

**Bioterrorism, Biodefense, and Biotechnology in the Military:  
A Comparative Analysis of Legal and Ethical Issues in the Research, Development, and  
Use of Biotechnological Products on American and British Soldiers**

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**Introduction and Overview of Issues**

Biology,<sup>1</sup> as one of the three primary natural sciences and, like its counterpart sciences of chemistry and physics, uses the experimental method<sup>2</sup> to gain knowledge.<sup>3</sup> However, unlike its counterparts, the study of biology inherently involves living things, including human beings.<sup>4</sup> Because of this distinction, which implicates both human rights and the Hippocratic Oath,<sup>5</sup> the experimental method becomes legally and ethically unacceptable as a means of studying biology,

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<sup>1</sup> “The prefix *bio-* comes from Greek *bios*, meaning “life.” When used to form words in English, *bio-* generally refers to living organisms or to *biology*, the science of living organisms.” THE AMERICAN HERITAGE, BOOK OF ENGLISH USAGE: A PRACTICAL AND AUTHORITATIVE GUIDE TO CONTEMPORARY ENGLISH 244 (Houghton Mifflin Co. 1996).

<sup>2</sup> The “experimental method” is defined as “the use of controlled observations and measurements to test hypotheses.” PRINCETON UNIVERSITY, WORDNET 2.0 (2003), at <http://www.cogsci.princeton.edu/cgi-bin/webwn1.7.1?stage=1&word=experimental+method>.

<sup>3</sup> *E.g.*, HARRY HILLMAN CHARTRAND, THE COMPETITIVENESS OF NATIONS IN A GLOBAL KNOWLEDGE-BASED ECONOMY 1.1, (April 2002), <http://members.shaw.ca/competitivenessofnations/698.6%20NeoPhysiocrats%201.htm>.

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

<sup>5</sup> A major portion of the Oath of Hippocrates states “I [the physician] will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.” BARRY R. FURROW ET AL., BIOETHICS: HEALTH CARE LAW AND ETHICS 27 (4<sup>th</sup> ed. 2001). This principle is inherently inconsistent with the experimental method, which values the integrity of the research procedure over the integrity of the research subject.

at least when human subjects are implicated.<sup>6</sup> Further, knowledge gleaned in this science does not truly come to fruition until applied and used in the real world through technological innovations, thus the term “biotechnology.”<sup>7</sup>

Although not officially defined until 1919 by Hungarian engineer, Karl Ereky,<sup>8</sup> the first example of biotechnological innovations noted in the literature dates back well before Ereky’s time to the selective breeding of livestock and growing of crops during the Agricultural Revolution.<sup>9</sup> Today, a sort of “biotechnological age” is being realized,<sup>10</sup> as the United States (U.S.) Government, alone, invested over \$18 billion in biotechnology research and development (R&D) for fiscal year 2000.<sup>11</sup> This figure dwarfs in comparison to the R&D budgets of large pharmaceutical companies and other commercial investors.<sup>12</sup>

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<sup>6</sup> CHARTRAND, *supra* note 3, at 1.1.

<sup>7</sup> *Id.* at 1.4.

<sup>8</sup> *Id.* at 1.5 (“biotechnology” means “all the lines of work by which products are produced from raw materials with the aid of living organisms”).

<sup>9</sup> *Id.* at 1.4 (six thousand years ago).

<sup>10</sup> *Id.* at 1.5 (according to Ereky’s prediction).

<sup>11</sup> INFO. ASSURANCE TECH. ANALYSIS CTR. (IATAC), EXPLORING BIOTECHNOLOGY: OPPORTUNITIES FOR THE DEPARTMENT OF DEFENSE: CRITICAL REVIEW AND TECHNOLOGY ASSESSMENT (CR/TA) REPORT 13-14 (January 31, 2002) [hereinafter IATAC REPORT]. The following figures represent U.S. Government expenditures for biotechnology research and development in FY ’00: \$15,185 million, National Institutes of Health (NIH); \$1,939 million, Centers for Disease Control (CDC); \$580 million, Department of Defense (DoD); \$305.8 million, Department of Energy (DoE). *Id.*

<sup>12</sup> *See generally* COMM. ON OPPORTUNITIES IN BIOTECHNOLOGY FOR FUTURE ARMY APPLICATIONS, BD. ON ARMY SCI. & TECH., DIV. ON ENG. & PHYSICAL SCI’S, NAT’L RESEARCH COUNCIL, OPPORTUNITIES IN BIOTECHNOLOGY FOR FUTURE ARMY APPLICATIONS 1 (2001)[hereinafter NRC REPORT],

Beyond the financial investment in biotechnology is the investment this field of science calls for from both individuals and society as a whole. Because the testing and use of biotechnological products inherently involves living organisms from microbes to human beings,<sup>13</sup> complex legal and ethical issues arise, the solutions to which have yet to be answered, and, at times, even addressed. Basic standards for research using human subjects have been

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<http://www.nap.edu/openbook/0309075556/html/R1/html>. The average cost for development of a new therapeutic compound exceeds \$400 million. *Id.* at 64.

<sup>13</sup> CHARTRAND, *supra* note 3, at 1.7. Each category of biotechnological “tools” identified involves the use of living organisms or constituent parts of living organisms:

- (a) Fermentation: using microbes to convert a substance such as starch or sugar into other compounds such as carbon dioxide and ethanol;
- (b) Selection and Breeding: manipulating microbes, plants or animals, and choosing desirable individuals or populations as breeding stock for new generations;
- (c) Genetic Analysis: studying how traits and genes for traits are passed from generation to generation and how genes and the environment interact to result in specific traits;
- (d) Tissue Culture: growing plant or animal tissues or cells in test tubes or other laboratory glassware for propagation, chemical production and/or medical research;
- (e) Genetic Engineering/Recombinant DNA (rDNA): transferring a DNA segment from one organism and inserting it into the DNA of another. The two may be totally unrelated – spiders and goats; and,
- (f) DNA Analysis: including polymerase chain reaction (PCR) to make copies of a DNA segment and RFLP mapping (restriction fragment length polymorphism) to detect patterns in DNA that may indicate the presence of a *trait* gene. Both PCR and RFLP analysis are used in “DNA fingerprinting” for genealogical studies and forensics. . . .

*Id.*

enunciated in international instruments beginning with the Nuremberg Code,<sup>14</sup> but, as history has shown, the research context has often dictated whether such standards would apply, and to what extent, in actual practice<sup>15</sup>. Furthermore, research involving the use of human “materials,” namely stem cells<sup>16</sup> and embryos,<sup>17</sup> raises perhaps even more controversial issues than human subject research. Once biotech products are developed, a new series of debates arises as to whether their use is appropriate, and, if so, by whom and for what purpose,<sup>18</sup> as well as what may be done with information obtained through the research or the use of biotechnology.<sup>19</sup>

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<sup>14</sup> 2 U.S. GOV'T PRINTING OFFICE, TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (containing full text of the Nuremberg Code); BARRY R. FURROW ET AL., BIOETHICS: HEALTH CARE LAW AND ETHICS 413-14 (4<sup>th</sup> ed. 2001) (also containing text of Code).

<sup>15</sup> See generally FURROW ET AL., *supra* note 14, at 419-421 (describing the history of abuse of human research subjects in U.S. Government-sponsored research, including, but not limited to, the Human Radiation Experiments and the Tuskegee Syphilis Study).

<sup>16</sup> See generally President George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), <http://www.whitehouse.gov/news/releases/2001/08/print/10010809-2.htm>.

<sup>17</sup> See generally THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 10, 2002) [hereinafter CLONING REPORT], <http://www.bioethics.gov/cloningreport/transmittal.html>.

<sup>18</sup> See generally THE PRESIDENT'S COUNCIL ON BIOETHICS, STAFF WORKING PAPER 7: DISTINGUISHING THERAPY AND ENHANCEMENT, <http://www.bioethics.gov/workpaper7.html> (last revised Aug. 20, 2002).

<sup>19</sup> To the greatest extent possible, the privacy of individual subjects' health-related information must be protected. Informing subjects of the actual and potential limits to privacy protection, as well as the possible consequences of disclosure of health-related information, is essential to meet voluntary and informed consent requirements. See, e.g., COUNCIL FOR INT'L ORGS. OF MED. SCIS. (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Aug. 2002), [http://www.cioms.ch/guidelines\\_sept\\_2002\\_fp.htm](http://www.cioms.ch/guidelines_sept_2002_fp.htm) (stating in Guideline 18 “The investigator must establish secure safeguards of the confidentiality of subjects' research data.

Ultimately, this question is presented: Do the benefits of biotechnology outweigh risks associated with these unresolved issues? Our answer may depend on what stands to be lost if testing and use of biotech products is not pursued. In the public health context, these products provide potential solutions to pressing concerns in the national, as well as global, arena. Developments in genetically engineered foods and drugs, for example, pose alternatives to addressing issues of world hunger and disease. In the medical context, biotech products have revolutionized health care by providing new options for injury and illness prevention, as well as treatment, in the form of pharmaceuticals, procedures, and devices.

Also affected on a global scale and, perhaps, ever-so-evident with the recent threats of bioterrorism, are the opportunities biotechnology presents in the military context,<sup>20</sup> which is

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Subjects should be told the limits, legal or other, to the investigator's ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.”).

<sup>20</sup> *E.g.*, IATAC REPORT, *supra* note 11, at 89-99 app. C, 101-111 app. D (including, but not limited to, the following Exemplars: Advanced Military Medicine, including advanced vaccines and immune enhancements for expeditionary warfare and homeland security, accelerated wound healing, and stasis for critical warfighter casualties; Human Performance Enhancement, including 24x7 operations, enhanced environmental endurance for the warfighter, and enhanced cognition for improved warfighter performance). The Report also contains legal position papers favorable to the following uses of biotechnology by DoD: genetic screening for missions selection; transitory genome altering enhancements; permanent genome altering enhancements. *Id.* at 73-88 app. B. *See also* NRC REPORT, *supra* note 12, at 2 tbl. ES-1 (containing the following “Prospective Army Applications” [of biotech products] and their respective descriptions:

Camouflage and concealment - Biomaterials with stealth characteristics; nonilluminating paints and coatings.

Combat identification – Biological markers to distinguish friendly soldiers.

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Functional foods – Additives to improved nutrition, enhance digestion, improved storage characteristics, enable battlefield identification, reduce detectability; edible vaccines; . . .

Health monitoring – Devices to provide feedback on soldier status, enable remote triage, and augment network of external sensors to provide intelligence on chemical, biological, or environmental agents.

. . .

Lightweight armor – Protection for soldiers and combat systems; systems with living characteristics, such as self-repairing body armor.

Novel materials – Biologically inspired materials; . . . ; genetically engineered proteins; . . .

Performance enhancement – Cortical implants; computer input and display interfaces; prostheses control; sensory enhancement; antidotal implants; gene-expression monitoring; performance-enhancing drugs.

. . .

Sensing battlefield environments – Laboratories-on-a-chip to detect and identify chemical, biological, and environmental threat molecules on the battlefield; coupling of diagnostic and therapeutic functions.

. . .

Soldier therapeutics – Drugs to counteract shock; genomics-based, directed therapies; optimized responsiveness to vaccines.

. . .

Vaccine development – Reduced development and production times for small-scale requirements to respond to disease encountered in exotic locales.

Wound healing – Engineered skin, tissue, and organs; wound dressings and treatments to curtail bleeding and accelerate healing.).

defined as “the exploitation and manipulation of biological systems to benefit overall military capability”<sup>21</sup>. According to a recent report by the Information Assurance Technology Analysis Center (IATAC), “history has shown that an infusion of technology can provide a significant military advantage to the side that first realizes its potential and exploits it.”<sup>22</sup> However, the historical examples described, namely invention of the tank, development of U.S. naval aviation capabilities, and technologies emerging from the Information Revolution, fail to invoke the legal and ethical complexities presented by biotechnological research, development, and use in the military. Such concerns become particularly relevant in light of the history of abuse of civilians and service member subjects in research conducted or sponsored by the militaries of both the U.S.<sup>23</sup> and its European Ally, the United Kingdom (U.K.).<sup>24, 25</sup>

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<sup>21</sup> Dr. Steve Nicklin, *Medical Issues: The Future Impact of Biotechnology on Human Factors*, in NATO RESEARCH & TECH. ORG., RTO MEETING PROCEEDINGS 77: HUMAN FACTORS IN THE 21<sup>ST</sup> CENTURY, RTO-MP-077 AC/323(HFM-062)TP/38 19-1 (June 11-13, 2001) (pub’d May 2002), <http://www.rta.nato.int/Abstracts.asp?RestrictPanel=HFM>.

<sup>22</sup> IATAC REPORT, *supra* note 11, at 2.

<sup>23</sup> Jacques G. Richardson, *Serious Misapplications of Military Research: Dysfunction between Conception and Implementation*, 7S CI. & ENGINEERING ETHICS 347, 349-51 (2001).

<sup>24</sup> The term “United Kingdom” as used in this paper refers to England. *See generally* Prof. David Price, *United Kingdom*, in 3 MEDICAL LAW, INTERNATIONAL ENCYCLOPEDIA OF LAWS ¶¶ 6, 8 (Prof. Dr. H. Hys, ed., Supp. 27 2002) [hereinafter Price, *United Kingdom*] (stating:

At one time the British Empire was over one-quarter of the earth’s surface but it has gradually retrenched and dissolved with the vast majority of former colonies having achieved their own independence . . . . [Regarding the U.K., itself,] [t]here have been very significant movements towards devolution within the United Kingdom in recent years, with Scotland, Northern Ireland and Wales becoming, to a greater or lesser extent, autonomous from England.).

Although legal and ethical requirements for human subject research technically do not exclude military entities, statutory and judicial “loopholes” have emerged in the U.S.,<sup>26</sup> while the U.K. has been slow to develop binding legal safeguards for non-military, much less military, research subjects<sup>27</sup>. As recently demonstrated by the joint U.S.-U.K. support for an invasion of

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<sup>25</sup> Rob Evans, *Guinea Pigs’ Grievance: Experiments undertaken at the laboratories of Porton Down have left a legacy of doubt. Now ministers must decide if inquiry is needed.* THE GUARDIAN, Feb. 26, 2001, <http://www.geocities.com/ukgulfwarhelp/guardian26022001.htm> (reporting that Britain’s Ministry of Defence (MoD), which is responsible for “the world’s longest programme of chemical warfare experiments on humans,” has subjected over 20,000 service members to the testing of poisonous gasses, chemical weapons and protective drugs at its lab in Porton Down, Wiltshire from 1916 to the present); see also Jim Green, *UK Admits Military Personnel Deliberately Exposed to Nuclear Tests*, ENVTL. NEWS SERVICE, May 18, 2001, <http://ens-news.com/ens/may2001/2001-05-18-04.asp> (reporting that on May 11, 2001, the MoD officially confirmed the use of service members from Britain, Australian and New Zealand for radiation experiments conducted in Australia in the 1950’s).

<sup>26</sup> See, e.g., George J. Annas, *Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat*, 24 AM. J. L. & MED. 245, 247-250 (1998) (discussing the use of investigational drugs and vaccines on soldiers without their informed consent, as allowed by 21 C.F.R. § 50.23(d) and upheld by the Court of Appeals for the District of Columbia in *Doe v. Sullivan*, 938 F.2d 1370 (1991)); Michael I. Braverman, Comment, *Allowing Free Reign in the Military Establishment: Has the Court Allowed Too Much Deference Where Constitutional Rights are at Stake? – United States v. Stanley*, 7 N.Y.L. SCH. J. HUM. RTS. 278, 278-81, 303-10 (1989) (criticizing the Majority holding in *U.S. v. Stanley*, 483 U.S. 669 (1987), for denying ex-serviceman a *Bivens* remedy for injuries sustained in experiments in which military researchers failed to obtain subject’s informed consent).

<sup>27</sup> See PRINCIPLES OF MEDICAL LAW ¶¶ 13.03, 13.65 (Ian Kennedy & Andrew Grubb, eds. 1998) [hereinafter KENNEDY & GRUBB] (stating that no overarching statutory framework exists to govern research involving human subjects, as compared to the comprehensive legislation covering use of animal research subjects, and, moreover, no present English case law directly relates to research conduct); ANDREW GRUBB, PRINCIPLES OF MEDICAL LAW ¶¶

Iraq,<sup>28</sup> these two countries are strong Allies. Their respective domestic laws and policies,<sup>29</sup> as well as international treaties,<sup>30</sup> call for collaboration in major military matters ranging from scientific R&D to the interoperability of forces.

However, collaboration presents controversy in the context of biotechnology.

Concerning biotech R&D, which inherently involves techniques such as stem cell research<sup>31</sup> and

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13.66-13.74 (4<sup>th</sup> ed. Supp. 2001) [hereinafter FOURTH CUMULATIVE SUPPLEMENT] (noting that new guidance has been issued, although still in *non-statutory* form, from the Department of Health (DoH): Research Governance Framework for Health and Social Care, March 2001; Governance Arrangements for NHS Research Ethics Committees, July 2001; Research Governance Implementation Plan, October 2001).

<sup>28</sup> See Anne E. Kornblut, *Blair Backs Bush Effort Against Iraq; Cites New Data; Call For Support is Strongest Yet*, THE BOSTON GLOBE, Sept. 8, 2002, at A.1; Glenn Frankel, *Blair Assails Hussein, Backs Bush on Iraq*, THE WASH. POST, Sept. 4, 2002, at A16.

<sup>29</sup> The U.S. has codified its policy in 32 C.F.R. Part 258, "Cooperation with Allies in Research and Development of Defense Equipment," which states "[t]he United States will cooperate with its Allies to the greatest degree possible in the development of defense equipment, where such cooperation is in the overall best interests of the United States." 32 C.F.R. § 258.3(a) (2002). Regarding U.K. policy, the MoD urges "In absolute terms, the US spends ten times as much as we do in the UK on defence research, whilst Europe as a whole spends four times as much as us. Maintaining close collaboration with these partners, . . . , will be vital . . . . Access to US technology will . . . continue to be of particular importance." MINISTRY OF DEFENCE, THE FUTURE STRATEGIC CONTEXT FOR DEFENCE 29 & 30 (2002), [http://www.mod.uk/issues/strategic\\_context/technological.htm](http://www.mod.uk/issues/strategic_context/technological.htm).

<sup>30</sup> International law is reflected in, for example, The Technical Cooperation Program (TTCP), a collaborative research treaty between the U.S., the U.K., and other nations, which directly implicates the Military Establishments. See DOD Instruction 3100.8 (Sept. 11, 1973) (stating, in paragraph 1.2, "the primary objective of TTCP is to acquaint participating countries . . . with military research and development programs conducted by each country, and to provide a means to carry out cooperative R&D ventures").

<sup>31</sup> Stem cells are those capable of replacing other dead or damaged cells. NRC REPORT, *supra* note 12, at 37. As stated by President Bush, "most scientists, at least today, believe that research on [human] embryonic stem cells

somatic cell nuclear transfer,<sup>32</sup> questions arise as to how the U.S., with its limit of federal funding to only existing stem cell lines<sup>33</sup> and potential for banning any funding of therapeutic cloning,<sup>34</sup> can effectively collaborate with the U.K., which already funds these techniques<sup>35</sup>. Considering the extent of federal funding allotted to military research<sup>36</sup> in light of the

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offer[s] the most promise because these cells have the potential to develop in all of the tissues in the body.” Bush, *supra* note 16.

<sup>32</sup> Also known as “cloning,” the controversy surrounding somatic cell nuclear transfer concerns “cloning-for-biomedical research,” or so-called “therapeutic cloning,” in which human embryos are cloned to provide a source of stem cells, a process that effectively “kills” the cloned embryo itself. *See generally*, CLONING REPORT, *supra* note 17; *see also* Associated Press, *Stem Cell Rules Spark Complaints* (Sept. 26, 2002) available at <http://www.jsonline.com/alive/ap/sep02/ap-stem-cells092602.asp>.

<sup>33</sup> *See* Bush, *supra* note 16.

<sup>34</sup> Senator Sam Brownback, with the support of President Bush, has proposed legislation criminalizing all cloning techniques, including therapeutic cloning. Ellen Sorokin, *Moral Outrage Follows Law Permitting Embryonic Study*, THE WASH. TIMES, Sept. 24, 2002.

<sup>35</sup> *See* CLONING REPORT, *supra* note 17 (stating that in the U.K., “cloning-for-biomedical-research is allowed, but only with cloned embryos no older than fourteen days”); *see also* Associated Press, *supra* note 31, (reporting that some American scientists are moving their research projects to England because “its government encourages stem cell research”).

<sup>36</sup> President Bush’s 2003 Department of Defense budget proposal calls for \$53.9 billion to fund research, development, testing and evaluation programs (RDT&E), with an additional \$9.9 billion proposed for Science and Technology (S&T). ANTHONY H. CORDESMAN, CTR. FOR STRATEGIC & INT’L STUDIES, THE NEW AMERICAN APPROACH TO DEFENSE: THE FY2003 PROGRAM, NOTES ON HOMELAND DEFENSE, COUNTERTERRORISM, ASYMMETRIC WARFARE, AND FORCE TRANSFORMATION 20 (Feb. 6, 2002).

collaboration required by both domestic and international instruments,<sup>37</sup> compliance with the proposed U.S. restrictions becomes, at best, illusory.

Moreover, joint operability of U.S. and U.K. forces presumably requires the use of jointly operable equipment and supplies, including biotech products. Even if these products go through testing and development in the more “liberal” U.K., they would, in practice, be used on both British and American soldiers<sup>38</sup>. Oftentimes, military matters demand the use of any product that could provide even a potential advantage over the adversary, regardless of whether the product has been fully tested.<sup>39</sup> Possible side effects of usage, especially long-term, are of little consequence in the face of a present and pressing enemy.<sup>40</sup>

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<sup>37</sup> See U.S. and U.K. policies, *supra* note 29; see also TTCP treaty, *supra* note 30.

<sup>38</sup> The interoperability of U.S. and U.K. forces is essential to serve the purposes of major international agreements such as North Atlantic Treaty Organisation (NATO)’s Washington Treaty, which sets forth a principle of “collective security.” See DEF. COMM., THE FUTURE OF NATO, SEVENTH REPORT 7 (July 30, 2002),

<http://www.publications.parliament.uk/pa/cm/cmdfence.htm>. Specifically, Article 5 of the Treaty states:

The Parties agree that an armed attack against one or more of them in Europe or North America shall be considered an attack against them all and consequently they agree that, if such an armed attack occurs, each of them . . . will assist the Party or Parties so attacked by taking forthwith, individually and in concert with the other Parties, such action as it deems necessary, including the use of armed force, to restore and maintain the security of the North Atlantic area.

*Id.*

<sup>39</sup> See 21 C.F.R. § 50.23(d)(1) (2002) (“Under 10 U.S.C. 1107(f) the President may waive the prior consent requirement for the administration of an investigational new drug to a member of the armed forces in connection with the member’s participation in a particular military operation.”); see also 10 U.S.C. § 1107(f)(1) (2000) (“In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member’s participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed

Beyond research, development, and use issues surrounding biotechnology in the military are related and equally complex privacy issues invoked by, for example, the collection and storage of DNA samples from individual service members<sup>41</sup>. Although knowledge of each soldiers' genetic make-up may be relevant, if not crucial, to present mission success,<sup>42</sup> that same knowledge could later prove disastrous for the individual service member if revealed outside the military context<sup>43</sup>. Allied collaboration efforts further hamper confidentiality by allowing not only a service member's own country, but potentially many foreign nations, access to the most detailed information, health-related and other, regarding individual service members.

Despite the legal and ethical concerns raised, biotechnology has, and will continue, to offer countless opportunities for enhancing military capabilities. As such, the research,

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under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President.”); DOD Directive 6200.2 (Aug. 1, 2000).

<sup>40</sup> For example, the cyclical use of chemical stimulants and depressants despite both known and suspected side effects has been a documented practice of military pilots throughout history and as recently as the present “war on terrorism.” See Brad Knickerbocker, *Military Looks to Drugs for Battle Readiness*, CHRISTIAN SCI. MONITOR, Aug. 9, 2002, at 1, <http://ebird.dtic.mil/Aug2002/e20020809military.htm>.

<sup>41</sup> See, e.g., *Mayfield v. Dalton*, 901 F. Supp. 300, 302 (D. Haw. 1995) (upholding constitutionality of DoD repository of individual soldiers' DNA collected from cheek swab, as information had limited purpose of identifying soldier remains), *vacated* on other grounds, 109 F.3d 1423, 1424 (9<sup>th</sup> Cir. 1997).

<sup>42</sup> See IATAC REPORT, *supra* note 11, at 73-77 app. B; NRC REPORT, *supra* note 12, at 63 (“Combat effectiveness can be increased by enhancing the performance of individual soldiers. Because genomics information offers clues to improving human performance, it could provide the Army with means of increasing combat effectiveness.”).

<sup>43</sup> See IATAC REPORT, *supra* note 11, at 74-75 (stating “Might dissemination of such information, acquired for legitimate national security purposes be used in civilian life to deny health benefits or employment to those affected service members.”).

development and utilization of biotech products are present realities in the U.S. and abroad, both within and outside of the defense context. However, testing and usage, as well as effective collaboration between Allies, calls for the resolution of complex and pressing issues presented by this intersection of science, technology, and human lives. Resolutions must take into account the history of abuses in military research, existing domestic and international legal and ethical safeguards, and a special respect for those serving to protect their country. In the present global “war on terrorism,”<sup>44</sup> the U.S. and its Allies should heed this caution:

The military enterprise is at once ethical and unethical. Ethical from “our” point of view because the nation is protected from aggressors, defended when attacked, determined to win at all costs. Unethical, especially as seen through the adversary’s eyes, because anything goes. The victimization of noncombatants, misinformation and disinformation, clever feints, deception and other ploys of elaborate trickery, are the stock-in-trade of the “other” side. “We”, of course, resort to the same (and often more) to preserve the power position, strategic balance, operational gain, or tactical advantage. Might makes right, in other words, and hopefully for our team, righter yet. Not only does anything go; *everything* goes. The ‘un-morality’ of war rubs off on, and too often guides, those charged with researching and developing new and more effective weapons systems.<sup>45</sup>

### **Domestic Law and Policy of the United States**

To date, the U.S. government has enacted federal legislation addressing the testing, usage, and privacy concerns presented by biotechnology. However, the extent that these broad protections apply to the Department of Defense (DoD) is debatable. Considerations affecting the actual influence of existing protections in the military context include the deference afforded this Establishment by other departments and agencies, the related judicial deference evidenced in

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<sup>44</sup> THE COALITION INFO. CTRS., THE GLOBAL WAR ON TERRORISM: THE FIRST 100 DAYS 3 (Dec. 2001),

<http://www.whitehouse.gov/news/releases/2001/12/100dayreport.htm>.

<sup>45</sup> Jacques Richardson, *supra* note 23, at 347-48.

both historical, as well as more recent, federal opinions, and the problem of oversight and enforcement of existing regulations by civilians in a non-civilian arena.

Concerning the research and testing of biotech products, both the U.S. Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) have promulgated rules for the protection of human research subjects. The basic DHHS Federal Policy (hereinafter Policy), set forth in 45 C.F.R. Part 46, applies to “all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency.”<sup>46</sup> The actual scope of the Policy is far-reaching in that it expressly states “[f]ederal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.”<sup>47</sup> Further, both the activity of “research”<sup>48</sup> and the covered class of “human subjects”<sup>49</sup> are broadly defined.

Clearly this Policy applies to the Defense Department as it constitutes a federal department<sup>50</sup> and, being a government entity, is dependant upon federal funding<sup>51</sup> for all of its

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<sup>46</sup> 45 C.F.R. § 46.101(a) (2002).

<sup>47</sup> *Id.* at § 46.122.

<sup>48</sup> This Policy defines “research” as “a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” *Id.* at § 46.102(d).

<sup>49</sup> A “human subject” is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. . . .” *Id.* at § 46.102(f).

<sup>50</sup> “Department . . . head means the head of any federal department . . . and any other office or employee of any department . . . to whom authority has been delegated.” *Id.* at § 46.102(a). In the defense context, the Secretary of Defense stands as the department head, but authority in the research context is delegated to numerous other offices and employees. *See* DOD DIRECTIVE 3210.1, ADMINISTRATION AND SUPPORT OF BASIC RESEARCH BY THE DOD 4.2 (Oct. 26, 1961) (Administrative Reissuance Incorporating Change 1, Apr. 3, 1970) (stating “The Director of Defense

activities, including research<sup>52</sup>. Moreover, defense-related research implicates human subject participants in that the individual warfighter is the single most determinative factor of overall mission success<sup>53</sup>. Any doubt as to the Policy's impact on research "conducted, supported, or subject to regulation by [DoD]" is resolved by the explicit adoption of the "Common Rule"<sup>54</sup> at

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Research and Engineering is responsible to the Secretary of Defense for the review and direction of the basic research program of the Military Departments and other Agencies of the Department of Defense authorized to conduct or support basic research, . . .").

<sup>51</sup> See Office of the Under Secretary of Defense (Comptroller), Department of Defense Budget: Fiscal Year 2003 II (Feb. 2002), [http://www.dtic.mil/comptroller/fy2003budget/fy\\_2003r1.pdf](http://www.dtic.mil/comptroller/fy2003budget/fy_2003r1.pdf) (total appropriations for DoD Research, Development, Testing & Evaluation Programs (\$ in thousands): 41,748,375 for FY 2001; 48,504,626 for FY 2002; 53,856,962 for FY 2003).

<sup>52</sup> "Defense research" encompasses:

scientific study and experimentation directed toward increasing knowledge and understanding in those fields of the physical, engineering, environmental, biological-medical, and behavioral-social sciences directly related to explicitly stated long-term national security needs. It provides fundamental knowledge for the solution of identified military problems. It also provides part of the base for subsequent exploratory and advanced developments in defense-related technologies and of new or improved military functional capabilities in areas such as communications, detection, tracking, surveillance, propulsion, mobility, guidance and control, navigation, energy conversion, materials and structures, and personnel support.

DOD DIRECTIVE 3210.1, *supra* note 49, at 3.

<sup>53</sup> See IATAC REPORT, *supra* note 11.

<sup>54</sup> The "Common Rule" denotes the regulation that exactly duplicates DHHS (Federal) Policy and has been adopted by multiple Federal Agencies for the protection of human research subjects. See DOD DIRECTIVE 3216.2, PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DOD-SUPPORTED RESEARCH 4.3.1, E2.1.1 (Mar. 25, 2002). Therefore, in practice, DoD funding of research is limited to those research activities

32 C.F.R. Part 219. Additionally, 10 U.S.C. § 980 limits the use of defense-appropriated research funds to only those experiments in which the subject has given informed consent.<sup>55</sup>

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meeting Policy requirements. *See generally* 45 C.F.R. Part 46 (listing requirements, which include, but are not limited to, the following:

§ 46.109(a) An IRB [Institutional Review Board] shall review and have authority to approve, require modification in (to secure approval), or disapprove all research activities covered by this policy. . . .

§ 46.111(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- (1) Risks to subjects are minimized: . . .
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. . . .
- (3) Selection of subjects is equitable. . . .
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.
- (5) Informed consent will be appropriately documented, . . .
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.).

<sup>55</sup> The statute states:

Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless – (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.

10 U.S.C. § 980(a) (2000).

Department-specific regulation in the form of a DoD Directive implements Part 219, along with § 980, and “establishes other DoD policies for the ethical conduct of research.”<sup>56</sup> This Directive governs research involving human subjects<sup>57</sup> that is either “conducted by a DoD Component” or “supported<sup>58</sup> by a DoD Component . . . through a contract, grant, cooperative agreement, or other arrangement.”<sup>59</sup> Once a research activity meets this scope provision, human subject participants are protected not only through the implementation of federal legislation but also by DoD-specific policy provisions. Safeguards contained in the latter address education and training regarding human subject protections,<sup>60</sup> internal<sup>61</sup> and external<sup>62</sup> oversight mechanisms,

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<sup>56</sup> DOD DIRECTIVE 3216.2, *supra* note 54, at 1.2-1.4.

<sup>57</sup> “Research involving human subjects” means “an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (reference omitted).” *Id.* at E2.1.3. “Intervention or interaction” includes, but is not limited to, “a physical procedure, a drug, a manipulation of the subject or the subject’s environment, the withholding of an intervention that would have been undertaken if not for the research purpose.” *Id.*

<sup>58</sup> “Support” is generally defined as “the provision of funding, personnel, facilities, and all other resources.” *Id.* at E2.1.4.

<sup>59</sup> *Id.* at 2.2.

<sup>60</sup> “Awareness of human subjects protection requirements shall be established for all DoD personnel involved in the conduct, review, or approval of research covered by this Directive.” *Id.* at 4.5. Notably, this provision applies to all DoD personnel engaged in carrying out the research but fails to address the education of subjects, themselves, regarding their own protections.

<sup>61</sup> “All DoD Components shall establish procedures to monitor and review the ethical conduct of research.” *Id.* at 4.8.

<sup>62</sup> Medical monitors:

4.4.3. For research involving more than minimal risk (reference omitted) to subjects, *an independent medical monitor shall be appointed* by name. Medical monitors shall be physicians,

and the potential for influence of superior officers over service members serving as research subjects<sup>63</sup>.

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dentists, psychologists, nurses, or other healthcare providers *capable of overseeing the progress of research protocols*, especially issues of individual subject/patient management and safety. *Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.*

4.4.3.1. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, or data storage and management.

4.4.3.2. At the discretion of the IRB, the medical monitor may be assigned to discuss research progress with the principal investigator, interview subjects, consult on individual cases, or evaluate adverse event reports. *Medical monitors shall promptly report discrepancies or problems to the IRB.* They shall have the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the medical monitor's report.

*Id.* at 4.4.3 - 4.4.3.2 (emphasis added).

<sup>63</sup> Potential for influence:

4.4.4. For research involving more than minimal risk and also involving military personnel, *unit officers and noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not to participate as research subjects.* Unit officers and senior NCOs in the chain of command *shall not be present at the time of research subject solicitation and consent during any research recruitment sessions* in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, *an ombudsman not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual*

Despite these military-specific protections, military-specific “loopholes” exist. Section 980, as implemented through Directive 3216.2, allows for waiver of the consent requirement in a specific research project if such project “advance[s] the development of a medical product necessary to the armed forces,” “may directly benefit the subject,” and complies with all other applicable laws.<sup>64</sup> With regard to the testing of chemical and biological agents, research using human subjects is generally prohibited, yet exceptions exist “for research for prophylactic, protective, or other peaceful purposes.”<sup>65</sup> Further, all protections in the Directive are at least potentially subject to exception “if justified by special circumstances and consistent with law.”<sup>66</sup> These “loopholes” appear particularly relevant to military R&D of biotechnology, as the potential offered by biotech products,<sup>67</sup> combined with recent threats of bioterrorism<sup>68</sup> should readily qualify as “necessary to the armed forces,” “prophylactic” and “protective” against chemical and biological agents, and “justified by special circumstances.”

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*participants is adequately stressed and that the information provided about the research is adequate and accurate.*

*Id.* at 4.4.4 (emphasis added).

<sup>64</sup> 10 U.S.C.A. § 980(b) (Supp. 2002) (providing for waiver by the Secretary of Defense); DOD DIRECTIVE 3216.2, *supra* note 53, at 4.4.2 (providing for waiver by the Head of a DoD Component).

<sup>65</sup> DOD DIRECTIVE 3216.2, *supra* note 53, at 4.4.5.

<sup>66</sup> *Id.* at 5.1.6 (allowing the Director of Defense Research and Engineering to grant exceptions to policy under this Directive).

<sup>67</sup> *See supra* note 20.

<sup>68</sup> *See* Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002, S. 3148, 107<sup>th</sup> Cong. § 2 (Oct. 17, 2002) (stating “The threat of biological and chemical weapons is real,” and citing related evidentiary support).

However, classifying a biotech intervention as some form of *use*, rather than *research*, achieves perhaps the most significant military “loophole” yet. Notably, none of the protections from Directive 3216.2 apply to activities that are not “research.” The Directive expressly states that neither “the use of investigational new drugs, biological products, or devices for purposes of Force Health Protection”<sup>69</sup> or “accepted medical practice, including the use of investigational products in such practice, undertaken for purposes of treatment”<sup>70</sup> constitutes “research.”

Instead, regulation of these investigational products, including new drugs and devices, falls under the Federal Food, Drug, and Cosmetic Act (“FDC Act”)<sup>71</sup>. Especially relevant to the emerging biotechnology industry is section 505, “New drugs,” which states, “No person shall

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<sup>69</sup> DOD DIRECTIVE 3216.2, *supra* note 53, at 2.2 (stating “Such use is not research and is governed by DoD Directive 6200.2”).

<sup>70</sup> *Id.* at 2.3.

<sup>71</sup> 21 U.S.C. §§ 301 *et seq.* (2000). *See generally* Leonard H. Glantz, *The Influence of the Nuremberg Code on U.S. Statutes and Regulations*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 183, 186 (George J. Annas & Michael A. Grodin, eds., 1992 ) (noting history of Food and Drug Administration (FDA) as follows:

The FDA’s entry into the regulation of research came as a result of the Drug Amendments Act of 1962. The primary purpose of the law was to keep unsafe or useless drugs off the market by requiring proof of safety and efficacy from the drug companies. . . . the final version of the 1962 law contained a provision that required ‘experts using such drugs for investigational purposes’ to inform persons to whom they are to be administered that they are being given drugs for investigational purposes and to obtain the consent of these individuals or their representatives, except ‘where they deem it not feasible or, in their professional judgment, contrary to the best interest of such human beings.’ [Footnote omitted.] It was not until 1966 that the FDA promulgated patient consent regulations, at least partially in recognition of the widespread failure of the industry to obtain patient consent.)

introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.”<sup>72, 73</sup> Exempt from the application and

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<sup>72</sup> 21 U.S.C. § 355(a) (2000).

<sup>73</sup> Terminology:

“Drug” is defined as

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in (A), (B), or (C). . . .

*Id.* at § 321(g)(1).

“New drug” is defined as

- (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . . ; or
- (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

*Id.* at § 321(p).

approval process are so-called “investigational new drugs,”<sup>74</sup> although their use does require the prior informed consent of any human subject<sup>75</sup>. Even the latter is circumvented “where it [consent] is not feasible or it is contrary to the best interest of such human beings.”<sup>76, 77</sup>

The Defense Department, first through administrative,<sup>78</sup> and subsequently through legislative<sup>79</sup> and executive<sup>80</sup> action, obtained its own exception to the consent requirement, which has been upheld against Constitutional challenge<sup>81</sup>. Coverage encompasses drugs, including

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<sup>74</sup> See FDC Act § 505(i), 21 U.S.C. § 355(i) (2000) (exempting, in paragraph (1), “drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs”).

<sup>75</sup> The prior consent requirement states:

[E]xemption [of investigational new drugs] shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, . . . .

FDC Act § 505(i)(4), 21 U.S.C. § 355(i)(4) (2000); *see also* 21 C.F.R. § 50.20 (2002).

<sup>76</sup> 21 U.S.C. § 355(i)(4).

<sup>77</sup> Non-feasibility is limited to a narrow set of circumstances involving life-threatening situations in which subjects are unable to consent and time is limited. *See* 21 C.F.R. § 50.23(a)-(c) (2002).

<sup>78</sup> *See* 21 C.F.R. § 50.23(d) (2002). The original interim rule amending § 50.23 by adding a new paragraph (d) went into effect Dec. 21, 1990. *See* 55 Fed. Reg. 52, 814, 52, 817 (1990) (subsequently codified at 21 C.F.R. § 50.23).

<sup>79</sup> *See* 10 U.S.C. § 1107(f) (2000).

<sup>80</sup> *See* Exec. Order No. 13,139, 64 Fed. Reg. 54,175 (1999).

<sup>81</sup> *See* *Doe v. Sullivan*, 938 F.2d 1370, 1381-83 (D.C. Cir. 1991) (holding (1) the FDA’s promulgation of Rule 23(d), allowing military use of investigational drugs for unapproved purposes and without service members’ consent, was

antibiotics, and biological products,<sup>82, 83</sup> and contemplates not only drugs or products lacking approval or licensing, respectively, but also unapproved uses of an otherwise approved drug or licensed product<sup>84</sup>.

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within the authority granted to the agency by Congress; (2) use of investigational drugs under Rule 23(d) did not violate the informed consent provision from the 1985 Defense Authorization Act; and (3) application of Rule 23(d) under the particular circumstances, i.e., administration of preventative drugs to “combat-ready personnel” serving in Operation Desert Storm, presented no violation of the Fifth Amendment’s Due Process Clause).

<sup>82</sup> Terminology:

“Drug,” as defined in note 69. *See* 21 U.S.C. § 321(g)(1) (2000).

“Antibiotic drug” means “any drug ... composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, choramphenicol, bacitracin, or any other drug intended for human use containing any quantity of micro-organisms in dilute solution ... or any derivative thereof. *Id.* at § 321(jj).

“Biological product” means “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or [derivative thereof] ... , applicable to the prevention, treatment , or cure of a disease or condition of human beings. 42 U.S. C. § 262(i) (West, WESTLAW through P.L. 107-245 2002). This definition also applies to the FDC Act’s regulation of biological products. *See id.* at § 262(j).

<sup>83</sup> *See* 21 C.F.R. § 50.23(d)(1) (2002) (describing process for Presidential waiver of prior consent requirement for the use of investigational new drugs in the military and referencing investigational drug as “including an antibiotic or biological product”); *see also* DOD DIRECTIVE 6200.2, USE OF INVESTIGATIONAL NEW DRUGS FOR FORCE HEALTH PROTECTION 3.2 (Aug. 1, 2000) (including in definition of “investigational new drug” both “a drug or biological product”). However, the Title 10 version of this policy refers only to an “investigational new drug or drug unapproved for its applied use,” with each respective definition covering only the term “drug” as used in section 505 of the FDC Act, 21 U.S.C. § 355 (2000). *See generally* 10 U.S.C. § 1107 (2000).

<sup>84</sup> *See* 10 U.S.C. § 1107(f) (describing process for requesting and obtaining Presidential waiver of prior consent requirement for “administration of an investigational new drug or a drug unapproved for its applied use”); *see also* DOD DIRECTIVE 6200.2, *supra* note 81, at 3.2, 3.2.1-3.2.2 (setting forth policy for the use of investigational new

As codified in § 1107 of Title 10, “Armed Forces,” the exception states:

The Secretary of Defense may request the President to waive the prior consent requirement with respect to the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member’s participation in a particular military operation.<sup>85</sup>

The President may grant the Secretary’s request only if the President makes a written determination “that obtaining consent -- (A) is not feasible; (B) is contrary to the best interests of

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drugs, which are defined to include “a drug not approved or a biological product not licensed by the FDA” and “a drug unapproved for its applied use”). The latter is further defined as “a drug or biological product administered for a use not described in the labeling of the drug or biological product approved by the FDA . . . , and for which FDA requirements of use authorization and prior informed consent . . . are applicable . . .” *Id.* at 3.3.

<sup>85</sup> 10 U.S.C. § 1107(f)(3) (2000); *see also* Exec. Order No. 13,139 at Sec. 3(d), 21 C.F.R. § 50.23(d)(1); *see also* DOD DIRECTIVE 6200.2, *supra* note 82, at 4.1, 4.1.1-1.3 (setting forth DoD policy to implement the aforementioned references:

Personnel carrying out military operations shall be provided the best possible force health protection, including safe and effective medical countermeasures to chemical, biological or radiological warfare and endemic disease. DoD Components shall make preferential use of products approved by the FDA . . . . When no FDA-approved product is available to meet a foreseeable threat, the Secretary of the Army, . . . , shall carry out appropriate research and development program activities . . . . When, at the time of the need for a force health protection countermeasure against a particular threat, no safe and effective FDA-approved drug or biological product is available, DoD Components may request approval of the Secretary of Defense to use an IND [investigational new drug]. Such requests must be justified based on the available evidence of the safety and efficacy of the drug against the nature and degree of the threat to personnel.)

“Force health protection” is defined as “An organized program of healthcare preventative or therapeutic treatment, or preparations for such treatment, designed to meet the actual, anticipated, or potential needs of a group of military personnel in relation to military missions.” *Id.* at 3.1.

the [service] member; or (C) is not in the interests of national security.”<sup>86</sup> With respect to (A) and (B), the President must apply relevant FDA regulations in order to grant the waiver upon either ground.<sup>87</sup> The statute lacks any guidance as to a determination based on the final ground, “in the interests of national security.”

Also absent is any guidance from the courts, with the only legal challenge to a military-based consent waiver being ruled upon prior to enactment of § 1107. In *Doe v. Sullivan*, the U.S. Court of Appeals for the District of Columbia upheld the FDA’s promulgation of “Rule 23(d),” an interim regulation allowing the administration of investigational drugs to service members without their consent.<sup>88</sup> As promulgated in 1990, the FDA, recognizing both the importance of informed consent but also the non-feasibility of obtaining it in the combat context, limited DoD requests under Rule 23(d) to “a specific military operation involving combat or the immediate threat of combat.”<sup>89</sup> The *Doe* court emphasized, throughout its opinion, the “combat”-based justification for forced use of investigational drugs.<sup>90</sup> Based on the specific facts of the case,<sup>91</sup>

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<sup>86</sup> 10 U.S.C. § 1107(f)(1) (2000); *see also* Exec. Order No. 13,139 at Sec. 3(b), 21 C.F.R. § 50.23(d)(1).

<sup>87</sup> “In making a determination to waive the prior consent requirement on a ground described in subparagraph (A) or (B) . . . , the President shall apply the standards and criteria that are set forth in the relevant FDA regulations for a waiver of the prior consent requirement on that ground.” 10 U.S.C. §1107(f)(2) (2000). Section 50.23, “Exception from general requirements,” contains relevant regulations. *See* 21 C.F.R. § 50.23(a)-(c) (2002).

<sup>88</sup> *Doe*, 938 F.2d at 1381-83.

<sup>89</sup> The original interim rule amending § 50.23 by adding a new paragraph (d) went into effect Dec. 21, 1990. *See* 55 Fed. Reg. 52, 814, 52, 817 (1990) (subsequently codified at 21 C.F.R. § 50.23).

<sup>90</sup> 938 F.2d at 1373-74, 1381-83.

<sup>91</sup> According to DoD, administration of the two unapproved drugs was necessary, as a preventative measure, to counter the potential use of biological weapons by the Iraqis. *Id.* at 1372, n.1. Further, conducting controlled

the court found that application of Rule 23(d) did not violate service members' Fifth Amendment rights under the Due Process Clause.<sup>92</sup>

Significantly, the current legislation governing military use of investigational drugs without consent,<sup>93</sup> as well as its corresponding FDA regulation,<sup>94</sup> fails to address, at least through explicit language, the "combat" concept.<sup>95</sup> As enacted in Title 10 and referenced in the current Code of Federal Regulations,<sup>96</sup> § 1107(f) eliminates the "combat" language found in original Rule 23(d) and replaces it with "in connection with the member's participation in a particular military operation"<sup>97</sup>. No statutory guidance exists as to what constitutes a "military operation," but at least common usage of the phrase denotes much more than activities involving combat or the immediate threat of combat.<sup>98</sup> In any event, questions arise as to whether the statutory

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clinical trials on humans [in order to obtain FDA approval] was not possible because intentional exposure to chemical or biological weapons for testing purposes is impermissible. *Id.*

<sup>92</sup> *Id.* at 1383.

<sup>93</sup> *See* 10 U.S.C. § 1107(f) (2000).

<sup>94</sup> *See* 21 C.F.R. § 50.23(d) (2002).

<sup>95</sup> Also of note are the following changes from *Doe's* version of Rule 23(d) to the current version, as based on 10 U.S.C. § 1107(f): the original Rule 23(d) provided that the Assistant Secretary of Defense (Health Affairs), as opposed to the Secretary of Defense, requested the waiver, which was made to the Commissioner of Food and Drugs, as opposed to the President.

<sup>96</sup> *Id.*

<sup>97</sup> *See* 10 U.S.C. § 1107(f)(1), (3) (2000).

<sup>98</sup> Department-specific regulation defines "particular military operation" as that "which involves any chemical, biological, or radiological warfare or endemic disease threats." DOD DIRECTIVE, *supra* note 81, at 3.4. However, federal legislation fails to offer any such definition, despite having a "definitions" subsection. *See* 10 U.S.C. § 1107(g) (2000).

language ultimately enacted is much broader than what the court contemplated and would actually infringe on Fifth Amendment Due Process guarantees.<sup>99</sup> Also absent from the original version of Rule 23(d), and, therefore, not considered by the *Doe* court, was the third ground now encompassed by § 1107 allowing waiver if obtaining consent “is not in the interests of national security.”<sup>100</sup> As mentioned, statutory guidance is lacking and regulatory requirements do not apply with regard to a waiver based on this ground.<sup>101</sup>

Issues concerning military use of investigational drugs without service members’ consent are especially relevant to biotechnology. Despite the apparently limited grounds for waiver set forth in § 1107, as well as extensive procedures required to implement at least the first two grounds, waiver based on “the interests of national security” presents a formidable “loophole.”

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<sup>99</sup> What the *Doe* court contemplated becomes especially relevant considering that current Supreme Court Justice Ginsburg wrote the majority opinion, with the dissent written by current Justice Thomas!

<sup>100</sup> See 10 U.S.C. § 1107(f)(1)(C) (2000).

<sup>101</sup> However, Department-specific regulation appears to address this ground, stating:

If the request [for waiver of consent] is based on . . . [grounds of non-feasibility or being contrary to members’ best interests] the documentation will include a statement that certifies and a written justification that documents that each of the criteria and standards set forth in 21 C.F.R. 50.23(d) (reference omitted) . . . have been met. If the Secretary finds it highly impracticable to certify that all such criteria and standards have been fully met because doing so would significantly impair the Department of Defense’s ability to carry out the particular military mission, the Secretary will provide to the President a written justification that documents which criteria and standards have or have not been met, explains the reasons for not meeting those which have not been met, and provides additional justification why a waiver should be granted solely on . . . [grounds of national security interests].

DOD DIRECTIVE 6200.2, *supra* note 81, at 4.6.2.

Moreover, the use of “particular military operation” instead of “combat or immediate threat of combat” expands the range of waiver situations even further. As is true with the military-specific research exceptions, the potential offered by biotech products to counteract current and pressing threats of biological warfare<sup>102</sup> substantially increases the likelihood that such “loopholes” will be exploited.

Further, Supreme Court precedent strictly limits remedies for harm to service members arising from testing or investigational use of products. Under the *Feres* doctrine, “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.”<sup>103</sup> However, in *Bivens*,<sup>104</sup> the Court recognized Constitutionally-based claims for damages brought against federal officials

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<sup>102</sup> See IATAC REPORT, *supra* note 11, at 26 (“Effective prophylactic vaccines are currently lacking for not only biological warfare agents, but also many naturally occurring endemic diseases. Novel solutions based on advanced biotechnology could provide protection from these threats for both civilian homeland security and for warfighters.”); NRC REPORT, *supra* note 12, at 65-67 (discussing the Army’s need to monitor commercial biotechnological developments for transfer over into biological and chemical weapons countermeasures). Further, recent federal legislation providing unprecedented incentives to biotech companies demonstrates the need for biotechnology R&D to combat bioterrorist threats. See Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002, S. 3148, 107<sup>th</sup> Cong. §§ 2(2)(A-E), 2(3)(A-L), 201-04, 211, 216 (2002) (finding that the threat posed by biological, chemical and radiological weapons is real and citing a multiplicity of evidentiary support; making provisions for: federal tax incentives; a terror weapon countermeasure purchase fund; patent and marketing protections; liability protections, including indemnification from “claims or civil actions arising from human clinical trials and research, development, and production of countermeasures;” accelerated procedures for approval of countermeasures; . . . ; construction of research facilities; . . . ).

<sup>103</sup> *Feres v. United States*, 340 U.S. 135, 146 (1950).

<sup>104</sup> *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388, 396 (1971).

acting in such capacity, but cautioned that either “‘special factors counseling hesitation’ or an ‘explicit congressional declaration that another remedy is exclusive would bar such an action.’”<sup>105</sup>

Applying this precaution to the military context, the Court held in *Chappell* that “taken together, the unique disciplinary structure of the Military Establishment and Congress’ activity in the field constitute ‘special factors’ which dictate that it would be inappropriate to provide enlisted military personnel a *Bivens*-type remedy against their superior officers.”<sup>106</sup> The Court extended this concept in *Stanley*, albeit in a 5-4 decision, holding “no *Bivens* remedy is available for injuries that ‘arise out of or are in the course of activity incident to service.’”<sup>107</sup> Under this established precedent, the involvement of service members in military-based R&D of biotech products, as well as the use of investigational biotech drugs and products for force health protection,<sup>108</sup> surely qualifies as “activity incident to service.” Accordingly, service members have no cause of action for injuries “arising out of or in the course of such service.”

Despite the extent of these statutorily- and judicially-created military exceptions, a January 2002 report issued at the behest of DoD calls for the creation and implementation of regulations specific to biotechnology testing and use in the military<sup>109</sup>. The authors state,

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<sup>105</sup> *United States v. Stanley*, 438 U.S. 669, 678 (1987) (referring to the Court’s subsequent decisions in *Davis v. Passman*, 442 U.S. 228, 246-47 (1979) and *Carlson v. Green*, 446 U.S. 14, 18-19 (1980)).

<sup>106</sup> *Chappell v. Wallace*, 462 U.S. 296, 304 (1983).

<sup>107</sup> 483 U.S. at 684 (quoting *Feres*, 340 U.S. at 146).

<sup>108</sup> DoD DIRECTIVE 6200.2, *supra* note 81.

<sup>109</sup> IATAC REPORT, *supra* note 11, at 21-23.

“[although] [c]urrent law does not prohibit the biotechnology applications listed in this study,<sup>110</sup> . . . there is no clear policy or guidance as to the use of these new and unique technologies, nor has the law begun to address these issues.”<sup>111</sup> They suggest the creation of an Institutional Review Board (IRB) analogous to the IRB implemented in the Human Genome Project conducted by the National Institutes of Health (NIH) and the Department of Energy (DoE).<sup>112</sup> Further, the authors urge the creation of accelerated procedures for FDA approval based on military exigency,<sup>113</sup> as well as a specific procedure for waiver of informed consent regarding the use of biotech products in the field, as based on 21 C.F.R. Parts 50, 312<sup>114</sup>.

Realization of biotech-specific protections has already begun to develop in the private sector. In October, Congress enacted the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.<sup>115</sup> The Act gives incentives for the research and development of biotech products as countermeasures to biological warfare.<sup>116</sup> Most notably, the Act provides liability protection to biotech companies engaged in countermeasures research.<sup>117</sup>

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<sup>110</sup> *Id.* at 21 (exemplars contemplated include, but are not limited to: advanced vaccines and immune enhancements, accelerated wound healing, stasis for warfighter casualties, 24x7 operations, enhanced environmental endurance and cognition).

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 21, 82.

<sup>113</sup> *Id.* at 22, 82.

<sup>114</sup> *Id.*

<sup>115</sup> Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002, S. 3148, 107<sup>th</sup> Cong. § 1(a) (2002).

<sup>116</sup> *Id.* at §§ 201-04, 211-21.

<sup>117</sup> *Id.* at § 204.

Companies are indemnified from claims for damages brought by human subject participants.<sup>118</sup> Further, the Act provides for accelerated FDA approval procedures for biotech products.<sup>119</sup> Although specifically applicable to the private sector, such protections carry over to the military sector considering the direct applicability of countermeasures to military functions.

### **Domestic Law and Policy of the United Kingdom**

In terms of its government structure, the United Kingdom<sup>120</sup> has a constitutional monarchy, with the monarch serving as the official chief of state and an elected Prime Minister fulfilling the actual head of government position.<sup>121, 122</sup> As compared to the U.S., the U.K. varies considerably in that its constitution remains unwritten, consisting of “legislative sources, common law and constitutional conventions and custom.”<sup>123</sup> However, analogous to the U.S., the U.K. has a bicameral legislative branch, Parliament, which contains the House of Lords and the House of Commons.<sup>124</sup> Also similar to the U.S. is the multi-tiered approach of the U.K. judicial system, which separates criminal from civil matters and provides for appellate review.<sup>125</sup>

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<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at § 211.

<sup>120</sup> The term “United Kingdom” as used in this paper refers to England. *See generally* Price, *United Kingdom*, *supra* note 24, at ¶¶ 6, 8.

<sup>121</sup> *See id.* at ¶¶ 3-4.

<sup>122</sup> At present, Queen Elizabeth is the British monarch and chief of state, with Anthony C. L. (Tony) Blair serving as Prime Minister.

<sup>123</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 3.

<sup>124</sup> *Id.* at ¶ 5. However, distinct from the election of members to both houses of the U.S. legislature, in the U.K., only one house, the House of Commons, consists of elected officials. *Id.*

<sup>125</sup> *Id.* at ¶ 7 (describing the structure as follows:

As opposed to the U.S., the U.K. system of health care is administered through a National Health Service (NHS), although, in practice, the trend is towards privatization of health care providers.<sup>126</sup> Separate from NHS, but still instrumental in its operation, is the Department of Health (DoH).<sup>127</sup> Further, an executive agency of DoH, the Medicines Control Agency (MCA), serves as the licensing authority for all medicinal products within the U.K.<sup>128</sup>

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The court system . . . is headed by the House of Lords and just below it, the Court of Appeal . . . , . . . the latter divides into a separate Criminal and Civil Division. . . . [C]ivil matters are dealt with at first instance by either the High Court ( . . . three divisions; the Queen’s Bench, Chancery and Family divisions) or the County Court. Criminal matters come first to either the Magistrates Court or the Crown Court.)

<sup>126</sup> See *id.* at ¶¶ 23-28. The National Health Service (NHS), implemented through passage of the National Health Service Act 1946, created in the U.K. a comprehensive system of health care free at the point of delivery. *Id.* After several legislative changes affecting its structure, NHS administration was dramatically simplified in 1996 through the Health Authorities Act 1995. *Id.* In terms of function, passage of the National Health Service and Community Care Act 1990 gave hospitals the right to opt out of Health Authority (HA) control and become, themselves, NHS Trusts. *Id.* Health Authorities then progressively converted from providers of health care to purchasers of these services from others, primarily hospitals/NHS Trusts. *Id.* Today’s trend cuts out even the HA step, with NHS Trusts holding an estimated ¾ of the NHS budget and using these funds for the direct purchase of health care services from private providers. *Id.* The emergence of joint service-provision ventures is breaking down the industry’s historical public/private-sector barrier. *Id.* Recent legislation in the form of the Health and Social Care Act 2001 has begun to implement the government’s “new NHS plan,” a 10-year course of action backed by significant funding increases and designed to modernize the system through investment and reform. See *id.*; Tony Blair, *Foreword to THE NHS PLAN* (Apr. 1, 2002), <http://www.doh.gov.uk/nhsplan/foreword.htm>.

<sup>127</sup> See, e.g., KENNEDY & GRUBB, *supra* note 27, at ¶ 1.03 (stating that the DoH supports the Secretary of State in carrying out Secretarial responsibilities set forth in the NHS Act 1977); Blair, *supra* note 126 (“The Department of Health is playing a key role in implementing the Government’s new NHS plan.”); Dep’t of Health, *About the Department* (Apr. 1, 2002), <http://www.doh.gov.uk/about/index.html> (“We [DoH] have more than 5000 staff who

The National Health Service Act 1977, as amended,<sup>129</sup> is the primary piece of legislation regulating the U.K. system of health care today.<sup>130</sup> The Act effectively designates the Secretary of State as head of NHS and provides for the delegation of Secretarial duties as appropriate.<sup>131</sup> Two additional bodies, the DoH and NHS Executive (NHSE), further support the Secretary in administering duties under the Act, with “strategic and managerial responsibility within NHS”

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are responsible for driving forward change and modernization in the NHS and social care, as well as improving standards of public health.”).

<sup>128</sup> Dep’t of Health, *supra* note 127, at *Executive Agencies*, <http://www.doh.gov.uk/about/agencies.htm>.

<sup>129</sup> National Health Service Act, 1977, c. 49 (Eng.).

<sup>130</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 36 (“Part I of the Act addresses secondary medical care in hospitals, as well as community health services . . . . Part II governs primary care . . . , [covering] general medical, dental, ophthalmic and pharmaceutical services.”); *see also id.* (relevant subsequent legislation includes the NHS (Primary Care) Act 1997 and the Health and Social Care Act 2001); KENNEDY & GRUBB, *supra* note 27, at ¶ 1.03 (noting that the NHS is organized in accordance with the NHS Act 1977, NHS and Community Care Act 1990, and NHS (Primary Care) Act 1997).

<sup>131</sup> *See* KENNEDY & GRUBB, *supra* note 27, at ¶ 1.03 (stating “[T]he Secretary of State is given wide enabling powers to fulfill his or her statutory obligations, supported by a team of ministerial colleagues to whom specific responsibilities may be delegated.”).

falling on the latter.<sup>132</sup> Statements of policy issued by both bodies serve as the main vehicle for internal system regulation.<sup>133</sup>

Separate from the provision of health care services under NHS is the regulation of medicinal products both domestically and throughout the European Community (EC).<sup>134</sup> Initially, the Medicines Act 1968 provided the U.K. with “a comprehensive system of licensing affecting manufacture, sale, supply and importation of medicinal products.”<sup>135</sup> After formally joining the EC in 1973, the Act was amended and additional legislation was enacted to bring

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<sup>132</sup> Specifically, DoH supports the Secretary of State in carrying out responsibilities [i.e., making policy and priority decisions, as well as allocating resources for the achievement of chosen objectives] by advising on policy development, proposing legislation, liaising with other government departments, etc. KENNEDY & GRUBB, *supra* note 27, at ¶ 1.03. The main function of NHSE is to ensure the appropriate, effective and efficient use of allocated resources, but, at times, may also serve to advise on policy matters. *Id.* at ¶ 1.04.

<sup>133</sup> *Id.* at ¶ 1.68 (“Internal regulation of the health service is most commonly achieved by means of health service circulars [aka Executive Letters], health service guidelines, and various other statements of policy from the NHSE and the [DoH].”).

<sup>134</sup> See generally Medicines Control Agency, *About the Agency: Regulatory framework, Current legal framework* (last updated Aug. 2, 2002), <http://www.mca.gov.uk/aboutagency/regframework/regframework.htm> (describing current system as follows:

The control of medicines in the UK is primarily through the system of licensing and conditional exemptions from licensing laid down in EC [European Community] legislation, the Medicines Act 1968 and in relevant subordinate legislation. This legislation covers *inter alia* the systems by which licences to manufacture, market, distribute, sell and supply medicinal products are granted by Ministers (“the Licensing Authority”) (or, in the new centralized system, by the relevant Community institutions), once they are satisfied about the safety, efficacy, and quality of the product.).

<sup>135</sup> *Id.* at *The Medicines Act*.

U.K. domestic law into conformity with European law.<sup>136</sup> Although the MCA continues to administer the domestic system as established by the original Act, the preferred method of licensing is now through the centralized system administered by the European Medicines Evaluation Agency (EMA).<sup>137</sup> Most notably, *biotechnology* products are always licensed through this European-wide centralized system.<sup>138</sup>

Despite the statutory framework governing both the provision of health care services, as well as the licensing of products used for such services, domestic legislation covering product R&D remains deficient. Although complex statutory schemes cover testing on animals and human gametes or embryos,<sup>139</sup> the U.K. has failed to enact any direct legislation concerning R&D involving actual human subjects.<sup>140</sup> Most significantly, no formal statutory requirement exists for the approval of research proposals by a research ethics committee (REC).<sup>141</sup> Further,

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<sup>136</sup> *Id.* at *European legislation*.

<sup>137</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 92 (stating that licensing through the European-wide centralized system is preferred because approval is then valid in all EC Member States).

<sup>138</sup> *Id.* at n.4.

<sup>139</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 697 (Supp. 28) (“[O]nly research involving human gametes or embryos, and animals, is directly regulated by statute; by the Human Fertilisation and Embryology Act 1990 (cross-reference omitted) and the Animals (Scientific Procedures) Act 1986 respectively.”).

<sup>140</sup> See KENNEDY & GRUBB, *supra* note 27, at ¶ 13.65 (noting that the U.K. currently lacks an overarching statutory framework governing the conduct of biomedical research on humans); see also FOURTH CUMULATIVE SUPPLEMENT, *supra* note 27, at ¶¶ 13.66-13.74 (Sept. 2001) (updating main text and noting the promulgation of a new standards framework for human research; however, still no indication of actual statutory regulations).

<sup>141</sup> KENNEDY & GRUBB, *supra* note 27, at ¶ 13.69 (“[T]here is no formal law regulating research . . . [which] means, among other things, that, as a matter of law, there is no requirement that a research proposal even be submitted to, let alone approved by, an REC.”)

healthy volunteer subjects participating in clinical trials fall outside the regulatory protections embodied in the domestic licensing scheme.<sup>142</sup> Fortunately, these deficiencies are eliminated in the European Union (EU) Clinical Trials Directive,<sup>143</sup> which the U.K., as a Member State, must incorporate into its own law on or before May 1, 2004.<sup>144</sup>

However, until such legislation is enacted, primary authorities having potential implications in human subject research consist of international<sup>145</sup> and European human rights instruments,<sup>146</sup> corresponding U.K. legislation implementing such instruments, the medicine

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<sup>142</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 727 (Supp. 28) (“Phase I trials, the first involving humans, are designed to determine the safe tolerable dose of the drug and are carried out on human volunteers as opposed to patients, as a consequence of which they are outside the regulatory scheme under the Medicines Act 1968 (cross-reference omitted).”)

<sup>143</sup> Council Directive 2001/20/EC, 2001 O.J. (L 121) 34.

<sup>144</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 699 (Supp. 28) (also noting that under this Directive, “a comprehensive legislative framework for medical research will be established in the UK in the near future”).

<sup>145</sup> International human rights instruments specifically covering medical ethics include: The Nuremberg Code, The Declaration of Helsinki, and The Council for International Organizations of Medical Sciences [CIOMS] “International Ethical Guidelines for Biomedical Research Involving Human Subjects.” No such instrument has legal force within a particular country until incorporated into its domestic law. *See, e.g.*, LAMMY BETTEN, THE HUMAN RIGHTS ACT 1998: WHAT IT MEANS 2 (1999) (describing this requirement in the UK:

In Britain, international agreements are concluded by the Crown under the Royal Prerogative, and, therefore they must not change the substance of the common law or statute. Consequently, treaties and Conventions need to be transformed into domestic law by an Act of Parliament in order to give effect to them within our national legal system.)

<sup>146</sup> European human rights instruments include the European Convention on Human Rights, which the U.K. has incorporated by way of the Human Rights Act 1998, and the Council of Europe Convention on Human Rights and Biomedicine, which opened for signature in 1997 but the U.K. has yet to sign, Price, *United Kingdom*, *supra* note

licensing scheme, and the common law. In the human rights arena, the European Convention on Human Rights,<sup>147</sup> as incorporated into U.K. law through the Human Rights Act 1998,<sup>148</sup> may provide implied protection to all research subjects. The Act prohibits any public authority, meaning a person whose function is of a public nature,<sup>149</sup> from acting in ways incompatible with Convention rights.<sup>150</sup> Considering the public nature of, at least, government entities such as NHS institutions, agencies, and RECs, research activity conducted or sponsored by these entities

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24, at ¶¶ 103, 105, 122; *see also* Council of Europe Treaty Office, *Convention for the Protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine, ETS no.: 164, Chart of signatures and ratifications* (status as of 14/11/02), <http://conventions.coe.int/Treaty/EN/WhatYouWant.asp?>.

<sup>147</sup> Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, 213 U.N.T.S. 221, E.T.S. 5.

<sup>148</sup> “An Act to give further effect to rights and freedoms guaranteed under the European Convention on Human Rights.” Human Rights Act, 1998, ch. 42 (Eng.). “In this Act ‘the Convention rights’ means the rights and fundamental freedoms set out in – Articles 2 to 12 and 14 of the Convention, Articles 1 to 3 of the First Protocol, and Articles 1 and 2 of the Sixth Protocol, as read with Articles 16 to 18 of the Convention.” *Id.* at § 1(1)(a-c). Convention rights include: Article 2 Right to Life; Article 3 Prohibition of Torture; Article 4 Prohibition of Slavery and Forced Labour; Article 5 Right to Liberty and Security; Article 6 Right to a Fair Trial; Article 7 No Punishment Without Law; Article 8 Right to Respect for Private and Family Life; Article 9 Freedom of Thought, Conscience and Religion; Article 10 Freedom of Expression; Article 11 Freedom of Assembly and Association; Article 12 Right to Marry; Article 14 Prohibition of Discrimination; Article 16 Restrictions on Political Activity of Aliens; Article 18 Limitation on Use of Restrictions on Rights. *Id.* at sched. 1, pt. I. First Protocol rights include: Article 1 Protection of Property; Article 2 Right to Education; Article 3 Right to Free Elections; *id.* at pt. II, and Sixth Protocol rights include: Article 1 Abolition of the Death Penalty; Article 2 Death Penalty in Time of War, *id.* at pt. III.

<sup>149</sup> *Id.* at § 6(3)(b).

<sup>150</sup> *Id.* at § 6(1).

should fall under the Act's proscriptions,<sup>151</sup> but duties owed to research subjects come only by implication.<sup>152</sup> On the other hand, the U.K. licensing scheme covers all entities, public and private, and provides specific protections in clinical trials, but only to "patient" subjects, as opposed to healthy volunteers.

Where questions arise as to legislative coverage of human subject research, common law concepts related to the torts of battery and negligence, combined with the doctrine of consent, provide answers. Analogous to the present status of U.K. statutory law, no case law directly addresses the protection of human research subjects. However, as is true with general principles of medical law, legally effective consent, and, specifically, consent to be touched, is necessary to counter a claim of battery. To qualify as "legally effective," issues of who may give consent, and the validity and limits of consent obtained must be satisfied. Reaching the latter two issues is the requirement that consent be sufficiently informed, with failure to provide adequate information potentially sounding in negligence.

Beyond these primary sources, government bodies, namely the NHSE and DoH, have promulgated protections in the form of directives and guidelines.<sup>153</sup> Both technically regulate

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<sup>151</sup> See Price, *United Kingdom*, *supra* note 24, at ¶106.

<sup>152</sup> Neither the Act nor the Convention rights incorporated, *see supra* note 148, explicitly mention humans serving as research subjects.

<sup>153</sup> KENNEDY & GRUBB, *supra* note 27, at ¶¶ 13.66-13.69 (stating:

[T]he Department of Health, having taken advice, issued Guidelines in 1991 through the NHS Management Executive (HSG 91(5)). Perhaps the principal factor which persuaded government to act, albeit in a *non-statutory* manner, was a concern at the lack of legal protection available to research subject. The Guidelines which emerged, . . . . . are the closest the United Kingdom government has come to regulating the conduct of research on human subjects. . . . The Guidelines lay certain duties on various bodies within the NHS . . . . Principal among these duties is the

only NHS bodies, but, in practice, affect all research activities in the U.K.<sup>154</sup> The most significant protection afforded through this mechanism calls for the creation of a REC to review all research proposals involving, in any way, the NHS.<sup>155</sup> Detailed guidelines govern the composition and operation of these RECs.<sup>156</sup> Moreover, their decisions are subject to judicial review, although

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creation of a local REC . . . . The Guidelines only apply, of course, to activities undertaken within the ambit of the NHS. . . . In practice, however, this limitation may be more apparent than real. Nonetheless, whatever the situation may be in practice, it remains odd, and some would say unfortunate, that there is no formal law regulating research. It means, among other things, that, as a matter of law, there is no requirement that a research proposal even be submitted to, let alone approved by, an REC.)

<sup>154</sup> *Id.* at ¶ 13.68 (describing reasons for the broad reach of the Guidelines:

The Guidelines only apply, of course, to activities undertaken within the ambit of the NHS. To that extent, those who conduct research outside the NHS are under no duty to comply with them. . . . In practice, however, this limitation may be more apparent than real. . . . [The Guidelines] extend to any research involving the use of NHS patients or premises. To the extent that non-NHS researchers, . . . , might wish to conduct research, it is difficult to do so without using NHS patients or premises. . . . [Also] companies sponsoring research will ordinarily wish to ensure that the Guidelines are followed, both because they represent considered public policy but also because it is clearly in their commercial interests to be seen to behave responsibly. . . . [Finally] the Guidelines' most significant regulatory mechanism, the REC, is now a standard feature of biomedical research . . . . Indeed, bodies which provide financial support for research and editors of journals which publish research results both tend to insist on evidence that research has received approval from an REC.).

<sup>155</sup> *Id.* at ¶ 13.67 (“The Guidelines lay certain duties on various bodies within the NHS . . . . Principal among these duties is the creation of a local REC . . . .”).

<sup>156</sup> See DEP'T OF HEALTH, *Governance Arrangements for NHS Research Ethics Committees* (July 2001).

liability falls on members in their individual capacities, as the REC itself has no legal personality.<sup>157</sup>

Additionally, secondary sources provide further protection through guidance issued by government-sponsored<sup>158</sup> and independent agencies,<sup>159</sup> as well as professional organizations hailing from both the U.K.<sup>160</sup> and abroad.<sup>161</sup> Termed “quasi-law,” such guidance assumes the force of law if adopted judicially or used as a template for domestic legislation.<sup>162</sup> In fact, international codes of medical research ethics espouse basic principles meant to apply to all human subject research.<sup>163</sup> Further, under formal international agreements, corresponding codes

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<sup>157</sup> *Id.* at ¶ 13.70.

<sup>158</sup> Government-sponsored entities are generally appointed to cover a particular bioethics issue or set of related issues, i.e. the Human Fertilisation and Embryology Authority. Price, *United Kingdom*, *supra* note 24 at ¶ 123. However, in contrast to almost all Western nations, the U.K. government has yet to establish a national bioethics committee. *Id.*

<sup>159</sup> For example, the Medical Research Council (MRC), which, although primarily funded through a grant-in-aid from Parliament, is not a government department and remains independent in its advisory functions. See Medical Research Council, *Home: About MRC: Organisation of the MRC*, <http://www.mrc.ac.uk/index/about/about-organisation.htm>.

<sup>160</sup> A principal such organization is the Royal College of Physicians (RCP). See Price, *United Kingdom*, *supra* note 24, at ¶ 701 (Supp. 28).

<sup>161</sup> For example, the World Medical Association (WMA)’s Declaration of Helsinki stands as the foremost international code governing medical research today. See *id.*

<sup>162</sup> *Id.* at ¶ 104.

<sup>163</sup> *Id.* at ¶ 701 (Supp. 28).

or guidelines may be incorporated by reference, thereby imposing duties upon signatory nations under international law.<sup>164</sup>

Despite this multitude of sources governing, directly or indirectly, human subject research in the U.K., allegations of horrific experiments conducted by the country's own Ministry of Defence (MoD) raise doubts as to whether protections actually extend to the Military Establishment. As is true in the U.S., the potential offered by biotechnology in the defense context makes its research, development, and rapid implementation into the armed forces essential. Also of significance to both nations is a history of abuse of service members serving as research subjects, thereby bringing to the forefront the issue of their protection in biotech R&D. Considering the military-specific need for rapid implementation of biotech products, service personnel using such products that are not yet licensed, or not licensed for the particular use, appear equally entitled to protections afforded research subjects.

Compared to exposure of such abuses in the U.S., investigation into similar events in the U.K. remains forthcoming. As recently as 1997 and to the European Court of Human Rights, no less, the MoD denied ever having used human subjects for radiation experiments.<sup>165</sup> Today, their

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<sup>164</sup> *Id.* at ¶ 103 (noting that principles of medical law are “increasingly becoming the subject of international provisions and obligations embedded in Conventions, Protocols, [etc.]”).

<sup>165</sup> Case of L.C.B. v. The United Kingdom, 4 B.H.R.C. 447 (1998) (circumstances of the case:

10. Between 1952 and 1967 the United Kingdom carried out a number of atmospheric tests of nuclear weapons in the Pacific Ocean and at Maralinga, Australia, involving over 20,000 servicemen. Among these tests were the “Grapple Y” and “Grapple Z” series of six detonations at Christmas Island in the Pacific Ocean (November 1957–September 1958) of weapons many times more powerful than those discharged at Hiroshima and Nagasaki.

official website tells a seemingly different story, stating that since 1916, at least 20,000 service members have participated as volunteer research subjects at the Porton Down defence laboratory.<sup>166</sup> Many such volunteers have since, in violation of the Official Secrets Act,<sup>167</sup> alleged injury connected with their participation, as well as insufficient information and even outright deception used to obtain their consent<sup>168</sup>. However, the MoD maintains, not surprisingly

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11. During the Christmas Island tests, service personnel were ordered to line up in the open and to face away from the explosions with their eyes closed and covered until twenty seconds after the blast.

The applicant alleged that the purpose of this procedure was deliberately to expose servicemen to radiation for experimental purposes. The Government denied this and stated that it was believed at the time of the tests, and was the case, that personnel were sufficiently far from the centre of the detonations to avoid being exposed to radiation at any harmful level and that the purpose of the line-up procedure was to ensure that they avoided eye damage and other physical injury caused by material blown about by the blast.);

Case of *McGingley and Egan v. The United Kingdom*, 4 B.H.R.C. 421 (1998) (circumstances as stated in paragraph 11 of *L.C.B.* case).

<sup>166</sup> Ministry of Defense, *Porton Down Volunteers: The Volunteer Programme* (page modified Feb. 2002) [hereinafter MoD Website], <http://www.mod.uk/issues/portondownvolunteers/programme.htm>.

<sup>167</sup> The Act states “A person who is or has been a Crown servant . . . is guilty of an offence if without lawful authority he makes a damaging disclosure of information, document or other article relating to defence which is or has been in his possession by virtue of his position as such.” Official Secrets Act, 1989, c. 6, § 2(1) (Eng.). “Crown servant” encompasses “any member of the naval, military or air forces of the Crown.” *Id.* at § 12(1)(d). “Defence” includes “the weapons, stores or other equipment of those forces and the invention, development, production and operation of such equipment and *research* relating to it.” *Id.* at § 2(4)(b) (emphasis added).

<sup>168</sup> MoD Website, *supra* note 166, at *Volunteer Complaints* (stating:

Some volunteers say that their health has suffered as a result of the trials in which they participated. . . .

in light of the current criminal investigation<sup>169</sup> and potential for significant civil litigation,<sup>170</sup> that no evidence exists to-date in support of volunteers' allegations<sup>171</sup>. Along similar lines, the MoD recently confirmed that military personnel were involved in nuclear weapons tests conducted in Australia in the 1950's, but stated the testing was of clothing not humans.<sup>172</sup>

Until last year, the protections afforded research subjects were, in effect, not applicable to armed forces personnel serving as such during the period of the alleged violations. Through Section 10 of the Crown Proceedings Act 1947, the Crown, including MoD, received blanket

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The second main complaint is that they were duped into attending the trials; particularly relevant being the story that people responded to a notice requesting volunteers for common cold research. . . .

A third complaint is that the nature of the trials was not explained to volunteers on arrival, or that the risks involved were substantially misrepresented to them.).

<sup>169</sup> Wiltshire Constabulary, *Operation Antler, History* (2002), <http://www.wiltshire.police.uk/antler/index.htm> (stating:

In July 1999 the Force commenced enquiries into allegations made by a former serviceman, who stated that during his National Service he took part in research . . . [and] that those carrying out the experiments on him have assaulted him. He further alleged that another serviceman had been killed in an illegal experiment involving Nerve Gas at Porton in 1953. As a result of this and other allegations the Force initiated a major enquiry. Named Operation Antler, its purpose is to examine the issues surrounding the Service Volunteer Programme at Porton Down in relation to experiments conducted into the use of chemical and biological agents during the period 1939-1989.).

<sup>170</sup> See *infra* notes 171-74 and accompanying text.

<sup>171</sup> MoD Website, *supra* note 166, at *Volunteer Complaints*.

<sup>172</sup> Jim Green, *UK Admits Military Personnel Deliberately Exposed to Nuclear Tests*, ENVTL. NEWS SERVICE, May 18, 2001, <http://ens-news.com/ens/may2001/2001-05-18-04.asp>.

immunity from liability to service members for injury or death attributable to their military service prior to 1987.<sup>173</sup> In January 2002, the High Court found Section 10 to be incompatible with the Human Rights Act guarantee of a fair trial, thereby opening the door for all veterans to bring compensation claims against the Crown in civil proceedings.<sup>174</sup> Although the Court of

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<sup>173</sup> As originally promulgated in 1947, the Act stated:

No proceedings in tort shall lie against the Crown for death or personal injury due to anything suffered by a member of the armed forces of the Crown if-

(a) that thing is suffered by him in consequence of the nature or condition of any such land, premises, ship, aircraft or vehicle as aforesaid, or in consequence of the nature or condition of any equipment or supplies used for the purposes of those forces; and (b) the Minister of Pensions certifies as mentioned in the preceding section; . . . .

Crown Proceedings Act, 1947, c.44, § 10(2) (Eng.).

Subsequent legislation repealed this section, but only as to liability for death or injury occurring from 1987 onward. Crown Proceedings Act, 1987, c.25, § 1 (Eng.) (“[S]ection 10 . . . shall cease to have effect *except in relation to anything suffered by a person in consequence of an act or omission committed before the date on which this Act is passed.*”) (emphasis added).

<sup>174</sup> Alan Robert Matthews v. The Ministry of Defence, 2002 C.P. Rep. 26 (Q.B. 2002); *see also*

Russell, Jones & Walker, *Landmark Decision Gives Hope to Thousands of War Veterans* (Jan. 23, 2002), <http://www.rjw.co.uk/newsandevents/news2002/jan23.aspx> (quoting Alan Care, attorney for over 450 Porton Down veterans:

We’ve been campaigning for years to overturn this draconian law which gives the Ministry of Defence blanket immunity. Before yesterday’s ruling the Ministry of Defence would issue a Section 10 certificate stating that injury or death was attributable to service, giving rise to the right to claim a war pension. However, the Porton Down volunteers received nothing . . . .

The Ministry of Defence is appealing the decision but this judgment at long last recognises that Section 10 immunity must not stand.).

Appeals has subsequently overturned the Ruling,<sup>175</sup> further appeal is pending in the House of Lords.<sup>176</sup> The extent of claims to follow will turn on the outcome of this final appeal in light of findings from Wiltshire's present criminal investigation surrounding events at Porton Down from 1939-1989<sup>177</sup>.

As demonstrated by the High Court ruling, protection of research subjects is intended, at least today, to apply to the Military Establishment. First, principles from international codes of research ethics theoretically cover all research activity.<sup>178</sup> Further, neither European-wide nor domestic sources of authority provide any military-specific exemption concerning human research protections. In fact, incorporation of the EU Clinical Trials Directive into domestic law will address a "loophole" in the current licensing scheme,<sup>179</sup> which fails to protect the largest category of military research participants, namely, healthy volunteers. Finally, even if the MoD were exempt from providing such protections, collaborative defense research partners, whether

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<sup>175</sup> *Matthews v. Ministry of Defence*, 2002 WL 820098 (C.A. Civ. Div. 2002).

<sup>176</sup> Coffin, Mew & Clover, *Personal Injury, Current Topics, Ex-servicemen lose chance to claim damages*, [http://www.coffinmew.co.uk/fla\\_current\\_injury.htm](http://www.coffinmew.co.uk/fla_current_injury.htm).

<sup>177</sup> Wiltshire Constabulary, *supra* note 169, at *History*

<sup>178</sup> Price, *United Kingdom*, *supra* note 24, at ¶ 701 (Supp. 28).

<sup>179</sup> Medicines Control Agency (MCA), *EU Directive on Good Clinical Practice in Clinical Trials, DH & MCA Briefing Note, Version 2* ¶ 18 (Feb. 8, 2002),

<http://www.mca.gov.uk/ourwork/licensingmeds/types/clinicaltrialbriefnote.pdf> ("Currently, studies in healthy volunteers . . . do not require regulatory approval and can commence after an ethics committee has given a favourable opinion. The Directive will require the submission to the MCA of an application for authorization and favourable ethics committee opinion before a healthy volunteer trial can commence.").

from another government sector, industry, or academia, remain bound to existing legal requirements<sup>180</sup>.

Because MoD no longer has blanket immunity from civil proceedings brought by service members,<sup>181</sup> the common law has assumed a special relevance to the Establishment's treatment of its members in connection with military service. In the area of military testing and use of experimental products, common law principles of consent set the standard to counter tort claims sounding in battery or negligence<sup>182</sup>. Considering that the majority of defense-related research is "non-therapeutic," or not intended to benefit the research subject,<sup>183</sup> and, as such, is typically carried out on healthy volunteers,<sup>184</sup> the standard of legally effective consent is high. Of primary concern in the military context is the following:

Voluntariness is of particular importance in the case of non-therapeutic research. The law is vigilant to ensure that participation results from genuine agreement rather than from duress or coercion. A particular area of difficulty relates to those who by virtue of their status or relationship with the researcher may find it difficult to refuse consent, though they might wish to do so. Groups that are vulnerable to exploitation include armed forces personnel asked by their superiors in rank.<sup>185</sup>

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<sup>180</sup> See *supra* note 154 (describing the broad reach of NHS Guidelines).

<sup>181</sup> See *supra* note 173-76 (no blanket immunity from liability for death or injury occurring after date of repeal and, pending House of Lords decision, potentially even for death or injury before date of repeal).

<sup>182</sup> KENNEDY & GRUBB, *supra* note 27, at ¶¶ 13.03, 13.06; Price, *United Kingdom*, *supra* note 24, at ¶¶ 707, 715 (Supp. 28).

<sup>183</sup> KENNEDY & GRUBB, *supra* note 27, at ¶¶ 13.05, 13.35.

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

Further, researchers must provide sufficient information for the subject's decision to qualify as being "informed."<sup>186</sup>

Even if the consent given is voluntary and informed, limits exist, at least by way of ethical constraints, as to what activities may be consented to. In short, healthy volunteers should never be exposed to more than "minimal risk,"<sup>187</sup> which one authority defines as "a small chance of a recognized reaction which is itself trivial, e.g., headache, or a very remote chance of a serious disability or death, e.g., that encountered by flying as a passenger in a scheduled aircraft."<sup>188</sup> Today's military R&D, especially that implicating human subjects, focuses on using biotechnology to develop countermeasures for biological and chemical weapons.<sup>189</sup> Such research, as well as the provision of yet investigational biotech products for use by personnel particularly susceptible to exposure, surely implicates more than "minimal" risk. A significantly higher standard of risk is permissible in therapeutic research,<sup>190</sup> but the issue then would be finding people already exposed to these warfare agents.

In light of these common law constraints, as well as the loss of MoD immunity, the on-going Porton Down investigation, and an overall increased awareness of human rights issues, the

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<sup>186</sup> *Id.*; Price, *United Kingdom*, *supra* note 24, at ¶ 715 ("Consent must be explicit and all relevant information must be provided. These remarks suggest that an absence of such knowledge would even go to battery rather than negligence." (footnotes omitted)).

<sup>187</sup> *Id.*

<sup>188</sup> *Id.* (citing definition from Royal College of Medicine, *Research on Healthy Volunteers*, in MANUAL FOR RESEARCH ETHICS COMMITTEES (4<sup>th</sup> ed. 1996)).

<sup>189</sup> See IATAC REPORT, *supra* note 11, at 25-28, 89-93; NRC REPORT, *supra* note 12, at 65-67.

<sup>190</sup> Therapeutic research is that which is conducted on patients, as opposed to healthy volunteers, and is intended to provide benefits to research subjects, as opposed to merely generating scientific data. KENNEDY & GRUBB, *supra* note 27, at ¶ 13.05; Price, *United Kingdom*, *supra* note 24, at ¶¶ 702, 706.

MoD should comply with ethical research principles whether or not legally bound to do so by any instrument or doctrine. Moreover, realizing that products may be implemented into the military regimen before full testing and licensure, service members using such products should receive the same protections as do research subjects.

### **Conclusion**

Because collaborative research efforts, both between the U.S. and the U.K.,<sup>191</sup> as well as with other allies,<sup>192</sup> industry,<sup>193</sup> and academia,<sup>194</sup> is imperative to reach military biotech goals, the protections afforded to research subjects must ultimately be commensurate in all arenas. Furthermore, most military operations are now conducted jointly, implicating the need for interoperability of forces.<sup>195</sup> Joint missions combining Allied forces inherently calls for a unified defense policy regarding the use of experimental products during these operations.

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<sup>191</sup> See *supra* note 29 and accompanying text.

<sup>192</sup> See *supra* note 30 and accompanying text.

<sup>193</sup> See, e.g., NRC REPORT, *supra* note 188, at 3 (concluding:

To keep pace with the unprecedented rate of discovery and the anticipated increase in biotechnology developments, the Army will have to establish new, effective partnerships with the emerging biotechnology industry, participate in research, leverage research and developments in the commercial sector, and develop its internal capabilities (organization and personnel) to act on opportunities as they arise.).

<sup>194</sup> See, e.g., Colleen Kinder, *Yale professors find deep pockets in Defense Dept.*, YALE HERALD, Oct. 19, 2001, at 5, <http://www.yaleheld.com/archive/xxxii/10.19.01/news/p5.html>.

<sup>195</sup> See *supra* note 38 and accompanying text; see also Ministry of Defence, *Key Facts, Defence and Technology* (page modified Feb. 6, 2002), <http://www.mod.uk.aboutus/factfiles/technology.htm> (“We need also to ensure that there is no technology gap between ourselves and our Allies and coalition partners, so that we can continue to work closely together around the world, as we do in Kosovo, Bosnia, and Iraq.”).

In sum, peacetime must be utilized to formulate, solidify, and implement protections to service members concerning biotech testing and use in the military. History has shown that addressing such issues in wartime inevitably leads to practices based on a “sacrifice of the few for the good of the many” mentality. In light of the sacrifices already made, as well as the risks inherently accepted by members by virtue of their military service, the nation they defend owes each member a reciprocal duty to respect individual human rights. As has been aptly stated, “Indeed the safest road to Hell is the gradual one - the gentle slope, soft underfoot, without sudden turnings, without milestones, without signposts.”<sup>196</sup>

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<sup>196</sup> CLIVE STAPLES LEWIS, THE SCREWTAPE LETTERS 61 (1942).