ADVANCING ETHICAL RESEARCH PRACTICES IN THE MILITARY

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Military Medical Research: A Necessary Challenge

“We have implanted a tiny chip in the brain… that can be used to control computers, turn lights on and off… [and] control robotic devices like an artificial hand…or a robotic arm.”1

Brain chips, once considered to be an implausible technology that only had a place in science fiction films, are now reality, being tested in research laboratories around the country. Interest in brain-chip research began with the hope of enabling disabled patients, in particular those with quadriplegia, to use their brain waves to communicate with an external computer system.2 Brain chips currently allow patients to control electrical devices from afar by monitoring the electrical activity in a small part of the brain and then relaying that information to the particular machine that the individual wants to use.3 Individuals with brain chips are able to surmount what is normally catastrophic neurological damage, and are able to perform common, manual tasks utilizing electronic devices that are controlled by their thoughts.4 Although brain chips are used by patients with physical disabilities for therapeutic purposes, the next step in developing this technology is to augment or replace normal human sensory and communicative capabilities.5

Military personnel will be the first group of individuals to participate in brain-chip research studies for enhancement purposes.6 The Defense Advanced Research Projects Agency (“DARPA”), established to maintain “the technological superiority of the U.S. military,” undertakes a myriad of scientific projects such as these to improve the performance of military personnel on the battlefield.7 DARPA already has launched a $26 million Brain-Machine Interface (“BMI”) research project, investigating the ability of individuals to use thoughts to control robots at a distance.8 Some of the possible benefits that may result from these chips include an increase in the range of sensory abilities, the capacity to interface with weapons, the enhancement of one’s memory or reflexes, and the ability for soldiers to communicate with other soldiers on the battlefield.9 As a result, brain-chip research
Think! (or the Whiteness of the Whale)

So what do Aretha Franklin, Herman Melville and a Nobel laureate in economics have in common? Read on, shipmates, read on.

I have long believed that a critical skill in the practice of law is the ability to understand the context of my clients’ problems. For me, this skill was largely learned during the years I spent working as a nurse practitioner. I was educated in the old school by clinicians who believed that the most important element of clinical decision-making was the patient history. As a founder of modern medicine, Sir William Osler, told his students, “Young doctor, listen to your patient. He is telling you his diagnosis.” From that one might deduce the nature of the patient’s illness. So too, the seasoned lawyer learns to examine the circumstances of his or her client’s problems and then to compare the findings with previous facts, observations and outcomes rooted in past experience, which, in turn, provide the basis for recommendations to the client. As lawyers, we are frequently asked by clients to assess the degree of risk inherent in a situation or to recommend a particular course of action, whether it be in litigation or a business transaction. We usually are able to provide an answer, even if it is hedged by the usual qualifiers. Nonetheless, we are satisfied that we have provided our clients with a reasonably accurate assessment. Is our confidence justified? Perhaps not.

It was a typical Saturday night in the ER of the county hospital in Oakland where I moonlighted on weekends. In between the heart attacks and gunshot wounds, one of the residents told me about an article she had read in Science that led to her changing the way she thought about practicing medicine. It was titled “Judgment under Uncertainty: Heuristics and Biases” by Israeli cognitive psychologists Daniel Kahneman and Amos Tversky. In the 27 years since I first encountered it, it remains the academic article that has most influenced me.

Kahneman, who received the Nobel Prize in economics in 2002 (the only person to have achieved this without graduate work in economics) and his friend and long-time collaborator, Tversky, are considered to be among the founders of the discipline of behavioral economics, which is the basis for such recent bestsellers as Nudge and Blink. Kahneman has recently summarized the results of his life’s work in this area in an eminently readable new book: Thinking, Fast and Slow. The article continued on page 35.
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provides a variety of opportunities for military applications.10

Brain-chip technology is only one example of a biological enhancement technology that the military is considering to augment soldiers’ performance.11 DARPA is continuing to develop and invest in biological enhancement technologies to maintain and improve the physical and cognitive performance of military personnel.12 The military is actively researching various “alertness” drugs such as Modafinil to combat exhaustion: it also pioneered Lasik surgery to rectify poor vision among its warfighters.13 In addition, Air Force pilots have taken a drug that is primarily used for Alzheimer’s disease to help them respond more efficiently to in-flight emergencies.14

The United States is not the only country to utilize these enhancement technologies. For example, Israel and the French Foreign Legion have administered Provigil and Donepezil to their troops to improve concentration, focus, and memory.15

In developing new technologies to keep pace with foreign militaries that are performing similar research, the U.S. military has utilized human subjects for testing.16 While this research is conducted with the goal of advancing national security, military leadership is faced with the need to adhere to basic bioethical principles when undertaking clinical research.17

Key to these principles is the right to preserve one’s autonomy in the research setting. To preserve such autonomy, one determines what he or she wants to do with his or her body by giving consent after being well informed of the risks and details that are associated with a study.18 However, military personnel are a vulnerable clinical research population warranting additional protections. The military fails to meet all of the requirements for informed consent, as the structure of military life influences military personnel who are deciding whether or not to participate in research. In addition, current regulations, the U.S. judicial system and internal military procedures fail to provide adequate protections from and remedies for the injuries that military personnel incur as a result of medical research.

To better protect the autonomy of military personnel while continuing to further medical research, the Department of Defense (“DOD”) and the Department of Health and Human Services (“HHS”) should implement additional protections, particularly with the development of more advanced and invasive technologies on the horizon. In addition, the courts should enable members of the military to bring a claim under the Federal Tort Claims Act (“FTCA”) against the government for injuries that result from military medical research studies as well as a Bivens action in order to punish officers who violate constitutional rights.

Informed Consent and Lack Thereof in the Military Environment

In the United States, one has the constitutional right to personal autonomy and bodily integrity in accordance with the Fourteenth Amendment.19 It is a fundamental concept in American jurisprudence that competent individuals should be able to determine what they do with their bodies by giving informed consent.20 In order to give informed consent, the individual must be competent and be able to comprehend the information given to him/her.21 In addition, one must be able to volunteer without being unduly influenced or coerced into making a decision, and the research investigator must provide all of the pertinent details and risks associated with the study.22 The hierarchical structure of the military, however, can adversely affect the ability of military personnel to give informed consent.

Coercive Forces in the Military Environment Prevent Voluntary Decisions

Many factors unduly influence military personnel when they decide to participate in human subject research, some of which cut against the norm of autonomy and the practice of informed consent. First, military personnel must relinquish certain aspects of their lives that are normally autonomous, contributing to an environment in which it may be difficult to abstain from participating in any task requested of them. For example, in accordance with Army Regulation 670-1, a soldier must maintain uniformity with regard to hair and grooming practices, keeping hair a certain length and only using certain color dyes.23 Military regulations also require soldiers to be vaccinated against a variety of diseases, regardless of a military member’s religious beliefs.24 When soldiers begin their training, they not only abide by these stringent rules, but they must also follow a strictly regimented schedule that the institution dictates.25 When forgetting many normally autonomous aspects of their lives, military personnel may interpret an option to take part in these studies as another task that is mandatory, rather than a voluntary choice.

Second, soldiers may feel pressure from superiors as well as comrades to participate in clinical research. Throughout the training process, the soldier learns to perform every activity in formation with his or her peers, and a “good” soldier is one who “follows directions laid down for him in the institutional situation.”26 A soldier may aim to please superiors
avoid punishment\textsuperscript{17} and earn a promotion. Military personnel may fear that they will not be asked to participate in particular missions if they do not receive the particular technology that is being studied.

For example, certain missions may require one to communicate “invisibly” with other soldiers or robotic technologies from afar. Without a brain chip, a soldier would be unable to communicate in this manner, and would not be able to partake in a mission that could result in a promotion. Furthermore, as a result of the camaraderie that is inherent in a military environment, a soldier may also feel obligated to participate in any medical research that his or her peers are completing. Soldiers may feel like they would lose the respect of their comrades if they were to fail to participate. These two sources of pressure may heavily influence soldiers to the point of coercing them into participating in research that they may otherwise not have completed.

Third, soldiers may feel pressure to participate in military medical experiments as a result of their fervent patriotism. Patriotism can be seen as a larger form of unit cohesion, seeing a duty to one’s country as being similar to the duty to one’s comrades.\textsuperscript{26} Many men and women enlist because “they want to do something bigger than themselves—something for their nation that they can be proud of.”\textsuperscript{29} Although patriotism is commendable, it may hinder a soldier’s ability to rationally weigh the costs and benefits of participating in a government-run medical study. Soldiers may feel pressured to participate in these human subject research studies, as they may see this action as an additional way to serve their country.

Despite these arguments, one may contend that military personnel are as capable of consenting to clinical research as members of the civilian population, and therefore do not need additional protections for human subject research. First, one may argue that the pressure from superior officers and comrades to participate in medical research is no different from the pressure that one feels from society to participate in medical research for the civilian population. In both scenarios one may choose not to participate regardless of what one’s peers or superiors choose to do.

In addition, military regulations impede superior officers and comrades from discovering whether an individual soldier has decided to participate in military research, thereby alleviating some of the pressure that the soldier may feel to participate in research.\textsuperscript{10} Furthermore, one might argue that even the most patriotic individuals can rationally weigh the costs and benefits of a research study. It is not irrational to believe that the benefit of serving the government outweighs the costs to one’s mental and personal health, and in fact, this view is not logically different from the common view held by military personnel who already have decided to risk their lives for their country.

Although these are valid arguments, it is unlikely that civilians feel the same amount of pressure from peers to participate in medical research as do military personnel, nor are their jobs tied in any way to participating in clinical research. In addition, even though regulations exist to prevent officers and comrades from knowing whether or not an individual decided to participate in research, these protections are not always effective from a practical standpoint. For example, if one chooses to participate in brain chip research, he or she may have a noticeable scar from the surgical procedure. Finally, as many who chose to join the military possess a fervent patriotism, they may accept government requests without evaluating the associated risks. As a result, that decision fails to meet all of the requirements of informed consent.

Lack of Full Disclosure Also Prevents Informed Consent

In addition to the undue influence that may result from being in a military environment, the military also has a history of failing to disclose the pertinent details and risks of its studies.\textsuperscript{31} Three examples of studies in which military personnel were deceived into participating in research include the Navy “Man Break” Experiments, the dispensation of Lysergic Acid Diethylamide (“LSD”) in Project MKULTRA and the administration of non-Food and Drug Administration (“FDA”) approved drugs during Operation Desert Shield. These experiments, which were conducted without obtaining informed consent from participants, resulted in numerous, egregious harms of military personnel.

Beginning in 1943, the U.S. Navy tested the protective abilities of clothing and gas masks against the effects of mustard gas, in what were known as the “Man Break” experiments.\textsuperscript{32} Mustard gas is an inconspicuous, toxic gas that can cause severe blistering of the skin, blindness and even death.\textsuperscript{33} The United States and Great Britain feared the possible use of mustard gas by both the German and Japanese armies.\textsuperscript{34} Members of the Navy who participated in these experiments were confined to small huts and then given masks before mustard gas was administered through the ceiling.\textsuperscript{35}

These individuals had not been told that they were going to be subjected to the gas.\textsuperscript{36} Many individuals were told instead that they were being asked to merely “test summer uniforms for the Navy.”\textsuperscript{37} Individuals also were told that if they did not participate,
they would receive a forty-year prison sentence in the army prison located at Fort Leavenworth. As a result of participation achieved through deception and coercion, a number of Navy personnel suffered permanent lung damage, heart attacks, blistering of the skin, and other horrific, long-term effects.

Project MK-ULTRA was a clandestine Central Intelligence Agency ("CIA") experiment that began in 1950, in which both U.S. civilians and military personnel were given various mind-altering drugs, including LSD, to enable the government to study mind-control techniques. The United States conducted these tests to counter perceived advances in brainwashing techniques by the Soviet and Chinese governments. The experiments utilized the use of unwitting subjects, as "...the effectiveness of interrogation... [could not] be established solely through testing on volunteer populations."

Dr. Sidney Gottlieb, the physician who headed these medical experiments, felt that informed consent was not necessary when "national survival might be concerned." Dr. Gottlieb specialized in the development of lethal biological agents designed to assassinate leaders who were hostile to U.S. interests. Some of the individuals who were administered these drugs suffered from permanent psychological problems as a result of the experiment. One research subject, himself an Army researcher, developed both depression and paranoia as a result of ingesting LSD and jumped to his death from a 10th floor hotel room. These experiments with psychedelic drugs were not halted until 1972, when Dr. Gottlieb concluded that the experiments were "too unpredictable in their effects on individual human beings... to be operationally useful."

The most recent example of deception in military medical research occurred during Operation Desert Shield, when medical drugs were administered to military men and women to protect them against chemical and biological warfare agents during the Persian Gulf War. The DOD informed the FDA that it was interested in giving troops a botulism vaccination in addition to a medication that protects against nerve agents. In accordance with the Food, Drug and Cosmetics Act ("FDCA"), all vaccines and medical products must be proven both safe and effective before the U.S. military utilizes the drugs. Under the FDCA, however, a medical product may be exempt from this regulation if the product is for "investigational use," as long as informed consent is obtained. The FDA, however, agreed to temporarily waive the informed consent requirement, as the Secretary of Defense for Health Affairs notified the agency that the vaccine would be given on a "voluntary basis." The DOD stated that it would put safeguards in place, including oral warnings regarding the vaccine and observation for 30 minutes of the military personnel who receive it.

Despite these promises, however, a high proportion of troops reported that they had no choice but to take the drugs, and most personnel claimed that they received no oral or written information about the drug or vaccine. In addition, several Persian Gulf War veterans interviewed reported that they were ordered to take these experimental vaccines or face time in prison. Military personnel also were ordered not to discuss their vaccination, under the threat of Article 15 or court martial. The consequences were catastrophic, with some soldiers suffering from incontinence, blurred vision, muscle weakness and memory loss.

On December 8, 1994, all three of these experiments came to light in a Senate Report prepared by the Committee on Veterans’ Affairs. Senator John Rockefeller, the chairman of the Committee, investigated the intentional exposure of military personnel to dangerous substances without consent for further Congressional deliberations. This report demarcated the limitations in obtaining informed consent in a military environment as well as the harms that resulted from placing thousands of U.S. service members at risk. In addition, the report noted that many veterans did not know that they were exposed to dangerous substances and were not properly monitored after the experiments ended. As a result, many harmed individuals would or did not apply for the medical care or compensation that they were entitled to, making these ethical violations even more problematic.

U.S. Regulatory Structure For Military Human Subject Research

In order to prevent atrocities like those previously described while continuing imperative medical research, HHS and the DOD have periodically issued directives and promulgated regulations aimed at improving the informed consent process to protect research participants. These guidelines have attempted to eliminate pressure from superior officers, prevent punishment of those who choose not to participate in research, ensure proper disclosure of study details and risks, and provide procedural guidelines for exceptional circumstances in which the obtaining of informed consent may be waived. These protections are insufficient, however, and additional guidelines are needed to preserve the autonomy of military personnel.

How These Regulations Developed

The regulations and directives pertaining to military human subject research have evolved since the first documented Army regulation issued in 1925 which provided that only volunteers should be utilized for experimental infectious disease research. Development in the field continued on page 6
of human subject research protection was expedited, however, in the aftermath of World War II. In 1953, the Secretary of Defense enacted the Wilson Memorandum, delineating safeguards to be implemented by the DOD when using human research subjects and to protect research subjects in DOD’s studies regarding atomic, biological and chemical warfare. These safeguards incorporated the principles of the Nuremberg Code — ten rules that were promulgated after the Nuremberg Medical Trials. The first of these rules emphasized the requirement to obtain informed consent from the subject prior to proceeding with human subject research.

After the enactment of the Wilson Memorandum, there was little discussion in the federal government regarding human subject research. During the 1970’s, several medical scandals were disclosed, including the Tuskegee Syphilis Study, in which hundreds of African Americans were not informed of their diagnosis or the nature of the study, and were denied proper treatment for their disease. As a result, Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to supervise all biomedical human subject research. This Commission created The Belmont Report, a guideline for human subject experimentation that emphasized three basic principles: respect for persons, beneficence and justice. This Report was later adopted as the “Common Rule” by many federal agencies, including the DOD in 1991.

**Current Regulations**

The Common Rule, which is also known as 32 C.F.R. 219, is important for human subject research in the military for three reasons. First, the Common Rule provides the general requirements for informed consent. In particular, it emphasizes the need to obtain one’s consent prior to his or her participation in research without any coercion or influence on that individual’s choice. Second, 32 C.F.R. 219 delineates the requirements for Institutional Review Boards (“IRBs”), groups with members of various backgrounds who review and must approve the research activities that are proposed by the various military branches. Most importantly, 32 C.F.R. 219 provides the pertinent criteria that need to be met for the research to be approved by the IRBs, including: the possible risks to subjects are minimized; informed consent is sought from each prospective subject or his or her legal representative prior to his or her participation in the study; and there is an opportunity for additional safeguards to be implemented in order to protect the welfare of participants who are more susceptible to coercion or undue influence.

In order to minimize undue influence and coercion from superior officers and military medical researchers, Department of Defense Directive (“DODD”) 3216.2 implements a requirement to prevent higher-ranked officers from influencing the decisions of lower-ranked military personnel. In addition, when a percentage of a unit is being recruited to participate in a study, an ombudsman not connected with the unit or the research experiment is required to be present to monitor the voluntary nature of the participants. The ombudsman also must monitor whether the information provided pertaining to the research is both adequate and accurate. DODD 3216.2 also enumerates the need for committees to ensure compliance with the various human research requirements. This includes creating procedures for the investigation and resolution of assertions of noncompliance with the requirements.

Army regulations 70-25 and 40-38, created in 1990 and 1989 respectively, provide additional direction for research, development, test, and evaluation programs carried out by the Army. One key element of these nearly identical documents is that they prevent military personnel from being subject to punishment under the Uniform Code of Military Justice if they choose not to participate as human research subjects. These documents also provide for Human Use Committees — groups of at least five members from diverse backgrounds who must approve studies involving human volunteers as research subjects. Despite these additional protections, however, these regulations fail to provide procedures for effective enforcement of compliance, resulting in inconsistent execution of human subject research protection programs.

In accordance with 10 U.S.C. § 980, informed consent must be obtained in advance of all DOD-funded research. That requirement may be waived, however, by the Secretary of Defense if the following criteria are met: 1) the research project is to develop a medical product that is necessary to the armed forces; 2) the research project may directly benefit the research participant; and 3) the research project is carried out in accordance with all applicable laws. There are a limited number of exceptions that qualify for this waiver, and IRBs must be consulted for experiments requiring third party consent (i.e. trauma or unconscious persons) to determine that there is a direct benefit to the research subject. An additional protection requires a military researcher who has obtained a waiver to provide public notification of the conduct of the study as well as to consult the community with regards to ethical concerns. It is unclear whether community consultation will be sought for experiments that are more confidential in nature, as the
government may not want other militaries to learn of recent scientific developments.

Problems with Redress in the Military Environment

In addition to concerns with coercion and lack of full disclosure when obtaining informed consent, military personnel additionally have trouble obtaining restitution for harms that result from some of these research studies. As a result of obstacles in both the U.S. judicial system as well as internal military procedures, injured military personnel are unable to voice concerns with medical human subject research, succeed in a claim for constitutional violations by superior officers or obtain tort damages for harms that occurred in these studies.

Inability to Redress Harms in the U.S. Court System

In Feres v. United States, which combined three pending federal cases: Feres, Jefferson and Griggs, the claimants sustained injuries while on active duty due to the alleged negligence of other military personnel. In Feres, the executrix of the decedent’s estate attempted to recover for a death that was allegedly caused by the negligent quarantining of the soldier in barracks that were unsafe due to a defective heater and an inadequate fire watch. The plaintiff in Jefferson, while an active member of the Army, had an abdominal surgery in which a large towel was negligently left in his body. In Griggs, the executrix of the decedent alleged that while on active duty, the decedent died as a result of army surgeons’ medical malpractice.

The Supreme Court reasoned that Congress did not intend to allow recovery through the FTCA since, although it is the statute that enables recovery against the government, 28 U.S.C. § 2672, it excludes claims that were “incident to service.” The Court also ruled that the FTCA did not apply to claims by military personnel because the government provides compensation for injuries or death of those in the armed forces or their families.

In accordance with Feres, a District Court granted summary judgment in favor of the government for a FTCA claim in United States v. Stanley. In that case, a serviceman volunteered for what he believed was a chemical warfare testing program, but was actually administered LSD instead. As a result of taking the drug, the respondent suffered from personality changes, which he claimed led to his discharge from the service as well as the dissolution of his marriage. The FTCA precluded government liability for this study, as it was deemed to be incidental to service, and therefore banned in accordance with Feres.

In addition to the FTCA claim, the respondent also brought a “Bivens” claim. This claim enables the courts to provide remedies against offending federal officials for violations of constitutional rights, even in the absence of a statute authorizing relief. The only exceptions to this relief are “if there are special factors counseling hesitation” or an “explicit congressional declaration” of another remedy. The Supreme Court found that the “unique disciplinary structure of the Military Establishment...” constituted a special factor that prevented the granting of a Bivens claim. The Court specifically mentioned that this denial of a Bivens claim also applied to situations in which there was no officer-subordinate relationship, as in the medical research setting.

As a result of these two cases, men and women in the military are unable to seek any damages from the government under the FTCA or through the use of a Bivens action, as an injury from military research experiment is seen as incidental to service. This result is arguably problematic for two reasons. First, although individuals may be approached by medical researchers while they are serving, a medical research study is not incidental to the service that they are providing. When one enlists in a particular military branch, the individual is not notified of the possibility of participating in medical research. During the enlistment process military personnel must take the Oath of Enlistment, which states that the individual: “...will obey...the orders of the officers appointed over me according to regulations and the Uniform Code of Military Justice.” Since participation in medical research studies is a voluntary procedure, and not an order from a higher-ranking officer, it seems difficult to label any injury that results from a study as “incidental” to one’s service.

Second, as a result of these court decisions, military personnel have lost an ability to voice their concerns regarding violations of ethical regulations in human research studies. By closing off the ability to redress a tort injury or to obtain a remedy for a constitutional violation against the government, government researchers can more easily engage in harmful research on military personnel without fear of punishment. This holding could lead to more violations of the constitutional rights of military personnel without any form of redress against those who commit these acts.

Shortcomings in Internal Military Procedures

In order to redress concerns regarding military human subject research, the military has provided ways for military personnel to raise complaints in a protected environment as well as to voice concerns to research investigators. Although information on who to contact and how one is protected is publicly accessible on the internet, military personnel may be unaware of what continued on page 8
right they have, and who they may contact. Department of Defense Instruction ("DODI") 3210.7 provides procedures and standards designed to prevent research misconduct. This instruction, however, does not specifically address problems involving coercion from research investigators and military officers. Also, the instruction fails to deter officers and research investigators, as it does not specify penalties that may be pursued for those who violate standards of conduct.

DODD 7050.06, pertaining to whistleblower protection, provides that members of the armed forces are free to voice a concern without any other person taking or threatening to take an unfavorable action against that individual. The directive also provides two sources that the individual may contact in order to make a communication: a member of Congress and the Inspector General of the DOD.

Although this regulation is publicly accessible, members of the armed forces may be unaware of their rights, either by not being informed of this regulation or by failing to read it. Also, even though the informed consent form provides the research subject with the name and number of an individual to whom he or she may voice a concern, military personnel may not believe that the given individual would help them. Without adequate notification of how their voiced concerns may be protected, and names of individuals they may contact, military personnel may feel pressured to remain silent.

DODI 3210.7, which pertains to research integrity and misconduct, provides procedures and standards for the DOD in order to prevent research misconduct. This instruction provides that "corrective actions will be administrative in nature," for example, terminating an award or debarment. The first part of the instruction is problematic, however, as it focuses primarily on the problems of data fabrication, data falsification, or a general departure from the accepted research practices in the medical community. The instruction does not mention coercion or undue influence concerns directly. The document does state, however, that if the research violates civil or criminal statutes, that "civil or criminal sanctions may be sought after as well." This section may apply to coercive behaviors committed by military officers and researchers, but it fails to describe the penalties that may be pursued if these actions are committed. DODI 3210.7 also fails to spell out the penalties for non-compliance with the rules pertaining to human subject research regulations.

As a result of these problematic internal procedures, military personnel may be more vulnerable to research misconduct.

**Improvements That Can Be Made to Protect Military Personnel**

To better protect military personnel, the U.S. government should employ additional procedural safeguards to provide a better informed consent process. In addition, the government should make it easier for servicemen and women to redress harms that result from research.

**Improvements To Further Aid Informed Consent**

Although the military has taken significant steps to improve the informed consent process, there are numerous changes that can be made to further medical enhancement research while protecting the autonomy of military personnel to the greatest extent possible.

The first additional safeguard that should be implemented would be to provide for stronger enforcement of the principles that are demarcated by the Common Rule. As outlined above, the Common Rule has been violated in previous military human research studies in that personnel could have received jail time if they did not participate. Although it is clear that coercive measures were taken, the information is unavailable to determine whether the IRB guidelines were upheld. To better preserve the goals of the Belmont Report, these Common Rule requirements should be strictly enforced.

The second additional safeguard that should be implemented is to require military recruiters to disclose to potential recruits the possibility that they may be solicited to participate in medical experiments. Currently, individuals are only given informed consent forms when they have already enlisted and are being recruited for a particular military research study. Potential recruits should understand that they may be approached for a medical research study, as this type of activity is not usually associated with military service. If recruits are given this notification, their future decisions as enlisted personnel may be more voluntary in nature.

The third safeguard that should be implemented is the imposition of strict penalties on superior officers and research investigators who coerce or who unduly influence military personnel into participating in human subject research. As previously mentioned, under DODD 3216.2 there are rules in place to prevent a higher-ranking officer from influencing soldiers into participating in human subject research. If an officer or a medical researcher attempts to coerce an individual to participate, he or she should face strict penalties in order to deter other officers or researchers from committing such acts. The penalties could include a dishonorable discharge, extensive fines, and the
possibility of jail time. These penalties should be made clear to officers and researchers throughout their time in the service. Soldiers also should be made aware of these penalties to alert them to the possibility of coercion and undue influence in their surrounding environment. As a result, one source of pressure that hinders informed consent may be eliminated, or at least significantly reduced.

A fourth protection that should be put in place is to improve the enforcement procedures for Army regulations 70-25 and 40-38, as military personnel have been threatened with punishment for refusal to participate in studies. This action should make Army personnel less afraid to refuse to participate in medical research studies since they would no longer be faced with time at Ft. Leavenworth or threat of a court martial. System-wide procedures would provide for better adherence to any branch-specific rules and would create a more consistent approach to human subject protection.

Congress could also amend 10 U.S.C. 980 to better protect the autonomy of those participating in an experiment in which informed consent can be waived. Currently, 10 U.S.C. 980 is only well suited for experiments that are not classified, such as public biomedical studies. For example, this statute can be utilized for the Polyheme study, an experiment that involves substituting man-made synthetic blood in place of real blood when a transfusion is not possible. Since information about this synthetic blood is publicly accessible, it is feasible to seek community consultation.

Research involving new technologies that are classified, however, cannot be discussed with the public for approval, leaving a gap for secretive studies that require a waiver of informed consent. Since the military has an interest in maintaining national security, approval for more covert projects could be sought through an IRB instead of through a community consultation. Through this method, the military will not have to reveal its confidential research to the public, but it will still be subject to the approval of a non-military group which can look out for soldiers' well-being.

Improvement of Redressability for Harms

When soldiers are harmed by military human subject research studies, they may attempt to redress these harms through both the U.S. judicial system and internal military procedures. Both of these methods of redress, however, fail to adequately protect military personnel. Military personnel are unable to file a claim under the FTCA for harms that they received as a result of military research as a result of the holding Feres v. United States, as the alleged negligence is “incidental to service.” As a result of United States v. Stanley, military personnel also are unable to seek remedies against federal officers for the violation of their constitutional rights through the use of a Bivens action. Military personnel are therefore unable to redress their injuries that result from military research through the court system.

A way should be devised for military personnel to seek remedies for injuries that result from medical studies. The government should not consider harms that result from military medical research as incidental to service, and therefore, should grant relief under the FTCA for any harm that resulted from negligence in the “administration, supervision, and subsequent monitoring of the experiment.”

For example, if the research investigators fail to state certain risks or details associated with the study, then that negligence could be redressed in court. If the research investigators were not negligent in the administration, supervision and subsequent monitoring of the experiment by delineating the risks, then the ability to sue the government should be limited. The ability to sue could be limited to legal measures provided for in the informed consent form, if any. This way, the government would be held accountable for those harms that resulted from studies in which certain risks or details were not disclosed, or for other requirements for human subject research that were not met. An incentive would therefore be provided to adequately disclose information and to abide by all rules associated with human subject research. As an unlimited amount of FTCA claims against the government would be an unreasonable bill for the U.S. Treasury, the ability to sue for known risks associated with research should not be allowed, unless the facts show that the individual was threatened with severe penalties, such as jail time, for failing to participate.

In addition, even if military personnel are unable to bring a claim against the government under the FTCA, soldiers should be able to bring a Bivens claim against higher-ranking military personnel in order to protect their constitutional rights. This change in the court system would hopefully prevent even more egregious violations of an individual’s constitutional rights when he or she serves in the armed services.

Internal military procedures could also be improved. These procedures delineate ways in which one may alert those in the higher echelons of the government about concerns related to human subject research studies. While DODI 3210.7 currently provides corrective actions for research misconduct, it is unclear how well information regarding whom to contact is brought to the attention of military personnel, possibly rendering that protection useless. Furthermore, DODI 3210.7 fails to address problems with coercion in the research environment and does not establish procedures for penalizing those who unduly influence soldiers in the research setting. This instruction could be improved through an addition of a clause addressing types of continued on page 10
coercive behaviors and how they will be penalized. In addition, military personnel should be made well aware of whom they could contact regarding concerns with research misconduct. Through these developments, DODI 3210.7 may provide better protection for military personnel.

In order to strengthen DODD 7050.06, procedures should be put into place to ensure that military recruits are provided with manuals that define their rights. Furthermore, military recruits should be obligated to read these rights prior to or momentarily after enlisting. In addition, informed consent forms should spell out who the military member may contact in order to voice a complaint. The ultimate goal should be to ensure that soldiers are aware of ways to have their complaints heard by those who may not try to suppress them. Since military personnel are currently unable to seek relief under the FTCA or a Bivens action against the government, it is imperative that the military not only enable, but also support military personnel in voicing their concerns.

Conclusion

In the unremitting struggle to improve the effectiveness and power of the armed forces, the United States will continue to perform medical research on military personnel. Military medical research requires a delicate balance – protecting the rights of those who serve while taking measures to improve the effectiveness of America’s fighting forces. Although it is impossible to perfect the informed consent process in the military environment, suggested improvements outlined herein may improve the protection of the autonomy of military personnel and enhance their ability to redress for harms. If these additional protections are not implemented, men and women who serve our country will continue to be abused by it.

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Endnotes

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5. Id. at 212.

9. Id.
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“PPACAnging” THE COURT (THE PATIENT PROTECTION AND AFFORDABLE CARE ACT BEFORE THE UNITED STATES SUPREME COURT)

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The enactment of the Patient Protection and Affordable Care Act of 2010 (“PPACA” or the “Act”) brought an instantaneous response from attorneys general of several states and other groups questioning the constitutionality of certain provisions of the Act. Suits were filed in Florida, Michigan, Ohio, Virginia, and the District of Columbia seeking to overturn the Act on, inter alia, the grounds that the provisions which mandated the purchase of health insurance by individuals (the “Individual Mandate”) violated provisions of the United States Constitution, specifically the Commerce Clause.

On March 26, 27 and 28, 2012, the United States Supreme heard arguments on several cases that had arisen from the various actions filed. Before looking at the issues argued before the Court, a short history of the lower court cases is helpful in understanding the context of the appeals.

The Virginia Case

One of the first cases challenging PPACA arose in the District Court for the Eastern District of Virginia. After having heard the government’s motion to dismiss on August 2, 2010, United States District Judge Henry E. Hudson issued his Memorandum Opinion on the cross-motions for summary judgment filed by the Commonwealth of Virginia and the Secretary of the Department of Health and Human Services (“HHS”).

In his Opinion, Judge Hudson concluded that the Individual Mandate was unconstitutional. This decision was based on Judge Hudson’s interpretation of the Commerce Clause as well as the Necessary and Proper Clause. In addition, Judge Hudson struck down the Individual Mandate on the grounds that the Constitution did not grant to the federal government permissable taxation power to enforce the Individual Mandate.

As to the Commerce Clause, Judge Hudson’s analysis of the issues focused on the distinction between “action” and “inaction”; i.e. the Commerce Clause cannot regulate the failure of a person to not do an act. Judge Hudson’s analysis stated that the parties had briefed and argued only the third power of Congress under the Commerce Clause. As such, Judge Hudson accepted the Commonwealth of Virginia’s argument that a decision not to purchase a product, such as health insurance, is not an economic activity. Thus, since the power of Congress does not extend to the regulation of inactivity (i.e., an enumerated power), the Individual Mandate is not saved by the Necessary and Proper Clause.

The government appealed the case to the Court of Appeals for the Fourth Circuit, which dismissed it on the grounds that, under the Anti-Tax Injunction Act, the plaintiffs did not have standing to bring the suit since the “tax” under the Individual Mandate had not gone into effect and, thus, the case was not a ripe controversy.

The Florida Case

The Florida case was the first case filed, brought by the attorney general of the state of Florida, other attorneys general and other persons against HHS. On October 14, 2010 the Florida case was decided in part when the Court (United States District Judge Roger Vinson) allowed the suit by the plaintiffs to proceed by rejecting a motion to dismiss by the federal government. The parties filed cross-motions for summary judgment seeking a declaratory judgment regarding the constitutionality of the Individual Mandate, and on January 31, 2011, Judge Vinson issued his ruling granting summary judgment to the plaintiffs.

Based upon the Court’s interpretation of the Commerce Clause (i.e., that such Clause cannot be used to regulate inactivity – in this case, to purchase health insurance), the Court ruled that the entire Act was unconstitutional because the Individual Mandate was “inextricably bound” to the other provisions of the law. While the Court declined to enjoin the government from promulgating regulations, the Court stated that its declaratory judgment should, in essence, be treated as an injunction by the parties to the suit.

The government appealed to the Court of Appeals for the Eleventh Circuit.

On August 12, 2011, in a two-to-one decision, the Eleventh Circuit ruled that PPACA was unconstitutional in that the requirement of the purchase of health insurance violated the Commerce Clause since the Commerce Clause did not regulate inactivity. The Court also ruled that the Individual Mandate could not be severed from PPACA and, thus, the entire Act was unconstitutional.

At this point in time, PPACA looked doomed, but further cases were to follow that leveled the playing field and set the stage for Supreme Court review.
The Michigan and Ohio Cases

The Court in the Michigan case didn’t follow the interpretations noted in Virginia and Florida, instead upholding the Individual Mandate as constitutional.\(^12\) Noting the unusual healthcare insurance market as being “unlike other markets,” the Michigan Court distinguished the “inactivity” argument relied upon by the Virginia Court.\(^13\) The Court cited the potential need of all persons to have access to healthcare across state lines and concluded that such need provided a sufficient basis to allow the federal government to regulate such commerce.\(^14\) The Court noted that the healthcare market is unique from regular commercial markets and, thus, allows such regulation.\(^15\)

Contrary to the Michigan case, in Ohio a United States District Court Judge refused to dismiss the legal challenge concerning the Individual Mandate to buy insurance.\(^16\) The Court rejected the government’s motion to dismiss based on the fact that other Courts, such as Virginia and Florida, were considering the same matter.\(^17\)

Both the Michigan Case and the Ohio Case were appealed to the Court of Appeals for the Sixth Circuit, which upheld the constitutionality of the Individual Mandate on July 20, 2011.\(^18\)

The District of Columbia Case

On November 8, 2011, the Court of Appeals for the District of Columbia Circuit upheld the constitutionality of the Individual Mandate which had been upheld by the District Court for the District of Columbia dismissing the challenge of the appellants.\(^19\) The Appellate Court affirmed the decision of the District Court, with one judge dissenting as to the jurisdictional issues only.\(^20\)

The Questions Presented

From each of the foregoing decisions, there arose a patchwork of conflicting decisions and analysis. Thus, on November 14, 2011, the United States Supreme Court granted certiorari on the following issues:

1. The constitutionality of the Individual Mandate;
2. The severability of the Individual Mandate;
3. The application of the Anti-Injunction Act so as to bar the plaintiffs from bringing their actions before a tax or penalty is imposed; and
4. The constitutionality of the expansion of the Medicaid program under PPACA.

The Commerce Clause and the Necessary and Proper Clause

The Commerce Clause is an enumerated power set forth in Article 1, Section 8, Clause 3 of the Constitution.\(^21\) The Clause states that Congress shall have the power to “regulate commerce with foreign nations, and among the several states, and with the Indian Tribes.”\(^22\) Central to the challenges to PPACA is the second phrase … “among the several states,”..., which is referred to as the “Interstate Commerce” Clause.\(^23\)

At the center of the debate between strict constructionists and those who take a broader view of the Constitution is the interpretation of the “Necessary and Proper” Clause which states that Congress has the power “[t]o make all laws which shall be necessary and proper for carrying into execution the foregoing Powers, and all other Powers vested by the Constitution in the Government of the United States, or in any Department or Office thereof” (emphasis added).\(^24\) The issue is whether or not the Clause can be read to be independent of the Commerce Clause.\(^25\) The Necessary and Proper Clause is “a caveat that the Congress possesses all the means necessary to carry out the specifically granted ‘foregoing’ powers of [Section 8] ‘and all other Powers vested by this Constitution.”\(^26\)

Cases over the past two hundred years have sought to interpret the reach of the Commerce Clause. These sixteen words of the Commerce Clause have been applied to situations as diverse as civil rights and the growing of marijuana.

The Early Precedents

From the time of McCulloch v Maryland,\(^27\) the Supreme Court has broadened its view on the application of the Commerce Clause. The trend, with certain exceptions, seems to be that the Court takes a more expansive interpretation when issues of economics or social legislation are involved. The following selected precedents show a trend toward granting more power to the federal government to regulate the interests that affect relationships among the states and their citizens.

McCulloch v Maryland

This seminal case, decided by the early Supreme Court in 1819, set forth an important distinction for the Necessary and Proper Clause. The question before the Court was whether or not the new government had the power to charter a national bank. The Court held that Congress had such power under the Necessary and Proper Clause to exercise its powers that were enumerated in the Constitution.\(^28\) Chief Justice Marshall, citing historical precedent (that of Congress having established a national bank before) wrote that Congress had the power to establish a second bank, and the State of Maryland could not tax its notes.\(^29\) Marshall, as a response to the argument that the states were sovereign, argued that it was not the states, but the people, who had ratified the Constitution and, thus, the people were the sovereigns.\(^30\)

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Gibbons v. Ogden

The Gibbons case in 1824 created powers in Congress through the Commerce Clause to regulate the interstate commerce of steamboats. According to the majority opinion, again written by Chief Justice John Marshall, the phrase “commerce among the several states” means that the powers of Congress to regulate interstate commerce do not “stop at the external boundary line of each State, but may be introduced into the interior.” Again, the powers of the federal government trumped that of the states.

The Economic Legislation Precedents

Swift and Company v. United States

The Swift case in 1905 held that the Sherman Act was constitutional. This case, which dealt with a restraint of trade in the meat packing industry, introduced the concept of combining practices to show that such practices were in the “stream of commerce.” The combining of these practices by the defendants created a situation where the effect on interstate commerce was palpable and, thus, under the Commerce Clause.

Schecter Poultry Corp. v. United States

In 1933 Congress passed the National Industrial Recovery Act (“NIRA”). The case, decided in 1935, challenged the enforcement of regulations promulgated pursuant to the statute, which affected poultry.

The decision held that NIRA was unconstitutional in that it allowed the President to issue industrial “codes of fair competition,” dealing a blow to President Roosevelt’s national economic recovery strategy. The Court distinguished between direct effects on interstate commerce and indirect effects. The former were the type that Congress could regulate; the latter were to be left to the states under the Tenth Amendment.

Carter v. Carter Coal Company

The Court found that a tax imposed on coal produced by coal mines pursuant to the Bituminous Coal Conservation Act of 1935 was unconstitutional, reasoning that simply because a commodity will at sometime in the future enter interstate commerce does not mean that Congress has the power to regulate it.

National Labor Relations Board v. Jones & Laughlin Steel Corporation

This case came to the Court involving a matter under the National Labor Relations Act (“NLRA”) that prohibited discrimination against persons wishing to join a union. The Court, reasoning that Jones & Laughlin Steel Corporation was a very large steel producer, upheld the NLRA as constitutional since the activities of the defendant had a “close and substantial” relationship to interstate commerce.

United States v Darby

This decision, rendered in 1941, reversed the case of Hammer v. Dagenhart (discussed below), and upheld the Fair Labor Standards Act of 1938 (the “FLSA”). The Court overturned the distinction set up in Hammer between manufacturing and interstate commerce and held that the FLSA was constitutional since the goods manufactured were shipped in interstate commerce. The Court also held that it was an appropriate use of Congressional power to regulate the wages of workers nationally so that the states would not undercut one another by cutting wages to the bone.

Wickard v. Filburn

This case involved a farmer who wanted to grow wheat on his land. The question was whether or not such activity would violate the Commerce Clause. The Court held that regulations limiting the amount of wheat that farmers could grow, even for non-commercial purposes, affected the broader regulation of the interstate wheat market and, therefore, was subject to the Commerce Clause. The Court specifically stated:

But even if appellee's [the farmer's] activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce and this irrespective of whether such effect is what might at some earlier time have been defined as 'direct' or 'indirect.' … "The stimulation of commerce is a use of the regulatory function quite as definitely as prohibitions or restrictions thereon (emphasis added).

The Social Legislation Precedents

Hammer v. Dagenhart

This case involved the power of Congress to enact child labor laws. Public concern forced many states to enact such laws, many of which turned out to be less than effective. Congress stepped in with the Keating-Owen Act of 1916 to regulate child labor. Roland Dagenhart, a cotton mill worker in North Carolina, along with his two sons, sued to have this law declared unconstitutional.

The Supreme Court held that the law was unconstitutional in that the manufacture of cotton at Dagenhart’s mill did not involve interstate commerce. The Court distinguished its earlier decisions concerning the federal control of lottery schemes, prostitution and liquor as being “inherently evil” while cotton manufacturing was not.

Heart of Atlanta Motel, Inc. v. United States

The Civil Rights Act of 1964 was passed in order to prohibit...
discrimination. The Heart of Atlanta Motel was a large motel in Atlanta, Georgia, and it excluded African-Americans from renting.

The Supreme Court held in favor of the United States in seeking to enforce the Civil Rights Act and issued a permanent injunction requiring the Heart of Atlanta Motel to stop its racially discriminatory practices.

The Supreme Court that seems fraught with inconsistency, especially when it comes to controversial topics such as gun control or marijuana. Alfonso Lopez, Jr., was a Texas high school student who carried a concealed 38 caliber revolver along with cartridges into his school. He admitted to having a weapon after being confronted by school authorities, and was charged with violation of the Federal Gun-Free School Zones Act of 1990, which prohibited such an activity.

Lopez moved to dismiss the indictment on the grounds that Section 922(q) of the Act was "unconstitutional as it is beyond the power of Congress to legislate control over our public schools." The trial court disagreed, and Lopez was tried and convicted.

The Fifth Circuit Court of Appeals reversed on appeal, holding that Section 922(q) was beyond the power of Congress to legislate under the Commerce Clause, stating "that Section 922(q) in the full reach of its terms, is invalid as beyond the power of Congress under the Commerce Clause." The majority opinion, delivered by Chief Justice Rehnquist, concluded that a law which prohibits guns close to a school is a criminal statute that does not relate to commerce or economic activity and was, therefore, unconstitutional.

Specifically the Court looked at four factors to determine the valid efforts to use the Commerce Clause: (1) economic v. non-economic activity; (2) whether or not interstate commerce was involved; (3) whether or not there had been Congressional evidence of a link between the activity and the regulation; and (4) how attenuated such link was.

Justice Breyer wrote the dissent in which he applied three principles: (1) the Commerce Clause gives the power to Congress to regulate local activity as long as the same "significantly affect" interstate commerce; (2) the court must consider the cumulative effect of acts and not just one single act; and (3) did Congress have "a rational basis" for concluding that interstate commerce was affected.

The Court summarized current thinking on Congressional authority as including "the power to regulate those activities having a substantial relation to interstate commerce, i.e., those activities that substantially affect interstate commerce (emphasis added)."

student was allegedly assaulted and raped repeatedly by two members of the school’s football team, one of whom was Antonio Morrison. Morrison admitted having sexual contact with the student, but the grand jury involved did not find sufficient evidence to charge Morrison with the crime. The female student then filed suit under the civil remedies section of the Violence Against Women Act seeking damages.77

The Supreme Court, reversing the Court of Appeals for the Fourth Circuit, held five to four that Congress lacked the authority under the Commerce Clause to enact the law.78 The Court relied on the holding in United States v. Lopez, which excluded activity that was not directly economic in nature, even if there were indirect economic consequences.79 The majority opinion cited a passage from NLRB v Jones & Laughlin Steel Corporation which reads in part:

[the breadth of the power of Congress to regulate interstate commerce] must be considered in the light of our dual system of government and may not be extended so as to embrace effects upon interstate commerce so indirect and remote that to embrace them, in view of our complex society, would effectually obliterate the distinction between what is national and what is local and create a completely centralized government.80

Gonzalez v. Raich

California Proposition 215 legalized the medical use of marijuana in California. The defendant, Angel Raich, used marijuana for homegrown medical purposes. Such use was legal under California law but illegal under federal law.81

The Drug Enforcement Administration (“DEA”) seized Raich’s plants under authority of the Controlled Substances Act (“CSA”). Raich and two others sued the federal government for injunctive and declaratory relief, claiming that the CSA did not apply to the intrastate growing of medical marijuana. The Ninth Circuit Court of Appeals agreed and granted the injunction.82

The Supreme Court disagreed, holding that the CSA was a valid exercise of the Commerce Clause. Speaking for the majority, Justice Anton N. Scalia wrote:

Unlike the power to regulate activities that have a substantial effect on interstate commerce, the power to enact laws enabling effective regulation of interstate commerce can only be exercised in conjunction with congressional regulation of an interstate market, and it extends only to those measures necessary to make the interstate regulation effective. As Lopez itself states, and the Court affirms today, Congress may regulate noneconomic intrastate activities only where the failure to do so “could … undercut” its regulation of interstate commerce.… This is not a power that threatens to obliterate the line between “what is truly national and what is truly local.” … The necessary and proper Clause “empowers Congress to enact laws … that are not within its authority to enact in isolation” provided those laws are “in effectuation of [Congress’] enumerated powers.83

However, Justice Sandra Day O’Connor wrote in her dissent:

Federalism promotes innovation by allowing for the possibility that “a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country… .” Relying on Congress’ abstract assertions, the Court has endorsed making it a federal crime to grow small amounts of marijuana in one’s own home for one’s own medicinal use. This overreaching stifles an express choice by some States, concerned for the lived and liberties of their people, to regulate medical marijuana differently. If I were a California citizen, I would not have voted for the medical marijuana ballot initiative; if I were a California legislator I would not have supported the Compassionate Use Act. But whatever the wisdom of California’s experiment with medical marijuana, the federalism principles that have driven our Commerce Clause cases require that room for experiment be protected in this case.84

Justice Clarence Thomas wrote a separate dissent, stating:

Respondents’ local cultivation and consumption of marijuana is not “Commerce … among the several States.”… Certainly no evidence from the founding suggests that “commerce” included the mere possession of a good or some personal activity that did not involve trade or exchange for value. In the early days of the Republic, it would have been unthinkable that Congress could prohibit the local cultivation, possession, and consumption of marijuana.…” If the Federal Government can regulate growing a half-dozen cannabis plants for personal consumption (not because it is interstate commerce, but because it is inextricably bound up with interstate commerce), then Congress’ Article I powers — as expanded by the Necessary and Proper Clause — have no meaningful limits. Whether Congress aims at the possession of drugs, guns, or any number of other items, it may continue to “appropriat[e] state police powers under the guise of
regulating commerce.” … If the majority is to be taken seriously, the Federal Government may now regulate quilting bees, clothes drives, and potluck suppers throughout the 50 States, the end is near. This makes a mockery of Madison’s assurance to the people of New York that the “powers delegated” to the Federal Government are “few and defined,” while those of the States are “numerous and indefinite.”

Analysis

The topic of healthcare has not been addressed by the Court involving the Commerce Clause to-date, making the cases on review ones of first impression.

A review of some of the briefs filed with the Court, as well as the arguments in the courts below, reveals that the major topic is the disfunction between “action” and “inaction.” The Individual Mandate is perceived by those opposing PPACA as requiring the purchase of a good or service as opposed to the Commerce Clause cases which, to-date, have regulated activities. This perceived distinction leads to an almost “Zen”-like analysis since the buying of insurance and the non-buying of insurance are both “actions” or “activities” that produce a result, i.e., coverage or non-coverage.

Constitutionality and Severability

There is no severability clause in PPACA. The path of PPACA in Congress, through passage in the Senate and then in the House prevented the normal “back and forth” of House and Senate amendments that could have resulted in a severance clause being added. The Senate bill contained none and the House could not add one since that would have required a Senate vote which, at the time of passage, could not have been obtained. Due to a special election in Massachusetts, Scott Brown became a Senator from that state and vowed to be the “41st vote” to stop PPACA from being enacted. Thus, as a technical matter, if the Supreme Court finds one of the challenged provisions to be unconstitutional, the entire Act shall be unconstitutional. However, the Supreme Court has granted certiorari on the question of whether or not the Individual Mandate, if unconstitutional, can be severed from the rest of PPACA, allowing the rest of PPACA to stand. The arguments set forth in briefs filed provide clues as to the positions of the parties. According to briefs opposing the severance of the Individual Mandate from the rest of PPACA, severability is a matter of legislative intent, and Congress, in not placing a severability Clause into PPACA, indicated that PPACA should stand in full or not at all.

Furthermore, the Individual Mandate, it is argued by the opponents of PPACA, is such a crucial provision of PPACA that to sever it from the rest of the legislation would invalidate most, if not all, of the provisions of PPACA. In other words, the Individual Mandate is the reason the whole bill was passed.

However, it can also be argued that the Individual Mandate was not the reason the law was enacted. There are many other provisions that were included in PPACA that have nothing to do with the Individual Mandate. For example, the ban on new physician-owned hospitals and the federal adoption of the “one purpose rule” under the Anti-Kickback Law have nothing to do with the Individual Mandate or its structure. Indeed, it was argued by the government that a court must not strike down a statute to any greater extent than is constitutional. The government cited a recent decision by the Court addressing this issue where the Court stated it must “try to limit the solution to the problem.”

The Anti-Injunction Act

The Anti-Injunction Act provides that “no suit for the purpose of restraining the Assessment or collection of any tax shall be maintained in any Court by any person.” In this context, since the Individual Mandate does not go into effect until 2014, there is no tax or penalty yet for not obtaining health insurance. Thus, the Supreme Court has taken up the question of whether or not the Anti-Injunction Act bars the suits brought by the plaintiffs since, until the 2014 tax is imposed, there can be no judicial relief.

The question here is whether or not the monetary assessment on individuals who do not choose to obtain health insurance constitutes a “tax” so as to fall under the Anti-Injunction Act. The analysis applied by the courts in the past is to look to the legislative intent in the passage of legislation. Here, both Congress and President Obama have said that this assessment is not a tax, although, in reality, it could be considered as such.

Medicaid

The Medicaid issue involves the extent to which Congress may go in forcing states to spend more of their Medicaid funds in furtherance of the goals of PPACA. Medicaid is a federal program that is run by the states. Congress appropriates money for the states to manage; the states also provide their own funds for the program. The threat of PPACA is that the federal government will withhold federal Medicaid funds if the states do not comply with the expansion, arguably placing the burden of further taxation on the states. Actually, one of the amici briefs filed opposing this aspect of PPACA puts the situation in terms of a “Hobson’s choice;” i.e., the states will end up spending more money either way.

The seminal case is South Dakota v. Dole which held that Congress could pressure South Dakota by withholding road funds if South Dakota did not increase its legal drinking age.

The question before the Court was whether or not Congress had exceeded
its powers in enacting the National Drinking Age Amendment which conditioned the receipt of federal highway funds upon establishing a uniform drinking age of twenty-one years.

South Dakota, which had law setting the minimum age for beer drinking at eighteen years, challenged the Act. The Court, in a 7-2 decision, held that this “indirect” action by Congress did not violate Congress’s ability to act in the interest of the “general welfare” nor did it violate the spending limits of the Twenty First Amendment.

Conclusion

The Supreme Court’s decision on PPACA is expected in late June of this year. Presidents since Theodore Roosevelt in 1912 have put forth the concept of universal health-care coverage. PPACA is the most ambitious effort to-date to do so. From a policy viewpoint, PPACA may or may not be a valid solution. However, from a legal aspect, the Justices are bound by their oaths to uphold the Constitution through the interpretation of precedent. How well they fulfill that duty under PPACA will be the subject of analysis for years to come.

Bruce F. Howell, J.D., M.S., is a board certified health lawyer (Texas State Board of Legal Specialization) and a shareholder in the Portland, Oregon law firm of Schwabe, Williamson & Wyatt, PC. Mr. Howell is a founder and past chairman of the Health Law Section of the Dallas Bar Association, immediate past Chair of the Health Law Section of the Texas State Bar, past Chair of the American Bar Association Interest Group on Medical Research, Biotechnology and Clinical Ethics, and Vice Chair of the American Bar Association Health Lawyer Editorial Board. He has been a member of the Board of Directors of Southwest Transplant Alliance (organ transplant organization), the French-American Chamber of Commerce, and the University of North Texas Health Science Center Institutional Review Board. He is also admitted as a Fellow of the Dallas Bar Foundation. He is a frequent writer and speaker on physician, clinical, genetic and ethical issues, and has been voted a Texas Super Lawyer and one of the “Best Lawyers in America” for the past five years. He can be reached at bhowell@schwabe.com.

Endnotes


3 Commonwealth of Virginia ex rel Kenneth T. Cuccinelli in his official capacity as Attorney General of Virginia v. Kathleen Sebelius, Secretary of the Department of Health and Human Services, in her official capacity, E.D. Virginia; Civil Action No. 3:10-CV-188-HEH.

4 Id. at 24.

5 Id., see infra for a full explanation of these clauses.

6 Id. at 32.

7 Id. at 24 et seq.

8 Id. at 63.

9 Anti-Injunction Act of 1867, codified in the Internal Revenue Code of 1954. In pertinent part, the Anti-Injunction Act states that “... no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax is assessed.” 26 USC 7421(a); see also infra.


11 Id.

12 Thomas More Law Center; Jann Demars; John Ceci; Steven Hyder; Salina Hyder, vs. Barack Hussein Obama, in his official capacity as President of the United States; Kathleen Sebelius, in her official capacity as Secretary, United State Department of Health and Human Services, Eric H. Holder, Jr., in his official capacity as Attorney General of the United States; Timothy F. Geithner, in his official capacity as Secretary, United States Department of Treasury, 6th Cir., No 10-2388 (June 29, 2011).

13 Id.

14 Id.

15 Id.

16 See U.S. Citizens Association v. Sebelius, supra.

17 Id.

18 Id. Some challenges to PPACA were dismissed outright. For example, in Virginia, Liberty University, Inc. filed a lawsuit against PPACA on the grounds that the Individual Mandate would require federal funding of abortions. The District Court dismissed the action, and stated that such requirement was not within the Individual Mandate. The United States Court of Appeals for the Fourth Circuit upheld the lower court decision.


20 Id.

21 U.S. Constitution, Article I, Section 8, Clause 3.

22 Id.

23 Id.

24 U.S. Constitution, Article I, Section 8, Clause 18.


26 Id.

27 McCulloch v. Maryland, 17 US (Wheat 4) 316; 4 L. Ed. 579; 1819 U.S. LEXIS 320 (1819).

28 Id.

29 Id.

30 Id.


32 Id.


34 Id.

35 Id.
38 Id.
39 Id. The Tenth Amendment states that powers not granted to the federal government or prohibited to the states are reserved to the states or the people. U.S. Const. 10th Amendment.
40 49 Stat. 991.
43 Id.
46 Id.
47 Id.
49 Id.
50 Id.
53 Id.
54 Id.
57 Id.
58 Id.
59 Id.
60 Id.
62 Id.
63 Id.
64 Id.
67 Id.
68 Id.
69 Id.
70 Id.
71 Id.
72 Id. Congress eventually rewrote the legislation to bring in the interplay with the Commerce Clause, and the Gun-Free School Zones Act has been upheld.
73 Id.
74 Id.
75 Id.
76 Pub. L. 103-322.
78 Id.
79 Id.
80 Id.
81 Gonzalez v. Raich, 545 U.S. 1; 125 S. Ct. 2195; 162 L. Ed. 2d 1; (http://supreme.justia.com/us/545/1/case.html) (2005).
82 Raich v. Ashcroft, 352 F. 3d 1222 (9th Cir. 2003).
83 Id.
84 Id.
85 Id.
87 Id.
89 Id.
90 Id.
91 Id.
92 Id.
93 26 U.S.C.A. 5000A.
95 26 U.S.C. 7421(a).
96 Id.
98 Id.
101 Id.
102 Id.
103 Id.
106 South Dakota v. Dole at 206. The Twenty-First Amendment repealed the Eighteenth Amend-ment, which had mandated Prohibition.

**REMEMINDER:**
ABA Health Law Section members can access past issues of The Health Lawyer on the Section’s website. To access back issues and The Health Lawyer’s full index, go to http://www.americanbar.org/publications/health_lawyer_home.html.
Emerging Issues in Healthcare Law
13th Annual Conference

Over 300 health law professionals from all over the country gathered in San Diego February 22-25 for the Section’s premier conference. In addition to the high quality CLE programming, the Section held business meetings and social gatherings.

To build on its commitment to diversity, this year the Section hosted its inaugural Diversity Reception. The reception affords the Section an opportunity to continue to build bridges and strengthen relationships with attorneys and law students having diverse backgrounds. The reception featured as its speaker, Manuel (Manny) A. Abascal, Esq. Mr. Abascal is the Chair of the Board of MLK-LA Healthcare Corporation in South Los Angeles and a partner at the law firm of Latham & Watkins, LLP.

The Section was pleased to host the winner of the 10th Annual Law Student Writing Competition, Jennifer Siegel, a student at the University of Maryland Francis King Carey School of Law, Baltimore, Maryland. Jennifer won first place for her excellent paper, Advancing Ethical Research Practices in the Military, published on page 1.

Law student meet and greet. Twenty-five law students attended the conference. Here, several law students met with the Section’s officers and Council members at the law student meet and greet.

The Section’s Council Dinner featured an unprecedented nine former Section Chairs.

Front row, from left to right, David H. Johnson, Chair; Linda A. Baumann, Immediate Past Chair; David W. Hilgers, 2009-2010; J.A. “Tony” Patterson, 2004-2005; and Paul R. DeMuro, 2006-2007.


MISSED OUT ON THE EMERGING ISSUES IN HEALTHCARE CONFERENCE?

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Jennifer Siegel is featured here with the Law Student Writing Competition Chair, Marcelo N. Corpuz III.

Photos by Brian Vaughn, www.azcastincolor.com
HLS Bylaw Notification

Notice is hereby given to all members of the Health Law Section in accordance with its bylaws.

On February 25, 2012 the Health Law Section Council approved an amendment to Article VI, Section 1 of its bylaws. The change is emphasized below.

Nominating Committee. At any time, not later than the close of the Midyear Meeting of the House of Delegates, a Nominating Committee shall be designated consisting of the Chair, who shall serve as chair of the committee, the Chair-Elect, the Vice Chair, and four other members of the Section appointed by the Chair who may, but need not be, Past Chairs of the Section. Not more than one person employed by the same law firm or entity shall serve simultaneously as members of the Nominating Committee. The nominating committee membership shall be of a diverse nature.

If the Chair is not able to serve, the Chair-Elect shall assume the Nominating Committee duties of the Chair. If any other member of the Nominating Committee is unable to serve, then the Chair shall designate another member of the Section to serve in such person’s stead. The Chair shall promptly announce the names of and contact information for the members of the Nominating Committee in a notice to Section members, which notice may be made by electronic communication, by inclusion in a Section publication or by other appropriate means. One or more candidates may be nominated by the Nominating Committee for each position to be filled by election as provided in these Bylaws. The Nominating Committee shall determine that the nominee agrees to be nominated. The Nominating Committee shall report to the Council the identity of each nominee and shall include a brief statement of activities of the nominee in the Section and in the legal profession not later than 60 days prior to the beginning of the Annual Meeting.

The proposed amendment is subject to the approval of the ABA's Board of Governors and of the Health Law Section Membership at its annual business meeting during the 2012 Annual Meeting, August 2-7, 2012 in Chicago. If you have any questions or concerns, please contact Wanda Workman at wanda.workman@americanbar.org.

Health Law Section Nominating Committee Formed

Pursuant to the Section Bylaws, Article VI, Section 1, Section members are to be notified of the names and contact information of the Nominating Committee which will determine the slate of Officers and Council members beginning with the bar year 2012. The membership of the Nominating Committee consists of:

Chair of the Committee:
• David H. Johnson, Albuquerque, NM

Members:
• David L. Douglass, Washington, DC
• Kathleen Scully-Hayes, Baltimore, MD
• C. Joyce Hall, Jackson, MS
• Hilary Young, Austin, TX
• David W. Hilgers, Austin, TX
• Eugene M. Holmes, Washington, DC

HLS Co-sponsors 2012 Cancer Rights Conferences

The ABA Health Law Section, in collaboration with the Section's Breast Cancer Task Force, once again is co-sponsoring the Cancer Legal Resource Center's 2012 Cancer Rights Conferences. These one-day conferences provide participants with comprehensive information about the most common cancer-related legal issues. They will be attended by patients, survivors, caregivers, health care providers, advocates, and business and community leaders. Other sponsors include the Disability Rights Legal Center, Loyola Law School Los Angeles, LIVESTRONG, Genentech, and the University of Michigan Comprehensive Cancer Center. Registration to all conferences is complimentary.

The four conferences will be:
• May 29, 2012, Boston, MA
• September 7, 2012, Chicago, IL
• October 5, 2012, Fresno, CA
• October 19, 2012, Houston, TX

For more information, or to register for any of the four Cancer Rights Conferences, please visit cancerrightsconference.org. For more information about the ABA Breast Cancer Task Force, please visit www.americanbar.org/groups/health_law/breast_cancer_task_force.html.
Peter Leininger, Esq.
Fulbright & Jaworski
Washington, D.C.

In February, The Health Lawyer published an article analyzing the overpayment reporting and refund requirements established by the Patient Protection and Affordable Care Act (“PPACA”). In the article, the authors outlined the challenges presented by PPACA’s overpayment requirements, which establish a 60-day deadline to report and refund overpayments, and the questions that remain about their scope and applicability. As the authors noted, one of the most substantial questions revolves around when the 60-day clock begins to run. Under PPACA, any “person” is required to report and return any overpayments received no more than 60 days after “the overpayment was identified.” The statute does not, however, define the term “identified.” As a result, in many cases it is difficult to determine whether the deadline has been triggered, especially in the context of suspected overpayments, where healthcare providers and suppliers require time to investigate whether an obligation to repay the government exists.

On February 16, 2012, The Centers for Medicare & Medicaid Services (“CMS”) published its proposed rule interpreting the PPACA overpayment requirements. The proposed rule clarifies several aspects of the reporting and refund process, including the reporting mechanism to be used, the impact of third-party violations of the Anti-Kickback Statute, and the applicable lookback period. In some instances, the proposed rule imposes regulatory requirements that seem to exceed the scope of the statutory requirements.

Moreover, in an attempt to address the problem of overpayment identification, CMS created additional confusion. The agency indicated that providers have time to investigate suspected overpayments before the 60-day deadline begins to run, as long as they conduct their investigations with “all deliberate speed.” The agency’s decision to use the phrase “all deliberate speed” is puzzling. After serving as the murky standard for the implementation of desegregation under Brown v. Board of Education, the phrase has become synonymous with endless delay. As a result, stakeholders in the healthcare industry now may face even more uncertainty as they try to determine the scope of their obligations under PPACA.

PPACA’s Overpayment Reporting and Refund Requirements

PPACA’s overpayment requirements were designed to eliminate ongoing uncertainty regarding a person’s liability for improperly retaining funds paid by the government under the False Claims Act, often referred to as “reverse” false claims. The uncertainty was largely the result of a previous legislative attempt to clarify the scope of liability for reverse false claims under the FCA. In 2009, as a part of the Fraud Enforcement and Recovery Act (“FERA”), Congress established subsection 3729(a)(1)(G) of the FCA, which prohibited any person from “knowingly conceal[ing] or knowingly and improperly avoid[ing] or deceas[ing] an obligation to pay or transmit money or property to the Government.” FERA defined an “obligation” as “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.” However, FERA did not include a specific timeframe that would establish when a retained overpayment becomes an “obligation” for the purposes of the statute.

In Section 6402(a) of PPACA, Congress attempted to clarify the requirements relating to overpayments by establishing a specific deadline to act. PPACA Section 6402(a), which is codified as 42 U.S.C. § 1320a-7k(d), provides:

**Reporting and Returning of Overpayments**

1. In general –
   If a person has received an overpayment, the person shall –
   a) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
   b) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

2. Deadline for reporting and returning overpayments –
   An overpayment must be reported and returned under paragraph (1) by the later of –
   a) the date which is 60 days after the date on which the overpayment was identified; or
   b) the date any corresponding cost report is due, if applicable.

3. Enforcement –
   Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation…for purposes of [the False Claims Act].

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**ALL DELIBERATE SPEED? CMS CREATES MORE UNCERTAINTY BY INVOKING INFAMOUS CIVIL RIGHTS STANDARD IN PROPOSED RULE ON OVERPAYMENTS**
The term “overpayment” is defined broadly as “any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.” However, the term “identified,” which triggers the 60 day deadline, is not defined. As a result, the PPACA overpayment requirements addressed one question and created many more. For instance, the statute does not clarify whether a provider has “identified” an overpayment as soon as it receives a complaint about potential overpayments through a compliance hotline or whether the provider has an opportunity to investigate the potential overpayment (including the amount of the potential overpayment) before the 60 day deadline begins to run. Moreover, the statute does not identify the mechanism providers should use to report and refund the overpayments, or what specific information should be included in the reports.

The proposed rule attempts to address these issues and provides some helpful guidance regarding the contours of the reporting and refund requirements. Unfortunately, some of the guidance has only caused more confusion.

The CMS Proposed Rule on Reporting and Returning Overpayments

The proposed rule would establish a new subpart D in Part 401 of the Title 42 regulations “to set forth the policies and procedures for reporting and returning overpayments to the Medicare program...” The proposed rule addresses various aspects of the reporting and refund process, providing guidance on procedural issues along with broader statutory interpretations.

Refund and Reporting Process

CMS proposed using the existing voluntary refund mechanism described in Publication 100-06, Chapter 4 of the Medicare Financial Management Manual, to process overpayment refunds and reports. Under the existing process, providers and suppliers can report overpayments using forms posted on the website of each Medicare Administrative Contractor (“MAC”). CMS explained that it is planning to develop a uniform reporting form, but until that form is released, providers and suppliers should utilize the existing forms created by each MAC.

In proposed regulation § 401.305(d), CMS established the following specific information requirements for overpayment reports:

1. Person’s name.
2. Person’s tax identification number.
3. How the error was discovered.
4. The reason for the overpayment.
5. The health insurance claim number, as appropriate.
6. Date of service.
7. Medicare claim control number, as appropriate.
9. A description of the corrective action plan implemented to ensure that the error does not occur again.
10. Whether the person has a corporate integrity agreement with the Department of Health and Human Services’ Office of Inspector General (“OIG”) or is under the OIG Self-Disclosure Protocol.
11. The timeframe and the total amount of the refund for the period during which the problem existed that caused the refund.
12. If a statistical sample was used to determine the overpayment amount, a description of the statistically valid methodology used to determine the overpayment.
13. A refund in the amount of the overpayment.

Some of these categories of information go beyond what is required by the statute. As noted above, the statute merely requires individuals to “notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.” In the proposed rule, “the reason for the overpayment” is merely one piece of information that must be provided.


The proposed rule would suspend the obligation to return overpayments under Section 6402(a) of PPACA “when OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.” CMS also explained that “once the provider or supplier notifies OIG of the identified overpayment through the OIG [Self-Disclosure Protocol], such notice would constitute a report for purposes of the reporting requirement...”

The proposed rule also addresses the impact of Stark-related overpayment reports made under the CMS Self-Referral Disclosure Protocol (“SRDP”). The SRDP was developed after OIG announced in March 2009 that it would “no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation.” The proposed rule establishes that disclosures made under the SRDP also toll the deadline to refund overpayments under Section 6402(a) when CMS acknowledges receipt of the disclosure. However, CMS emphasized that, unlike reports made through the OIG Self-Disclosure Protocol, reports made through the SRDP do not satisfy the reporting requirement under Section 6402(a). CMS explained that the distinction is relevant “because the process of reporting continued on page 26
and returning overpayments...cannot resolve any potential False Claims Act or OIG administrative liability associated with the overpayment (even though returning an overpayment may, among other benefits, limit any FCA or administrative liability arising from the retention of an overpayment). Although CMS is implying that providers must seek a separate release from OIG regarding Stark-related overpayments, CMS seems to be confused about how to proceed given that the OIG is refusing to consider Stark violations under its Self-Disclosure Protocol. CMS explicitly requested comments on alternative approaches that would allow providers and suppliers to avoid making multiple reports of overpayments related to Stark violations.

Overpayments Resulting from Third-Party Kickbacks

CMS also addressed questions about the applicability of Section 6402(a) to overpayments resulting from third-party violations of the Anti-Kickback Statute. CMS acknowledged that there are many circumstances in which providers might submit a claim for payment without knowing that it is tainted by a kickback:

We recognize that, in many instances, a provider or supplier is not a party to, and is unaware of the existence of, an arrangement between third parties that causes the provider or supplier to submit claims that are the subject of a kickback...Moreover, even if a provider or supplier becomes aware of a potential third party payment arrangement, it would generally not be able to evaluate whether the payment was an illegal kickback or whether one or both parties had the requisite intent to violate the anti-kickback statute.

As a result, CMS clarified that the requirements of Section 6402(a) are generally inapplicable to providers who are unaware of kickbacks that might impact the validity of the claims they have submitted, although providers with “sufficient knowledge” of a kickback arrangement must report it:

[W]e believe that providers who are not a party to kickback arrangements are unlikely in most instances to have “identified” the overpayment that has resulted from the kickback arrangement and would therefore have no duty to report it...To the extent that a provider or supplier who is not a party to a kickback arrangement has sufficient knowledge of the arrangement to have identified the resulting overpayment, the provider or supplier must report the overpayment to CMS in accordance with [PPACA] and corresponding regulations. Although the government may always seek repayment of claims paid that do not satisfy a condition of payment, where a kickback arrangement exists, HHS’s enforcement efforts would most likely focus on holding accountable the perpetrators of that arrangement. Accordingly, we would refer the reported overpayment to OIG for appropriate action and would suspend the repayment obligation until the government has resolved the kickback matter.

Overpayments and Cost Reporting

CMS also provided its interpretation in the proposed rule of the requirements applicable to overpayments identified on a cost report. As noted above, PPACA provides that the deadline to report and refund an overpayment is either “(A) the date which is 60 days after the date on which the overpayment was identified; or (B) the date any corresponding cost report is due, if applicable.” CMS emphasized that the phrase “if applicable” limits the circumstances in which a provider could wait until the cost report deadline:

[For those providers that submit cost reports, if the overpayment is such that it would generally be reconciled on the cost report by the provider, the provider would be permitted to report and return the overpayment either 60 days from the identification of the overpayment or on the date the cost report is due, whichever is later.]

As a result, CMS noted that overpayments relating to upcoding, for example, must be reported and returned within 60 days of identification because the upcoded claims are not submitted to Medicare in the form of cost reports. On the other hand, overpayments relating to graduate medical education reimbursement can be reconciled on the provider’s next cost report.

10-Year Lookback Period

CMS proposed establishing a 10-year lookback period for overpayments, noting that the overpayment requirements would only apply “if a person identifies the overpayment within 10 years of the date the overpayment was received.” CMS also proposed amending the reopening rules under Section 405.980(b), which governs reopening of initial determinations, redeterminations, and reconsiderations under Medicare Parts A and B, to permit reopening for a period of 10 years.

CMS explained that the 10 year period was selected “because this is the outer limit of the False Claims Act statute of limitations.” This lookback period, however, is not consistent with the generally applicable limitations period for
Identification of Overpayments

Finally, CMS attempted to address the ambiguity surrounding when the 60 day deadline is triggered. Unfortunately, the agency’s guidance on when overpayments have been “identified” for the purposes of Section 6402(a) did not achieve the clarity providers had hoped for. In its proposed rule, CMS established proposed Section 401.305(a)(2), which provides:

A person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of an overpayment.35

CMS explained that this provision “gives providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists.”36 Thereafter, CMS clarified that, in the context of suspected overpayments, the 60 day deadline does not begin to run until an overpayment has actually been revealed through a “reasonable inquiry”:

In some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment.37

CMS does not attempt to distinguish between an inquiry into the existence of an overpayment and an inquiry into the amount of an overpayment. As a result, it is reasonable to assume that CMS is treating both issues as different aspects of the same broader inquiry. This inevitably raises questions about how long a provider or supplier can take to conduct the inquiry. CMS attempted to address that question by indicating that the inquiry should be conducted “with all deliberate speed”:

[F]ailure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment (emphasis added).38

Shortly thereafter, CMS repeated its chosen standard, stating that “[a]s noted previously, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information…” would result in the improper retention of overpayments.39

Given the historical burden borne by that phrase, it is difficult to take the proposed rule at face value. Following the upheaval caused by the Supreme Court’s decision in Brown v. Board of Education, the Supreme Court infamously watered down its ruling by ordering courts “to enter such orders and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate its purposes and decrees…necessary and proper to effectuate 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Endnotes
1 The Patient Protection and Affordable Care Act, Pub. L. 111-148 (March 23, 2010) and the Health Care and Education Affordability Reconciliation Act, Pub. L. 111-152 (March 25, 2011) are referred to collectively as “PPACA”; see Chananie et al., Disclosing and Refunding Overpayments in Healthcare Cases, The Health Lawyer, Volume 24, Number 3, February 2012.
2 The term “person” is defined as any “provider of services, supplier, medicare managed care organization,… Medicare Advantage organization,… or PDP sponsor.” See 42 U.S.C. § 1320a-7k(d)(4)(C).
3 Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9180 (Feb. 16, 2012). CMS noted that the proposed rule only implements the refund and reporting requirements as they relate to Medicare Part A and Part B providers and suppliers, and that rules regarding other stakeholders would be forthcoming.
4 Id. at 9181.
5 Id.
6 The OIG Self-Disclosure protocol is available to providers who wish to voluntarily disclose evidence of potential fraud. See Publication of the OIG’s Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399 (Oct. 30, 1998). As discussed below, the OIG has established certain limitations on the type of conduct that can be reported through the protocol. See note 20, infra.
7 Although CMS did not clarify this issue, providers submitting reports utilizing a statistical sample would seemingly be forced to exclude some of the required information, including specific claim numbers and dates of service for each overpayment.
8 Id. at 9187.
9 Id.
10 See, e.g., Griffin v. County School Board, 377 U.S. 218 (1964) (holding that “[t]he time for mere ‘deliberate speed’ has run out…”); see also Alexander v. Holmes County Board of Education, 396 U.S. 1218, 1220 (1969) (explaining that “there is no longer any excuse for permitting the ‘all deliberate speed’ phrase to delay the time when Negro children and white children will sit together and learn together in the same public schools.”).
12 Id. at 9187.
13 Id.
14 Id.
15 The OIG Self-Disclosure protocol is available to providers who wish to voluntarily disclose evidence of potential fraud. See Publication of the OIG’s Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399 (Oct. 30, 1998). As discussed below, the OIG has established certain limitations on the type of conduct that can be reported through the protocol. See note 20, infra.
16 Although CMS did not clarify this issue, providers submitting reports utilizing a statistical sample would seemingly be forced to exclude some of the required information, including specific claim numbers and dates of service for each overpayment.
17 Id. at 9187.
19 Id. at 9187.
20 Id.
21 Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9180 (Feb. 16, 2012). CMS noted that the proposed rule only implements the refund and reporting requirements as they relate to Medicare Part A and Part B providers and suppliers, and that rules regarding other stakeholders would be forthcoming.
24 Id.
25 Id.
26 Id. at 9183.
27 Id. at 9184.
28 42 U.S.C. § 1320a-7k(d)(2).
29 77 Fed. Reg. at 9182.
30 Id.
31 Id. at 9184.
32 Id.
33 Id.
34 31 U.S.C. § 3731(b) provides that “[a] civil action under section 3730 may be brought (1) more than 6 years after the date on which the violation of section 3729 is committed, or (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.”
35 Id. at 9187.
36 Id. at 9182.
37 Id.
38 Id.
39 Id.
41 222 U.S. 17, 19-20 (1911).
43 Griffin v. County School Board of Prince Edward County, 377 U.S. 218, 234 (1964).

Health Law Section Offers Publishing Opportunities

The Health Law Section is always interested in publishing material from our members and others. We strive to produce top quality, relevant and interesting articles, books, toolkits, and the like for the health law bar. Opportunities include:

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HEALTH PLANS 2012: HEALTHCARE REFORM CONTINUES

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Introduction
The ongoing implementation of federal healthcare reform continues to strongly impact group health plans, as the mandate for most Americans to have health insurance in 2014 looms closer. Like our previous articles, this article addresses the effect of the Patient Protection and Affordable Care Act (“PPACA”) and other laws on employer-sponsored group health plans.

Most of the PPACA regulations affecting group health plans are issued simultaneously by three federal agencies — the Department of Labor, the Department of Health and Human Services (“HHS”), and the Treasury Department (“Regulatory Agencies”).

Constitutionality of PPACA’s Individual Mandate
The U.S. Supreme Court has accepted an appeal from a decision of the 11th Circuit in which the individual mandate of PPACA was found to be unconstitutional. If the Supreme Court agrees that the individual mandate is unconstitutional, it will also have to decide whether the individual mandate is severable from the rest of PPACA. If it is not severable, the Court could strike down all of PPACA as unconstitutional. The Court heard oral arguments March 26 through 28, 2012, and is scheduled to hand down its decision in June 2012.

New Preventive Care Requirements
PPACA requires that non-grandfathered plans provide certain preventive care benefits without cost-sharing (such as deductibles or copayments). The scope of preventive care covered by this requirement is based on recommendations from certain agencies and regulatory bodies. When these agencies add new recommendations, non-grandfathered plans are given at least a year to begin covering those new preventive care benefits.

In July 2011, additional preventive care services were added to the list of recommendations, including contraception, HPV testing, HIV screening, and breastfeeding supplies and counseling. The full list of new recommendations is available at http://www.hrsa.gov/womensguidelines/. Non-grandfathered plans must cover all of these services for plan years starting on or after August 1, 2012 (January 1, 2013 for most plans). Initially, there was an exemption for certain religious employers from the requirement to provide contraceptive devices to women. After receiving 200,000 public comments on the rules regarding religious employers and contraception, HHS created a one-year enforcement safe harbor to allow additional time to develop regulations to address some of the concerns expressed in the public comments.

Essential Health Benefits
One of the key provisions of PPACA is the establishment of state health insurance exchanges, which will allow individuals, small businesses, and eventually large businesses to purchase health coverage that complies with certain standards. Health exchanges are scheduled to be in operation by January 1, 2014. To be included in an exchange, an insurance policy or health plan must offer certain minimum “essential health benefits” including 10 categories of benefits. In December 2011, HHS released a bulletin indicating that, in lieu of a nationwide definition of “essential health benefits,” HHS would allow each state to designate a “benchmark plan” to set the standard for the essential health benefits for the health insurance and plans to be offered by the state’s health insurance exchanges.

The new policy announced in this bulletin also affects group health plans even if such plans do not intend to seek inclusion in the state exchanges, because PPACA bans lifetime and annual limits on essential health benefits. In a Frequently Asked Questions on Essential Health Benefits Bulletin issued February 17, 2012, FAQ Question 10, HHS stated that for purposes of the ban of annual and lifetime limits on essential health benefits, the Regulatory Agencies will allow self-insured and certain other plans to use any definition of “essential health benefits” that is authorized by the Secretary of HHS, including any available “benchmark” option as described in the bulletin. This FAQ replaced earlier guidance allowing a more flexible approach for self-insured plans, under which the Regulatory Agencies were to take into account “good faith” efforts to comply with a reasonable interpretation of which benefits are “essential health benefits” so long as the health plan applied the definition consistently.
W-2 Reporting

As noted in last year's article, PPACA requires employers to report the cost of employer-provided health coverage on each employee's W-2 form, although the cost of coverage is not included in the employee's taxable income. Most employers are required to comply beginning with the W-2 issued for 2012 income (typically issued in January 2013).

As explained in two IRS Notices on the subject, the cost of coverage includes both the amount paid by the employer and the amount paid by the employee. It also includes the cost of coverage for any dependents covered as a result of their relationship with the employee (e.g., spouse, children, domestic partner, etc.), whether or not such amount is taxable to the employee. Employers with insured plans can use the insurance premium for the employee and family as the reportable cost of coverage. Employers with self-funded plans can use the same method used to calculate the COBRA premium.

Some of the costs to be excluded from the reported costs are employee contributions to a health flexible spending account, amounts contributed to a health savings account (“HSA”), or a health reimbursement account (“HRA”), and the costs of separate vision or dental coverage. The cost of wellness programs, employee assistance programs, or on-site medical clinics must be included in the reportable amount only if the program is covered by COBRA and the employer charges a COBRA premium for the program.

Summary of Benefits and Coverage

PPACA requires plan administrators and insurers to distribute a four-page Summary of Benefits and Coverage (“SBC”). The purpose of the SBC is to give participants or insured individuals a short, straightforward, standardized explanation of the key rules of a group health plan or health insurance policy, much in the same manner that nutrition labels give guidance on the key ingredients of packaged food. This allows participants to compare group health plans and insurance policies and make an informed decision on which plan or policy is best for them and their families. Final SBC rules were issued in February 2012.

The SBC rules take effect for open enrollment periods that begin on or after September 23, 2012. Most plans will need to provide SBCs to participants during the open enrollment period at the end of 2012 for participation in 2013.

Contents of the SBC

An SBC must contain 11 types of information, eight of which are listed in PPACA: (1) a description of coverage; (2) a list of the limitations on coverage; (3) information on cost-sharing provisions; (4) sample coverage/cost scenarios for certain medical conditions; (5) information on renewability/continuation of coverage provisions; (6) a statement about whether the plan provides minimum essential coverage (in 2014 and thereafter); (7) a warning statement that the SBC is only a summary and that the plan documents should be consulted for more information; and (8) a telephone number to call for help and an internet address where the plan documents can be reviewed and obtained. The final regulations added three requirements not specifically listed in PPACA:

• An internet address for obtaining a list of network providers;
• An internet address for additional information on prescription drug coverage;
• Information on how an individual may obtain a “uniform glossary” of commonly used terms.

Although the proposed rules included coverage/cost scenarios for diabetes, having a baby, and breast cancer, the final rules removed the requirement for a breast cancer scenario because of concerns about the significant variability in breast cancer treatment and, thus, its cost.

Distribution and Style Requirements

The final rules require SBCs to be provided at the following times:

• By the first day of the initial enrollment period (the first day that an employee is eligible to join the plan);
• Within 90 days of a request for a special enrollment under HIPAA;
• On the first day of each renewal period (i.e., open enrollment);
• If renewal is automatic, 30 days prior to first day of the plan year;
• Within seven days of a request for an SBC.

The final rules require separate SBCs for each benefit option. Each SBC must follow a uniform four-page, double-sided format with 12-point or larger font, and must use understandable terminology. The SBC must also provide information in non-English languages if it is being provided to participants in counties with large non-English speaking populations.

New Requirement for Advance Notification of Changes

If a group health plan or insurance policy significantly changes the terms of coverage as reflected in the SBC, the rules require that plan participants be notified at least 60 days in advance of the effective date of the change. Thus, if a group health plan will be changed effective January 1, 2014, the notice must be sent by the end of October 2013 (either in the form of a new SBC or as a separate notice).

Amended Claims and Appeals Regulations

The group health plan claims and appeals procedures under the

continued on page 32
Employee Retirement Income Security Act ("ERISA") and PPACA were amended in significant ways by the adoption of new federal regulations in June 2011. Highlights of these changes include the following:

- The Regulatory Agencies rejected the initial proposal that urgent care claims decisions be made as soon as possible but not later than 24 hours after the receipt of the claim. Instead, the deadline for urgent care claims decisions will remain at 72 hours, but only if the plan defers to the attending medical provider’s determination of whether the claim involves urgent care.

- If a plan participant resides in a county in which 10 percent of more of the population is literate only in the same non-English language, the plan or insurer must (1) provide oral language services, such as a customer assistance hotline where questions can be answered in the non-English language; (2) provide certain plan materials in the non-English language; and (3) include a one-sentence statement in certain plan materials in the non-English language about the availability of the language services.

- The regulations clarify that plan benefits must be paid as soon as the final decision of an external review organization ("ERO") is rendered, regardless of whether the plan or insurer intends to seek judicial review of the ERO’s decision.

- Unless the plan is providing appeals to an ERO under applicable state law, only two types of claims are currently eligible for appeal: (1) those involving medical judgment; and (2) those involving a recission (retroactive termination) of coverage.

### Other Developments

#### Patient-Centered Outcomes ("PCO") Fee

In the first federal fee of its type, insurers and sponsors of self-insured health plans are required by PPACA to pay an annual fee beginning in the 2012 plan year (for calendar year plans) and ending with the 2018 plan year. In 2012, the fee is $1 multiplied by the average number of lives covered under the plan. For 2013 through 2018, the fee is $2 (adjusted for health expenditure inflation) multiplied by the average number of lives covered under the plan. This fee will be used to fund a new Patient-Centered Outcomes Research Institute. Regulatory guidance on the particulars of the new PCO fee is expected in the spring of 2012, such as instructions on how to calculate the average number of lives and when and to whom the PCO fee should be sent.

#### The End of the Early Retiree Reinsurance Program ("ERRP")

PPACA includes a one-time allocation to create the Early Retiree Reinsurance Program ("ERRP"). ERRP provided funds to organizations, including businesses, unions, non-profits, and governments, to cover some of the cost of healthcare coverage provided to early (pre-age 65) retirees. The purpose of the temporary program was to lower the cost of providing early retiree coverage, and thereby encourage organizations to continue providing such coverage. As of December 2, 2011, $4.5 billion of the funds had been paid out. Because ERRP has almost paid out the entire $5 billion allocated by PPACA, HHS announced that ERRP would not reimburse any claims incurred after December 31, 2011.

### Medicare Part D

Medicare Part D provides subsidized prescription drug coverage to anyone with Medicare. Individuals who do not sign up for a Medicare Part D prescription drug plan when they are first eligible for Medicare must pay a penalty if they sign up later, unless they had “credible coverage” during the intervening time period. “Credible coverage” means prescription drug coverage that is expected to pay out, on average, as much as standard Medicare prescription drug coverage. Each year, group health plans are required to send a Medicare Part D notice to Medicare-eligible participants prior to the beginning of the open enrollment period, in which the plan discloses to the participant whether the plan’s prescription drug benefit qualifies as “credible coverage.”

PPACA changed the Medicare open enrollment period to October 15 through December 7 (previously it was November 15 through December 31); thus, the deadline for distributing these Medicare Part D notices is a month earlier in the year. In addition, PPACA provides enhanced Medicare Part D benefits at intervals between 2012 and 2021, so plans will need to reevaluate whether their prescription drug coverage is considered credible coverage.

#### Medical Loss Ratio

PPACA requires health insurance issuers to spend a certain portion of premiums on claims and activities that improve healthcare quality for enrollees (the “medical loss ratio” or “MLR”). Health insurance issuers that do not spend the required portion of premiums on such costs must give rebates to enrollees. The first rebates will be issued early in 2012 based on the 2011 medical loss ratios.
States are allowed to request waivers from the federal MLR regulations. Seventeen states and Guam have requested such waivers from HHS, but a vast majority of the requests have either been completely rejected or granted with exceptions.  

Although these medical loss ratio regulations do not directly apply to group health plans, it is possible that insured group health plans may receive rebates as a result of these regulations. In such a situation, the regulations require that such rebates be split proportionally between the group health plan participants and the group health plan based on the amount of the premium that each paid.  

The Journey Ahead

If all or part of PPACA is held to be unconstitutional, group health plans and their sponsoring employers will have to see if and how Congress reacts to the decision, and then decide whether they wish to keep some of the plan design changes made as a result of PPACA (such as coverage for children up to age 26) even if not required by federal law to do so. If PPACA is found to be constitutional, group health plans will continue to be subject to new and amended rules under PPACA for years to come. On the horizon loom changes such as (1) the elimination of all preexisting conditions exclusions; (2) automatic enrollment of new employees into health coverage; (3) a prohibition on requiring employees to wait more than 90 days after hire to join the employer’s group health plan; (4) the individual mandate and the employer pay-or-play penalties; (5) the imposition of a $2,500 maximum for health flexible spending accounts in 2013; and (6) the establishment of state health insurance exchanges.

As they have in the past, group health plans and the employers who sponsor them must continue to plan, react, and adapt to changing legal requirements under PPACA and other laws as well as seemingly ever-increasing costs.

Mr. Bye-Torre has written and spoken on healthcare reform, HIPAA, domestic partners and same-sex marriage benefits issues, Medicare Part D, wellness programs, ERISA, and other state and federal law benefit topics. In addition to his work with ERISA plans, he has extensive experience with governmental and church plans. He is a contributing author to EBIA's HIPAA: Portability, Privacy & Security and Employee Benefits for Domestic Partners: Design, Taxation, and Administration. He can be reached at 206-386-7631 or hdbytorre@stoel.com.

Endnotes


3 This article is limited to PPACA’s implications for group health plans and does not address the effect of PPACA on hospitals, doctors, or other medical providers.


5 Grandfathered plans are plans that were in existence on March 23, 2010 and have not been amended in a way that causes them to lose their grandfathering status. See PPACA § 1251 (general grandfathering provisions); 75 Fed. Reg. 34,538, 34,558 (June 17, 2010) (Treas. Reg. § 54.9815-1251T(a), (g)) (parallel provisions at 75 Fed. Reg. at 34,562 (29 C.F.R. § 2590.1251T(a), (g) (DOL/EBIA)), and 75 Fed. Reg. at 34,566 (45 C.F.R. § 147.140(a), (g) (HHS)).


7 These agencies include the U.S. Preventive Services Task Force (more information about this independent group of medical experts at http://www.ahrq.gov/clinic/uspdfx.htm), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (“CDC”) (more information about this committee at http://www.cdc.gov/vaccines/recs/acip/), and the Health Resources and Services Administration (“HRSA”) (more information about this federal agency at http://www.hrsa.gov/index.html). The current list of recommended preventive care services is available at http://www.healthcare.gov/center/regulations/prevention/recommendations.html.

8 PPACA § 1001 (adding § 2713(b) to PHSA).

9 There is an exemption for contraceptive methods and counseling for certain religious employers. 45 C.F.R. § 147.130(a)(1)(iv)(A).

10 The rules regarding the temporary enforcement safe harbor are available at http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf. The White House has proposed a compromise for religious institutions that it hopes to finalize during the one-year temporary enforcement safe harbor. See http://www.whitehouse.gov/the-press-office/2012/02/10/fact-sheet-womens-preventive-services-and-religious-institutions.


12 See PPACA, Title I, Subtitle D. HHS has issued final regulations on the establishment of healthcare exchanges and the qualified health plans to be offered through such exchanges, which were published in the March 27, 2012 edition of the Federal Register.

13 PPACA § 1311(b)(1).

14 PPACA § 1302.


16 See PPACA § 1001 (adding § 2711 to PHSA).


18 75 Fed. Reg. 37,188, 37,191 (June 28, 2010).

19 Bye & Lennon, Health Plans 2011: Healthcare Reform Begins, supra, at 47.

20 PPACA § 9002.

21 However, employers are exempt from this requirement for 2012 W-2 forms (issued in continued on page 34
Health Plans 2012: Healthcare Reform Continues
continued from page 33

January 2013) if they were required to file fewer than 250 W-2 forms in 2011.

22 See IRS Notices 2010-69 (available at http://

23 COBRA is continuation coverage, on a self-
pay basis, available under federal law to
individuals who lose employer-based care.
More information on COBRA is available at http://www.dol.gov/dol/topic/
health-plans/cobra.htm.

24 An HSA is a tax-advantaged savings account
available to individuals enrolled in high
deductible health plans. More information
about HSAs is available in IRS Publication
969 (available at http://www.irs.gov/pub/irs-
pdf/p969.pdf).

25 An HRA is an employer-funded account that
individuals can use to pay for medical
expenses. More information about HRAs is
available in IRS Publication 969 (available at

26 The regulations enlarge the maximum size to
four double-sided pages, or eight pages of
material.

27 PPACA § 1001 (adding § 2715 to PHSA).

19, 2012, the Regulatory Agencies posted
a set of FAQs on SBCs on the DOL's
website at http://www.dol.gov/dol/topic/
health-plans/cobra.htm.

29 PPACA § 1001 (adding § 2715(b)(3) to
PHSA).

30 77 Fed. Reg. 8,698 (Treas. Reg. § 54.9815-
2715(a)(2)(i)).

31 76 Fed. Reg. 37,208 (June 24, 2011) PPACA
required certain changes to ERISA's claims
and appeals procedures. The Regulatory
Agencies amended ERISA's claims and
appeals to include these and other additional changes.

32 In addition to regulating the privacy and
security of protected health information, HIPAA
also contains “portability” rules that mandate,
among other things, that group health plans
allow employees to enroll when certain events
occur, such as marriage or the addition of new

33 The template, a sample completed SBC, the
uniform glossary, and other documents are
available at http://www.dol.gov/ebsa/
healthreform/. However, the SBC template is
authorized only for coverage beginning before
January 1, 2014.

34 Details about how to obtain information in a
non-English language must be included if the
SBC is being provided to an individual who
resides in a county where 10% or more of the
population are literate only in the same non-
English language. A list of counties is
available at www.dol.gov/ebsa/healthreform.

35 PPACA § 1001 (adding § 2715(d)(4) to
PHSA); 77 Fed. Reg. at 8,699 (Treas. Reg. §
54.9815-2715(b)).

36 76 Fed. Reg. 37,208 (June 24, 2011) PPACA
required certain changes to ERISA’s claims and
appeals procedures. The Regulatory Agencies
amended ERISA’s claims and appeals to
include these and other additional changes.

37 See Interim Final Rules, 75 Fed. Reg. 43,330
(Treas. Reg. § 54.9815-2719T(b)(2)(iii)(B))
(July 23, 2010).

38 The regulations provide a state-by-state list
of these 255 counties, in which the non-English
languages are Spanish, Chinese, Tagalog, or
Navajo.

39 PPACA §§ 4375, 4376.

40 Information on this Institute is available at

41 PPACA § 1102 (more information about ERRP

42 Id.


44 For more information about the Medicare
Part D program, see http://www.medicare.gov/
navigation/medicare-basics/medicare-benefits/
part-d-l.aspx.

45 Id.

46 Id.


48 PPACA § 3204.

49 PPACA § 1101.

50 PPACA § 1001 (adding § 2718(b) to PHSA).

51 Id.

52 A complete list of the states requesting MLR
waivers and HHS's responses is available at
http://cciio.cms.gov/programs/marketreforms/
mlr/index.html.


54 PPACA § 1001 (adding § 2704 to PHSA).

55 See U.S. Department of Labor, Technical
Release 2012-01 (Feb. 9, 2012), available at
http://www.dol.gov/ebsa/newroom/
tr12-01.html (indicating that PPACAs auto-
matic enrollment provision would be delayed
until 2014).

56 PPACA § 1001 (adding § 2708 to PHSA).

57 PPACA § 9005.

58 See PPACA Title I, Subtitle D. HHS has issued
final regulations on the establishment of
healthcare exchanges and the qualified health
plans to be offered through such exchanges,
which were published in the March 27, 2012
dition of the Federal Register.

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and Kahneman’s book focus upon largely automatic mental mechanisms or shortcuts (heuristics) by which people draw conclusions about the meaning of information presented to them or the likelihood of certain outcomes. These heuristics often lead a person to useful conclusions, and are thus adaptive. However, they also often lead people, even experienced social scientists, to dramatically wrong conclusions.

The truth is that abstract reasoning is inherently more difficult than we realize and that in the course of making complex decisions we unconsciously utilize mental shortcuts in reaching these decisions. Moreover, because these shortcuts are evolutionary in their development, we are generally unaware of their existence, not to mention how they shape our thinking.

Kahneman and Tversky's insight was to realize that the unconscious biases that affect our reasoning can be described by references to categories of common errors in thinking and processing information. Representativeness refers to the probability that event or object A is related to event or object B, whether as members of the same category or in a causal sense. Consider the following question. Susan is a 40-year-old professional who belongs to a women's book group and is on the Board of Planned Parenthood. Which is more likely to be her occupation: professor of women's studies or attorney? By a relatively large percentage, respondents to the question arrive at the wrong answer. They pick professor because the description conforms to a stereotype. Attorney is the correct answer because the number of attorneys greatly outnumbers the number of women's studies faculty. This example demonstrates the failure to take into account the prior probability of a particular outcome, i.e. that attorneys are much more numerous than women's studies professors.

According to an old joke, for lawyers the plural of anecdote is data. This may lead to misattribution of causality where the sample size is small. Take, for example, an unusually high rate of cancer in a small town of 5,000 with a nearby petrochemical plant. While it is tempting to draw an inference of causality from the association of a high cancer rate to the chemical plant, an equally plausible explanation is that the association is simply a statistical artifact arising from a small sample size. In this case the base cancer rate is derived from a large sample (the U.S. population) as compared to the size of the town (5,000). It is well-established in statistics that small samples are more likely to yield extreme values than larger ones. The error in assuming causation in this case comes from failing to consider the effect of a small sample size on the observed findings. (Imagine conducting a study of the average height of American men based upon a sample from a neighborhood with a high proportion of college and professional basketball players).

A related problem arises when we fail to take into account the statistical principle of regression to the mean in making predictions and, as a result, create inaccurate explanations to account for the effects observed. Regression to the mean is a term for the statistical principle that if a value is extreme when it is first measured then it will tend toward an average value upon the second measurement. For example, if Tiger Woods scores a 63 on his first round at the Masters, he is more likely to be closer to par on his second round.

A common human mistake is to impute causality for an outcome when the observed results can be simply explained as regression to the mean. An example is the well-known “Sports Illustrated jinx” in which an athlete who appears on the cover of Sports Illustrated is thought to be “jinxed” and thereby doomed to a less successful season the following year. This ignores the effect of regression on the outcome. The athletes on the cover are there because they are having an exceptional season (usually with a good deal of luck thrown in). The following season they are more likely to perform closer to their baseline performance. This example also illustrates the human tendency to impute causality in circumstances in which only correlation is present. Thus appearing on the cover of SI is correlated with a less successful season the following year, but there is no causal relationship.

A second type of shortcut is the availability heuristic. That is the tendency to base estimates of likelihood or probability upon the ease by which the brain retrieves examples of similar facts or occurrences. Thus, one may estimate the probability of heart attack in middle-aged women by recalling specific instances of such occurrences. Notwithstanding the utility of such calculations, the ease of recall reflects more than just the frequency or probability and the use of the availability heuristic often leads to inaccurate estimates and, in particular, a tendency to overestimate the likelihood of certain outcomes.

Consider a situation in which a client asks you to estimate the range of potential jury awards. While attorneys may do research on the question, often they will “guesstimate” based on their knowledge of jury awards in similar cases. In particular, they may recall a recent huge settlement with dramatic facts, some of which may be similar to the case at hand. Research has repeatedly shown that people will overweight the value of recent dramatic events in predicting the likelihood of a similar outcome in another context.
situation. Thus, following 9/11, people were much more likely to overestimate the likelihood of being killed in a terrorist attack.

A third heuristic, anchoring, describes the impact of starting an analysis with an initial value which is then adjusted to provide a final answer. Research has shown that providing subjects with an initial number, even when that number has no relevance to the situation at hand, has a substantial impact on their judgments. For example, shoppers who are exposed to a sign that states “limit of 12 cans per purchase” buy twice as many cans as do those who are not exposed to the sign. Litigators may be familiar with this concept through participation in the mediation of lawsuits in which the initial demand impacts the subsequent negotiation. Plaintiffs who make a high initial demand may intuitively be relying on the anchoring effect and subsequent adjustments to influence upwards the amount of the final settlement.

Kahneman and others have found that research subjects also tend to embrace narratives that they can use to make sense of events that have already occurred. These narratives, in turn, may be used as the basis for understanding or predicting future events. For example, the story of Bill Gates starting what became Microsoft in a garage in Albuquerque is a compelling narrative regarding intelligence, perseverance, determination and enormous luck. Its utility in describing how an enterprising entrepreneur should approach a start-up business is limited in that a simple narrative is incapable of providing the rich detail that an accurate assessment requires. In addition, even a “thick” narrative will not address what is often the most important factor of all—the role of luck (or if you prefer inherent random variation) on subsequent events. The result is that we have a tendency to overestimate the degree to which skill determines outcomes and underestimate the role of luck. Thus, to go back to Tiger, his 63 on the first day of the Masters, while carding a 74 on day two, is more likely explained by luck or random events than by fluctuations of his skill. Trial attorneys seem to appreciate this tendency in jurors and attempt to craft narratives that simplify (or ignore) facts and impute causation in ways that benefit their clients.

What all this suggests to me is that as lawyers we need to be particularly careful when relying on past experience or intuition as guides for decisions. The shortcuts described by Kahneman are both useful and dangerous for the same reason—they operate below the level of conscious experience. We are not aware of their impact on our decision-making and they can easily lead us to incorrect or invalid recommendations. Caution is advised.

Oh yeah, what about Aretha and Melville? Where do they fit in? As Aretha tells us (and as she told Elwood and Jake Blues) – you better think about it. Then think about it again. Set your preconceptions aside. Weigh her words carefully and give her the time she deserves.

Melville’s Ahab is another story. His was the wrong narrative. He over-relied on his past experience and failed to read the signs (e.g. the whiteness of the whale, Queequeg’s construction of his coffin) and proceeded ahead recklessly, thereby dooming his crew. Ishmael, as he beckons us to call him, has the real narrative here. An exploration of mind and fate, spread out across a vast sea, the narrator banished to his fate to die drifting alone on the currents, until, with the appearance of dawn at last, a sail appears on the horizon.

David
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The accountable care organization ("ACO") Task Force was formed to address the myriad issues that surround the development of accountable care organizations, both in response to the provisions of PPACA and the interest of commercial payors in finding new ways to bend the cost curve.

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The Long Term Care Task Force focuses on legal issues for providers and organizations that serve senior and disabled populations in need of long term or chronic care services. As a result, the Task Force addresses many areas of law related to long term care, including reimbursement, corporate governance, labor and employment matters, housing issues, continuing care communities, financing and risk management, to name a few.

Native American Health Task Force
Chair, Rakel Meir, Associate General Counsel, Tufts Health Plan
The Native American Health Task Force examines healthcare issues unique to the Native American population with the goal of improving access to high quality care.

Breast Cancer Task Force
Chair, Shelley K. Hubner, Executive Counsel, Health Net, Inc.
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Health Care Fraud Conference
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5/18/2012 – 5/20/2012
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Webinar

6/14/2012 – 6/15/2012
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See page 29 for more details

7/26/2012
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