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## Human Enhancement and Experimental Research in the Military

Efthimios Parasidis

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## Article

### Human Enhancement and Experimental Research in the Military

EFTHIMIOS PARASIDIS

*For over a century the U.S. military has conducted and sponsored cutting-edge medical and technological research. While such projects have often resulted in transformative innovations, in a number of instances, researchers have deliberately violated legal requirements and/or ethical norms governing research with human subjects. This Article explores these matters by discussing the history of misfeasance in military research and examining contemporary military endeavors that aim to exploit biomedical advancements.*

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# Human Enhancement and Experimental Research in the Military

EFTHIMIOS PARASIDIS\*

## I. INTRODUCTION

This Article examines experimental research in the U.S. military through the eyes of the human subject. It explores the egregious legal and ethical violations committed by military researchers in the mid-to-late twentieth century and evaluates investigational studies that have shadowed military medicine for the past two decades. At a time when the U.S. military is actively pursuing transformative biomedical and technological innovations, analyzing the history of misfeasance in military research informs contemporary discussion as to the extent to which legal and regulatory reforms are desirable.

Modern military medicine has evolved from its traditional role of “preserving the fighting force,”<sup>1</sup> to enhancing it through application of novel biotechnologies.<sup>2</sup> Current research sponsored by the U.S. Department of Defense (“DoD”) and the Defense Advanced Research Projects Agency (“DARPA”) includes drugs that can keep soldiers awake for seventy-two hours or more, a nutraceutical that fulfills a soldier’s dietary needs for up to five days, and sophisticated brain-to-computer interfaces that endeavor to permit human-to-human and human-to-

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\* Eftimios Parasidis, Assistant Professor of Law, Center for Health Law Studies, Saint Louis University School of Law. This Article is based on my presentation at the *Connecticut Law Review* Symposium titled, *Healthcare Reform in the United States: Legal Implications and Policy Considerations*, where I served on a panel that addressed current health issues facing veterans and service members. I thank Symposium Editors Marco Allocca and Stephanie Bartone for inviting me to the symposium and hosting a well-organized and enlightening event. Special thanks to Editor-in-Chief Abigail Langer, Managing Editor Paul Costa, and the staff of the *Connecticut Law Review* for outstanding editorial assistance. This project benefited from discussions with Symposium panelists and participants. Monica Eppinger, Chad Flanders, Jeff Redding, and Magdalen Sarrinikolaou provided insightful comments on early drafts of this work.

<sup>1</sup> Mike Mitka, *US Military Medicine Moves to Meet Current Challenge*, 286 JAMA 2532, 2532–33 (2001) (describing the evolution in battlefield medical priorities).

<sup>2</sup> See, e.g., JONATHAN D. MORENO, MIND WARS: BRAIN RESEARCH AND NATIONAL DEFENSE 11–13 (2006) (cataloguing neuroscience innovations by DARPA that aim to improve the military’s fighting capabilities); Catherine L. Annas & George J. Annas, *Enhancing the Fighting Force: Medical Research on American Soldiers*, 25 J. CONTEMP. HEALTH L. & POL’Y 283, 287 (2009) (noting the shift in medical priorities in the American military).

computer communication via thought alone.<sup>3</sup>

In addition to increased health risks associated with enhancement techniques, a number of challenging legal and bioethical issues have been insufficiently explored. Should enhancements be a mandatory aspect of military service? Who determines the parameters for an acceptable risk-benefit profile? What remedies should be available for service members who experience adverse health effects? Adequately addressing these concerns, particularly in the context of military hierarchy and demography, provides a socio-medical framework that facilitates sensible harmonization of national security interests with fundamental notions of human dignity and patient autonomy.

## II. A HISTORY OF UNCONSCIONABLE RESEARCH

The atrocities committed by German military researchers during World War II challenged the international community to directly address safeguards governing experimental research on human subjects. While the U.S. military played an integral role in the prosecution of the German researchers and the drafting of the Nuremberg Code, the U.S. government failed to publicly disclose its involvement in unethical, if not illegal, experimental research on American civilians and service members.<sup>4</sup> Three examples include studies related to mustard gas, nuclear weapons, and psychotropic drugs.

The mustard gas experiments involved approximately 60,000 American soldiers in “race-based human experimentation” that sought to determine whether race or skin complexion influences one’s susceptibility to injuries from mustard gas.<sup>5</sup> Researchers created “man-break” tests

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<sup>3</sup> See MORENO, *supra* note 2, at 51 (discussing innovations in the “human-computer combination”); Annas & Annas, *supra* note 2, at 285–86 (describing projects that seek technologies which would make it possible for soldiers to perform for several days without sleep); Hannah Hoag, *Remote Control*, 423 NATURE 796, 796 (2003) (discussing DARPA’s quest to develop technologies to interface the brain and computers); Noah Shachtman, *Darpa Offers No Food for Thought*, WIRED (Feb. 17, 2004), <http://www.wired.com/print/medtech/health/news/2004/02/62297> (describing DARPA’s “Metabolic Dominance” project).

<sup>4</sup> See David P. Rall et al., *Preface to VETERANS AT RISK: THE HEALTH EFFECTS OF MUSTARD GAS AND LEWISITE* v–vii (Constance M. Pechura & David P. Rall eds., 1993) (discussing U.S. medical research during World War II and failures to disclose the extent of the program) [hereinafter IOM Report]. In the 1940s and 1950s, articles in the popular press “suggest[ed] some tension between the [American] words at Nuremberg and the practices in America.” FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS 87 (Oxford Univ. Press 1996) [hereinafter Human Radiation Experiments Report].

<sup>5</sup> IOM Report, *supra* note 4, at v; Susan L. Smith, *Mustard Gas and American Race-Based Human Experimentation in World War II*, 36 J.L. MED. & ETHICS 517, 517 (2008). Researchers suspected that non-whites would have a different response than whites. *Id.* at 518. For example, researchers at Cornell University Medical Center believed that non-whites had thicker skin which may make them less sensitive to mustard gas when compared to whites. Marion B. Sulzberger et al., *Skin*

whereby service members were locked in gas chambers that were inundated with mustard gas until the point that the men became incapacitated.<sup>6</sup> During the experiments, some soldiers were exposed to gas levels that were equivalent to those reported on World War I battlefields.<sup>7</sup>

The “man-break” tests caused severe injuries to the service members. Soldiers experienced “immediate and severe eye injuries” and “enormous, grotesque blisters and oozing sores” on their “face, hands, underarms, buttocks, and genitals.”<sup>8</sup> Exposure to mustard gas also caused blindness, intense vomiting, internal and external bleeding, and damage to the lungs and respiratory system.<sup>9</sup> Many soldiers suffered long-term health effects that included cancer, asthma, and psychological disorders.<sup>10</sup>

For decades, the U.S. government refused to acknowledge the existence of the studies or provide injured service members with compensation or long-term health care. It was not until 1991—nearly five decades after the first studies began—that the government officially admitted to the use of soldiers in experimental research. The government also admitted that it did not fully disclose safety risks or obtain informed consent from the research participants, and that the service members may have suffered adverse health effects as a result of their participation in the studies.<sup>11</sup>

Contemporaneous with the mustard gas experiments, the U.S. military conducted radiation experiments on American soldiers and civilians.<sup>12</sup> In addition to testing the destructive capabilities of nuclear weapons, military researchers examined the effects of nuclear warfare on humans, animals, and the environment.<sup>13</sup> As early as 1942, the military understood that exposure to radiation was likely to be quite dangerous, since “the deleterious effects of radiation could not be seen or felt and the results of over-exposure might not become apparent for long periods after such exposure.”<sup>14</sup>

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*Sensitization to Vesicant Agents of Chemical Warfare*, 8 J. INVESTIGATIVE DERMATOLOGY 365, 365 n.1, 372 (1947).

<sup>6</sup> Smith, *supra* note 5, at 518. Other experiments had soldiers stand in a field, wearing various levels of protective clothing, as low-flying airplanes sprayed the men with mustard gas. *Id.*

<sup>7</sup> IOM Report, *supra* note 4, at vii.

<sup>8</sup> Smith, *supra* note 5, at 518.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> IOM Report, *supra* note 4, at v–vi. In turn, the government offered compensation and medical treatment for research-related injuries. *Expanded Benefits for Vets Hurt by Gas Tests*, CHI. TRIB., Jan. 7, 1993, at N14.

<sup>12</sup> Human Radiation Experiments Report, *supra* note 4, at xxx, 14 (noting that the experiments were conducted from 1944 to 1974).

<sup>13</sup> Leonard W. Schroeter, *Human Experimentation, the Hanford Nuclear Site, and Judgment at Nuremberg*, 31 GONZ. L. REV. 147, 213 (1996).

<sup>14</sup> Human Radiation Experiments Report, *supra* note 4, at 6 (citation omitted).

After years of detonating atomic weapons in the South Pacific, the military began open air testing of nuclear weapons on American soil in the 1950s.<sup>15</sup> Thousands of soldiers were placed, without protective clothing, in the immediate vicinity of atomic detonations. The military did not inform the soldiers of potential health risks or seek to obtain informed consent prior to participation in the trials.

While the military publicly denied any potential harm to humans, plants, or animals, internal documents indicate that government officials had determined that there existed a causal relationship between radiation exposure and serious adverse health effects.<sup>16</sup> Despite the health and environmental hazards, the Commissioner of the U.S. Atomic Energy Commission privately asserted that “[w]e must not let anything interfere with this series of tests—nothing.”<sup>17</sup> It was later revealed that radiation exposure at the test sites was comparable to that of Hiroshima and Nagasaki.<sup>18</sup>

Coupled with the open-air nuclear tests, the military funded studies at a number of well-respected American universities, including the University of Chicago and the University of California, whereby researchers injected unsuspecting civilians with radioactive elements that included plutonium, uranium, and polonium.<sup>19</sup> This work continued through the 1970s, with researchers targeting the elderly, patients in mental institutions, prisoners, and others “who did not have full faculties for informed consent.”<sup>20</sup> A congressional investigation later found that “[n]o evidence was elicited that informed consent was granted in any of the cases,” and that “[t]he government covered up the nature of the experiments and deceived the families of deceased victims . . . .”<sup>21</sup>

In the 1990s, the government acknowledged that hundreds of thousands of American service members had been involved in at least 1400 radiation projects over a thirty-year period during and after World War II.<sup>22</sup> These figures do not include exposure suffered by American civilians in connection with hundreds of “intentional radiation releases,” where

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<sup>15</sup> See Howard Ball, *Downwind from the Bomb*, N.Y. TIMES, Feb. 9, 1986, (§ 6), at 33 (recounting the history of American nuclear testing beginning in the 1950s). Approximately one hundred atomic detonations occurred on U.S. soil during the 1950s. *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> See Schroeter, *supra* note 13, at 213.

<sup>19</sup> See Human Radiation Experiments Report, *supra* note 4, at 160–61.

<sup>20</sup> See Schroeter, *supra* note 13, at 157–58. For example, the Massachusetts Institute of Technology fed elderly patients radium and thorium, two radioactive elements that could have no benefit to the test subjects. *Id.* at 158. Over a period of eight years, the University of Washington Medical School x-rayed the testes of prisoners to examine the effects of ionizing radiation on human fertility and testicular function. *Id.*

<sup>21</sup> *Id.* at 157–58.

<sup>22</sup> Schroeter, *supra* note 13, at 151.

researchers deliberately emitted radioactive substances into densely populated cities and other locations to test human response and environmental contamination.<sup>23</sup> Although the government was aware that the radiation releases were likely to contaminate food and water supplies, many of the releases “took place with no public awareness or understanding.”<sup>24</sup> Within ten years after the commencement of the detonations in America, childhood leukemia deaths and diagnoses, as well as adult cancer deaths and diagnoses, were exponentially higher in several detonation regions.<sup>25</sup>

Along with the mustard gas and radiation experiments, the U.S. military engaged in decades of classified research, beginning in the 1940s and continuing through the 1970s, to ascertain whether psychotropic drugs could be used as chemical weapons or interrogation-facilitating agents.<sup>26</sup> The products under investigation included lysergic acid diethylamide (LSD), synthetic mescaline, synthetic marijuana, and over a dozen other drugs. During the early stages of the research, the U.S. military recruited Nazi scientists who had studied and participated in torture and brainwashing.<sup>27</sup> Several of the Germans had been recently identified as war criminals, and the U.S. falsified documents to conceal their true identities.<sup>28</sup> The military later justified its actions by arguing that national security interests far outweighed any ethical concerns.<sup>29</sup>

The psychotropic drugs were given to service members and civilians without their knowledge or consent.<sup>30</sup> Studies were conducted in military facilities and university medical centers, and many human subjects experienced serious adverse side effects.<sup>31</sup> Internally, the military justified the secret testing on “unwitting, nonvolunteer’ Americans” by arguing that national security interests permit “a more tolerant interpretation of moral-ethical values, but not legal limits.”<sup>32</sup> The military went on to argue

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<sup>23</sup> Human Radiation Experiments Report, *supra* note 4, at 318–22.

<sup>24</sup> *Id.* at 318.

<sup>25</sup> Ball, *supra* note 15, at 33.

<sup>26</sup> See Paul J. Amoroso & Lynn L. Wenger, *The Human Volunteer in Military Biomedical Research*, in 2 MIL. MED. ETHICS 563, 570 (Thomas E. Beam & Linette R. Sparacino eds., 2003) (discussing the military’s use of LSD on unknowing Americans); see also David H. Price, *Buying a Piece of Anthropology*, 23 ANTHROPOLOGY TODAY 8, 8–9 (2007) (discussing the CIA’s programs to study mind control, brainwashing, interrogation, and torture).

<sup>27</sup> See John Gimbel, *German Scientists, United States Denazification Policy, and the Paperclip Conspiracy*, 12 INT’L HISTORY REV. 441, 441–42 (1990); Peter A. Masley, *The Paperclip File: America’s Secret Agenda to Import Nazi Intelligence*, WASH. POST, Aug. 16, 1991, at D3.

<sup>28</sup> See Gimbel, *supra* note 27, at 441–42.

<sup>29</sup> *Id.* at 441–42; Andrew Walker, *Project Paperclip: Dark Side of the Moon*, BBC NEWS (Nov. 21, 2005), [http://news.bbc.co.uk/2/hi/uk\\_news/magazine/4443934.stm](http://news.bbc.co.uk/2/hi/uk_news/magazine/4443934.stm).

<sup>30</sup> Price, *supra* note 26, at 9.

<sup>31</sup> *Id.* at 9–11.

<sup>32</sup> *United States v. Stanley*, 483 U.S. 669, 686, 688 (1987) (Brennan, J., concurring in part and dissenting in part) (citations omitted).



that legal liability could be avoided by covering up the experiments.<sup>33</sup>

### III. PRESERVING AND ENHANCING THE FIGHTING FORCE

There is nothing to suggest that the U.S. military is currently supporting research that utilizes methods similar to those employed during the mustard gas, radiation, or psychotropic drug experiments. However, recent controversies have highlighted the military's efforts to mandate use of medical products for off-label or investigational purposes, and its emphasis on developing biotechnologies that seek to facilitate the cognitive and physical enhancement of service members.<sup>34</sup> This Part will focus on these two areas of research.

#### A. *Investigational and Off-Label Use of Medical Products*

Since at least the 1990s, the U.S. military has required service members to subject themselves to both investigational and off-label use of medical products.<sup>35</sup> Both off-label and investigational use involve utilization of a medical product for an indication that has not earned FDA approval.<sup>36</sup> While each is properly characterized as experimental research because the FDA has not found that the underlying product is safe and effective for the stated use, there is an important distinction between the two categories. For products that are used off-label, the FDA has determined that the product is safe and effective for at least one indication.<sup>37</sup> Investigational medical products, on the other hand, have not been approved for any indication.<sup>38</sup>

Nonconsensual use of off-label or investigational medical products raises a number of serious concerns. While physicians may prescribe drugs for off-label indications or investigational purposes, the decision to do so must be based on an evaluation of a patient's particular health

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<sup>33</sup> *Id.* at 689.

<sup>34</sup> See Annas & Annas, *supra* note 2, at 301–04 (discussing how, in the war on terror, physicians have participated in prisoner interrogations and prisoner hunger strikes, and the military has prescribed psychotropic medications, particularly selective serotonin-reuptake inhibitors, to soldiers in order to keep them in combat areas or to have them serve another tour of duty).

<sup>35</sup> See Stuart L. Nightingale et al., *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13 EMERGING INFECTIOUS DISEASES 1046, 1047 (2007) (stating that in preparation for the Persian Gulf War, the U.S. military administered unapproved drugs to service members without informed consent).

<sup>36</sup> See generally U.S. FOOD AND DRUG ADMIN., “OFF-LABEL” AND INVESTIGATIONAL USE OF MARKETED DRUGS, BIOLOGICS, AND MEDICAL DEVICES (1998), available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>.

<sup>37</sup> *Id.*; Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (2008).

<sup>38</sup> See Susan Okie, *Access Before Approval—A Right to Take Experimental Drugs?*, 355 NEW ENG. J. MED. 437, 439 (2006) (noting that only eleven percent of drugs that enter clinical trials are ultimately approved by the FDA).

condition and risk factors, and should only occur where medical data reflect meaningful evidence that the potential benefits are likely to outweigh the known or expected risks and the patient provides informed consent to the treatment. In a number of instances, the military has made off-label and investigational use of medical products compulsory for service members as a whole, and has not sought to obtain informed consent or provide adequate risk disclosures to individual soldiers. The discussion below explores four recent examples—pyridostigmine bromide (“PB”), the botulinum toxoid (“BT”) vaccine, the anthrax vaccine, and selective serotonin reuptake inhibitors (“SSRIs”).

After petitioning the FDA to establish a new rule that waives informed consent requirements for investigational use of medical products in times of existing or anticipated combat activities, the DoD sought and obtained permission from the FDA to use PB and the BT vaccine pursuant to the new regulation.<sup>39</sup> Fearing use of chemical weapons during the Gulf War, the military decided to administer PB and the BT vaccine to all soldiers.<sup>40</sup> At the time, the FDA was evaluating the safety and efficacy of both products as pretreatments for chemical warfare.<sup>41</sup>

In its informed consent waiver request to the FDA, the DoD argued that it would not be feasible to obtain informed consent because a soldier’s “personal preference” does not supersede the military’s view that the drug and vaccine would contribute to the “safety of other personnel in a soldier’s unit and the accomplishment of the combat mission.”<sup>42</sup> The DoD also argued that “obtaining informed consent in the heat of imminent or ongoing combat would not be practicable.”<sup>43</sup>

The FDA granted the DoD’s requests, but the decision was not without controversy. The DoD claims that it trusted that the FDA had granted permission to use the investigational drug without informed consent because the FDA believed that the drug was deemed to be safe.<sup>44</sup> The FDA, on the other hand, claims that it granted the waiver because it believed that the DoD determined that military necessity required an informed consent waiver.<sup>45</sup>

Regardless of the reason why the FDA granted the waiver, as a condition of the FDA’s permission to use the investigational medical products without informed consent, the DoD agreed to: (1) provide information on PB to all service members; (2) collect, review, and make

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<sup>39</sup> Doe v. Sullivan, 938 F.2d 1370, 1372 n.1, 1374 (D.C. Cir. 1991).

<sup>40</sup> *Id.* at 1371–72, 1372 n.1.

<sup>41</sup> *Id.* at 1372 n.1.

<sup>42</sup> *Id.* at 1373.

<sup>43</sup> *Id.*

<sup>44</sup> Annas & Annas, *supra* note 2, at 301–02.

<sup>45</sup> *Id.* at 302.

reports of adverse events related to PB; (3) label PB as an investigational product that was solely for “military use and evaluation;” (4) ensure that each dose of the BT vaccine was recorded in each service member’s medical record; and (5) maintain adequate records related to the receipt, shipment, and disposition of the BT vaccine.<sup>46</sup> The DoD failed to comply with each of these requirements.<sup>47</sup>

Following use of PB and the BT vaccine during the Gulf War, veterans began suffering from serious health problems that include cognitive difficulties, chronic headaches, widespread pain, skin rashes, respiratory and gastrointestinal problems, and other chronic abnormalities.<sup>48</sup> Gulf War veterans have been diagnosed with amyotrophic lateral sclerosis (“ALS”) at a much higher rate than that of the general population or veteran populations from other wars.<sup>49</sup> Children of Gulf War veterans are also born with birth defects at an alarming rate.<sup>50</sup> Commonly referred to as Gulf War illness, these health problems affect over 175,000 Gulf War veterans, which amounts to more than twenty-five percent of the fighting force during the war.<sup>51</sup> PB is included in the list of factors that are most likely to be a contributing factor to Gulf War illness.<sup>52</sup>

The military’s off-label use of vaccines continued after the Gulf War. In 1998, the DoD implemented the Anthrax Vaccine Immunization Program (“AVIP”), which requires the anthrax vaccine for all service members who are deemed by DoD to be at risk for anthrax exposure.<sup>53</sup> Although the vaccine had earned FDA approval to protect against

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<sup>46</sup> Revocation of 1990 Interim Final Rule, 64 Fed. Reg. 54180, 54184 (Oct. 5, 1999) (codified at 21 C.F.R. pts. 50 & 320 (2010)) (“There was a failure to meet the conditions set by the Commissioner for granting a waiver from the informed consent requirements under the 1990 interim rule . . .”).

<sup>47</sup> *Id.*

<sup>48</sup> RESEARCH ADVISORY COMM. ON GULF WAR VETERANS’ ILLNESSES, GULF WAR ILLNESS AND THE HEALTH OF GULF WAR VETERANS I (2008) [hereinafter Gulf War Illness Report].

<sup>49</sup> *Id.* at 6 (reporting that Gulf War veterans developed ALS at twice the rate of non-deployed veterans of the same era).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 4.

<sup>52</sup> *Id.* at 7–10; see also *Justice Delayed: Acknowledging the Reality of Gulf War Illness*, 372 LANCET 1856, 1856 (2008) (“Gulf War veterans have long complained of cognitive problems, headaches, fatigue and pain, and chronic digestive, respiratory, and skin disorders. . . . The constellation of symptoms has now been attributed to two agents: pesticides and pyridostigmine bromide . . .”). In 2003, more than two decades after use of PB by the U.S. military, the drug was approved for use in combat through the Bioterrorism Act’s animal-efficacy standard. See William J. FitzPatrick & Lee L. Zwanziger, *Defending Against Biochemical Warfare: Ethical Issues Involving the Coercive Use of Investigational Drugs and Biologics in the Military*, 3 J. PHIL., SCI. & L. 1, 2 (2003) (“This ‘animal efficacy rule’ allows for the possibility of moving some hitherto ‘investigational’ compounds into the category of *approved* drugs or biologics, which would also obviate the need in such cases for a special Presidential waiver of the consent requirement for the administration of such compounds . . . . This change in status has in fact just occurred in the case of pyridostigmine bromide . . . which was approved for combat use on 5 February 2003 . . .”).

<sup>53</sup> *Rempfer v. Sharfstein*, 583 F.3d 860, 863 (D.C. Cir. 2009).

cutaneous anthrax, the military sought to use the vaccine as a pretreatment for inhalation anthrax.<sup>54</sup>

In 2003, six service members filed a lawsuit seeking to enjoin the military from continuing AVIP because the military did not obtain informed consent prior to inoculations, nor did the DoD obtain a waiver for the informed consent requirements.<sup>55</sup> A federal district court issued a preliminary injunction that halted AVIP.<sup>56</sup> Days later, the FDA approved the anthrax vaccine “independent of the route of exposure,” which captured the indication of inhalation anthrax.<sup>57</sup> The court then vacated the FDA’s decision on procedural grounds because the agency did not follow its requirement to certify that the vaccine was safe and effective against inhalation anthrax.<sup>58</sup> In essence, the court found it impossible for the FDA to have adequately evaluated the products, pursuant to the statutory requirements, in such a short time period.

Congress stepped in to aid the DoD by enacting the Project BioShield Act of 2004,<sup>59</sup> which granted the FDA the ability to permit off-label or investigational use of medical products during a declared emergency.<sup>60</sup> In turn, the FDA used its newfound power to grant the DoD the ability to continue using the anthrax vaccine.<sup>61</sup> During the time that the DoD was permitted to continue with AVIP pursuant to the emergency order, the FDA approved the vaccine regardless of the route of exposure.<sup>62</sup> Although service members once again challenged the FDA’s decision, the Court of Appeals for the D.C. Circuit dismissed the action because it found that the FDA had not acted arbitrarily or capriciously in approving the new indication during its second review.<sup>63</sup> Since March 1998, over 2,700,000 service members have received the anthrax vaccine.<sup>64</sup> For a number of

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<sup>54</sup> *Id.* at 863–64.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 864.

<sup>57</sup> *Id.* at 863–64.

<sup>58</sup> *Id.* at 864.

<sup>59</sup> 21 U.S.C. § 360bbb-3 (2006).

<sup>60</sup> See Nightingale et al., *supra* note 35, at 1046 (describing the Project BioShield Act’s establishment of the comprehensive Emergency Use Authorization (“EUA”) program, which permits the FDA to “approve the emergency use of drugs, devices, and medical products . . . that were not previously approved, cleared, or licensed by FDA . . . or the off-label use of approved products in certain well-defined emergency situations”).

<sup>61</sup> *Id.* at 1050.

<sup>62</sup> See *Rempfer*, 583 F.3d at 864 (stating that, after issuing a proposed order for comment and reviewing those comments, the FDA issued a new final order on December 19, 2005 that classified the anthrax vaccine as “safe and effective in the prevention of anthrax regardless of the route of exposure”).

<sup>63</sup> *Id.* at 867–68.

<sup>64</sup> See *Why Get Vaccinated*, BIOTHRAX, <http://www.biothrax.com/whatisbiothrax/whygetvaccinated.aspx>, (last visited Feb. 16, 2012) (stating that more than 10 million doses of BioThrax Anthrax Vaccine have been administered to 2.7 million people); see also *Anthrax Vaccine*

service members, however, the administration of the vaccine is not reflected in the official medical records maintained by the military.<sup>65</sup>

Today, some of the most pressing medical issues facing service members include traumatic brain injury (“TBI”), post-traumatic stress disorder (“PTSD”), and other mental health issues.<sup>66</sup> A decade of intense fighting in Afghanistan and Iraq has resulted in a “substantial mental health burden for war veterans and their families.”<sup>67</sup> Blast-related TBI has been labeled the signature injury of the wars, and countless soldiers have reported post-concussive symptoms.<sup>68</sup> Veterans of these wars have required mental health treatment for serious mental disorders much more than veterans of previous wars, and suicide rates for enlisted service members and veterans are at an all-time high.<sup>69</sup>

Increasingly, treatments for depression, TBI, PTSD, and anxiety disorders utilize newer psychotropic medications, particularly selective serotonin-reuptake inhibitors.<sup>70</sup> Military psychiatrists have recommended that physicians in war zones have SSRIs “in large quantities, to be used for both depressive disorders and anxiety disorders.”<sup>71</sup> However, a number of studies have questioned the safety and efficacy of SSRIs.<sup>72</sup> Off-label use of SSRIs is particularly troubling, with some studies finding no meaningful clinical benefit and long-term adverse health effects.<sup>73</sup> To the extent that SSRIs are the standard of care for both on-label and off-label indications,

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*Immunization Program: Questions and Answers Overview*, MIL. VACCINE (MILVAX) AGENCY, <http://www.anthrax.osd.mil/> (last visited March 30, 2012) (indicating that the military’s AVIP program has resulted in vaccination of 1.5 million DoD personnel).

<sup>65</sup> See *Anthrax Vaccine Immunization Program: Questions and Answers Anthrax and the Persian Gulf War*, MIL. VACCINE (MILVAX) AGENCY, <http://www.anthrax.osd.mil/resource/qna/qaAll.asp?cID=313> (last visited March 30, 2012) (acknowledging that more effort is still needed in documenting vaccinations in service members’s medical records).

<sup>66</sup> See Charles W. Hoge, *Interventions for War-Related Posttraumatic Stress Disorder*, 306 JAMA 549, 549 (2011) (stating that about ten to twenty percent of U.S. infantry personnel have developed post-deployment PTSD along with depression, substance abuse, and other health issues); Charles W. Hoge et al., *Mild Traumatic Brain Injury in U.S. Soldiers Returning from Iraq*, 358 NEW ENG. J. MED. 453, 454 (2008).

<sup>67</sup> Hoge, *supra* note 66, at 549.

<sup>68</sup> Hoge et al., *supra* note 66, at 454.

<sup>69</sup> Annas & Annas, *supra* note 2, at 304.

<sup>70</sup> *Id.* Examples of SSRIs include Prozac, Paxil, and Zoloft.

<sup>71</sup> *Id.*

<sup>72</sup> E.g., IRVING KIRSCH, *THE EMPEROR’S NEW DRUGS: EXPLODING THE ANTIDEPRESSANT MYTH* 75 (2010); Hoge, *supra* note 66, at 550; Marcia Angell, *The Epidemic of Mental Illness: Why?*, N.Y. REV. BOOKS, June 23, 2011 [hereinafter Angell, *Epidemic*] (examining the risk-benefit profile for SSRIs); Marcia Angell, *The Illusions of Psychiatry*, N.Y. REV. BOOKS, July 14, 2011 [hereinafter Angell, *Illusions*].

<sup>73</sup> See, e.g., KIRSCH, *supra* note 72, at 61; Hoge, *supra* note 66, at 550 (discussing specific side effects such as weight gain and cardiac effects); Angell, *Epidemic*, *supra* note 72 (discussing industry’s role in suppressing clinical trials where the data reveal a product that is ineffective and unsafe); Angell, *Illusions*, *supra* note 72 (identifying conflicts of interest in the pharmaceutical industry and off-label promotion of SSRIs absent reliable evidence of safety and efficacy).

and service members are not provided with accurate risk-benefit profiles, such use may place service members at a heightened risk for both short-term and long-term health problems.<sup>74</sup>

### B. *Physical and Cognitive Enhancement of Service Members*

The fundamental goal of military training is to enhance service members—to make them smarter, stronger, and more able fighters. Increasingly, enhancement techniques have sought to leverage innovative medical products and technologies. As the director of DARPA explains, the agency’s goal is to exploit “the life sciences to make the individual warfighter stronger, more alert, more enduring, and better able to heal.”<sup>75</sup>

Such endeavors have raised a number of challenging questions. Is there a valid distinction between “artificial” and “natural” enhancement? Under what circumstances should enhancements that are under development be administered to service members? Should medical enhancements ever be a required aspect of service in the military? Examining current enhancement projects helps frame these concerns.

DARPA’s “Persistence in Combat” program aims to create soldiers who are “unstoppable because pain, wounds, and bleeding are kept under their control.”<sup>76</sup> This program includes research directed at developing a vaccine that will block intense pain within seconds, use of photobiomodulation to accelerate wound healing, and the creation of a chemical cascade to stop bleeding within minutes.<sup>77</sup> The agency’s Metabolic Dominance program seeks to create a “‘nutraceutical,’ a pill with nutritional value that would vastly improve soldiers’ endurance.”<sup>78</sup> DARPA’s vision is “to enable superior physical and physiological performance by controlling energy metabolism on demand. An example is continuous peak physical performance and cognitive function for 3 to 5 days, 24 hours per day, without the need for calories.”<sup>79</sup>

Coupled with these programs, “the security establishment’s interest and investment in neuroscience, neuropharmacology . . . and related areas [are] extensive and growing.”<sup>80</sup> Under the Augmented Cognition program, DARPA seeks to “develop the technologies needed to measure and track a subject’s cognitive state in real-time.”<sup>81</sup> Another goal is to create brain-to-

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<sup>74</sup> See Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 987 (discussing factors that negatively impact risk-benefit disclosures).

<sup>75</sup> MORENO, *supra* note 2, at 11 (internal quotation marks omitted).

<sup>76</sup> Annas & Annas, *supra* note 2, at 286 (internal quotation marks omitted).

<sup>77</sup> *Id.*

<sup>78</sup> MORENO, *supra* note 2, at 121.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 4.

<sup>81</sup> *Id.* at 51.

computer interfaces, whereby soldiers can communicate by thought alone.<sup>82</sup> This includes systems that can relay messages, such as images and sounds, between human brains and machines, or even from human to human.<sup>83</sup> Service members can receive commands via electrodes implanted in their brains, or be wired directly into the equipment they control.<sup>84</sup>

Through implanted electrodes, DARPA is researching whether neurostimulation can improve impaired cognitive performance and reduce the effects of sleep deprivation on soldiers.<sup>85</sup> This research dovetails with two other DARPA endeavors, the Continuous Assisted Performance program and the Applications of Biology to Defense Applications program.<sup>86</sup> The former is “investigating ways to prevent fatigue and enable soldiers to stay awake, alert, and effective for up to seven days straight without suffering any deleterious mental or physical effects and without using any of the current generation of stimulants.”<sup>87</sup> The latter incorporates neuroscientific studies such as

[b]iological approaches for maintaining the warfighter’s performance, capabilities and medical survival in the face of harsh battlefield conditions, biological approaches for minimizing the after-effects of battle injuries, including neurotrauma from penetrating and non-penetrating injuries as well as faster recuperation from battlefield injury and wounds[,] . . . [b]iomolecular motors and devices[,] . . . [m]icro/nano-scale technologies for non-invasive assessment of health[,] . . . techniques for the decoding of neural signals in real time[,] . . . [n]ovel interfaces and sensor designs for interacting with the central . . . and peripheral nervous systems[,] . . . [and n]ew approaches for understanding and predicting the behavior of individuals and groups, especially those that elucidate the neurobiological basis of behavior and decision making.<sup>88</sup>

Though DARPA-funded research is often cutting-edge and visionary, about ninety percent of its projects fail.<sup>89</sup> Those that succeed, however,

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<sup>82</sup> Hoag, *supra* note 3, at 798.

<sup>83</sup> *Id.* at 796, 798.

<sup>84</sup> *Id.* at 796.

<sup>85</sup> MORENO, *supra* note 2, at 127.

<sup>86</sup> *Id.* at 11–13.

<sup>87</sup> *Id.* at 11 (internal quotation marks omitted).

<sup>88</sup> *Id.* at 12–13.

<sup>89</sup> *Id.* at 12.

often prove transformative for both military and civilian life.<sup>90</sup> DARPA-funded research has resulted in the creation of the Internet (initially called the Darpanet), the computer mouse, the Stealth Fighter, and unmanned aerial vehicles.<sup>91</sup> As one DARPA official explains, “DARPA is about trying to do those things, which are thought to be impossible, and finding ways to make them happen.”<sup>92</sup>

#### IV. CONCLUSION

I have focused my discussion in this Article on military medicine and research methods employed by the U.S. military in furtherance of its mandate to protect national security interests. One need not question the validity of the government’s motivations to conduct experimental research to understand that current and past research methods run contrary to fundamental constitutional liberties and well-established research protocols governing human subjects research.

Importantly, the unique relationship between a service member and his or her commanding officer, and in turn, between the commanding officer and his or her superiors, creates an environment with enormous potential for abuse from a socio-medical context. Service members are legally obligated to submit to biomedical treatments deemed necessary for the good of the armed forces, even in instances where the treatments are purely investigational or involve unapproved uses of FDA-approved medical products.<sup>93</sup> Refusing “treatment” may be viewed as disobeying an order, which can result in punitive measures that include a court-martial and dishonorable discharge from the military. Coupled with the threat of punitive measures, military hierarchy often compels soldiers to submit to experimental treatment in instances where they otherwise may not have provided consent.<sup>94</sup>

The risks to service members are compounded when one considers the broad legal immunities that shield military researchers and the U.S. government from civil claims. Under the *Feres* doctrine, service members are precluded from raising tort claims against the government, government employees, or third party contractors working in furtherance of governmental research, if the underlying injury is sustained “in the course

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<sup>90</sup> See *id.* at 12–13 (providing examples of military research resulting in unprecedented civilian life innovations).

<sup>91</sup> *Id.* at 12.

<sup>92</sup> *Id.* (internal quotation marks omitted) (quoting a DARPA official).

<sup>93</sup> *Doe v. Sullivan*, 938 F.2d 1370, 1372–74 (D.C. Cir. 1991).

<sup>94</sup> See IOM REPORT, *supra* note 4, at v–vii (explaining that the recruitment of “volunteer[]” soldiers during World War II was accomplished through “lies and half-truths”); MORENO, *supra* note 2, at 134; Annas & Annas, *supra* note 2, at 308 (“It seems likely that most soldiers will volunteer . . . to take whatever their superior officers recommend.”); Smith, *supra* note 5, at 518.



of activity incident to service.”<sup>95</sup> Service members are also precluded from raising tort claims against the United States when the underlying injury relates to a “discretionary function” of military policy.<sup>96</sup> The U.S. Supreme Court has interpreted the *Feres* doctrine broadly to encompass claims that arise from experimental research, even in instances where the government covertly experimented upon soldiers and civilians, or intentionally disregarded legal requirements and informed consent protocols.<sup>97</sup>

Understanding the history and dynamics of experimental research in the military, along with the legal and regulatory framework that facilitates such research, informs contemporary discussion of how best to harmonize national security interests with fundamental notions of human dignity and patient autonomy.<sup>98</sup> While the goal of this Article has been to use human enhancement and experimental research as paradigms to highlight the legal and regulatory shortcomings of the current framework, proposals for reform measures addressing these concerns will be the subject of future scholarship.<sup>99</sup>

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<sup>95</sup> *Feres v. United States*, 340 U.S. 135, 146 (1950) (“We conclude that the Government is not liable under the Federal Tort Claims Act for injuries to servicemen where the injuries arise out of or are in the course of activity incident to service. Without exception, the relationship of military personnel to the Government has been governed exclusively by federal law. We do not think that Congress, in drafting this Act, created a new cause of action dependent on local law for service-connected injuries or death due to negligence. We cannot impute to Congress such a radical departure from established law in the absence of express congressional command.”).

<sup>96</sup> *Boyle v. United Tech. Corp.*, 487 U.S. 500, 511 (1988).

<sup>97</sup> *United States v. Stanley*, 483 U.S. 669, 671, 683–84 (1987).

<sup>98</sup> Although commentators have highlighted medical and bioethical concerns affecting veterans and service members, as discussion during the Symposium has revealed, the current debate surrounding the constitutionality of the Patient Protection and Affordable Care Act has overshadowed meaningful dialogue of a number of fundamental public health matters.

<sup>99</sup> See Efthimios Parasidis, *National Security, Military Research, and the Interests of Humanity*, 73 OHIO ST. L.J. (forthcoming 2012).