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STUDENT NOTE

The National Security Implications and Potential Solutions for the Unintended Consequences of the 1980 Bayh-Dole Act on Brain-Injured Veterans from the Wars in Iraq and Afghanistan

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ABSTRACT

Traumatic brain injury (TBI) is the “signature wound” seen in veterans from the wars in Iraq and Afghanistan, from which the U.S. now has over 20,000 young veterans living with TBI. However, some unintended consequences of the Bayh-Dole Act of 1980, a law designed to tap the “secret weapon” of federally funded research & development (R&D) to help the U.S. return to competitiveness after the recession of the late 1970’s, are now preventing these heroes from getting the treatment and cures they need. This article reviews the history of American academia’s close cooperation with the U.S. government in solving military medical problems from WWI through the Vietnam War, where those cures have now benefited millions worldwide. It then shows how this relationship has changed since the enactment of Bayh-Dole Act, and then examines the Act’s current and future impact on U.S. national security and the all-volunteer force. The article concludes that the Bayh-Dole Act should not be completely

¹ University of Miami School of Law, Class of 2015 and United States Army War College DEP, Class of 2015. The views expressed here are the author’s personal views and do not necessarily reflect those of the Department of Defense, the United States Army, the U.S. Army War College, or any other department or agency of the United States government. The analysis presented here stems from academic research of publically available sources, not from protected operational information. The author would like to thank Professor Frances Hill, Law Library Associate Director Robin Schard, Attorneys Emily Horowitz and Ana Ramirez, and NSAC Law Review Chief Notes Editor Sarah Fowler for their guidance on this article.

repealed, but recommends some amendments be enacted in order to take better care of the 1% of the U.S. population that fights and sacrifices to protect the other 99%.

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I. SAVED, NOT CURED¹

On January 28th, 2014, President Obama made his fifth State of the Union address to a staunchly divided Congress and a politically divided nation.² According to media experts, about 90% of the speech was not particularly memorable.³ But, of the 6,778 words that the President spoke for over an hour, everyone in the attendance—and almost everyone watching across the nation—found common ground in only 10% of the content.⁴ Americans discovered this commonality in their unqualified support for brain-injured veterans from the wars in Iraq and Afghanistan such as Army Ranger Sergeant First Class Cory Remsburg.⁵ This support was evidenced by an almost two minute standing ovation for this hero's sacrifice- a hero who "never gives up, and does not quit!" on behalf of this country and its citizens.⁶

When Cory Remsburg's parents brought him home from the hospital as a newborn in Phoenix, Arizona, they were filled with the expectant joy of most young parents. As Cory matured, he later moved to St. Louis, Missouri, where he lived with his father and stepmother, Craig and Annie Remsburg.⁷ Like many typical American kids, Cory played varsity volleyball, performed in the marching band, orchestra, and jazz band, and participated in the German Club.⁸ "He just loved life, he was always swimming and running and doing all the

¹ Michael M. Phillips, *Saved Not Cured: Brain-Injured Vets Search for Solace*, WALL ST. J., Feb. 20, 2014, available at <http://search.proquest.com/newsstand/docview/1500218206/B84C9DFAE324546PQ/4?accountid=14585>.

² Steve Holland, *Obama Warns Divided Congress That He Will Act Alone*, YAHOO (Jan. 29, 2014), <http://news.yahoo.com/obama-lay-alone-approach-state-union-speech-003623143--business.html>.

³ John Cassidy, *The Meaning of Cory Remsburg*, THE NEW YORKER, Jan. 29, 2014, available at <http://www.newyorker.com/online/blogs/johncassidy/2014/01/the-meaning-of-cory-remsburg-state-of-the-union.html>.

⁴ Dan Merica, *A Bipartisan Outpouring for Wounded War Hero at State of the Union*, CNN, available at <http://politicalticker.blogs.cnn.com/2014/01/29/a-bipartisan-outpouring-for-wounded-war-hero-at-state-of-the-union/>.

⁵ *Id.*

⁶ *Id.*

⁷ 9Line, LLC, *Committed to the Wounded Warrior*, 9LINELLC.COM, http://www.9linellc.com/wits/WITS_2012_Feb_CoryRemsburg.htm (last visited Feb. 24, 2014).

⁸ *Id.*

things that made his life very full,” explained Cory’s stepmother.⁹ “We always called him our wild-child because if you told Cory he couldn't do something—that is what he was going to do,” which is where his impetus to join the Army probably came from.¹⁰ ““At 17, Cory went to his dad and said I want to go into the military—would you sign for me?”” said his father Craig.¹¹ But Craig wanted his son to give college a try first, which he did, until the morning of his eighteenth birthday.¹² According to Cory’s stepmother Annie, on that day, the “doorbell rang at about 5:30 a.m., and Cory went bounding down the stairs as my husband and I were waking up. The Army recruiter came through the door.”¹³ Cory entered the Army in July 2001 and shipped off to boot camp at Ft. Benning, Georgia, which is where he learned about the U.S. Army Rangers, the Army’s elite special operations infantry unit.¹⁴

Cory attended One Station Unit Training, the Basic Airborne Course and the Ranger Assessment and Selection Program and was then assigned to 1st Battalion, 75th Ranger Regiment, Hunter Army Airfield, Savannah, Georgia where he had served since 2002.¹⁵ But, on October 1, 2009, on his tenth deployment to war (Rangers deploy more often, but for shorter durations than conventional units), and while returning from leading a Ranger squad into combat on the outskirts of Kandahar, where they killed nine insurgents,¹⁶ Cory was “thrown like a rag doll into an Afghanistan canal by the blast from a 500-pound roadside bomb, also known as an improvised explosive device (IED), with the right side of his head caved in by shrapnel.”¹⁷

⁹ Alice Massimi, *Road Back: A Wounded Savannah Soldier's Journey*, WSAV, (Oct. 28, 2010, 7:29 PM), *available at* <http://www.wsav.com/story/20677231/the-road-back-a-wounded-savannah-soldiers-journey>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Gregg Zoroya, *For Troops With Brain Trauma, a Long Journey Back*, USA TODAY, (July 29, 2010), *available at* http://usatoday30.usatoday.com/printedition/news/20100729/1aawakening29_cv.art.htm. (last visited Feb. 24, 2014); *Rangers: A Day in the Life*, SOFREP.COM, <http://sofrep.com/army-rangers/a-day-in-the-life> (last visited Feb. 24, 2014).

¹⁷ Alice Massimi, *Road Back: A Wounded Savannah Soldier's Journey*, WSAV, (Oct. 28, 2010 7:29 PM), *available at* <http://www.wsav.com/story/20677231/the-road-back-a-wounded-savannah-soldiers-journey>; Zoroya, *supra* note 16.

According to Cory's former battalion commander, Colonel Brian Mennes, the blast wounded eight members of Cory's unit, killing Sergeant Roberto Sanchez, severing a second Ranger's leg below the knee, and leaving Cory's "leg badly mangled and part of his face and head torn off."¹⁸ One of Cory's best friends from the Rangers told his parents "when we cut Cory out of his uniform during medical treatment, we thought we were saying goodbye to him."¹⁹ After a medical evacuation and six operations at military hospitals across the world from Afghanistan to Germany and then to Bethesda, Maryland, including two that removed skull sections allowing his brain to swell, Cory arrived at the James A. Haley Veterans Hospital in Tampa, Florida, in November 2009 in a vegetative state.²⁰ It took more than three months after Cory was pulled from the canal, with his parents constantly by his side, for him to emerge from his coma.²¹ On January 13, 2010, Veterans Affairs (VA) doctors finally announced that Cory was "officially" awake.²²

However, if this was another time or another war, such as the last major war the U.S. fought in- the Vietnam War, which ended in 1975, Cory probably would have just died on the battlefield.²³ Or, if Cory had been the Ranger that had lost his leg below the knee from the same IED instead, the solution for doctors today would be relatively easy: just give him a custom-fit, high-tech prosthetic leg, and get him back out the battlefield to fight after a few months of rehabilitation.²⁴

But, this type of treatment is not possible for victims of TBI,

¹⁸ ; Zoroya, *supra* note 16; Editorial: *Cory Remsburg: Not Just Another Number*, PRESS REPUBLICAN, available at

http://www.pressrepublican.com/0201_editorials/x91133077/EDITORIAL-Cory-Rensburg-Not-just-another-number, (last visited Feb. 24, 2014).

¹⁹ Massimi, *supra* note 9.

²⁰ Zoroya, *supra* note 16.

²¹ *Id.*

²² *Id.*

²³ Ronald H. Spector, *Vietnam War*, ENCYCLOPAEDIA BRITANNICA, (Dec. 23, 2013), available at <http://www.britannica.com/EBchecked/topic/628478/Vietnam-War>; Steve Almasy, *The Toll of War Now Includes More Amputees*, CNN, (Oct. 29, 2012), available at <http://www.cnn.com/2012/05/27/us/amputee-veterans-come-home/>.

²⁴ *Ranger Writes Memoir About Losing His Leg*, COLUMBUS LEDGER-ENQUIRER (Georgia), (June 8, 2013), <http://www.military.com/daily-news/2013/06/08/ranger-writes-memoir-about-losing-his-leg.html>.

like Cory's, which is seen in veterans from the wars in Iraq and Afghanistan.²⁵ Hundreds of "Cory Remsburgs" return from the war zone with TBI each year.²⁶ This means that as a result of almost thirteen years of war, we now have over 20,000 young U.S. veterans living with TBI.²⁷ According to Retired General Peter W. Chiarelli, former Vice Chief of Staff of the Army, and now Chief Executive Officer for One Mind for Research, TBI and other mental health injuries to include Post Traumatic Stress (PTS), are the "signature wounds" of these wars.²⁸ In fact, the Institute of Medicine (IOM) Report *Gulf War and Health, "Long Term Effects of Blast Exposures,"* stated that since 2001, more than 1,000 U.S. soldiers in the Afghanistan war have been killed in action and nearly 10,000 Wounded in Action (WIA) because of IED's. And, from March 2003 to November 2011, more than 2,000 U.S. soldiers in the Iraq war were killed in action and close to 22,000 wounded in action due to IED's.²⁹ Further, according to the Defense and Veterans Brain Injury Center, between January 1, 2001, and September 30, 2013, more than 265,000 U.S. troops suffered traumatic brain injuries.³⁰ Most were mild concussions, but 26,250 troops suffered penetrating head wounds or brain injuries classified as moderate or severe, which caused unconsciousness from 30 minutes to more than a day.³¹ Even the long-term effects of concussions are significant, as evidenced by the recent rejection of the National Football League's \$760 million proposed settlement with 4,000 former players by Federal District Judge Anita Brody on January 14, 2014, where she stated "on the basis of the present record, I am not yet satisfied that the Settlement has no obvious deficiencies, grants no preferential treatment to

²⁵ *Department of Defense Numbers for Traumatic Brain Injury*, DEFENSE.GOV, (Feb. 10, 2012), http://www.defense.gov/home/features/2012/0312_tbi/chartaf_hires.jpg.

²⁶ *Id.*

²⁷ *Id.*

²⁸ Peter W. Chiarelli, *The Invisible Wounds of War*, USO ON PATROL, BRAIN LINE MILITARY, available at http://www.brainlinemilitary.org/content/2011/08/the-invisible-wounds-of-war_pageall.html (last visited Feb. 24, 2014).

²⁹ *Gulf War and Health, Volume 9: Long-Term Effects of Blast Exposures*, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, (Feb. 13, 2014), available at <http://www.iom.edu/Reports/2014/Gulf-War-and-Health-Volume-9-Long-Term-Effects-of-Blast-Exposures.aspx>.

³⁰ Phillips, *supra* note 1.

³¹ *Id.*

segments of the class, and falls within the range of possible approval.”³²

The Bayh-Dole Act of 1980, also known as the University and Small Business Patent Procedures Act of 1980, was designed to tap the “secret weapon” of federally funded R&D, and helped the U.S. return to competitiveness—boosting the economy after the recession of the late 1970’s.³³ However, one of the most devastating unintended consequence of the Bayh-Dole Act is that thousands of brain-injured soldiers, who were represented by Cory Remsburg at the State of the Union address, may have to continue to learn to live with TBI, PTS, and other mental health injuries for many years to come, despite the fact that some treatment methods could already exist. In other words, because of the Bayh-Dole Act, potential treatments and cures, with the majority of the research being paid for by the U.S. taxpayers (who are also bearing the actual cost of the wars and the treatment of the injured soldiers as well) may not reach our brain-injured soldiers, or benefit the general public—until they become “profitable” to certain entities.

II. INTRODUCTION

The premise behind the Bayh-Dole Act of 1980 and its effort to stimulate competitiveness in R&D for the benefit of the taxpayers and the U.S. economy will be outlined in Section III of this article. Section IV will then trace the history of the medical technological advances from WWI through the Vietnam War and how they have benefitted the U.S. military, U.S. society, and millions of people world-wide. Section V will examine the passage of laws like Bayh-Dole after the Vietnam War, as well as some other policies our government has pursued, which may unintentionally have left our nation’s war-footing somewhat off balance, and have national security implications for the next war. Section VI will analyze the “signature wound” of the wars in Iraq and Afghanistan, brain injury, and explain how some of the

³² Doug Farrar, *Judge Anita Brody Denies Preliminary Approval for NFL Concussion Settlement*, SPORTS ILLUSTRATED, (Jan. 14, 2014), available at <http://nfl.si.com/2014/01/14/nfl-concussion-lawsuit-settlement-2/>.

³³ Bayh-Dole Act Pub.L. No. 96–517, § 6(a), 94 Stat. 3018, (Dec 12, 1980); Sen. Birch Bayh, Joseph P. Allen, Howard W. Bremer, *Universities, Inventors, and the Bayh-Dole Act*, LIFE SCIENCES LAW & INDUSTRY REPORT, 3, 1266 (BNA, INC., 2009).

unintended consequences of the Bayh-Dole Act are negatively impacting brain-injured veterans. Next, the author will advocate for the position that Congress should create some exceptions to the Bayh-Dole Act, or enact some reforms for the benefit of brain-injured veterans.

III. WHAT IS THE BAYH-DOLE ACT?

The Bayh-Dole Act: A Guide to Implementing the Law and Regulations states, "technology transfer--the transfer of research results from universities to the commercial marketplace for the public benefit--is closely linked to fundamental research activities in universities."³⁴ In 1945, the success of the Manhattan Project³⁵ showed the importance of university research to national defense, and the report entitled "Science - The Endless Frontier," which Vannevar Bush wrote for President Roosevelt, recognized the value of university research in improving the economy by increasing the flow of science knowledge to industry.³⁶ As a result, Bush's report was key in the formation of the National Institutes of Health (NIH) and the National Science Foundation (NSF), where today 60% of R&D funding that goes to universities is provided by the federal government (the U.S. taxpayers contributed \$40.1 billion in fiscal year 2012), as this research is considered vital to the national interest.³⁷

But, during the Korean and Vietnam War eras, there was no government-wide policy regarding ownership/patent of inventions created by government contractors and grantees using federal

³⁴ *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations*, COUNCIL ON GOVERNMENT RELATIONS, (Sept. 1999), available at <http://www.ucop.edu/ott/faculty/bayh.html>, (last visited Feb. 24, 2014) (hereinafter "Council on Government Relations").

³⁵ Research funded by the U.S. government conducted at Columbia University, the University of Chicago, and the University of California at Berkley led to the development of the atomic bomb, and its application led to the end of the war through Japan's unconditional surrender just five days later. U.S. GOVERNMENT HISTORY: PRE-COLUMBIAN TO THE NEW MILLENNIUM, 51F. MANHATTAN PROJECT, available at <http://www.ushistory.org/us/51f.asp>, (last visited June 2, 2014).

³⁶ *Id.*

³⁷ Ronda Britt, *Higher Education R&D Expenditures Remain Flat in FY12*, NATIONAL SCIENCE FOUNDATION (Nov. 2013), available at <http://www.nsf.gov/statistics/infbrief/nsf14303/>.

funding.³⁸ The government retained title of the inventions and issued non-exclusive licenses to entities that wanted to use them.³⁹ For example, in early 1980 the federal government held title to approximately 28,000 patents, but fewer than 5% of these were licensed to industry for development of commercial products.⁴⁰ As a result, private companies did not have exclusive rights under government patents to manufacture and sell resulting products, and were worried that the competition could duplicate their efforts.⁴¹ Although taxpayers were paying for the research, because the government was not effective in attracting private industry to manufacture and sell the inventions, the public was not benefiting from their investment.⁴² In business terms, the incentives were not properly aligned with the desired outcomes.⁴³

However, later in 1980, congressional lawmakers concluded that the taxpayers would benefit from a policy that permitted universities and small businesses to keep ownership of inventions made with federal funding, such as NIH grants, and should become directly involved in the commercializing (“exploiting for profit”) of the product.⁴⁴ The goal was to stimulate the U.S. economy by licensing new inventions from universities to businesses for the public good, which would manufacture them in the U.S. (creating jobs, generating new tax revenues, etc.).⁴⁵ As a result, the Bayh-Dole Act “has been largely credited with the creation of the modern biotechnology

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ U.S. GOVERNMENT ACCOUNTING OFFICE (GAO) REPORT TO CONGRESSIONAL COMMITTEES ENTITLED “TECHNOLOGY TRANSFER, ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES” (MAY 7, 1998), *available at* <http://www.gao.gov/archive/1998/rc98126.pdf>.

⁴¹ Council on Governmental Relations, *supra* note 34.

⁴² *Id.*

⁴³ Bill Crounse, MD, *Aligning Properly Placed Incentives to Improve Health and Healthcare Services*. MICROSOFT DEVELOPER NETWORK, (Mar. 7, 2011), *available at* <http://blogs.msdn.com/b/healthblog/archive/2011/03/07/aligning-properly-placed-incentives-to-improve-health-and-healthcare-services.aspx>, (last visited Feb. 24, 2014).

⁴⁴ Council on Governmental Relations, *supra* note 34; *Commercializing Definition*, MERRIAM-WEBSTER.COM, <http://www.merriam-webster.com/dictionary/commercialize> (last visited Feb. 24, 2014).

⁴⁵ Council on Governmental Relations, *supra* note 34.

industry.”⁴⁶

Prior to 1980, medical technological advances had been force multipliers for the U.S. in WWI through the Vietnam War and had provided U.S. forces a decisive advantage over their adversaries.⁴⁷ In addition, these advances would then be used to save the lives and improve the quality of life and productivity of civilians in the U.S. and in some cases, all around the world. In short, millions and millions of people have “profited” from these medical advances devised to mitigate or cure some of the horrors of war. In many cases, these medical advances were funded with U.S. taxpayer money and resulted in the direct benefit to American forces and a good return on investment for the American people.⁴⁸ Until the Global War on Terrorism (GWOT), the U.S. had not fought a major war since the enactment of the 1980 Bayh-Dole Act. The Vietnam War (the U.S.’ last major war) ended in 1975. Subsequently, there were conflicts of short duration with very minimal casualties compared to the size of the forces involved: Grenada in 1983, Panama in 1989, Desert Storm in 1991, and Somalia in 1993.⁴⁹ It was not until the commencement of the GWOT in 2001 and the advent of the enemy’s signature weapon (the IED) that the unintended consequences of 1980’s Bayh-Dole Act truly came to light.⁵⁰ If the Bayh-Dole Act had been in place before

⁴⁶ Jeffery A. Baumel, *The Bayh-Dole Act: The Technology Revolution Shows its Age*, VENTURE CAPITAL REVIEW, (Winter 2009), available at http://nysstlc.syr.edu/media/documents/2009/6/The_BayhDole_Act_The_Technology_Revolution_Shows_its_Age.pdf.

⁴⁷ Air University, *Military Medicine During the Twentieth Century* at 3-15, available at <http://www.au.af.mil/au/awc/awcgate/milmedhist/chapter3.htm> (last visited April 13, 2014).

⁴⁸ Sean Pool & Jennifer Erickson, *The High Return on Investment for Publically Funded Research*, 2-4, (Dec 12, 2012), available at <http://www.americanprogress.org/wp-content/uploads/2012/12/InnovationResearchInvestments-1.pdf>.

⁴⁹ Hanna Fischer, *American War and Military Operations Casualties: Lists and Statistics*, NAVY DEPARTMENT LIBRARY, (July 13, 2005), <http://www.history.navy.mil/library/online/american%20war%20casualty.htm>, (last visited Feb. 24, 2014).

⁵⁰ Jeffrey A. Drezner, Raj Raman, Irv Blickstein, John Ablard, Melissa A. Bradley, Brent Eastwood, Maria Falvo, Dikla Gavrieli, Monica Hertzman, Darryl Lenhardt, & Megan McKernan, *Measuring the Statutory and Regulatory Constraints on DoD Acquisition*, RAND NATIONAL DEFENSE RESEARCH INSTITUTE, (2006), available at

WWI, or enacted at any time through the Vietnam War, many of the medical technological advances outlined *infra* may have never come to fruition, or they would certainly have taken significantly longer to go from idea to operation, which, as history shows us, would have been detrimental to improving the quality of life for people throughout the world.⁵¹

IV. MILITARY MEDICAL TECHNOLOGICAL ADVANCES: WWI THROUGH THE VIETNAM WAR

“The War to End All Wars,” WWI, “produced casualties on a previously unknown scale among armies of an unprecedented size.”⁵² During an average day on the western front, there were over 9,000 casualties, with the number escalating dramatically during offenses.⁵³ WIA outnumbered killed in action (KIA) three-to-one, and there were as many disease non-battle injuries (DNBI) casualties as there were casualties from enemy action due to soldiers being highly susceptible to diseases in the close-quarters of damp trenches.⁵⁴ For example, in the Battle of Verdun, Germany had 434,000 men KIA, and the French suffered 542,000 KIA, a number not comprehensible in today’s military operations.⁵⁵ It is easy to see that medical innovations were greatly needed to sustain the Allied effort. It is possible that some of the seeds of medical innovation for WWI were planted a few years prior when General Leonard Wood, a Harvard Medical School graduate and former Army physician, became U.S. Army Chief of Staff in 1910.⁵⁶ The appointment of a physician as the Army Chief of Staff was extremely unlikely and almost impossible in today’s environment,

http://www.rand.org/content/dam/rand/pubs/technical_reports/2006/RAND_TR347.pdf.

⁵¹ *A Ballad to Balad: A Look into Medical Marvels in the Military*. YALE JOURNAL OF MEDICINE & LAW, (Nov. 3, 2006), <http://www.yalemedlaw.com/2006/11/a-ballad-to-balad-a-look-into-medical-marvels-in-the-military/> (last visited Feb. 24, 2014).

⁵² S. FORTY, *WORLD WAR I: A VISUAL ENCYCLOPEDIA* 301 (PRC PUBLISHING LTD., 2002).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ M. CAVENDISH, *HISTORY OF WORLD WAR I: VOLUME 3, HOME FRONTS TECHNOLOGIES OF WAR* 876 (2002).

⁵⁶ *Major General Leonard Wood*, LEONARD WOOD INSTITUTE, *available at* <http://www.leonardwoodinstitute.org/documents/MajorGeneralLeonardWoodbiography.pdf>.

but General Wood's stature as a Harvard-trained physician had a positive impact on the American Army's ability to greatly expand its medical forces during WWI.⁵⁷

"The key to the issue of medical care in WWI was prevention of illnesses and diseases in a general sense and the need to offer effective and prioritized medical aid to a casualty as quickly as possible after a wound had been sustained."⁵⁸ Technological advances addressed a myriad of medical problems. The persistent nature of mustard gas used in chemical warfare was countered with the creation of mobile degassing units.⁵⁹ The typhoid vaccine, developed by Army physicians in 1911 in coordination with British and U.S. Navy researchers, drastically reduced the combatant death rate from typhoid in 1917-18 versus Army operations conducted in the late 1800's.⁶⁰ Powerful magnets were used to extract shell fragments from the eyeball.⁶¹ The use of X-ray machines and laboratories attached to hospitals contributed to rapid diagnosis close to the fight, and "shell shock" was first recognized as a true medical problem, not just a case of cowardice.⁶² But the most important and greatest medical technological advance in WWI was the adoption of blood transfusions to reduce the deadly effects of shock among wounded soldiers.⁶³

Americans built on the medical advances of WWI during WWII by focusing physicians on specialty training, such as neurology, in part to combat "shell shock" and to provide specific care for the treatment of abdominal and chest trauma.⁶⁴ In addition, the military adopted a superior prophylaxis against malaria, originally produced by the Germans, and instituted mass production of penicillin, which greatly improved the chances that a wound victim would overcome

⁵⁷ *Id.*

⁵⁸ CAVENDISH, *supra* note 55.

⁵⁹ SHIRLEY D. TUORINSKY, MEDICAL ASPECTS OF CHEMICAL WARFARE 79 (2008).

⁶⁰ COMMUNICABLE AND OTHER DISEASES, VOLUME 9, THE MEDICAL DEPARTMENT OF THE UNITED STATES ARMY IN THE WORLD WAR (THE OFFICIAL HISTORY SERIES) 16 *available at* , <http://history.amedd.army.mil/booksdocs/wwi/communicablediseases/chapter1.html#table3>.

⁶¹ MILITARY MEDICINE DURING THE TWENTIETH CENTURY

<http://www.au.af.mil/au/awc/awcgate/milmedhist/chapter3.htm>.

⁶² J.W. CHAMBERS, THE OXFORD COMPANION TO AMERICAN MILITARY HISTORY 428, (1999).

⁶³ *Id.*

⁶⁴ *Id.*; I.C. B. DEAR, THE OXFORD COMPANION TO WORLD WAR II 727 (1995).

infection.⁶⁵ The wide-scale use of dichlorodiphenyltrichloroethane (DDT) also controlled a serious outbreak of typhus in Italy.⁶⁶ According to history professor J.W. Chambers, defeating typhus was *critical* to the Allied cause.⁶⁷ The disease was only quelled by a massive overall “dusting” with DDT, which saved thousands of lives. Nevertheless, we now know DDT causes birth defects in many species and is internationally banned.⁶⁸

The sheer size of American military medicine expansion and its innovations throughout WWII explained much of its success. For instance, in 1942-45, 40% of the country’s physicians and healthcare providers were serving in the military versus only 8% still in purely civilian practice.⁶⁹ However, it is just the opposite today. With the majority taxpayer’s dollars provided through NIH grants going to university laboratories, where the universities can now transfer technology to the private sector for a “profit,” enabled by the Bayh-Dole Act, the physicians can share in; physicians are now underrepresented in the military (there is a shortage, as now more lucrative opportunities are available).⁷⁰ For example, is it really reasonable to believe today, with the advent of the Affordable Care Act (ACA) providing funding for more patients, and healthcare costs making up almost one-fifth of the gross domestic product (GDP), that Harvard University would directly send ninety doctors and nurses to man the Fifth General Hospital and deploy overseas as they did in World War II?⁷¹

Leveraging medical technological advances provided strategic, operational, and tactical advantages for the Allies over the Axis

⁶⁵ DEAR, *supra* note 64, at 723-727.

⁶⁶ *Id.*

⁶⁷ *Id.* (emphasis added).

⁶⁸ *Eagle Virtual Field Trip*, BRIDGEWATER STATE UNIVERSITY, available at http://www.bridgew.edu/http://webhost.bridgew.edu/jhayesboh/trips/eagles/facts_about_ddt.htm (last visited Feb. 24, 2014).

⁶⁹ CHAMBERS, *supra* note 51.

⁷⁰ Baumel, *supra* note 45.

⁷¹ Linda J. Blimes, *The Financial Legacy of Iraq and Afghanistan: How Wartime Spending Decisions Will Constrain Future National Security Budgets*, HARVARD KENNEDY SCHOOL FACULTY WORKING RESEARCH PAPERS, (March 2013), RWP13-006 available at <https://research.hks.harvard.edu/publications/>; *5th General Hospital Unit History*, WWII MEDICAL RESEARCH CENTRE, available at http://www.med-dept.com/unit_histories/5_gen_hosp.php (last visited Feb. 24, 2014).

powers and contributed to their victory.⁷² And, it is clear the Axis powers' ability to leverage medical technology was not as great as the Allies' and contributed to their defeats in both WWI and WWII.⁷³ However, tough DNBI lessons that were learned in the past were not always heeded by major combatants for both the Axis and the Allies, as the incidence of disease varied greatly in different armies from one theater to another.⁷⁴ For instance, infection from diphtheria amongst Allied troops increased greatly in 1944-45 as they came into contact with heavily infested areas in the formerly German-occupied territories, and heavy losses were suffered by the Allies due to malaria in Asia until newly developed anti-malaria drugs were used.⁷⁵ Hygiene and preventive medicine usually were high priorities for both side's commanders, but there are some important exceptions that contributed to the demise of the German effort.⁷⁶ Worth noting is the absence of any field sanitation precautions in the German lines of the Western Desert Campaign.⁷⁷ British observers state that during the second battle of El Alamein, they could easily identify German defensive positions as indicated by the amount of human feces lying on the ground.⁷⁸ The lack of the ability to leverage medical technology for better field hygiene cost the German Afrika Corps dearly in terms of DNBI and severely hindered its ability to combat the Allied offensive.⁷⁹ German soldiers were 2.6 times more likely to be incapacitated from dysentery, malaria, hepatitis, and skin diseases than their British opponents.⁸⁰ In the two months before the second battle of El Alamein, more than one-in-five Germans had been sick from disease causing even the elite 15th Panzer Division to be well below strength.⁸¹ Again, this is further evidence that it was the U.S. government's dedication to medical technological advances that directly benefited the troops and helped enable the Allies to victory over the Axis.

⁷² DEAR, *supra* note 64.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

In addition, during the Korean War, due to technological advances, new laws were enacted by Congress to ensure the soldiers in harm's way "profited" from and got the benefit of the U.S. taxpayer's dollars that were being spent to train physicians.⁸² Case in point in terms of legislation, there was such a critical shortage of physicians that Congress passed Public Law 779, known as the Doctor Draft Law, in September 1950.⁸³ This legislation provided for the drafting of physicians who had gone to medical school at government expense during World War II, but who graduated after the war was over and whose services were no longer needed.⁸⁴ Now they were required to take care of soldiers, and many physicians were recalled to active duty in support of the Korean War effort.⁸⁵ This law was renewed in 1955, but has since fallen by the wayside.⁸⁶ In terms of medical technology in the Korean War, medical advances such as the Mobile Army Surgical Hospital (MASH) and helicopter ambulances were first used.⁸⁷ In addition, the national blood banking program was rapidly geared up with new techniques such as plastic bags used for collection and delivery.⁸⁸ Lastly, body armor that allowed for more mobility, while offering protection, was also developed and put into common use.⁸⁹

The Vietnam War gave us the technological advance of Huey helicopters, where medical treatment was provided on-board, being used for evacuation of wounded soldiers. Now, many civilian trauma centers in the U.S. have similar life-flight helicopters and heliports.⁹⁰

⁸² *Pentagon Panel Project: Navy Medicine in the Korean War*, KOREAN WAR 60TH ANNIVERSARY, available at <http://www.koreanwar60.com/medical-advances> (last visited Feb. 24, 2014).

⁸³ *Doctor Draft Law Extended Through Parliamentary Maneuver*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA), (July 30, 1955), available at <http://jama.jamanetwork.com/article.aspx?articleid=301622> (last visited Feb. 24, 2014).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ M.S. Baker, *Military Medical Advances Resulting From the Conflict in Korea, Part I: Systems Advances That Enhanced Patient Survival*, MILITARY MEDICINE, available at (Apr. 2012), <http://www.ncbi.nlm.nih.gov/pubmed/22594133>.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ The role of the helicopter in support activities in the Vietnam War must not be overlooked, as thousands of missions were flown to resupply and reinforce troops

Vietnam also spurred major advances in vascular surgery, which were recorded for surgical posterity in the “Vietnam Vascular Registry,” a database with records of over 8,000 vascular wound cases contributed to by over 600 battlefield surgeons.⁹¹ This is one of the first examples of the use of “big data” to search for cures or better treatment modalities for soldiers and civilians alike.⁹² Each of these technological advances was used by the military to save lives on the battlefield and then was leveraged by civilians to save lives in the U.S. and later, worldwide.⁹³

V. NATIONAL SECURITY IMPLICATIONS

In addition to impacting veterans like Cory Remsburg who suffer from PTS and TBI, the Bayh-Dole Act may also have an unintended consequence leading to a lack of balance in the U.S.’s national security posture in the future. A “military revolution” characterizes profound changes in how war is waged at the strategic level—there are systemic changes in politics, society, and how forces and resources are mobilized to achieve national objectives through military means.⁹⁴ “Military revolutions recast society and the state as well as military organizations. They alter the capacity of states to create and project military power.”⁹⁵ The French Revolution changed how the entire French country waged war—“it widened and deepened the state’s grip upon the wealth and manpower of its citizens. The leaders of France declared a *levée en masse* that placed

on the ground, to evacuate American and South Vietnamese wounded, and to offer countless other services in pursuance of the war effort. Indeed, the Vietnam War was the Helicopter War. *Vietnam, the Helicopter War*, TEXAS TECH UNIVERSITY: THE VIETNAM CENTER & ARCHIVE, available at <http://www.vietnam.ttu.edu/exhibits/helicopter/>; Paul E. Stepansky, PhD, *Medicine, Health, and History: Medicine in Vietnam: An Irony of War*, A DOSE OF HISTORY, (Feb. 11, 2012), available at <http://adoseofhistory.com/category/military-psychiatry/medicine-in-vietnam/>.

⁹¹ N. M. Rich, A. Leppäniemi, *Vascular Trauma: A 40-Year Experience with Extremity Vascular Emphasis*. SCANDINAVIAN JOURNAL OF SURGERY, (2002), available at <http://www.fimnet.fi/sjs/articles/SJS12002-109.pdf>.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ M. KNOX, & W. MURRAY (EDS.). THE DYNAMICS OF MILITARY REVOLUTION 1300-2050. (2001).

⁹⁵ *Id.*

the French people and their possessions at the state's disposal for the duration of the war."⁹⁶ This major change at the strategic level centralized resources and injected a "level of ferocity" in war that had not been previously seen.⁹⁷ Similarly, it can be inferred that a "military revolution" in the U.S. has been taking place since the end of the Vietnam War. The U.S. no longer relies upon drafting forces to fill its ranks.⁹⁸ This is a major departure for U.S. policy, at the strategic level, from how forces and resources were mobilized during most of the twentieth century in order to achieve national objectives through military means. For example, following the Japanese attack on Pearl Harbor, war was declared and America mobilized.⁹⁹ In effect, all elements of famed military theorist Clausewitz's "paradoxical trinity"—violence and passion; uncertainty, chance and probability; and political purpose and effect, and reason—were in balance. "War," according to Clausewitz is "an act of force to compel our enemy to do our will."¹⁰⁰ All three elements of the "paradoxical trinity" are required in order to be ultimately successful, and they must be kept in balance in order to influence success in the conduct of war.¹⁰¹ During WWII these elements were kept in balance by the U.S.—leading to victory.¹⁰² Once again, war was declared by Congress, the draft was enacted, "Rosie the Riveter" started building aircraft and tanks, food was rationed, and war bonds were sold to raise needed financial resources.¹⁰³ Similar actions followed in the Korean Conflict and the Vietnam War. However, the U.S. ran into trouble later in the Vietnam

⁹⁶ *Id.*

⁹⁷ Steve T. Ross, "Napoleon and Maneuver Warfare." *The Harmon Memorial Lectures in*

Military History, 1959–1987, OFFICE OF AIR FORCE HISTORY.

⁹⁸ R. Norman Moody, *After 40 Years, Return of Military Draft Not in Sight*, (July 23, 2013) FLORIDA TODAY, available at <http://www.usatoday.com/story/news/nation/2013/07/23/return-of-military-draft-not-in-sight/2578847/> (last visited Feb. 24, 2014).

⁹⁹ *The Japanese Attacked Pearl Harbor December 7, 1941*, AMERICA'S LIBRARY, available at http://www.americaslibrary.gov/jb/wwii/jb_wwii_pearlhar_1.html (last visited on Feb. 24, 2014).

¹⁰⁰ M. HOWARD, & P. PARET, CARL VON CLAUSEWITZ: ON WAR 75, (EDS. AND TRANS.) (1976).

¹⁰¹ *Id.*

¹⁰² *Rosie the Riveter-Changing American History*, FEDERAL HIGHWAY ADMINISTRATION, (March 8, 2012), available at <http://www.fhwa.dot.gov/wit/rosie.htm> (last visited Feb. 24, 2014).

¹⁰³ *Id.*

era as policies were changed that took the “paradoxical trinity” out of balance (educational/political deferrals from the draft, no bombing of the North Vietnamese center of gravity, etc.).¹⁰⁴ Today, the unintended consequences of laws such as the Bayh-Dole Act of 1980, which in effect puts potential “profits” ahead of the health of our brain-injured soldiers, are extending this lack of balance into the twenty-first century. Reforming the Bayh-Dole Act of 1980, or creating some exceptions to it on behalf of our brain-injured veterans, will help our wounded soldiers regain their balance, as well as help our country regain its balance.

Since the end of the Vietnam War, the U.S. has relied on an all-volunteer force, much like the Prussians did in their conflict with the French. For most Prussian soldiers, fighting in a war was a job, and for the French, it was a “call to the colors.”¹⁰⁵ France’s ability to mobilize resources and its willingness to fight was the strategic difference that led it to resolute victory over the Prussians.¹⁰⁶ Even so, since the September 11, 2001 attacks on the World Trade Center and Pentagon, and despite President Bush statement on the rubble of the entombed terrorism victims declaring that “the people who knocked down these building will hear all of us soon,” implying that everyone in the country is now involved, the U.S. has chosen to continue its “military revolution” of the all-volunteer force and has not called the U.S. people or its resources to the colors.¹⁰⁷ In fact, in a move that would seem opposite a “call to colors,” the U.S. even lowered taxes in May 2003.¹⁰⁸ In addition, in another move that would seem contrary to a

¹⁰⁴ *How the Draft Has Changed Since Vietnam*, SELECTIVE SERVICE SYSTEM, (Apr. 30, 2002) available at <http://www.sss.gov/viet.htm>; HARRY G. SUMMERS, ON STRATEGY: A CRITICAL ANALYSIS OF THE VIETNAM WAR 154 (2009).

¹⁰⁵ Ross, *supra* note 97.

¹⁰⁶ *Id.*

¹⁰⁷ G. W. Bush, *Standing upon the ashes on the worst terrorist attack on American soil President Bush pledges*, GEORGEWUSH-WHITEHOUSEARCHIVES.GOV, (Sept. 14, 2001), <http://georgewbush-whitehouse.archives.gov/president/response/05.html> (last visited Feb. 24, 2014).; R. Norman Moody, *After 40 years, return of military draft not in sight*, (July 23, 2013 3:44 PM) FLORIDATODAY.COM, <http://www.usatoday.com/story/news/nation/2013/07/23/return-of-military-draft-not-in-sight/2578847/> (last visited Feb. 24, 2014).

¹⁰⁸ Richard Cheney, *U.S.: Best pro-growth, pro-jobs environment in industrialized world*, AMERICAN PRESIDENCY PROJECT, available at (March 29, 2004 10:20 AM), <http://www.presidency.ucsb.edu/ws/?pid=80848> (last visited Feb. 24, 2014).

“call to colors,” the U.S. allowed the Taliban a safe-haven, for political reasons, in the mountains of Waziristan, an under-governed region of Pakistan.¹⁰⁹ This seems oddly similar to the safe-haven that the U.S. provided the North Vietnamese Army in North Vietnam and Cambodia during the Vietnam War.¹¹⁰ Services that were provided to the flag in WWII by draftees, including the sale of war bonds and the “eminent domain-ing” of hotels by the U.S. Army in Miami Beach to serve as military training barracks, have been replaced by, according to Representative Charles Rangel on Good Morning America, an “economic draft”- enlistment bonuses, conversion of the Reserves from a strategic reserve to an operational force, and the use of contractors (i.e. KBR, Blackwater, privatized housing, etc.) working for a profit.¹¹¹ Again, in the case of our brain-injured warriors, the unintended consequences of the Bayh-Dole Act of 1980 exacerbate this focus on “profits” over the health of our people and may have a negative impact on raising an all-volunteer force for the next war. And, as history shows us, it is not a question of whether there will be a next war, but instead, *when* that next war will be.¹¹²

¹⁰⁹ Seth G. Jones, *What Went Wrong in Afghanistan? Allowing a Sanctuary in Pakistan*, RAND CORPORATION, (Mar. 5, 2013), available at <http://www.rand.org/blog/2013/03/what-went-wrong-in-afghanistan-allowing-a-sanctuary.html> (last visited Feb. 24, 2014).

¹¹⁰ Edwin E. Moise, *Limited War: Vietnam: Privileged Sanctuaries?* (Nov. 24, 1998), available at <http://www.clemson.edu/caah/history/FacultyPages/EdMoise/limit3.html> (last visited June 4, 2014).

¹¹¹ D. Markus, *Miami 1941-1945 From VIP Suites to GI Barracks*, MIAMI BEACH VETS, available at <http://www.miamibeachvets.com/>; *Congressman Fired Up by Prospect of Draft. As War Trudges on, Bush Advisor Suggests Military Draft Might be Worth Considering*, ABC NEWS, (Aug. 12, 2007), available at <http://abcnews.go.com/print?id=3471496>; *Army Force Generation*, APD.ARMY.MIL, (Mar. 14, 2011), available at http://www.apd.army.mil/jw2/xmldemo/r525_29/main.asp; Jeremy Scahill, *Flush with Profits from the Iraq War, Military Contractors See a World of Business Opportunities*, ALTERNET, (Aug. 13, 2007), available at http://www.alternet.org/story/59571/flush_with_profits_from_the_iraq_war_military_contractors_see_a_world_of_business_opportunities; Captain Stacie A. Remy Vest, *Military Housing Privatization Initiative: A Guidance Document for Wading Through the Legal Morass*, 53 A. F. L. REV. 1, 2 (2002), available at <http://www.afjag.af.mil/shared/media/document/AFD-081204-025.pdf>.

¹¹² David Piper, *North Korea's New Threat: War Not a Question of If, but When*, FOX NEWS, (Apr. 5, 2013), available at

Now that the war in Iraq has ended and the war in Afghanistan is winding down, economic pressures resulting from the recession, the ACA, and "sequestration" are putting pressure on the military to reduce personnel and readiness costs.¹¹³ In fact, on February 23, 2014, the Defense Secretary released a plan to cut U.S. military costs by reducing personnel and benefits.¹¹⁴ These cutbacks could potentially force the U.S. into a draft in the future. In 2007, U.S. Army Lieutenant General Douglas Lute, the newly-appointed White House war czar, urged the consideration of implementing a draft and stated, "I think it makes sense to certainly consider the draft and I can tell you, this has always been an option on the table. But ultimately, this is a policy matter between meeting the demands for the nation's security by one means or another."¹¹⁵ His comments were quickly clarified by National Security Council spokesman Gordon Johndroe, who stated, "The President's position is that the all-volunteer military meets the needs of the country and there is no discussion of a draft."¹¹⁶ However, in July 2007, Admiral Mike Mullen, the nominee to serve as the next chairman of the Joint Chiefs of Staff, candidly said, "the U.S. did not fully integrate all elements of national power in Iraq."¹¹⁷ It can be speculated that one of those powers Admiral

<http://video.foxnews.com/v/2280404232001/north-koreas-new-threat-war-not-a-question-of-if-but-when/#sp=show-clips> (last visited Feb 24, 2014).

¹¹³ Katie Pavlich, *Obama Pushing ObamaCare on Troops, Forcing Them to Pay at Least Triple for Care*, TOWNHALL.COM, (Feb. 28, 2012), available at http://townhall.com/tipsheet/katiepavlich/2012/02/28/obama_cutting_medical_care_for_troops_to_push_obamacare; Dylan Mathews, *The Sequester: Absolutely Everything You Could Possibly Need to Know, in One FAQ*, WASH. POST, (Mar. 1, 2013), available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/02/20/the-sequester-absolutely-everything-you-could-possibly-need-to-know-in-one-faq/> (last visited Feb. 24, 2014).

¹¹⁴ Dion Nissenbaum & Julian E. Barnes, *U.S. Military to Unveil Plan to Cut Personnel Costs*, WALL ST. J., (Feb. 21, 2014), online.wsj.com/news/articles/SB10001424052702303636404579397333410583004?mg=reno64-wsj&url=http%3A%2F%2Fonline.wsj.com%2Farticle%2F%2FSB10001424052702303636404579397333410583004.html (last visited Feb 24, 2014).

¹¹⁵ R. Lardner, *War Czar Says Draft is Worth Considering*, ARMY TIMES, (Aug. 13, 2007), available at http://www.armytimes.com/news/2007/08/ap_draft_lute_070810/ (last visited Feb. 24, 2014).

¹¹⁶ *Id.*

¹¹⁷ W.H. McMichael, *Senate Approves Mullen to Lead Joint Chiefs*, AIR FORCE TIMES,

Mullen was referring to, and on the “back shelf” of everyone’s mind in Congress, is the Selective Service System.¹¹⁸ If we are in fact a nation totally committed to an all-volunteer force, why do U.S. taxpayers bear the expense of having every eighteen to twenty-five year old male still register?¹¹⁹

VI. ANALYSIS OF THE MEDICAL-LEGAL PROBLEM

There is no doubt that the U.S.’s ability to leverage medical technological advances provided strategic, operational, and tactical advantages over our enemies and contributed to our success from WWI through the Vietnam War. In addition, so far no country in the history of the world has dedicated more resources to its military or to the advancement of medical technology and medical support on the battlefield on behalf of its soldiers than the U.S. has.¹²⁰ Despite these advancements, the medical-legal problem caused by the unintended consequences of the Bayh-Dole Act of 1980 is now negatively impacting our country’s ability to care for its brain-injured veterans returning home from Iraq and Afghanistan. On one hand, much of the problem can be attributed to the choice of weaponry used by Islamic terrorists, IED’s, and the “signature wound” which they cause, brain injury. On the other hand, the problem is being contributed to by the “sentinel effect” in trauma treatment, which is what is seen by physicians with their own eyes and usually gets treated first.¹²¹

(Aug. 7, 2007), *available at*

http://www.airforcetimes.com/news/2007/08/army_mullen_070803w/ (last visited Feb. 24, 2014).

¹¹⁸ SELECTIVE SERVICE SYSTEM, *supra* note 104.

¹¹⁹ *Id.*; R. Norman Moody, *After 40 Years, Return of Military Draft Not in Sight*,

FLORIDA TODAY, (July 23, 2013), *available at*

<http://www.usatoday.com/story/news/nation/2013/07/23/return-of-military-draft-not-in-sight/2578847/> (last visited Feb. 24, 2014).

¹²⁰ Brad Plumer, *America’s Staggering Defense Budget, in Charts*, WASH. POST, (Jan. 7, 2013), *available at*

<http://www.washingtonpost.com/blogs/wonkblog/wp/2013/01/07/everything-chuck-hagel-needs-to-know-about-the-defense-budget-in-charts/> (last visited Feb. 24, 2014).

¹²¹ David H. Wisner, M.D., Noel S. Victor, M.D., & James W. Holcroft, M.D., *Priorities in the Management of Multiple Trauma: Intra-Cranial Versus Intra-Abdominal Injury*. 35 (2) J. TRAUMA 274-275 (1993); Shirzad Houshian, M.D., Morten S. Larsen, M.D., & Carsten Holm, M.D., *Missed Injuries in a Level I Trauma Center*. 52 (4) J. TRAUMA,

According to General Chiarelli, who, as the U.S. Army's number two general in charge, oversaw the operation of the Army Medical Department, "this is why we treat amputated legs with advanced prosthetics--where people are walking in a few months, but we are still very limited in treatments to help people think properly again."¹²² General Chiarelli continued, "if the force of the blast is enough to severe a soldier's legs, it has probably affected their brain as well."¹²³

In his keynote address to the American Health Lawyers Association (AHLA) national meeting in July 2013, General Chiarelli stated, "of the injuries that have a single disability diagnosis of greater than 30% (which is a significant number, providing enhanced disability benefits) by the VA from the GWOT; 67% of these cases were soldiers with either BI or PTS (over eleven-thousand soldiers)."¹²⁴ He emphasized, "TBI has tremendous costs in terms of long-term care for both soldiers and civilians," with the NFL concussion lawsuit again as just one example.¹²⁵ In addition, scientific evidence suggests that TBI can lead to the early onset of Alzheimer Disease and Parkinson's Disease, which going forward "will need to be considered by the courts," and the VA, in determining disability compensation settlements.¹²⁶ Furthermore, as the world's population ages, Alzheimer Disease International projects that over 115 million people will suffer from Alzheimer Disease by 2050.¹²⁷ Even our potential

INJURY, INFECTION, & CRITICAL CARE 715-719 (2002).

¹²² Feng Yi, Shi Zhonghua, Wang Yuhai, Dong Jirong, & Cai Xuejian, *Missed Injury in Patients With Severe Traumatic Brain Injury Complicated by Multiple Trauma*, TURKISH NEUROSURGERY (2013), available at <https://www.readbyqxmd.com/read/23546905/missed-injury-in-patients-with-severe-traumatic-brain-injury-complicated-by-multiple-trauma>; Peter W. Chiarelli, *Annual Meeting Keynote Address*, HEALTH LAWYERS, (July 2013), available at <http://www.healthlawyers.org/Events/AnnualMeeting/2013/Pages/AM2013.aspx> (last visited Feb. 24, 2014).

¹²³ Chiarelli, *supra* note 122.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ Tanya C. Lye & E. Arthur Shores, *Traumatic Brain Injury as a Risk Factor for Alzheimer's Disease: A Review*, NEUROPSYCHOLOGY REV., (June 2000); C.H. Tsai, et. al., *Environmental Risk Factors of Young Onset Parkinson's Disease: A Case-Control Study*, CLINICAL NEUROLOGY & NEUROSURGERY, (Sept. 2002); A "Tsunami" Headed at Veterans, 60 MINUTES, (May 5, 2013), available at <http://www.cbsnews.com/video/watch/?id=50146243n> (last visited Feb. 24, 2014).

¹²⁷ *Policy Brief for Heads of Government: The Global Impact of Dementia 2013-2050*,

military adversaries, such as China, are now facing an Alzheimer Disease crisis in their population, and it is only projected to get much worse.¹²⁸

According to General Chiarelli, this is a \$78 billion problem, as scientific studies show that 8% of total population will experience some form of PTS or other brain injury in their lifetime. Nonetheless, the NIH spent only less than 1% (\$84 million) of their \$40.1 billion annual grants on this problem, and there are really no drugs in the R&D pipeline for TBI or PTS (that the public knows of).¹²⁹ Meanwhile, the taxpayers expect the U.S. military, while trying to fight and win wars using their money, to share data in order to save soldier's lives and save taxpayer resources. In spite of this, because of the Bayh-Dole Act, research institutions using taxpayer dollars for R&D that might have shared information in prior wars for the benefit of the soldiers, do not normally share data now because it might eat into their potential profits. Simultaneously, the plight for brain-injured veterans is not getting much better. *The Wall Street Journal's* article "Saved but Not Cured: A Brain-Injured Vet's Search for Solace," lends further support to the hypothesis that recent advances in battlefield medicine keep alive troops with head wounds that might have killed them in World War II, Korea, or Vietnam but that science has not kept pace in its ability to cure.¹³⁰

So, what can be done about the unintended consequences of the Bayh-Dole Act on behalf of our brain-injured heroes of Iraq and Afghanistan?

ALZHEIMER'S DISEASE INTERNATIONAL, *available at*

<http://www.alz.co.uk/research/GlobalImpactDementia2013.pdf>.

¹²⁸ Rosalind Mathieson, *China Adopts Board-Game Strategy to Blunt U.S. Pivot to Asia*, BLOOMBERG NEWS, (Dec. 10, 2013), <http://www.bloomberg.com/news/2013-12-09/china-adopts-board-game-strategy-to-blunt-u-s-rebalance-in-asia.html> (last visited Feb. 24, 2014); Anjali Cordeiro, *At 71 Farmer Dresses Wife as China Faces Alzheimer's Crisis*, BLOOMBERG NEWS, (Jan. 27, 2014), <http://www.bloomberg.com/news/2014-01-27/at-71-farmer-dresses-wife-amid-china-alzheimer-s-crisis.html> (last visited Feb. 24, 2014).

¹²⁹ *Dispelling the Myths About Post-Traumatic Stress Disorder (PTSD) & Other Psychological Health Issues*, AMERICA'S HEROS AT WORK, *available at* <http://www.americasheroesatwork.gov/forEmployers/factsheets/dispellMyth/> (last visited Feb. 24, 2014); Chiarelli, *supra* note 122.

¹³⁰ Phillips, *supra* note 1.

VII. POTENTIAL SOLUTIONS

First, this author echoes former President Bush's new initiative announced on February 20, 2014, to provide better funding and support to the 1% of the U.S. population that has kept the other 99% safe over the past decade of war.¹³¹ According to a Harvard University report released in 2013, the cost of the wars, including health care for veterans, could be up to \$6 trillion, with many of the healthcare costs yet to be realized.¹³² With the scientific link between brain injury and debilitating diseases like Alzheimer's and Parkinson's, which are projected to affect hundreds of millions of people world-wide in the next thirty-five years, we need a new Manhattan-type project for the twenty-first century to cure brain injury and disease.¹³³ This project should be headed by the federal government, which needs to start better helping our brain-injured veterans returning home from Iraq and Afghanistan. The passing of the ACA into law, and the enrollment of over 7.5 million people in government regulated health plans, which surpassed expectations, strongly suggests that American citizens want their federal government to become more involved with the provision of healthcare.¹³⁴ The potential reduction in healthcare costs that would result from cures to brain injury and diseases presents an opportunity for our federal government to save money.¹³⁵

This author does not argue for a complete repeal of the Bayh-Dole Act, recognizing that parts of the Act were hailed "as possibly the most inspired piece of legislation to be enacted in America over the

¹³¹ Lee Ann Caldwell, *Bush Calls Out the 99%*, CNN, (Feb. 20, 2014), available at <http://www.cnn.com/2014/02/19/politics/bush-veterans/>.

¹³² Blimes, *supra* note 70.

¹³³ Michael Copeland, *The Government's New BRAIN Initiative: The Next Manhattan Project?*, SPARK.QUALCOMM.COM, (Apr. 22, 2013), available at <http://spark.qualcomm.com/blog/government-s-new-brain-initiative-next-manhattan-project> (last visited Feb 24, 2014).

¹³⁴ David Morgan, *Obamacare Enrollment to Surpass 7.5 Million: U.S. Official*, REUTERS U.S. (April 10, 2014, 3:01 PM), available at <http://www.reuters.com/article/2014/04/10/us-usa-healthcare-obama-idUSBREA3918920140410>.

¹³⁵ Galantly Miller, *49 Percent of Americans Support the Majority Opinion: The Sociology of Obamacare Poll Numbers*, HUFFINGTON POST, available at http://www.huffingtonpost.com/galanty-miller/obamacare-poll-numbers_b_4008923.html.

past half-century” because they “helped to reverse America's precipitous slide into industrial irrelevance.”¹³⁶ Despite its accolades, this author agrees with Dr. Joseph Fins, of New York Presbyterian-Weill Cornell Medical Center, that the Bayh-Dole Act should be revised “by suspending transfer rights of intellectual property until Phase II studies are ready to commence.”¹³⁷ In Phase I studies, “researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects, but in Phase II studies, “the drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.”¹³⁸ As a result, this author advocates that during this crisis in brain injury research, the U.S. government should retain all rights to Phase I studies, so that potential Phase II studies and treatments can be fast-tracked directly to brain-injured veterans of the wars in Iraq and Afghanistan.

Second, the Bayh-Dole Act should be reformed to force any research entity that is receiving NIH (taxpayer) funding to publish the results of, or enter into a national database, all of their Phase I, and potentially Phase II, studies that did *not* work. This will help mitigate the costs by minimizing the duplications of effort taking place in different entities on things that do not work.¹³⁹ As a result of Bayh-Dole, many organizations now hoard their data in an effort to protect their potential profitability from competitors.¹⁴⁰ A new policy of forcing entities to share their failures in a timely manner should lead to the quicker and less expensive development of cures for the benefit of the soldiers, the taxpayers, and society, while still being profitable for the actual discoverer. The sharing of data is not unheard of and is taking place in the field of Genomics, where in June

¹³⁶ Howard Markel, M.D., Ph.D., *Patents, Profits, and the American People — The Bayh-Dole Act of 1980*, NEW ENG. J. MED., (Aug. 29, 2013), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1306553#t=article>.

¹³⁷ Joseph J. Fins, M.D., *Deep Brain Stimulation, Free Markets and the Scientific Commons: Is It time to Revisit the Bayh-Dole Act of 1980?*, NEUROMODULATION 10; 13: 156, available at <http://www.ncbi.nlm.nih.gov/pubmed/21992826>.

¹³⁸ U.S. NATIONAL LIBRARY OF MEDICINE, FAQ CLINICALTRIALS.GOV-CLINICAL TRIAL PHASES, available at <http://www.nlm.nih.gov/services/ctphases.html>.

¹³⁹ *Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs*, NATIONAL INSTITUTES OF HEALTH, (Jan. 3, 2014), available at http://grants.nih.gov/grants/funding/sbirsttr_programs.htm

¹⁴⁰ Peter W. Chiarelli, *supra* at note 122.

2013 the U.S. Supreme Court issued a unanimous opinion in *Association for Molecular Pathology v. Myriad Genetics* that invalidated the claim of ownership of the breast cancer 1, early onset (BRCA1) and breast cancer 2, early onset (BRCA2) genes from research that was funded by NIH grants under the Bayh-Dole Act.¹⁴¹

VIII. CONCLUSION

While Congress intended to stimulate the economy and help bring the country out of the recession of the late 1970's by passing the Bayh-Dole Act, Congress unfortunately failed to anticipate the unintended consequences that the Act would have on War Veterans, such as Sergeant Cory Remsburg, who are now suffering from TBI/MTBI and/or PTS. Who knew it would take a twenty-first century war, against terrorists (not a state), with a new weapon system, the IED, and a new "signature injury," the brain injury, to realize the problem? It also appears that Congress did not foresee the potential impact the Act may have on the balance of U.S. national security posture in the future, as we continue to rely on an all-volunteer force.

While the U.S. has historically had a clear advantage over its opponents, due in large part due to technological advances, the current structure of Bayh-Dole Act weakens that advantage by providing an undeniable incentive for private organizations to keep the results of their research experiments to themselves, even though early intervention in brain-related injuries could potentially be life-changing for wounded veterans and their families. There is some evidence that Congress' views may be changing. H.R. 3547 became law on January 17, 2014 and includes language that requires Health and Human Services and other government departments with research budgets of \$100 million or more to provide the public with online access to articles resulting from federally funded research within twelve months of publication in a peer-reviewed journal.¹⁴² However, as General Chiarelli states, "publication in peer reviewed

¹⁴¹ Markel, *supra* note 135; http://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=1100; http://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=1101.

¹⁴² Consolidated Appropriations Act, 2014, Pub. L. No. 87-195, 75 Stat. 424, <http://beta.congress.gov/bill/113th-congress/house-bill/3547>.

journals is far too long for our wounded warriors to wait.”¹⁴³

While the Bayh-Dole Act has been largely successful in achieving its original goals, the Act should be modified to require recipients of NIH grants to share their early research findings specifically with the federal government, considering that only 1% of the U.S. population, the military, selflessly fought to protect the other 99% of us in the wars over the past decade.

Or lastly, in light of the recent issues with the VA, maybe the benefits of ACA law can be better leveraged by the federal government for the benefit of our brain-injured veterans.¹⁴⁴ Instead of an estimated 20,000-plus brain-injured veterans from the wars in Iraq and Afghanistan going to the VA for their care, perhaps the funds allocated to the VA for brain injury treatment could be used by the federal government to create tax-subsidies for brain-injured veterans to buy private health insurance through the ACA healthcare exchanges instead.¹⁴⁵ It is a fact that by the end of 2014 there can no longer be a prohibition on pre-existing conditions in any U.S. health insurance plan.¹⁴⁶ Therefore, maybe these brain-injured veterans could use ACA health insurance to seek their care directly from the academic institutions that are already receiving NIH funding to conduct traumatic brain injury research, such as the University of Miami Miller School of Medicine, or other prominent institutions.¹⁴⁷

Exploring these solutions to the unintended consequences of the Bayh-Dole Act is the least we can do for these heroes, but in the end, these solutions also have the potential to benefit millions more world-wide that suffer from brain injury and disease.



¹⁴³ Chiarelli, *supra* note 122.

¹⁴⁴ Bill Chappell, *VA Chief Eric Shinseki Resigns Post, Obama Announces*, NPR (May 30, 2014, 10:15 AM), available at <http://www.npr.org/blogs/thetwo-way/2014/05/30/317350806/calling-va-problems-indefensible-shinseki-will-fire-phoenix-leaders>.

¹⁴⁵ Department of Defense Numbers for Traumatic Brain Injury, *supra* note 25.

¹⁴⁶ Julie Rovner, *Are Pre-Existing Condition Bans For Health Insurance Still With Us?* (June 2, 2014), available at <http://www.wbur.org/npr/318210356/are-pre-existing-condition-bans-for-health-insurance-still-with-us>.

¹⁴⁷ *NIH Grant Funds Traumatic Brain Injury Research* (April 1, 2014), available at <http://med.miami.edu/news/nih-grant-funds-traumatic-brain-injury-research>.