe the procedure that must be employed when an informed consent waiver is granted, nor does the law limit the type of research that may be conducted.

Taken together, in the context of human subjects research protections, the military biomedical complex presents a case where the exceptions swallow the rule. For example, the ability to obtain an informed consent waiver, or bypass the clinical trial setting, and “field-test” experimental products eviscerates meaningful safeguards for service members. Likewise, when “activities,” as anticipated by DoD Directive 3216.02, include use of non-FDA approved medical products or enhancements, procedures that would trigger human subjects research regulations in the civilian context fail to do so for military personnel. The risks borne by service members are significant.

24. 10 U.S.C. § 139 (2008); *see also* U.S. Dep’t of Def., *supra*, note 24 (“research involving a human being as an experimental subject” includes activities where “an intervention or interaction with a human being for *the primary purpose* of obtaining data regarding the effect of the intervention or interaction”) (emphasis added).

25. *See* Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004) (codified at 42 U.S.C. §201 (2004)).

26. *Id.*

27. 10 U.S.C. § 1107(f) (2004).

28. 10 U.S.C. § 980(b) (2001).

Recent examples highlight the dangers. In the 1990s, fearing use of chemical weapons during the first Gulf War, the military “pretreated” service members with pyridostigmine bromide (PB) and the botulinum toxoid (BT) vaccine, two products that the FDA was evaluating as prophylaxis aimed at mitigating the effects of chemical warfare.²⁹ Following the war, veterans began suffering from serious health problems that included cognitive difficulties, chronic headaches, musculoskeletal problems, respiratory ailments, and widespread pain, and had children born with birth defects at an alarming rate.³⁰ In 2008, nearly two decades after administration of the experimental products, studies revealed that PB was one of the factors that most likely caused the health problems.³¹ Commonly referred to as Gulf War Illness, the symptoms affect between 175,000 and 250,000 veterans, which equates to approximately one-third of the fighting force during the war.³²

The DoD’s anthrax vaccine immunization program (AVIP), which commenced in 1998, was no less controversial. AVIP mandated off-label use of an existing anthrax vaccine for service members deemed to be at risk for anthrax exposure.³³ Although the FDA approved the vaccine to protect against cutaneous anthrax (anthrax that comes into contact with the skin), the military sought to use the vaccine as a pretreatment for inhalation anthrax (anthrax that is inhaled) despite the fact that the FDA had not evaluated the safety or effectiveness of the vaccine for inhalation anthrax.³⁴

A congressional report, published in 2000, criticized AVIP, characterizing the program as an “overwrought response to the threat of anthrax” and one that “compromises the practice of medicine to achieve military objectives.”³⁵ The report found that the DoD provided service members with “heavy handed, one-sided

29. Doe v. Sullivan, 938 F.2d 1370, 1372 n.1 (D.C. Cir. 1991).

30. See RES. ADVISORY COMM. ON GULF WAR VETS.’ ILLNESSES, GULF WAR ILLNESS AND THE HEALTH OF GULF WAR VETERANS: SCIENTIFIC FINDINGS AND RECOMMENDATIONS (2008), available at http://www.va.gov/rac-gwvi/docs/committee_documents/gwiandhealthofgwveterans_rac-gwvireport_2008.pdf?tab_tab_group_id=2_1&url=%2Fwebapps%2Fblackboard%2Fexecute%2Flauncher%3Ftype%3DCourse%26id%3D_79042_1%26url%3D.

31. *Id.*; *Justice Delayed: Acknowledging the Reality of Gulf War Illness*, 372 LANCET 1856 (2008).

32. RES. ADVISORY COMM. ON GULF WAR VETS.’ ILLNESSES, *supra* note 29 at 4.

33. Rempfer v. Sharfstein, 583 F.3d 860, 863 (D.C. Cir. 2009).

34. *Id.* at 863.

35. U.S. DEF. DEP’T, ANTHRAX VACCINE IMMUNIZATION PROGRAM: UNPROVEN FORCE PROTECTION, H. REP. NO. 106-556, at 2 (2000).

informational materials,” and that the agency was “far more concerned with public relations than effective force protection or the practice of medicine.”³⁶ The DoD refused to suspend the program, and subsequent studies found that approximately one-in-five service members suffered systemic adverse events, which are adverse health consequences that last more than seven days and sometimes can last for years or even a lifetime.³⁷ The systemic adverse events were more than one hundred times those reported by the vaccine manufacturer, and adverse reactions affected women at a rate more than twice that of men.³⁸ Moreover, AVIP was implemented despite the fact that the vaccine had not been evaluated for the potential to impair fertility or cause fetal harm.³⁹

Not only is medical research highly uncertain—on average, five of six products under review by the FDA fail to earn regulatory approval⁴⁰—but a mélange of legal doctrines and immunities also shield the government from liability in the event of injuries caused by negligence or intentional harm. Given the military’s checkered history of research with human subjects, the real-world impact of the immunities is stunning. For example, the *Feres* doctrine prevents service members from suing the government, government employees, or agents working on behalf of the government in situations where a service member’s injuries “arise out of or are in the course of activity incident to service.”⁴¹ Courts have interpreted the *Feres* doctrine broadly to encompass claims raised by service members who suffered severe injuries after military officials locked them in gas chambers and exposed them to mustard gas against their will,⁴² as well as soldiers who were harmed by coerced or compelled participation in the military’s atomic experiments⁴³ and the DoD’s clandestine psychotropic drug experiments.⁴⁴ In each case, since the conduct occurred while the soldiers were subject to military command, the *Feres* doctrine served to foreclose legal remedies.

36. *Id.* at 2-3.

37. *Id.* at 38.

38. *Id.* at 35-36.

39. *Id.* at 40.

40. Leonard Sacks, et al., *Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012*, 311 J. AM. MED. ASS’N 378, 379 (2014).

41. *Feres v. United States*, 340 U.S. 135, 146 (1950).

42. *Schnurman v. United States*, 490 F. Supp. 429, 438 (E.D. Va. 1980).

43. *Jaffee v. United States*, 663 F.2d 1226, 1239 (3d Cir. 1981).

44. *United States v. Stanley*, 483 U.S. 669, 705 (1987).

Coupled with the broad immunities provided by the *Feres* doctrine, under the political question doctrine, courts are also barred from reviewing military decisions that are political in nature.⁴⁵ Political questions include instances where it is impossible for a court to render a judgment without making a policy decision that is beyond the court's discretion, or where a court's decision would express "a lack of respect for a coordinate branch of the government."⁴⁶

In addition to outright dismissal of a case pursuant to the *Feres* doctrine or the political question doctrine, the state secrets privilege provides the government with the ability to withhold information in instances where officials believe that the information could expose facts that may compromise national security.⁴⁷ The government has invoked the privilege often, including cases related to rendition, torture, interrogation, warrantless wiretapping, widespread surveillance of American and foreign civilians, drone attacks, and lethal targeting of American and foreign citizens.⁴⁸ Courts rarely uphold challenges to the government's assertion of the privilege, though investigators have uncovered instances where the government used the privilege not to protect a state secret, but rather to cover-up wrongful conduct.⁴⁹ The recent controversies surrounding drone-targeted killings and the NSA's surveillance programs are examples where the government has used the state secrets privilege to prevent disclosure of facts directly related to legal challenges to the programs,⁵⁰ and there is nothing that prevents the government from invoking the privilege to withhold information in the event of a research-related injury or a challenge to a research protocol. While there are important reasons for limiting the ability of courts to pass judgment on matters of national security, equally as important is maintaining a judicial system that adequately holds government actors responsible for the outcomes of their decisions.

45. *Baker v. Carr*, 369 U.S. 186, 227 (1962).

46. *Id.* at 217.

47. *See, e.g., United States v. Reynolds*, 345 U.S. 1, 10 (1953); *Tenet v. Doe*, 544 U.S. 1, 11 (2005).

48. Amanda Frost, *The State Secrets Privilege and Separation of Powers*, 75 *FORDHAM L. REV.* 1931, 1945–46 (2007).

49. *Id.* at 1942–50.

50. Spencer S. Hsu, *Obama Invokes 'State Secrets' Claim to Dismiss Suit Against Targeting of U.S. Citizen al-Aulaqi*, *WASH. POST* (Sept. 25, 2010, 1:49 AM), <http://www.washingtonpost.com/wp-dyn/content/article/2010/09/25/AR2010092500560.html>; Ellen Nakashima, *U.S. Reasserts Need to Keep Domestic Surveillance Secret*, *WASH. POST* (Dec. 21, 2013), http://www.washingtonpost.com/world/national-security/us-reasserts-need-to-keep-domestic-surveillance-secret/2013/12/21/9d2b4538-6a7e-11e3-a0b9-249bbb34602c_story.html.

For service members, the implications of the legal and regulatory regime must be analyzed in light of obligations imposed by the Uniform Code of Military Justice (UCMJ), which is the legal system governing the armed forces. Under the UCMJ, a subordinate officer must obey a lawful order of a superior officer.⁵¹ This provision applies in equal force if the order is a split-second combat-related command given on the battlefield, or an order given on a U.S. base that relates to a medical treatment deemed by officials to be necessary for the good of the armed forces.⁵² With respect to the latter, existing regulations do not limit medical-related orders to products approved by the FDA.⁵³ And, on a number of occasions, the DoD has mandated that soldiers submit to non-FDA-approved medical products as a requirement of service.⁵⁴ Under the UCMJ, refusal to submit equates to disobeying an order and can result in punitive measures that include reduction in rank, docked pay, jail time, and dishonorable discharge.⁵⁵

Sanctions pursuant to this provision are not merely theoretical. Since the 1990s, the DoD has prosecuted hundreds of service members, including military physicians, who refused administration of medical products that were not approved by the FDA for the use intended by the DoD.⁵⁶ During the prosecutions, military courts consistently denied requests by soldiers to submit evidence of safety concerns, holding that such information was irrelevant to the underlying issue of whether the soldier obeyed a lawful command.⁵⁷

51. United States v. Washington, 57 M.J. 394, 396 (C.A.A.F. 2002).

52. *Id.* at 398.

53. See Determination that Informed Consent is Not Feasible or Is Contrary to the Best Interests of the Recipients, 64 Fed. Reg. 54,180 (Oct. 5, 1999) (to be codified at 21 C.F.R. pts. 50 & 312) (describing military exemption from informed consent requirements); *Waiving Informed Consent: Military Use of Non-FDA-Approved Drugs in Combat*, RAND (2000), http://www.rand.org/pubs/research_briefs/RB7534/index1.html (analyzing the impact of the proposed rule).

54. See Application of Food and Drug Administration (FDA) Rules of Department of Defense Force Health Protection Programs, DoD Instruction 6200.02 (Feb. 27, 2008) (stipulating, *inter alia*, considerations upon Heads of DoD Components when deciding whether to order vaccination of military forces using non-FDA-approved medicines).

55. See *Washington*, 57 M.J. at 396 (describing that Airman Washington's refusal to be inoculated with an anthrax vaccine was properly regarded as insubordination by his superior officer and the Air Force court martial).

56. Randall D. Katz, *Friendly Fire: The Mandatory Military Anthrax Vaccination Program*, 50 DUKE L. J. 1835, 1837, 1853, 1863 (2001).

57. See, e.g., *Bates v. Rumsfeld*, 271 F. Supp. 2d 54, 64 (D.D.C. 2004); see *Washington*, 57 M.J. at 398–99.

III. THE MILITARY'S EMERGING FOCUS ON BIOMEDICAL INNOVATIONS

The legal framework governing military medicine is particularly troubling when one considers that a significant component of the military's contemporary agenda focuses on biomedical enhancements. In recent years, a notable shift has occurred whereby military research and military medicine have coalesced. The traditional role of military medicine has been to "conserve the fighting force" by providing medical care to military personnel.⁵⁸ These services have long included preventative care, such as FDA-approved vaccines for typhoid and yellow fever, and acute care, such as surgery in response to a combat injury.⁵⁹ While military physicians continue to fulfill their traditional roles of providing preventative and acute care, the concept of conservation has broadened to encompass regimens such as inoculations with experimental vaccines and prescriptions for human enhancements.⁶⁰ Insofar as the military's research agenda is fueled by combat-related goals, there is a natural tendency to want to test new technologies on the battlefield as quickly as possible.

Consider Dexedrine and Provigil, two drugs that are FDA-approved to treat narcolepsy and other disorders. Both are used as stimulants to keep soldiers awake during combat missions, despite the fact that the FDA has not analyzed whether the drugs are safe or effective for individuals who do not suffer from the underlying illnesses.⁶¹ Although the U.S. government bans commercial pilots from using the substances, the Air Force has created dose-specific regimens for its pilots.⁶²

While Dexedrine and Provigil may keep soldiers awake for extended periods of time—studies have found that service members on Provigil can remain awake for more than eighty hours straight—complications have arisen as to what a soldier experiences when alertness begins to fade.⁶³ People using Provigil tend to think that they are more functional than they actually are, and some service members have cited enhancements as the root cause in "friendly fire" bombings and unprovoked attacks on civilians.⁶⁴ "Go" pills, such as

58. See Annas & Annas, *supra* note 2, at 287.

59. *Id.*

60. *Id.*

61. See MAXWELL J. MEHLMAN, THE PRICE OF PERFECTION: INDIVIDUALISM AND SOCIETY IN THE ERA OF BIOMEDICAL ENHANCEMENT 16 (2009).

62. *Id.* at 21.

63. See JONATHAN D. MORENO, BRAIN RESEARCH AND NAT'L DEFENSE 115–116 (2006).

64. See Annas & Annas, *supra* note 2, at 294.

Dexedrine or Provigil, must often be balanced with “no-go” sedatives, such as Ambien or Restoril.⁶⁵ “No-go” pills carry their own risks—they are addictive and can cause anxiety, depression, confusion, hallucinations, risk-taking behavior, memory problems, loss of coordination, and suicidal thoughts.⁶⁶

With biomedical enhancements, the public health impact is largely unpredictable. Despite the military’s regimented use of some enhancements, studies on the short- or long-term health effects have not been conducted. Notably, known side effects of enhancements such as Provigil and Dexedrine include dizziness, confusion, heart palpitations, hallucinations, abnormally excited moods, anxiety, depression, extreme psychological dependence, psychotic episodes, and suicidal thoughts.⁶⁷ When coupled with the military epidemic of traumatic brain injury (TBI), which impacts an estimated twenty percent of troops deployed since 2001,⁶⁸ the adverse effects of enhancements are likely to be compounded.⁶⁹ Indeed, the VA has witnessed an astronomical rise in the number of veterans seeking treatment for TBI and other mental disorders, so much so that the agency was recently chastised for falsely entering data into patient medical records in order to cover-up the backlog.⁷⁰ The military’s moral obligation to ensure that service members are not exposed to undue medical risks must take into account the limitations of the VA health care system.

The emergence of the biomedical military is not solely an American concern, it is an international one. As the raid on Osama

65. *Id.* at 291, 293.

66. Jamie Reno, “*Medicating Our Troops Into Oblivion*”: *Prescription Drugs Said To Be Endangering U.S. Soldiers*. INT’L BUS. TIMES (Apr. 19, 2014), <http://www.ibtimes.com/medicating-our-troops-oblivion-prescription-drugs-said-be-endangering-us-soldiers-1572217>.

67. See *Dexedrine Side Effects*, RXLIST.COM <http://www.rxlist.com/dexedrine-side-effects-drug-center.htm> (last visited Mar. 21, 2015).

68. See Jesse Bogan, *Afghan War Vets, St. Louis Researchers Seek Answers on Head Injuries*, ST. LOUIS POST-DISPATCH (Jan. 27, 2014), http://www.stltoday.com/news/local/metro/afghan-war-vets-st-louis-researchers-seek-answers-on-head/article_daaa0082-4d39-5d0d-899a-7e942109c103.html.

69. See generally CMTE. ON ASSESS. ONGOING EFFORTS TREAT. POSTTRAUM. STRESS. DISORDER, TREATMENT FOR POSTTRAUMATIC STRESS DISORDER IN MILITARY AND VETERAN POPULATIONS: INITIAL ASSESSMENT (2012) (detailing, *inter alia*, military-specific factors that cause or enhance PTSD in military personnel and veterans).

70. See, e.g., *Witness Testimony of Ms. Debra A. Draper, Director, Health Care Government Accountability Office*, HOUSE CMTE. ON VETERANS’ AFF. (Mar. 14, 2013), <http://veterans.house.gov/witness-testimony/ms-debra-a-draper>.

bin Laden's complex and other targeted missions illustrate, rather than waging large-scale wars across the globe, the national security strategy of the U.S. has shifted to focusing on special operations by elite fighters.⁷¹ In many instances, U.S. operations are conducted in conjunction with special forces from other nations.⁷² Not only does the U.S. provide extensive training for the joint missions, in some parts of the world the U.S. trains foreign forces which then are expected to conduct military missions without direct U.S. support.⁷³ If U.S. policy permits or encourages use of investigational products or biomedical enhancements, researchers and policy makers must consider the global impact of such policies.

The question becomes increasingly complex as one examines the regulatory frameworks of other nations. For example, during the recent wars in Iraq and Afghanistan, the U.K. made the anthrax vaccine optional for its troops,⁷⁴ while the U.S. had a mandatory anthrax vaccination program.⁷⁵ Should enhancements, such as implantable brain electrodes, become field-tested or used in military missions, what impact will this have on nations who fight alongside the U.S., but do not adhere to the U.S. model? Furthermore, international law may not have an adequate remedy for a problem that may arise in this context. Under the Geneva Convention, it is unclear whether enhancements, or enhanced soldiers, are a "weapon" or a "means or method of warfare", or if they should be deemed "biological agents."⁷⁶ Moreover, under the Biological and Toxin Weapons Convention, use of biological agents that are "repugnant to the conscience of mankind" are prohibited; while, under the Hague Convention, warfighting that disturbs the "public conscience" is forbidden.⁷⁷ The extent to which these international laws and norms apply to enhancements must be analyzed objectively.

71. See, e.g., JEREMY SCAHILL, *DIRTY WARS* 139 (2013).

72. *Id.* at 25.

73. *Id.* at 66 (highlighting efforts in Africa).

74. *UK Troops Raise Fears Over Anthrax Jab*, *GUARDIAN* (Jan. 8, 2003), <http://www.theguardian.com/world/2003/jan/08/iraq.military>.

75. See *Anthrax (Bacillus anthracis)*, DEF. HEALTH AGENCY (Mar. 20, 2015), <http://www.vaccines.mil/Anthrax>.

76. See PATRICK LIN, MAXWELL MEHLMAN, & KEITH ABNEY, *ENHANCED WARFIGHTERS: RISK, ETHICS & POLICY* 28, 31 (2013).

77. *Id.* at 32–36.

IV. CONCLUSION

The billions of dollars invested by the DoD and the Defense Advanced Research Projects Agency (DARPA) have not been provided merely to advance the progress of science. As DARPA explains, the investments are intended to create biomedical innovations that will transform military strategy and the warfighter.⁷⁸ As with weapons of the past, nations will work fervently to acquire or copy the newest technologies in order to promote their own military agendas, as will non-state-based militaries and terrorist organizations. At some point, many technologies will invariably work their way into the global community of civilians. Take drones, for example, where municipal police and private companies are both examining ways to incorporate unmanned aerial vehicles into operations on American soil.

With human enhancements, as bioethicists have discussed, civilian uses are both common and, oftentimes, encouraged by custom or circumstance.⁷⁹ Studies have highlighted the extensive use of enhancements across socio-economic backgrounds, including use by doctors, lawyers, academics, students, and truck drivers.⁸⁰ Insofar as military developments will unquestionably impact civilians, a socio-medical evaluation of the military biomedical complex is necessary.

While biomedical innovations may provide soldiers with special competitive advantages, they also come with special risks. Although medical risk cannot be eliminated—all treatments carry the chance of adverse events—the degree of risk of a particular treatment is proportional to the robustness of information related to that treatment. Simply stated, the more one knows about a medical treatment, the better one can predict risks and benefits, and assess whether utilization of the treatment is justifiable. This calculation contains procedural and substantive components, and deriving an accurate risk-benefit profile requires diligence and intellectual honesty at each stage of the analysis. One weak link—be it in the process of approving use of a biomedical product on military personnel, the evaluation of data related to risks and benefits, or the decision to use a product for a particular individual—can increase risk exposure

78. *Our Work*, DEF. ADV. RES. PROJECTS AGENCY (Nov. 28, 2014, 3:05pm), http://www.darpa.mil/our_work/.

79. See, e.g., Mehlman, 2009; Human Enhancement, eds. Julian Savulescu and Nick Bostron. 2009. Oxford: Oxford University Press; Joel Garreau, *Radical Evolution: The Science and Peril of Enhancing Our Minds, Our Bodies—And What it Means to be Human*. 2006. New York: Random House 2006; Eric Juengst, “The Meaning of Enhancement” in *Enhancing Human Traits: Ethical and Social Implications*, edited by Erik Parens. 1998. Washington D.C.: Georgetown University Press.

80. See, e.g., SCAHILL, *supra* note 70, at 25.

significantly and unnecessarily. The potential harms to service members are exacerbated when one considers the inadequacies of the health care system for veterans.⁸¹

It is in this context that law can play a transformative role, by guiding behavior and incentivizing risk management and risk mitigation. Yet, rather than mitigating risk by establishing protocols that balance national security concerns with clinical uncertainties, medical ethics, and constitutional liberties, the current legal and regulatory regime increases risk for U.S. service members. In the name of national security, the law embeds military command structure into military medicine and prevents injured service members from seeking redress through the courts.

The socio-medical impact of the existing regime is striking. Studies have consistently found that the odds of a person entering the military are correlated with economic status, race, family structure, high school academic achievement, and parental education.⁸² Individuals who grow up in families of a low socioeconomic status are more likely to enlist in the military, while those in the top income distribution are under-represented in the armed forces.⁸³ Individuals who enlist in the military are less likely to have grown up with both biological parents and are more likely to come from families where the parents had less education.⁸⁴ When compared to the general population, enlistees have fewer years of formal education and are more likely to have dropped out of high school.⁸⁵ In 2010, African-Americans comprised 17% of the armed forces and 12.6% of the general population, which equates to over-representation of approximately 35%.⁸⁶ African-American women are enlisting in the military at a rate far higher than white or Latino women; 31% of

81. See, e.g., *Witness Testimony of Ms. Debra A. Draper*, *supra* note 69; Scott Bronstein, Nelli Black, & Drew Griffin, *Hospital Delays are Killing America's War Veterans*, CNN (Nov. 20, 2013), <http://www.cnn.com/2013/11/19/health/veterans-dying-health-care-delays/>.

82. See Alair MacLean & Nicholas L. Parsons, *Unequal Risk: Combat Occupations in the Volunteer Military*, 53 SOCIOLOGICAL PERSPECTIVES 347, 348 (2010).

83. *Id.*; See Amy Lutz, *Who Joins the Military?: A Look at Race, Class, and Immigration Status*, 36 J. POL. & MIL. SOC. 167–188 (2008).

84. See MacLean & Parsons, *supra* note 81, at 359–60.

85. *Id.*

86. See OFC. DEPUTY UNDER SEC'Y DEF., DEMOGRAPHICS 2010: PROFILE OF THE MILITARY COMMUNITY iv (2011), *available at* http://www.militaryhomefront.dod.mil/12038/Project%20Documents/MilitaryHOMEFRONT/Reports/2010_Demographics_Report.pdf; SONYA RASTOGI ET AL., U.S. CENSUS BUREAU, THE BLACK POPULATION: 2010 3 (2011), *available at* <http://www.census.gov/prod/cen2010/briefs/c2010bn-06.pdf>.

women service members are African-American, which is double the percentage of the civilian female population that identifies as African-American.⁸⁷

To the extent that laws disproportionately impact under-privileged segments of society, elected officials have an indispensable moral responsibility to remedy the shortcomings of the existing framework. That said, regardless of how elected officials address this problem, the fact that a disproportionate impact stems from the status quo challenges bioethicists to reconsider notions of equality and vulnerability.

At a broader level, the military biomedical complex provides an illuminating paradigm for analyzing the extent to which power imbalances should influence the structure of laws governing one's freedom to contract, and for examining the relationship between an individual and the sovereign as it relates to the commodification of the human body. Should an individual be permitted to contract away their right to autonomy? To what extent is a service member the "property" of the military or the national security state? Does the answer to this question change if a draft is implemented? For voluntary or compulsory military service, are there liberties that the state should be precluded from usurping?

Privatization of the U.S. military adds another layer of complexity. The post-9/11 security state has developed a substantial private militia that utilizes cutting-edge military technologies and conducts, among other military endeavors, highly classified special-op missions.⁸⁸ Does the law treat warriors working for private companies differently? Should it?

Military exceptionalism is largely based on the notion that collective interests trump individual interests in matters of national security. If history is any guide, there must be limits to this principle. Proponents of the status quo rely largely on consequentialist or utilitarian rationales. At a broader level, however, principles of virtue ethics should inform the rule of the law, particularly in instances where, as in the military context, vulnerable populations bear what may be reasonably characterized as undue risks.

87. James Dao, *Black Women Are Joining the American Military at a Disproportionate Rate*, N.Y. TIMES, Dec. 23, 2011, at A14.

88. See, e.g., SCAHILL, *supra* note 70, at 23–25; MARK MAZZETTI, *THE WAY OF THE KNIFE* (2013); NICK TURSE, *THE CHANGING FACE OF EMPIRE: SPECIAL OPS, DRONES, SPIES, PROXY FIGHTERS, SECRET BASES, AND CYBERWARFARE* (2012); JEREMY SCAHILL, *BLACKWATER: THE RISE OF THE WORLD'S MOST POWERFUL MERCENARY ARMY* (2008).

