



THE HEALTH LAWYER

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MALPRACTICE LIABILITY AND MEDICAL MARIJUANA

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Introduction

As of mid-year 2016, twenty-five states and the District of Columbia authorized the use of raw or botanical marijuana to treat various categories of medical conditions, and an additional fifteen states authorized the use of low-potency delta-9-tetrahydrocannabinol ("THC")¹ marijuana to treat a limited number of medical conditions.² These developments reflect a rapidly growing perception on the part of the U.S. public and policy makers that marijuana has proven health benefits.³ At the same time, however, a large number of national practitioner and scientific organizations have taken official positions against medical marijuana on scientific grounds,⁴ a growing number of studies are uncovering serious negative health consequences associated with its use,⁵ and evidence supporting its effectiveness is confined to a small cluster of medical conditions.⁶

This apparent disconnect between public policy and scientific knowledge could lead to malpractice exposure or other liability for physicians certifying or recommending marijuana for their patients. Physicians in medical

marijuana states do not prescribe marijuana, but rather certify that a patient has a statutorily covered medical condition and meets other criteria to receive a medical marijuana permit or authorization. As will be discussed, this distinction is unlikely to alter the fundamental nature of the doctor/patient relationship or lessen the physician's obligation to render competent professional care.⁷

State laws vary considerably in terms of what medical conditions may be treated with marijuana.⁸ They also vary in terms of the educational and professional obligations they impose on physicians; however, many states require physicians to receive several hours of continuing education on medical marijuana, personally examine each patient, obtain informed consent from the patient, develop a treatment plan, seek consultation if indicated, review the patient's progress in treatment, and maintain accurate medical records.⁹ Failing to abide by the statutory provisions can lead to a loss of medical marijuana certification privileges, professional disciplinary action,¹⁰ and possibly to criminal prosecution.¹¹ It also provides convincing evidence in a malpractice action that the physician's conduct fell below the requisite standard of care, and may even constitute negligence *per se* (on its face) because the provisions are

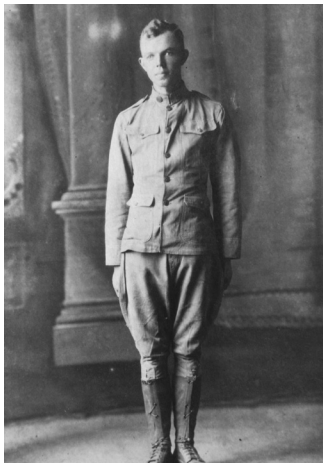
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C. Joyce Hall

My Veteran

For a Southern girl, possibly the only relationship to rival the relationship between a girl and her daddy is the bond between a girl and her granddaddy. I introduce you to my grandfather, Allen G. Monroe, pictured here in his WWI uniform. Pawpe, as he was affectionately known to his eight grandchildren, taught us many life lessons that he was quite sure we were not being taught in school—how to ride a horse, milk a cow, plow a mule (well, I walked behind him), pick peas and beans, dig potatoes and shuck corn. But more importantly, my grandfather taught me to fiercely love my family, my friends, my neighbors, and my country. He also taught me to always honor and respect those who fought for the freedom that we enjoy.



Pawpe trained at Camp Beauregard in Louisiana, and he was preparing to be shipped off when Germany signed the Armistice Agreement on November 11, 1918. He never left American soil, but his devotion to our country's military and veterans' affairs never waned. As a recipient of care at the VA medical center, he often visited his friends or family members who were veterans receiving care at the VA. Pawpe watched his son leave for WWII, and he proudly welcomed him home again when the war ended. He listened to his daughter (my mom) deliver her Salutatorian speech at her high school graduation in 1945 entitled "Our Debt to Our Veterans."

How do we measure what we owe to those who have served on our behalf? I submit that their service should be considered and treated as priceless to all of us who bask in the freedom they preserve for us. From a practical standpoint, what can we do as health lawyers to give

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THE ABA HEALTH LAW SECTION

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Malpractice Liability and Medical Marijuana

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intended specifically to protect patients from foreseeable harm.¹²

Physicians may still be sued for malpractice even if they follow the statutory provisions meticulously. Physicians are often sued for malpractice for treatments that are unquestionably lawful and authorized by applicable licensing and regulatory statutes. The dispositive question in malpractice cases is not whether the physician's actions were legally authorized but whether they were performed in accordance with professional standards of care.¹³

No published court opinion has thus far considered the issue of malpractice liability for a physician certifying or recommending the use of medical marijuana. Although there are numerous instances of consumers being injured by other types of botanical products and herbal remedies, most law suits related to those substances have been product liability actions against the distributors or manufacturers of the products.¹⁴ Medical marijuana raises different legal issues from prior cases because patients are usually required by law to receive a physician's approval to use the drug, whereas other herbal products can be obtained readily without physician involvement. In the absence of analogous legal precedent, courts confronting medical marijuana cases will in many respects be writing on a blank slate.

This article provides a review of scientific research on the proven health benefits and health risks of marijuana, and considers how professional malpractice principles might be applied in medical marijuana cases. It is concluded from this review of the medical and legal literatures that malpractice liability will likely depend on several factors, including: (1) what legal test is applied in a given jurisdiction to define the medical standard of care, (2) the extent to which national practice guidelines and scientific studies are admissible as evidence to

establish the standard of care, and (3) whether the patient was adequately informed about the potential risks and benefits of marijuana, its relative effectiveness compared to alternative treatments for the patient's condition, and the degree to which scientific evidence and expert consensus support or refute its use. It behooves physicians and health lawyers to familiarize themselves with these principles, consider how they are likely to be applied in their jurisdictions, and take reasonable precautions to avoid or reduce malpractice exposure.

This article does not address the issue of legalization or decriminalization of marijuana for recreational purposes. Every citizen has a right to engage in lawful conduct so long as that conduct does not endanger the welfare and safety of others. Different legal principles apply, however, when learned professionals such as physicians are involved in the decision. Patients and society at large have a reasonable expectation that physicians will conduct themselves competently and in accordance with scientific evidence when rendering medical services, and physicians may find themselves liable to patients and foreseeable third parties if that duty is breached.

Health Benefits of Marijuana

Marijuana has no officially recognized health benefits according to the U.S. Food and Drug Administration ("FDA")¹⁵ and more than twenty leading medical and scientific organizations.¹⁶ Recent studies, however, have identified potential benefits from marijuana for treating a limited number of medical conditions, including chronic neuropathic or cancer pain, spasticity associated with neurological disorders like multiple sclerosis, nausea, appetite loss, and severe weight loss associated with wasting illnesses such as cancer and AIDS.¹⁷ Comparable benefits are

often achieved, however, from FDA-approved pharmaceutical medications that are synthesized from chemicals found in the marijuana plant (cannabinoids), which are not smoked and have far less or no intoxicating effects.¹⁸

Pursuant to the U.S. Controlled Substances Act,¹⁹ the FDA and Drug Enforcement Administration ("DEA") work collaboratively to establish a drug's legal status. A drug that has no recognized medical benefit and a high potential for abuse or addiction is listed in Schedule I.²⁰ Drugs that are listed in Schedules II through V have recognized medical benefits and pose respectively less degrees of risk for abuse and other dangerous medical side effects.²¹

The FDA employs a highly rigorous review process in determining whether a drug has proven medical benefits and is safe and effective for medical use.²² An applicant must first conduct preclinical testing on animals to demonstrate that the drug is safe for human testing. If it passes this minimum threshold, studies may then be conducted on healthy human volunteers to assess common side effects of the drug and determine how it is metabolized and excreted in humans. If there is no evidence of toxicity, preliminary efficacy studies are next conducted on patients having a relevant disease or condition to examine the drug's ability to treat that condition. To ensure that the findings are scientifically reliable, at least some of the studies must be concurrent controlled clinical trials, meaning that participants are assigned randomly or in an otherwise unbiased manner to receive either the experimental drug or a placebo (inactive) substance, a different medication, or another form of treatment such as counseling.²³

If the results of the preliminary efficacy studies are favorable, the drug then moves on to large-scale effectiveness studies involving large numbers of

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subjects (often in the hundreds) to examine its effects in different populations, at varying dosages, and in combination with other commonly used medications or treatments. Finally, an independent team of physicians, statisticians, toxicologists, pharmacologists, chemists and other scientists review all of the findings and approve the drug for sale if its proven benefits are determined to outweigh the known risks. Once approved, post-marketing surveillance continues to identify infrequent adverse reactions which may arise when the medication is administered in daily practice to large numbers of patients. If adverse reactions are identified, they are typically described in package inserts or box warnings which must accompany the medication and alert physicians to potential contraindications and warnings about its use.²⁴ In some instances, approved medications may be withdrawn from the market if it is determined that emerging risks outweigh the benefits that the medication may provide.²⁵

Marijuana is presently listed as a Schedule I drug, reflecting the FDA's conclusion that it has no proven medical benefit and carries a high risk for abuse or addiction. As indicated on the FDA's website, "[t]he FDA has not approved any product containing or derived from botanical marijuana for any indication. This means that the FDA has not found any such product to be safe or effective for the treatment of any disease or condition."²⁶ The FDA has, however, approved two pharmaceutical cannabinoids, dronabinol and nabilone, which contain the primary psychoactive ingredient in marijuana, THC, and have relatively minimal intoxicating or addictive effects.²⁷ These medications are approved for the treatment of nausea and to increase appetite and weight gain in patients suffering from wasting illnesses associated with diseases like AIDS or cancer. Other countries, including the United Kingdom and Canada, have approved a

third medication, nabiximols (Sativex), which contains THC and another non-intoxicating chemical found in marijuana, cannabidiol, which may offer benefits for treating neurological conditions such as childhood epilepsy.²⁸

Importantly, an absence of FDA approval does not prove that marijuana is ineffective or unsafe. It simply means that the benefits and risks of the drug have not been studied sufficiently to meet FDA standards, and the risk/benefit ratio is therefore undetermined. Because marijuana is a Schedule I drug, researchers have had a very difficult time studying its effects.²⁹ Researchers must first obtain a license from the DEA and have the study approved by the FDA. In addition, they must generally obtain research-grade marijuana (marijuana of a proven potency that has no impurities) through the National Institute on Drug Abuse ("NIDA"). NIDA provides research-grade marijuana for studies that have received funding from the National Institutes of Health ("NIH"), or for non-NIH-funded projects that have an approved Investigational New Drug ("IND") application on file with the FDA and have been approved as scientifically valid by a Department of Health and Human Services ("HHS") scientific review panel. Since 1970, the University of Mississippi has been the only facility approved by the DEA to grow and harvest marijuana for NIDA-sponsored studies; however, the DEA recently announced that it will allow additional growers to apply for a registration to produce and distribute marijuana for research purposes.³⁰

These manifold obstacles have led several leading scientific and practitioner organizations to call for the FDA to reclassify marijuana from Schedule I to a less restrictive schedule to permit freer research into its potential medicinal benefits.³¹ Yet, in August 2016 the DEA denied a

petition to reclassify marijuana from Schedule I based on an exhaustive review of the scientific literature conducted by HHS.³² The DEA and HHS concluded that there is no statutorily authorized basis to reschedule marijuana because "marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision."³³ Nevertheless, the DEA indicated a willingness to ease restrictions on research into the potential medical benefits of marijuana, including, as mentioned, permitting additional growers to produce research-grade marijuana for federally funded studies.³⁴

Despite substantial hurdles to conducting good-quality research, recent studies have identified potential health benefits from marijuana for treating a limited number of medical conditions. The quality of these studies does not come close to satisfying FDA standards for effectiveness; nevertheless, they provide sufficient promise or "proof of concept" to justify conducting additional research. Systematic reviews performed by leading medical researchers have concluded there is high-quality evidence suggesting that marijuana may be beneficial for treating chronic neuropathic or cancer pain, and for ameliorating spasticity associated with certain neurological disorders such as multiple sclerosis.³⁵ However, comparable benefits may be achieved from nonintoxicating and nonaddictive pharmaceutical cannabinoids.³⁶ Moreover, while there is also considerable evidence that marijuana increases appetite and reduces nausea for persons suffering from wasting illnesses, the effects appear to be no better than for medications already approved by the FDA for treating these conditions.³⁷ Where there is comparable evidence of effectiveness for both marijuana and an FDA-approved pharmaceutical cannabinoid, leading medical experts advise physicians to

begin treatment with the cannabinoid because an acceptable risk/benefit profile has been established for that medication, and switch to marijuana if the cannabinoid proves ineffective.³⁸

Although anecdotal testimonials abound from some patients and physicians, to date there is insufficient evidence to conclude whether marijuana or cannabidiol is effective for treating childhood epilepsy, movement disorders such as Parkinson's or Tourette's syndrome, glaucoma, or urinary tract disorders.³⁹ Moreover, any assertions that marijuana or pharmaceutical cannabinoids can treat other medical conditions, such as mental health disorders, substance use disorders, Alzheimer's disease, autism, insomnia or autoimmune disorders are speculative at this juncture.⁴⁰ In fact, as will be discussed further, evidence suggests that marijuana is likely to worsen the prognosis for many mental health and substance use disorders and interfere with the effects of proven treatments for these conditions.⁴¹

Recommending the use of a non-FDA-approved substance is not necessarily evidence of malpractice. Physicians frequently recommend alternative therapies to their patients, including herbal plants and extracts.⁴² The Dietary Supplement Health and Education Act of 1994⁴³ classifies most herbal plants as dietary supplements, which can be produced, sold and marketed without demonstrating their safety or efficacy. The FDA bears the regulatory burden of proving that a dietary supplement is unsafe before it can be removed from the market.⁴⁴ The opposite burden of proof applies to pharmaceutical medications, which must be proven safe and effective before they can be marketed or sold.⁴⁵

Physicians also frequently prescribe FDA-approved medications for conditions or disorders that are not approved by the FDA.⁴⁶ For example, a medication might be approved for the treatment of epilepsy but physicians

might prescribe it to treat migraine headaches, sleep disorders, or depression. Once a medication has been approved by the FDA for a specified use, physicians are generally free to prescribe it for other off-label uses if, in their professional judgment, it is likely to be safe and effective for those conditions.⁴⁷ In many instances, off-label use is based on anecdotal impressions or clinical observations rather than on scientific evidence of safety and effectiveness.⁴⁸

The terms innovative therapy, alternative medicine, complementary medicine or unorthodox medicine are commonly used to describe non-FDA-approved treatments lacking scientific evidence of effectiveness, and may also refer to off-label uses of FDA-approved medications that have not been evaluated.⁴⁹ Although patients do not have a fundamental right to bypass the FDA review process for pharmaceutical medications,⁵⁰ courts will generally recognize a patient's right to seek unorthodox homeopathic remedies, naturopathic treatments, faith-healing practices, and off-label uses of approved medications.⁵¹ Providing or recommending such alternative treatments typically heightens the physician's duty to inform the patient about the limited scientific basis for the treatment, any known risks of the treatment, the possibility of unknown or unstudied risks, and the availability of FDA-approved treatments, if any, that are proven to be effective for the same condition.⁵²

Health Risks of Marijuana

Although the potential health benefits of marijuana have not been studied nearly sufficiently, a wide range of health risks has been reliably identified. Every intoxicating substance has a dependence liability, defined as the statistical probability that a person who uses that substance will develop a compulsive addiction. The dependence liability for marijuana is approximately nine percent for adult users, 17

percent if use begins during adolescence (which it often does), and nearly 40 percent for persons who use marijuana several times per week.⁵³ A hallmark symptom of substance dependence is uncomfortable or painful withdrawal symptoms when levels of the substance decline in the bloodstream. When marijuana-dependent individuals stop taking marijuana, they experience a withdrawal syndrome comparable to that of nicotine.⁵⁴ Cannabis dependence has been an officially recognized psychiatric diagnosis since 1980,⁵⁵ and cannabis withdrawal syndrome is now recognized, as well.⁵⁶

Chronic marijuana use is reliably associated with apathy or reduced motivation to engage in goal-directed behaviors, a syndrome referred to as an amotivational state.⁵⁷ Neuroimaging studies suggest this may occur, in part, because marijuana blunts transmission of or sensitivity to the neurotransmitter dopamine in brain regions which are responsible for reward-based learning, thus reducing motivation to accomplish intellectual tasks.⁵⁸ Researchers have not ruled out the possibility that impaired motivation may lead to marijuana use rather than the other way around. Unmotivated people may simply be more inclined to use marijuana. Nevertheless, if marijuana were an FDA-approved medication, such a strong and consistent correlation with a serious adverse syndrome would be more than sufficient to require a package insert alerting physicians to the potential medical risk.⁵⁹

Even when chronic marijuana users are not intoxicated, they perform significantly worse than nonusers on neuropsychological tests of cognitive functioning, including attention, learning, memory, motor skills, and verbal abilities.⁶⁰ Faced with novel or complex intellectual tasks, their decision-making processes tend to be more impulsive, irrational, and ineffective than those of nonusers.⁶¹ Some evidence suggests that these deficits may improve after at least 30 consecutive days of abstinence.⁶² However, when use begins in adolescence, the effects

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are far more likely to be long-lasting or permanent. Repetitive use of marijuana during the teen years is associated with a six- to eight-point decline in Intelligence Quotient (“IQ”).⁶³ This impairment in intelligence appears to be global, meaning that deficits are found in a wide range of areas, including verbal intelligence, memory, processing speed, perceptual reasoning, visual perception, manual dexterity, psychomotor speed, and executive functioning (planning, judgment, and insight).⁶⁴ Lower IQ scores among adolescent-onset marijuana users have been measured for at least a full year after complete cessation of usage,⁶⁵ poorer physical and mental health outcomes have been measured for at least nine years,⁶⁶ reduced occupational productivity has been measured for at least 17 years,⁶⁷ lesser quality of life has been measured for 21 years,⁶⁸ and greater odds of physical or mental disability have been measured for 39 years.⁶⁹

These serious cognitive and adaptive impairments occur primarily in adolescent-onset or young-adult-onset marijuana users, and medical marijuana laws typically exclude or curtail access for teens to medical marijuana. Yet, whenever marijuana has been decriminalized for medical or recreational purposes, the largest upsurge in use has typically been among teens and young adults,⁷⁰ the persons most susceptible to long-term brain impairment. As large numbers of older adults now also use marijuana—often for the first time or after decades of nonuse—in response to medical marijuana laws, it is unknown what cognitive impairments may ensue for these marijuana-inexperienced individuals whose brain functioning may already be compromised by incipient dementia or normal aging.⁷¹

Even when used sporadically, marijuana can cause lasting structural or neurochemical changes in the

human brain. Recent studies employing advanced brain-imaging techniques have uncovered specific brain regions in which some of these changes are occurring. Scientists have discovered structural abnormalities among occasional marijuana users in the nucleus accumbens and amygdala (responsible, in part, for emotional regulation and learning from experience),⁷² the prefrontal cortex (responsible for planning, judgment, and inhibition of risky behaviors),⁷³ and the limbic striatum (responsible for motivation and attention).⁷⁴ Again, scientists have not disentangled cause and effect. Preexisting neurological impairments may predispose some individuals to use marijuana. Nevertheless, in the face of such persistent and powerful correlations with serious adverse syndromes, the FDA would almost certainly require a package insert if marijuana were an approved pharmaceutical medication.

The cognitive effects of marijuana have important implications for risky and impaired driving. Occasional use of marijuana by non-addicted individuals increases the odds of becoming involved in a car accident by more than two fold.⁷⁵ In laboratory simulation studies, single-dose administration of marijuana significantly increased lane weaving, impaired subjects’ ability to visually track other cars, reduced subjects’ reaction times, and interfered with their ability to divide their attention (e.g., drive and change the radio station at the same time).⁷⁶ Among chronic marijuana users, these impairments have been found to last for at least three weeks following complete abstinence, when the subjects were no longer experiencing the intoxicating effects of the drug.⁷⁷ Individuals may believe wrongly that they are capable of driving when, in fact, they are dangerously impaired. In Colorado, traffic fatalities involving marijuana roughly doubled in the first two years after

marijuana was legalized, and marijuana caught up with alcohol as the leading cause of traffic accidents.⁷⁸

Longitudinal studies show a consistent association between adolescent-onset marijuana use and subsequent development of severe psychotic disorders, including schizophrenia.⁷⁹ Scientists have recently identified specific genes or gene-clusters (genotypes) that are activated or inhibited by marijuana use, and which significantly increase the risk of developing a severe psychotic disorder such as schizophrenia.⁸⁰ Following an initial psychotic episode, continued use of marijuana is also associated with a significantly poorer prognosis, including more hospital readmissions, more days spent in the hospital, and a greater likelihood of being involuntarily committed for treatment.⁸¹

Increased rates of other mental health disorders are also known to co-occur with marijuana use, including major depression, bipolar disorder (manic-depression), and post-traumatic stress disorder (“PTSD”).⁸² However, it is unclear which disorder, if any, is responsible for this co-morbidity. Some mentally ill individuals may use marijuana as an effort to self-medicate psychiatric symptoms, or perhaps marijuana may trigger a latent genetic predisposition to mental illness. By following participants prospectively for several years, researchers have determined that the onset of mental illness typically occurs after marijuana use,⁸³ which would appear to be inconsistent with a self-medication hypothesis. However, a recent national longitudinal study in the United States found no correlation after three years between marijuana use and subsequent rates of mood or anxiety disorders.⁸⁴ Perhaps three years is too soon for mental illness to manifest, or perhaps the relationship between mental illness and marijuana

use is more complicated than expected. For example, mental illness and marijuana use may emerge independently from a common genetic vulnerability, which would be difficult to detect in a longitudinal study. Additional neuroimaging and genetic studies are needed to better understand the comorbid relationship between marijuana use and serious mental illness.

Marijuana use is strongly linked to subsequently higher rates of dependence on alcohol and other drugs,⁸⁵ general psychological distress⁸⁶ and suicidality⁸⁷ after follow-up periods of three to eight years. For individuals who are dependent on other substances of abuse, such as heroin, alcohol or cocaine, use of marijuana is reliably associated with significantly higher rates of treatment failure and relapse to these other substances.⁸⁸

Smoking marijuana also causes many of the same respiratory and cardiac symptoms as tobacco, including frequent lung illnesses, a higher risk of lung infection, daily cough, and increased phlegm.⁸⁹ Marijuana use raises heart rate for up to three hours, which can increase the chance of a heart attack or dangerous cardiac event.⁹⁰ Marijuana smoke contains 50 percent more carcinogens than tobacco smoke;⁹¹ however, it is unknown whether marijuana smokers have a higher risk for lung cancer.⁹² Marijuana use during pregnancy or lactation is linked to an increased risk of brain and behavioral problems in babies and young children.⁹³ Finally, weekly use of marijuana is associated with a significantly lower sperm count and sperm concentration in young adult males.⁹⁴

Malpractice Liability for Medical Marijuana

As stated earlier, no published court opinion was found that has considered potential malpractice liability for a physician certifying or recommending medical marijuana. Courts may, however, be expected to confront such cases in light of the fact

that states are rapidly broadening patient access to medical marijuana, most expert organizations oppose these measures on scientific grounds, studies are increasingly uncovering serious health risks associated with its use, evidence is lacking or equivocal concerning its effectiveness for many health conditions, and less risky FDA-approved pharmaceutical cannabinoids are already available for the few conditions that marijuana may treat effectively. Presumably courts will analyze such cases by applying or adapting traditional medical malpractice principles to the new policy and scientific landscapes.

Duty of Care

The first issue courts will need to address in these cases is whether certifying the need for medical marijuana creates a traditional doctor/patient relationship, which carries with it a concomitant duty to render competent professional care.⁹⁵ The existence of a doctor/patient relationship does not turn on the question of whether a physician has prescribed an FDA-approved treatment. Rather, a professional duty of care is created by the virtue of the powers and authority vested in physicians through state licensure and accreditation laws, as well as the reasonable expectations of patients.⁹⁶ If a patient is legally obligated to obtain certification for medical marijuana from a physician, and if the patient reasonably believes that the physician will exercise professional judgment and training in making that decision, then a doctor/patient relationship is likely to be recognized. Courts typically find that a doctor/patient relationship has been created where the physician assumed some degree of responsibility for making a diagnostic or treatment decision, or saw the patient as part of a formal consultation even if the physician had no further involvement with the patient's care.⁹⁷

Breach of Duty

A more complicated issue is determining whether a physician has

breached the duty of care by engaging in substandard medical practice. For example, a question might arise as to whether a physician breached the duty of care by failing to take an adequate medical history of a patient which would have uncovered contraindicated conditions that are likely to be made worse by marijuana use, such as psychosis, addiction or respiratory disease. Similarly, a physician might be found to have breached the duty of care by certifying marijuana to treat a condition that is unlikely to improve from its use, such as autism or anxiety. In such cases, the potential medical risks associated with marijuana use might not be justified by any known or reasonably anticipated benefits that are likely to ensue.

Some states employ a custom-based test for determining the standard of care, requiring the physician to provide the type and level of care that an ordinary and prudent physician with comparable training and experience would have provided under similar circumstances in the same or a similar locality.⁹⁸ Expert testimony from physicians who are familiar with the relevant locality and area of practice is usually required to establish the customary standard of care.⁹⁹ Notably, in jurisdictions following a custom-based standard, medical experts are not required to describe, or even to consult, scientific studies to support their conclusions. The critical question is not whether the physician's actions were scientifically valid, but rather whether they were performed in accordance with customary medical practices in the relevant locality and area of specialization.¹⁰⁰

In contrast to a custom-based test, a growing number of jurisdictions apply a reasonable physician standard, which evaluates the physician's actions against what he or she should have done as opposed to what is customarily done.¹⁰¹ In these jurisdictions, scientific evidence supporting or refuting a given practice is directly on point to the question of whether the physician's

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treatment was reasonable and competent.¹⁰² On direct examination, expert witnesses may describe the results of scientific studies to support their conclusions about reasonable care, or on cross-examination may be called upon to defend their conclusions in the face of conflicting findings. For example, if a physician certified the use of medical marijuana for a patient with an anxiety disorder and a serious history of respiratory illness, a medical expert witness might testify that studies have found no evidence of medical benefits from marijuana for the treatment of anxiety, and have identified health risks for patients with anxiety and respiratory disease.

Several nationally recognized scientific and practitioner organizations have published official position statements against medical marijuana.¹⁰³ Given the current state of scientific knowledge, these organizations have concluded that the risk/benefit ratio for medical marijuana is unknown or does not justify its use to treat any recognized medical condition. Defendants in states applying a reasonable physician standard may face substantial uphill battles defending their actions in the light of these expert position statements.

Traditionally, documents such as these were inadmissible as hearsay to prove the truth of the matter asserted, but in some instances could be used on cross-examination to impeach or discredit a witness.¹⁰⁴ The more modern approach adopted by many states is to admit such evidence on direct or cross examination if the expert acknowledges that the source is reliable and authoritative, or if the court takes judicial notice of its reliability.¹⁰⁵ Regardless of what evidentiary standard is applied, lawyers with a modicum of ingenuity can often get this evidence admitted to impeach or resurrect testimony concerning the appropriate standard of care. In jurisdictions that

apply a reasonable physician standard, physicians who certify marijuana for medicinal use may find themselves having to explain away contradictory scientific advisories from a plethora of leading national organizations.

Notably, a small number of professional organizations have issued position statements in favor of medical marijuana,¹⁰⁶ and as discussed earlier scientific studies do lend support for its use in treating a limited number of medical conditions, including nausea, appetite loss, neuropathic pain, and spasticity associated with multiple sclerosis.¹⁰⁷ This evidence may be admissible to argue that there are two schools of thought concerning the use of marijuana for some medical conditions. The existence of two schools of thought generally serves as a conclusive defense against a medical malpractice claim.¹⁰⁸ Courts are reluctant to wade into disputes between opposing factions of the medical community because judges and lawyers are not qualified by knowledge or training to weigh the scientific bases of conflicting medical theories.¹⁰⁹ Many jurisdictions require a considerable number of recognized and reputable physicians to support a practice in order to establish a second school of thought.¹¹⁰ In these jurisdictions, physicians are more likely to prevail if they certify the use of marijuana for conditions like chronic pain or spasticity, for which there is some evidence of efficacy and support from at least some professional organizations. However, success is less likely for other conditions, such as anxiety or depression, for which there is little or no evidence of effectiveness and reputable professional support is largely absent.

A few jurisdictions, however, lend an expansive interpretation to the two schools of thought doctrine. These jurisdictions give substantially greater weight to divided medical opinion, and look more favorably on

a physician's actions if there is any reasonable difference of opinion among experts.¹¹¹ In these jurisdictions, a defense based on two schools of thought may also succeed for conditions such as anxiety, for which treatment with marijuana receives small pockets of support in the medical community.

Professional Practice Guidelines

State laws vary considerably in terms of the educational and professional obligations they place on physicians concerning the use of medical marijuana. As noted above, many states require physicians to receive several hours of continuing education, examine each patient personally, obtain informed consent for treatment, develop a treatment plan, review the patient's progress, and maintain accurate medical records.¹¹² These statutes establish a floor of acceptable practices, and failing to abide by the basic requirements may lead to professional disciplinary action, malpractice exposure, and potentially to criminal prosecution.

Professional organizations and leading medical experts have gone considerably further in proposing higher standards of practice for medical marijuana. Beyond the basic obligations imposed by many state statutes, experts have, for example, recommended that physicians have a preexisting and ongoing treatment relationship with each patient, as opposed to acting merely as a consultant; schedule routine follow-up visits with every patient; explicitly rule out the presence of contraindicated co-occurring conditions, including substance use disorders, major depressive disorder, anxiety disorders, and respiratory tract infections; begin treating patients with FDA-approved and evidence-based treatments, including pharmaceutical cannabinoids, before resorting to marijuana if those treatments fail; ensure that the physician has adequate information concerning

the specific dosage and composition of the marijuana product; and ensure that the physician is well-trained in addiction medicine and prepared to make immediate and appropriate referrals for substance use disorder treatment where indicated.¹¹³

In states that apply a reasonable physician standard, these practice guidelines might be admissible to show that a physician's conduct fell short of the appropriate standard of care, or to rebut or impeach a physician's assertion that he or she exercised due care in treating the patient.¹¹⁴ Whether courts will hold physicians accountable merely for complying with the basic conditions enumerated in medical marijuana statutes or whether they will raise the bar in the light of published practice guidelines is an open question. In the interests of "defensive medicine," physicians and their attorneys are advised to familiarize themselves with the practice guidelines promulgated by leading medical organizations and experts, and conform their practices accordingly. Needing to justify why one's actions fell short of recommended standards of care published by leading scientific and practitioner organizations is unlikely to sit well with a judge or jury. Worse, not being aware of the existence of these guidelines could be viewed quite negatively in a medical malpractice action.

Informed Consent and Assumption of the Risk

Patients generally have a right to forego accepted medical treatments and seek innovative or unorthodox therapies so long as they knowingly, intelligently and voluntarily assume the risk for that decision.¹¹⁵ Patients may not, however, waive a physician's duty to render competent professional care or adhere to professional practice guidelines and statutory provisions.¹¹⁶ Because these duties are imposed by law or reflect the medical profession's legitimate role in policing the conduct of its own members, patients

have no standing or authority to relieve a physician of the obligations. A patient may not, for example, waive a physician's duty to perform a thorough diagnostic assessment or take a detailed medical history before certifying or recommending the use of marijuana. Assuming a physician has performed a competent diagnostic assessment and reached an educated conclusion about potentially effective courses of action, it is the patient's prerogative to choose from among the promising alternatives.

Material Information

Except in limited circumstances such as medical emergencies, physicians are generally required to provide their patients with any material information that is likely to bear on the decision whether to choose or forego a medical treatment, including the likelihood and magnitude of foreseeable risks from the treatment, the likelihood and magnitude of anticipated benefits, and the relative odds of success compared with alternative treatments that may be available for the same condition.¹¹⁷ Some states employ a patient-based test for assessing materiality, requiring physicians to provide information that an ordinary, reasonable and prudent patient would want to know in making the decision.¹¹⁸ In these states, the factfinder (judge or jury) typically decides whether disclosure was adequate. Other states employ a custom-based test, requiring physicians to provide information that physicians practicing in the same or a similar locality and area of practice would ordinarily provide.¹¹⁹ In those states, expert medical testimony is typically required to define the customary standard for disclosure.

Studies indicate that numerous factors influence a patient's decision to seek alternative and complementary treatments, including lifestyle preferences and cultural beliefs. Chief among these factors is the perceived efficacy of the treatment in improving the patient's condition.¹²⁰ Patients

also frequently harbor false beliefs that herbal remedies are harmless when, in fact, many carry serious risks for adverse health effects and dangerous interactions with prescription medications.¹²¹ Therefore, material elements of informed consent should always include, at a minimum, a frank discussion with the patient about the proven and unproven health risks and benefits of marijuana, the known risk/benefit ratio, the possibility of unknown or unstudied risks, the availability of effective FDA-approved medications for the patient's condition, the possibility of dangerous interactions with other medications the patient might be taking, and the possibility that the product may contain contaminants resulting from inadequate quality control over the manufacturing process.¹²² It is ordinarily insufficient to deliver this information in a general consent form. Information must be provided concerning the specific treatment under consideration, the patient's specific medical condition, and the known risks and benefits of alternative treatments for that same condition.¹²³

Causality

Plaintiffs must also make a showing of causality, meaning not only that some harm was caused by ingesting medical marijuana but also that the patient would most likely not have used it if adequate disclosure had been made. Most states apply an objective test for causality, requiring a finding that an ordinary, reasonable and prudent patient would not have undergone the treatment if the potential harms had been disclosed.¹²⁴ Other states apply a subjective test, requiring the factfinder to conclude that the plaintiff in the instant case would not have undergone the treatment.¹²⁵ Whichever causality test is applied, the weight of national scientific opinion will usually bear directly on the question of whether the plaintiff or a reasonably prudent patient would have elected to proceed with a treatment in light of the known medical risks and benefits.¹²⁶ Plaintiffs can

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often make a strong case that the results of scientific studies, professional practice guidelines, and position statements issued by national organizations are material information that, if known, would have led them to choose a different course of action.

Physicians are not required to provide information that is widely known by the public or already known to the patient.¹²⁷ For example, the intoxicating effects of marijuana are widely known; therefore, physicians are probably not obliged to describe these effects. Many patients, however, are unlikely to be aware that impairments in cognitive and motor functioning can last for nearly a month after cessation of usage.¹²⁸ Therefore, patients should be advised not to drive a car, operate heavy machinery, or perform other potentially hazardous tasks for at least several hours after cessation of use,¹²⁹ and perhaps for up to one month for chronic users or those who have a low physiological tolerance to the drug. Many patients also believe that marijuana is beneficial for treating conditions such as anxiety, depression, PTSD, autism, addiction, glaucoma, and autoimmune disorders, when in fact it is likely to exacerbate these conditions and interfere with the benefits of effective treatments.¹³⁰ Physicians may be obliged, therefore, to affirmatively disabuse patients of such generally held and erroneous beliefs.¹³¹ For these reasons, several leading practitioner organizations and national experts have proposed augmenting the informed consent requirements for medical marijuana to include telling patients that marijuana is not FDA-approved, has little or no support from leading medical and scientific organizations, has not been shown to be effective for treating most medical conditions for which it has been studied, is not a standardized or purified product, and can precipitate relapse for persons with mental health and substance use

disorders.¹³² Whether courts will assign weight to these augmented expert disclosure recommendations remains an open question.

Failing to obtain adequate informed consent from patients may also expose physicians to third-party liability for foreseeable harms to other persons.¹³³ For example, physicians could be held liable to third parties who are injured in a car or work accident caused by a patient's use of medical marijuana. Although the physician has no doctor/patient relationship with such third parties, he or she may be liable in ordinary negligence for nonfeasance by failing to take simple precautions that could have avoided a foreseeable and serious injury. Courts have found physicians liable to third parties, for example, for failing to warn patients about potential driving hazards associated with the use of prescription medications.¹³⁴

Warning a patient about such risks is ordinarily sufficient to shield the physician from third-party liability even if the patient ignores the physician's advice and engages in hazardous activity. Courts will typically view a patient's willful noncompliance with a physician's directive as an intervening factor that breaks the legal chain of causation.¹³⁵ Once a physician has duly warned a patient about the known and reasonably anticipated risks of a medication, it becomes the patient's responsibility to act accordingly and with due caution.

Conclusion

Policy makers often make decisions based on the majority will of the electorate, but physicians and other healthcare practitioners do not. Authorizing physicians to certify or recommend medical marijuana does not, in any way, absolve them from rendering competent and scientifically informed medical care. Physicians who

wade into the terrain of medical marijuana must understand that although their actions may not be criminally culpable in legalizing states, they are nonetheless recommending or certifying a non-FDA-approved treatment that is not supported or recognized by the large majority of their professional colleagues. Doing so may expose them to malpractice liability no differently than if they prescribed any other potentially hazardous and scientifically controversial experimental treatment.

It is important, therefore, for physicians and health lawyers to familiarize themselves with the scientific evidence and applicable legal doctrines in their jurisdictions pertaining to medical marijuana. Physicians practicing in jurisdictions that apply a custom-based standard of care, or that construe the two schools of thought doctrine expansively to encompass any reasonable division of medical opinion, might take solace in the fact that medical marijuana receives pockets of support from certain sectors of the medical community. However, those practicing in states that apply a reasonable physician standard, or that require a substantial minority of opinion to establish an alternative school of thought, may find themselves pitted in court against the national weight of scientific opinion and the pillars of mainstream medicine. This is especially so if they recommend or certify marijuana for unproven or currently discredited purposes, such as to treat anxiety or depression.

Physicians are further advised to take informed consent procedures very seriously in these cases. Meticulous efforts are called for to educate patients about what is known and not known about marijuana, and to disabuse patients of any misconceptions they may have stemming from public advocacy campaigns that often overstate the proven health benefits of marijuana and understate the known

risks. Patients have a reasonable expectation that physicians, as learned professionals, will conduct themselves impartially and competently in rendering medical treatment, and the law may compensate them and foreseeably injured third parties if that duty of care is breached.

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Endnotes

- ¹ Delta-9-tetrahydrocannabinol or THC is the primary psychoactive ingredient in marijuana that causes intoxication.
- ² See ProCon.org, 25 Legal Medical Marijuana States and DC: Laws, Fees, and Possession Limits (last updated 6/28/2016), at <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>; ProCon.org, 16 States With Laws Specifically About Legal Cannabidiol (CBD) (last updated 3/17/2016), at <http://medicalmarijuana.procon.org/view.resource.php?resourceID=006473>; see also Jane C. Maxwell & Bruce Mendelson, *What Do We Know Now About the Impact of the Laws Related to Marijuana?*, 10 J. ADDICTION MED. 3, 5 Fig. 2 (2016) (reporting that 11 states had bills pending during the 2015 legislative session to broaden patient access to medical marijuana).
- ³ See Pew Research Center, Public Support for Legalizing Medical Marijuana 1 (2010) (finding that 73% of Americans support legalizing marijuana if authorized by a doctor), at <http://people-press.org/2010/04/01/public-support-for-legalizing-medical-marijuana/>; Pew Research Center, In Debate Over Legalizing Marijuana, Disagreement Over Drug's Dangers 4 (2015) (finding the primary reason for supporting legalization of marijuana is its perceived medicinal benefits), at <http://people-press.org/2015/04/14/in-debate-over-legalizing-marijuana-disagreement-over-drugs-dangers/>; see also Pew Research Center, View of Marijuana—Legalization, Decriminalization, Concerns 1 (2014) (finding that 54% of Americans favor legalizing marijuana for recreational purposes), at <http://people-press.org/2014/04/02/section-2-views-of-marijuana-legalization-decriminalization-concerns/>; Sharon R. Sznitman & Anne L. Bretteville-Jensen, *Public Opinion and Medical Cannabis Policies: Examining the Role of Underlying Beliefs and National Medical Cannabis Policies*, 12 HARM REDUCTION J. 46 (2015) (finding that 78% of Israeli citizens and 53% of Norwegians support medical marijuana).
- ⁴ For a discussion of national organizations taking positions against medical marijuana, see *infra* note 16 and accompanying text.
- ⁵ For a discussion of negative health consequences associated with marijuana use, see *infra* notes 53 to 94 and accompanying text.
- ⁶ For a discussion of the proven health benefits of marijuana, see *infra* notes 35 to 40 and accompanying text.
- ⁷ See *infra* notes 95 to 97 and accompanying text.
- ⁸ See Findlaw, Medical Marijuana Laws by State (2016) (listing covered medical conditions by state in medical marijuana laws), at <http://healthcare.findlaw.com/patient-rights/medical-marijuana-laws-by-state.html>; Esther K. Choo & Sherry L. Emery, *Clearing the Haze: The Complexities and Challenges of Research on State Marijuana Laws*, ANNALS N.Y. ACAD. SCI. 3 (2016) (noting that covered medical conditions vary from a few specific conditions to 45 conditions, and may include open-ended language permitting latitude in treating a wide range of debilitating symptoms), available at doi: 10.1111/nyas.13093; Jessica Bestrashniy & Ken C. Winters, *Variability in Medical Marijuana Laws in the United States*, 29

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- ⁹ See, e.g., California Dept. of Public Health, Medical Marijuana Identification Card Program, Physician Responsibilities (2016), at <https://cdph.ca.gov/programs/Pages/MMPDrRespon.aspx>; Massachusetts Department of Public Health, Bureau of Health Care Safety and Quality, Medical Use of Marijuana Program, Guidance for Physicians Regarding the Medical Use of Marijuana (as amended June 9, 2015), at <http://mass.gov/eohhs/docs/dph/quality/medical-marijuana/physician-guidance-2015-06-09.pdf>.
- ¹⁰ See, e.g., Massachusetts Medical Society, Massachusetts Medical Marijuana Law: Considerations for Physicians 3 (2013) (noting that physician disciplinary processes applicable to medical marijuana are well established by the Board of Medicine, and the Dept. of Public Health reserves the right to revoke a registration to certify medical marijuana if a physician commits fraud or fails to meet continuing education requirements), at <http://massmed.org/Advocacy/Key-Issues/Medical-Marijuana/Massachusetts-Medical-Marijuana-Law--Considerations-for-Physicians/#.V5aAt7grKUk>; Massachusetts Medical Society, Overview of Physician Sections of Medical Marijuana Regulations (2013) (listing grounds for revoking a physician's registration for medical marijuana), at <http://massmed.org/Advocacy/Key-Issues/Medical-Marijuana/Overview-of-Physician-Sections-of-Medical-Marijuana-Regulations/#.V5aDSLgrKUk>.
- ¹¹ See *Colorado v. Montante*, Co. Ct. App. No. 13CA1858 (Co. Ct. App. 2015) (affirming convictions for fraud and attempting to influence a public servant for a physician who misrepresented a patient's need for medical marijuana), available at <http://cases.justia.com/colorado/court-of-appeals/2015-13ca1858.pdf?ts=1428591942>; but see *Arizona v. Gear*, No. CR-14-0408-PR (Az., May 6, 2016) (holding that Arizona's medical marijuana statute shields physicians from criminal prosecution for failing to follow the requirements of the law), available at https://azag.gov/sites/default/files/State_of_AZ_VS_Gear.PDF.pdf.
- ¹² See BLACK'S LAW DICTIONARY 847 (7th ed., 2000) (defining negligence per se); Law and Physician Health Law Web Site, Negligence per se (1993), at <http://biotech.law.lsu.edu/Books/lbb/x133.htm>.
- ¹³ See *infra* notes 98 to 114 and accompanying text.
- ¹⁴ See Timothy Caulfield & Colin Feasby, *Potions, Promises and Paradoxes: Complementary and Alternative Medicine and Malpractice Law in Canada*, 9 HEALTH L. J. 183, 193-3 (2001) (noting that nearly one quarter of patients using homeopathic and herbal remedies have experienced serious adverse side effects, occasionally leading to product liability actions).
- ¹⁵ See U.S. Food and Drug Administration, FDA and Marijuana 1 (2016) (indicating the FDA has not approved marijuana as safe and effective for any medical use), at <http://fda.gov/newsevents/publichealthfocus/ucm421163.htm>.
- ¹⁶ See ALISON MACK & JANET JOY, MARIJUANA

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- 17 For a discussion of the measured health benefits of marijuana, see *infra* notes 35 to 37 and accompanying text.
- 18 See *infra* notes 36 to 37 and accompanying text.
- 19 Pub. L. No. 91–513, Title II, § 101, Oct. 27, 1970, 84 Stat. 1242, codified at 21 U.S.C. § 801 et seq.
- 20 21 U.S.C. § 812 (b)(1).
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 - 29 See generally Shauncy Ferro, *Why It's So Hard for Scientists to Study Medical Marijuana*, POPULAR SCI. (April 18, 2013), available at <http://popsci.com/science/article/2013-04/why-its-so-hard-scientists-study-pot>.
 - 30 See generally National Institute on Drug Abuse, NIDA's Role in Providing Marijuana for Research, at <https://drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research> (revised August 2016).
 - 31 See American Academy of Family Physicians, *supra* note 16, at 1 (requesting that the FDA change marijuana's classification to facilitate clinical research); American Academy of Neurology, *supra* note 16, at 1 (requesting reclassification of marijuana from Schedule I to improve access for approved scientific protocols); American Academy of Pediatrics, *supra* note 16, at 2 (recommending changing marijuana to Schedule II to facilitate research); American College of Physicians, *supra* note 16, at 1 (urging an evidence-based review of marijuana's status as a Schedule I controlled substance); American Epilepsy Society, *supra* note 16, at 1 (urging that marijuana's status as a DEA Schedule I controlled substance be reviewed); American Medical Association, *supra* note 16, at 1 (calling on the FDA to create a special schedule for marijuana with the goal of facilitating clinical research); American Nurses Association, *supra* note 16, at 1 (calling for the FDA to reschedule marijuana to reduce restrictions on research); Tuberosus Sclerosis Alliance, *supra* note 16, at 1 (supporting a review of marijuana's status as a DEA Schedule I controlled substance).
 - 32 See generally Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 FED. REG. 53687 (Aug. 12, 2016) (to be codified at 21 C.F.R. Chap. II Pt. 1301).
 - 33 *Id.* at 53688.
 - 34 *Id.* at 53689.
 - 35 See Kevin P. Hill, *Medical Marijuana for Treatment of Chronic Pain and Other Medical and Psychiatric Problems: A Clinical Review*, 313 J. AM. MED. ASS'N. 2474, 2477 (2015) (concluding there is high-quality evidence from multiple randomized clinical trials that marijuana is effective for treating chronic pain, neuropathic pain, and spasticity associated with multiple sclerosis); Barbara S. Koppel et al., *Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders*, 82 NEUROLOGY 1556, 1556 (2014) (concluding marijuana is probably effective for treating spasticity and central pain); Ziva D. Cooper & Margaret Haney, *Sex-Dependent Effects of Cannabis-Induced Analgesia*, 167 DRUG & ALCOHOL DEPENDENCE 112, 117 (2016) (finding the analgesic effects of marijuana are greater for males than for females).
 - 36 See Penny F. Whiting et al., *Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis*, 313 J. AM. MED. ASS'N. 2456, 2467 (2015) (finding moderate-quality evidence that pharmaceutical cannabinoids treat chronic pain and spasticity effectively).
 - 37 See Christopher Munsey, *Medicine or Menace? Psychologists' Research Can Inform Debate Over Legalizing Marijuana*, 41 MONITOR ON PSYCHOL. 50, 53 (2010) (concluding that dronabinol at adequate doses achieves the same effects as marijuana on appetite and weight gain); National Institute on Drug Abuse, *DrugFacts: Is Marijuana Medicine?* 3 (2015) (concluding that dronabinol and nabilone are effective for treating nausea caused by chemotherapy and appetite loss in patients with wasting illness caused by AIDS), available at <https://drugabuse.gov/publications/drugfacts/marijuana-medicine>; but see Penny F. Whiting et al., *supra*, at 2467 (concluding evidence is low quality for effects of pharmaceutical cannabinoids on nausea, vomiting and weight gain).
 - 38 See, e.g., Kevin P. Hill, *supra* note 35, at 2477 (recommending that treatment be initiated with dronabinol or nabilone and escalated to include marijuana only if these are not successful).
 - 39 See Barbara S. Koppel et al., *supra* note 35, at 1556 (concluding that marijuana is probably ineffective for treating bladder complaints and its effects are unknown for epilepsy and movement disorders); D. Gloss & B. Vickrey, *Cannabinoids for Epilepsy*, 3 COCHRANE DATABASE SYSTEMATIC REV. (2014) (concluding no reliable conclusions can be drawn concerning the efficacy of cannabinoids for treating epilepsy), available at <http://ncbi.nlm.nih.gov/pubmed/24595491>; American Epilepsy Society, *supra* note 16, at 1 (concluding robust scientific evidence is lacking to support marijuana for treating epilepsy); Kevin P. Hill, *supra* note 35, at 2477 (concluding only preliminary studies suggest marijuana might be effective for glaucoma).
 - 40 See Kevin P. Hill, *supra* note 35, at 2477 (concluding that the evidence supporting marijuana and cannabinoids for conditions other than chronic pain, neuropathic pain, and spasticity is “either equivocal or weak”); Michael Shermer, *The Quack of the Gaps Problem: Facilitated Communication, Autism and Patients' Rights*, Scientific American 75 (August, 2016) (noting the long list of failed treatments for autism includes marijuana); Deidre A. Conroy et al., *Marijuana Use Patterns and Sleep Among Community-Based Young Adults*, 35 J. ADDICTIVE DISEASES 135 (2016) (finding that symptoms of insomnia and sleep disturbances were worse for participants using marijuana on a daily basis), available at doi:10.1080/10550887.2015.1132986.
 - 41 See Kevin P. Hill, *supra* note 35, at 2478 (concluding that marijuana is contraindicated for patients with substance use, anxiety, mood, and psychotic disorders); Efrat Aharonovich et al., *Postdischarge Cannabis Use and its Relationship to Cocaine, Alcohol, and Heroin Use: A Prospective Study*, 162 AM. J. PSYCHIATRY 1507, 1511 (2005) (finding higher relapse rates for patients in substance use disorder treatment when they used marijuana); Mohammadali Mojarrad et al., *Marijuana Use and Achievement of Abstinence from Alcohol and Other Drugs Among People with Substance Dependence: A Prospective Cohort Study*, 142 DRUG & ALCOHOL DEPENDENCE 91, 94 (2014) (same); M. Alvarez-Jimenez et al., *Risk Factors for Relapse Following Treatment for First Episode Psychosis: A Systematic Review and Meta-Analysis of Longitudinal Studies*, 139 SCHIZOPHRENIA RES. 116 (2012) (finding higher relapse rates for patients with psychotic disorders when they used marijuana); Rashmi Patel et al., *Association of Cannabis Use with Hospital Admission and Antipsychotic Treatment Failure in First Episode Psychosis: An Observational Study*, 6 BRIT. MED. J. e009888 (same), available at doi:10.1136/bmjopen-2015-009888; Marcel O. Bonn-Miller et al., *Prospective Investigation of the Impact of Cannabis Use Disorders on Posttraumatic Stress Disorder Symptoms Among Veterans in Residential Treatment*, 5 PSYCHOLOGICAL TRAUMA: THEORY, RES. & PRACT. 193, 196 (2013) (finding poorer outcomes in PTSD treatment for military veterans with cannabis use disorders).
 - 42 See Timothy Caulfield & Colin Feasby, *supra* note 14, at 186-7 (reviewing studies finding that approximately 20% to 50% of citizens in the United States, Canada, France, Denmark and Australia make use of alternative medical treatments); Aimee Doyle, *Alternative Medicine and Medical Malpractice*, 22 J. LEGAL MED. 533, 534 (2001) (noting that nearly 60% of mainstream physicians refer patients for alternative therapies) (citing J. Borkan et

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- al., *Referrals for Alternative Therapies*, 39 J. FAM. PRAC. 545 (1994)); Stephen Bent, *Herbal Medicine in the United States: Review of Efficacy, Safety, and Regulation*, 23 J. GEN. INTERNAL MED. 854, 854 (2008) (noting that 20% of the U.S. population has used herbal products); Edzard Ernst, *Prescribing Herbal Medications Appropriately*, 53 J. FAM. PRAC. 985, 985 (2004) (noting the percentage of patients using herbal medications increased nearly 400% from 1990 to 1997).
- 43 Pub. L. No. 103-417, Oct. 25, 1994, 108 Stat. 4325, codified at 21 U.S.C. § 301 et seq.
- 44 21 U.S.C. § 342. Importantly, draft guidance from the FDA suggests that botanical products which are intended to treat disease may be regulated as a drug rather than a dietary supplement. See U.S. Food and Drug Administration, *Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration: Draft Guidance for Comment 3-4* (2006), available at <http://fda.gov/OHRMS/DOCKETS/98FR/06D-0480-GLD0001.PDF> (last updated December 1, 2006). If this provision is ultimately adopted, medical marijuana products could potentially be subjected to the FDA approval process.
- 45 See *supra* notes 22 to 25 and accompanying text.
- 46 See generally David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 ARCHIVES GEN. PSYCHIATRY 1021 (2006) (finding that 21% of prescriptions were for off-label use).
- 47 See Randall S. Stafford, *Regulating Off-Label Drug Use – Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (2008) (noting that off-label use of medications is legal and common).
- 48 *Id.* (noting that off-label use of medications is often unsupported by strong evidence).
- 49 See generally Dieter Giesen, *Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination*, 3 MED. L. REV. 22 (1995) (differentiating innovative therapy from traditional and experimental therapies); MICHAEL H. COHEN, *COMPLEMENTARY AND ALTERNATIVE MEDICINE: LEGAL BOUNDARIES AND REGULATORY PERSPECTIVES* (1998) (defining alternative and complementary therapies); J. Brad Kallmayer, *A Chimera in Every Sense: Standard of Care for Physicians Practicing Complementary and Alternative Medicine*, 2 IND. HEALTH L. REV. 225 (2005).
- 50 See generally *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (finding no constitutional right for terminally ill patients to receive experimental drugs undergoing lengthy FDA approval).
- 51 See *Schneider v. Revici*, 817 F.2d 987, 995 (2d. Cir. 1987) (finding no reason patients should not be allowed to forego currently approved medical treatments in search of unconventional remedies).
- 52 See Aimee Doyle, *supra* note 42, at 548 (recommending that physicians providing alternative treatments obtain comprehensive informed consent akin to what is required for experimental treatments) (citing Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J. L. & MED. 185, 187 (1998)); Timothy Caulfield & Colin Feasby, *supra* note 14, at 195 (same); *Schneider v. Revici*, *supra*, at 996 (finding that a patient may make an informed decision to seek unconventional treatment pursuant to a carefully documented consent form). For further discussion of recommended informed consent procedures for medical marijuana, see *infra* notes 117 to 132 and accompanying text.
- 53 See WORLD HEALTH ORG., *THE HEALTH AND SOCIAL EFFECTS OF NONMEDICAL CANNABIS USE* 40 (2016) (concluding that the risk of dependence for marijuana is approximately 1 in 10 among those who ever used the drug, 1 in 6 among adolescent users, and 1 in 3 among daily users), available at http://who.int/substance_abuse/publications/cannabis_report/en/; Nora D. Volkow et al., *Adverse Health Effects of Marijuana Use*, 370 NEW ENG. J. MED. 2219, 2219-20 (2014) (concluding that marijuana is addictive for approximately 9% of those who experiment with the drug, approximately 1 out of 6 people who start using it as a teenager, and 25% to 50% of daily users); Kevin P. Hill, *supra* note 35, at 2478 (concluding marijuana is addictive for 9% of adult users and 17% of adolescent users); Peggy van der Pol et al., *Predicting the Transition From Frequent Cannabis Use to Cannabis Dependence: A Three-Year Prospective Study*, 133 DRUG & ALCOHOL DEPENDENCE 352, 354 (2013) (finding 37% dependence liability for frequent marijuana users); James C. Anthony et al., *Comparative Epidemiology of Dependence on Tobacco, Alcohol, Controlled Substances, and Inhalants: Basic Findings From the National Comorbidity Study*, 2 EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY 244, 251, tbl.2 (1994) (finding 9% dependence liability for marijuana users in a national U.S. study); F. A. Wagner & James C. Anthony, *From First Drug Use to Drug Dependence: Developmental Periods of Risk for Dependence Upon Marijuana, Cocaine, and Alcohol*, 26 NEUROPSYCHOPHARMACOLOGY 479 (2002) (finding 8% dependence liability for marijuana users in a national study); Alan J. Budney & B. A. Moore, *Development and Consequences of Cannabis Dependence*, 42 J. CLINICAL PHARMACOLOGY 1S, 29S (2002) (concluding the dependence liability for marijuana is 9% overall, 20% to 30% for those have used marijuana at least 5 times, and 35% to 40% for those who use marijuana daily).
- 54 See Nora D. Volkow et al., *supra* note 53, at 2219 (noting there is a consensus among scientists that marijuana produces a bona fide withdrawal syndrome characterized by irritability, sleeping difficulties, depression, drug cravings, and anxiety); Alan J. Budney et al., *Marijuana Abstinence Effects in Marijuana Smokers Maintained in their Home Environment*, 58 ARCHIVES GEN. PSYCHIATRY 917 (2001); U. W. Preuss et al., *Cannabis Withdrawal Severity and Short-term Course Among Cannabis-Dependent Adolescent and Young Adult Inpatients*, 106 DRUG & ALCOHOL DEPENDENCE 133 (2010); Philip H. Smith et al., *Marijuana Withdrawal and Aggression Among a Representative Sample of U.S. Marijuana Users*, 132 DRUG & ALCOHOL DEPENDENCE 63 (2013).
- 55 See AM. PSYCHIATRIC ASS'N., *DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS* 175-6 (3d ed. 1980); AM. PSYCHIATRIC ASS'N., *DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS* 176-7 (3d ed. rev. 1987); AM. PSYCHIATRIC ASS'N., *DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS* 216 (4th ed. 1994); AM. PSYCHIATRIC ASS'N., *DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS* 236 (4TH ed. text rev. 2000).
- 56 See AM. PSYCHIATRIC ASS'N., *DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS* 517-9 (5th ed. 2013); see also Jordon P. Davis et al., *Cannabis Withdrawal, Posttreatment Abstinence, and Days to First Cannabis Use Among Emerging Adults in Substance Use Treatment: A Prospective Study*, 46 J. DRUG ISSUES 64, 76 (2016) (finding that cannabis withdrawal increases the risk of treatment failure and relapse to cannabis use).
- 57 See Nora D. Volkow et al., *Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review*, 73 J. AM. MED. ASS'N. 292, 293 (2016) (concluding from preclinical and clinical studies that cannabis use is associated with an amotivational state).
- 58 *Id.* at 294.
- 59 See U.S. Food and Drug Administration, *Warnings for Prescription Drugs*, *supra* note 24, at 3 (requiring a package insert or box warning if an adverse reaction associated with a drug could result in a “substantial disruption of the ability to conduct normal life functions”).
- 60 See generally Nora D. Volkow et al., *supra* note 57, at 292; E. A. Osuch et al., *Depression, Marijuana Use and Early-Onset Marijuana Use Conferred Unique Effects on Neural Connectivity and Cognition*, 134 ACTA PSYCHIATRICA SCANDINAVICA 399 (2016) (finding that frequent marijuana use was associated with changes in neuronal connectivity in brain regions responsible for motor planning, motor control, ventral emotion, and reward processing).
- 61 See generally Jon E. Grant et al., *Neuropsychological Deficits Associated with Cannabis Use in Young Adults*, 121 DRUG & ALCOHOL DEPENDENCE 159 (2012); Michael T. Kuciewicz et al., *Dysfunctional Prefrontal Cortical Network Activity and Interactions Following Cannabinoid Receptor Activation*, 31 J. NEUROSCIENCE 15560 (2011).
- 62 See generally A.M. Schreiner et al., *Residual Effects of Cannabis Use on Neurocognitive Performance After Prolonged Abstinence: A Meta-Analysis*, 20 EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY 420 (2012).
- 63 See generally Madeline H. Meier et al., *Persistent Cannabis Users Show Neuropsychological Decline from Childhood to Midlife*, PROC. NAT'L ACAD. SCI. (2012), available at www.pnas.org/cgi/

- doi/10.1073/pnas.1206820109; E. A. Osuch et al., *supra* note 60, at 402 (finding that early onset marijuana use was associated with significantly lower total and verbal IQ scores).
- 64 See Madeline H. Meier et al., *supra*, at E2659, E2661; Michael Takagi et al., *Verbal Memory, Learning, and Executive Functioning Among Adolescent Inhalant and Cannabis Users*, 72 J. STUD. ALCOHOL & DRUGS 96, 102 (2011); K. I. Bolla et al., *Dose-related Neurocognitive Effects of Marijuana Use*, 50 NEUROLOGY 1337 (2002).
- 65 See Madeline H. Meier et al., *supra*, at E2661.
- 66 See generally Amelia M. Arria et al., *Marijuana Use Trajectories During College Predict Health Outcomes Nine Years Post-Matriculation*, 159 DRUG & ALCOHOL DEPENDENCE 158 (2016).
- 67 See generally Motoaki Hara et al., *Concurrent Life-Course Trajectories of Employment and Marijuana-use: Exploring Interdependence of Longitudinal Outcomes*, 45 J. SUBSTANCE ABUSE TREATMENT 426 (2013), available at [http://journalofsubstanceabusetreatment.com/article/S0740-5472\(13\)00115-3/abstract](http://journalofsubstanceabusetreatment.com/article/S0740-5472(13)00115-3/abstract).
- 68 See generally Jane A. Fischer et al., *Cannabis Use and Quality of Life of Adolescents and Young Adults: Findings from an Australian Birth Cohort*, 47 J. PSYCHOACTIVE DRUGS 107 (2015).
- 69 See generally Anna-Karin Danielsson et al., *Cannabis Use in Adolescence and Risk of Future Disability Pension: A 39-Year Longitudinal Cohort Study*, 143 DRUG & ALCOHOL DEPENDENCE 239 (2014).
- 70 See generally Christian Thurstone et al., *Medical Marijuana Diversion and Associated Problems in Adolescent Substance Treatment*, 118 DRUG & ALCOHOL DEPENDENCE 489 (2011) (finding that 49% of adolescents in substance use disorder treatment reported obtaining marijuana from someone with a medical marijuana card), available at <http://ncbi.nlm.nih.gov/pubmed/21565453>; Joseph J. Palamar et al., *Correlates of Intentions to Use Cannabis Among US High School Seniors in the Case of Cannabis Legalization*, 118 INT'L J. DRUG POL'Y 489 (2014) (finding in a national U.S. survey that 10% of non-marijuana-using adolescents intended to use marijuana if it were legalized), available from <http://dx.doi.org/10.1016/j.drugpo.2014.01.017>; Jane C. Maxwell & Bruce Mendelson, *supra* note 2, at 10 (finding that adolescent perceptions about the dangers of marijuana decreased significantly in states that legalized marijuana for medicinal or recreational use); see also Magdalena Cerda et al., *Medical Marijuana Laws in 50 States: Investigating the Relationship Between State Legalization of Medical Marijuana and Marijuana Use, Abuse and Dependence*, 120 DRUG & ALCOHOL DEPENDENCE 22 (2010) (finding significantly higher rates of marijuana use, abuse and dependence in states with medical marijuana laws), available at [http://drugandalcoholdependence.com/article/S0376-8716\(11\)00274-2/abstract](http://drugandalcoholdependence.com/article/S0376-8716(11)00274-2/abstract); Joseph Schuermeyer et al., *Temporal Trends in Marijuana Attitudes, Availability and Use in Colorado Compared to Non-Medical Marijuana States: 2003-11*, 140 DRUG & ALCOHOL DEPENDENCE 145 (2014) (finding that legalization of marijuana in Colorado was associated with a lower perception of risks from marijuana and potentially higher rates of marijuana abuse and dependence), available at <http://ncbi.nlm.nih.gov/pubmed/24837585>.
- 71 See Namkee G. Choi et al., *Older-Adult Marijuana Users and Ex-Users: Comparisons of Sociodemographic Characteristics and Mental and Substance Use Disorders*, 165 DRUG & ALCOHOL DEPENDENCE 94, 100-101 (2016) (finding that older adult marijuana users had high rates of mental health disorders warranting clinical attention).
- 72 See generally Jodi M. Gilman et al., *Cannabis Use is Quantitatively Associated with Nucleus Accumbens and Amygdala Abnormalities in Young Adult Recreational Users*, 34 J. NEUROSCIENCE 5529 (2014).
- 73 See generally Young-Hoon Sung et al., *Decreased Frontal N-Acetylaspartate Levels in Adolescents Concurrently Using Both Methamphetamine and Marijuana*, 246 BEHAV. BRAIN RES. 154 (2013), available at <http://dx.doi.org/10.1016/j.bbr.2013.02.028>; Michael T. Kuczewicz et al., *supra* note 61.
- 74 See generally Michael A. P. Bloomfield et al., *The Link Between Dopamine Function and Apathy in Cannabis Users: An [18F]-DOPA PET Imaging Study*, 231 PSYCHOPHARMACOLOGY 2251 (2014), available at doi:10.1007/s00213-014-3523-4.
- 75 See generally Mark Asbridge et al., *Acute Cannabis Consumption and Motor Vehicle Collision Risk: Systematic Review of Observational Studies and Meta-analysis*, 344 BRIT. MED. J. e536 (2012), available at doi:10.1136/bmj.e536; Mu-Chen Li et al., *Marijuana Use and Motor Vehicle Crashes*, 34 EPIDEMIOLOGICAL REV. 65 (2011), available at doi:10.1093/epirev/mxr017; Rebecca L. Hartman & Marilyn A. Huestis, *Cannabis Effects on Driving Skills*, 59 CLINICAL CHEMISTRY (2012), available at <http://hwmain.clinchem.org/cgi/doi/10.1373/clinchem.2012.194381>.
- 76 See Rebecca L. Hartman & Marilyn A. Huestis, *supra*, at 1.
- 77 See UNITED NATIONS OFF. DRUGS & CRIME, CANNABIS: A SHORT REVIEW 4 (n.d.) (concluding that marijuana negatively affects reaction time, attention, motor performance, coordination, and information processing for up to 28 days after abstinence), available at https://unodc.org/documents/drug-prevention-and-treatment/cannabis_review.pdf; Wendy M. Bosker et al., *Psychomotor Function in Chronic Daily Cannabis Smokers During Sustained Abstinence*, 8 PLOS ONE e53127 (2013) (finding that impairments in critical tracking and divided attention skills were observable after 3 weeks of abstinence), available at doi:10.1371/journal.pone.0053127.
- 78 See ROCKY MOUNTAIN HIGH INTENSITY DRUG TRAFFICKING AREA, THE LEGALIZATION OF MARIJUANA IN COLORADO: THE IMPACT 2 (2015), available at <http://rmhidta.org/html/2015%20final%20legalization%20of%20marijuana%20in%20colorado%20the%20impact.pdf>; Stacy Salomonsen-Sautel et al., *Trends in Fatal Motor Vehicle Crashes Before and After Marijuana Commercialization in Colorado*, 140 DRUG & ALCOHOL DEPENDENCE 137 (2013), available at <http://dx.doi.org/10.1016/j.drugalcdep.2014.04.008>.
- 79 See generally Rajiv Radhakrishnan et al., *Gone to Pot – A Review of the Association Between Cannabis and Psychosis*, 5 FRONT PSYCHIATRY ONLINE (2016) (concluding that marijuana can be a component cause of psychotic disorders but is neither necessary nor sufficient for the condition), at <http://ncbi.nlm.nih.gov/pubmed/24904437>; David J. Castle, *Cannabis and Psychosis: What Causes What?*, 5 MED. REP. ONLINE (2013) (same), at <http://ncbi.nlm.nih.gov/pubmed/23361396>; Matthew Large et al., *Cannabis Use and Earlier Onset of Psychosis, A Systematic Meta-analysis*, 68 ARCHIVES GEN. PSYCHIATRY 555 (2011) (finding the average age of onset of psychosis is 2.7 years sooner for marijuana users than nonusers), available at doi:10.1001/archgenpsychiatry.2011.5; Nora D. Volkow et al., *supra* note 57, at 294 (concluding from longitudinal studies that marijuana use precedes psychosis after controlling statistically for alcohol and other drug consumption).
- 80 See generally Marta Di Forti et al., *Confirmation that the AKT1 (rs2494732) Genotype Influences the Risk of Psychosis in Cannabis Users*, 72 BIOLOGICAL PSYCHIATRY 811 (2012); see also Rajiv Radhakrishnan et al., *supra*, at 23 (concluding that genetic factors confer a vulnerability to psychosis from marijuana exposure).
- 81 See generally Tabea Schoeler et al., *Association Between Continued Cannabis Use and Risk of Relapse in First-Episode Psychosis*, 73 J. AM. MED. ASS'N. PSYCHIATRY 191 (2016) (finding a dose-dependent relationship between continued marijuana use and psychiatric rehospitalizations for patients following an initial psychotic episode); Nora D. Volkow, *supra* note 57, at 294; M. Alvarez-Jimenez et al., *supra* note 41; Rashmi Patel et al., *supra* note 41.
- 82 See generally EDWARD V. NUNES ET AL., SUBSTANCE DEPENDENCE AND CO-OCCURRING PSYCHIATRIC DISORDERS: BEST PRACTICES FOR DIAGNOSIS AND CLINICAL TREATMENT (Civic Research Inst., 2010); Stephen Ross, *The Mentally Ill Substance Abuser*, in TEXTBOOK OF SUBSTANCE ABUSE TREATMENT 537 (4th ed., Marc Galanter & Herbert D. Kleber eds., 2008); Daniel Rasic et al., *Longitudinal Associations of Cannabis and Illicit Drug Use With Depression, Suicidal Ideation and Suicidal Attempts Among Nova Scotia High School Students*, 129 DRUG & ALCOHOL DEPENDENCE 49 (2013).
- 83 See generally Melanie Gibbs et al., *Cannabis Use and Mania Symptoms: A Systematic Review and Meta-Analysis*, 171 J. AFFECTIVE DISORDERS 39 (2015); David W. Brook et al., *Drug Use and the Risk of Major Depressive Disorder, Alcohol Dependence, and Substance Use Disorders*, 50 ARCH. GEN. PSYCHIATRY 1039 (2002); Matthew Large et al., *supra* note 79; Russell C. Callaghan et al., *Methamphetamine Use and Schizophrenia: A Population-Based Cohort Study in California*, 169 AM. J. PSYCHIATRY 389 (2012); but see Marcel O. Bonn-Miller et al., *Cannabis Use Among Military Veterans After Residential Treatment for Posttraumatic Stress Disorder*, 25 PSYCHOLOGY ADDICTIVE BEHAV. 485, 489 (2011) (finding that PTSD symptoms typically occurred prior to marijuana use among military veterans).
- 84 See generally Carlos Blanco et al., *Cannabis Use and Risk of Psychiatric Disorders: Prospective Evidence from a US National Longitudinal Study*, 72 J. AM. MED. ASS'N. 388 (2016), available at doi:10.1001/jamapsychiatry.2015.3229.

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- ⁸⁵ See Carlos Blanco et al., *supra* note 84, at E5; David W. Brook et al., *supra* note 83.
- ⁸⁶ See generally Anna-Karin Danielsson et al., *Cannabis Use and Psychological Distress: An 8-Year Prospective Population-Based Study Among Swedish Men and Women*, 59 ADDICTIVE BEHAV. 18 (2016) (finding significantly higher rates of psychological distress after 8 years among female marijuana users than nonusers, but no differences for males).
- ⁸⁷ See generally Nadav Shalit et al., *The Association Between Cannabis Use and Suicidality Among Men and Women: A Population-Based Longitudinal Study*, 205 J. AFFECTIVE DISORDERS 216 (2016) (finding significantly higher rates of suicidality among male marijuana users after 3 years compared to nonusers, but no differences for females), available at <http://dx.doi.org/10.1016/j.jad.2016.07.010>.
- ⁸⁸ See generally Efrat Aharonovich et al., *supra* note 41, at 1511; Mohammadali Mojarad et al., *supra* note 41, at 94.
- ⁸⁹ See generally Jeanette M. Tetrault et al., *Effects of Marijuana Smoking on Pulmonary Function and Respiratory Complications: A Systematic Review*, 167 ARCHIVES INTERNAL MED. 221 (2007) (concluding that long-term marijuana smoking is associated with increased respiratory symptoms suggestive of obstructive lung disease); National Institute on Drug Abuse, *DrugFacts: Marijuana 3*, at <https://drugabuse.gov/publications/drugfacts/marijuana> (revised March 2016).
- ⁹⁰ See National Institute on Drug Abuse, *supra*, at 3; see also Barbara S. Koppel et al., *supra* note 39, at 1561 (finding 1% risk of serious adverse health events from medical marijuana).
- ⁹¹ See BRIT. LUNG FOUND., *THE IMPACT OF CANNABIS ON YOUR LUNGS 6* (2012), available at http://drugsandalcohol.ie/17670/1/The_impact_of_cannabis_on_your_lungs_-_BLF_report_2012.pdf.
- ⁹² See National Institute on Drug Abuse, *supra* note 89, at 3.
- ⁹³ See American College of Obstetricians and Gynecologists, *supra* note 16, at 2-3 (concluding that marijuana may impair the neurodevelopment of a fetus).
- ⁹⁴ See generally Tina D. Gundersen et al., *Association Between Use of Marijuana and Male Reproductive Hormones and Semen Quality: A Study of 1,215 Healthy Young Men*, AM. J. EPIDEMIOLOGY (2016), at doi:10.1093/aje/kwv135.
- ⁹⁵ See MARK A. HALL ET AL., *MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS* 169-170 (3rd ed., Wolters Kluwer, 2013) (noting that courts find enhanced protections for medical patients based on the implied or expressed belief that the treatment relationship is a fiduciary one in which physicians owe heightened duties to protect the vulnerable patient's interests).
- ⁹⁶ *Id.* at 114-115.
- ⁹⁷ *Id.* (citing, in part, *Crisp Regional Hospital v. Oliver*, 621 S.E.2d 554, 560-561 (Ga. App. 2005); *White v. Harris*, 36 A.2d 203 (Vt. 2011)).
- ⁹⁸ See, e.g., *McCourt v. Abernathy*, 457 S.E.2d 603, 606-607 (S.C. 1995) (upholding jury instruction applying custom-based standard of care in a medical malpractice case).
- ⁹⁹ See, e.g., *Locke v. Pachtman*, 446 Mich. 216, 222 (1994) (noting the long-recognized importance of expert testimony in establishing the custom-based standard of care in medical malpractice cases).
- ¹⁰⁰ See Philip G. Peters, *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 913 (2002) (noting that a custom-based standard defers conclusively to medical opinion and removes other evidence concerning reasonable medical practice from jury consideration), available at <http://scholarship.law.missouri.edu/cgi/viewcontent.cgi?article=1311&context=facpubs>.
- ¹⁰¹ *Id.* at 913-916 (reviewing movement away from custom-based standard to a reasonable physician standard).
- ¹⁰² See Timothy Caulfield & Colin Feasby, *supra* note 14, at 198-200 (discussing the emergence of evidence-based medicine and its implications in malpractice actions for reasonable medical practices).
- ¹⁰³ See *supra* note 16 and accompanying text.
- ¹⁰⁴ See, e.g., *Stang-Starr v. Byington*, 532 N.W.2d 26, 30 (Neb. 1995) (finding that learned treatises and similar publications may be admissible to impeach, contradict or discredit a witness but not as evidence to support an opinion or theory).
- ¹⁰⁵ See MARK A. HALL ET AL., *supra* note 95, at 377-378 (citing in part Federal Rules of Evidence 701, 702, 703 & 803).
- ¹⁰⁶ See U.S. Pain Foundation, *supra* note 16, at 1 (concluding that people living with chronic illness and pain should have access to timely and appropriate treatments, which includes medical marijuana); American Nurses Association, *supra* note 16, at 1 (concluding that marijuana has been shown to be effective in treating a wide range of symptoms in a variety of conditions).
- ¹⁰⁷ See *supra* notes 35 to 37 and accompanying text.
- ¹⁰⁸ See, e.g., *Jones v. Chidester*, 531 Pa. 31, 40, 610 A.2d 964 (1992) (finding that two schools of thought is an absolute defense to medical malpractice).
- ¹⁰⁹ See, e.g., Brennen McKenzie, *Complementary and Alternative Medicine (CAM) and the Law Part 3: Malpractice 3*, at <https://sciencebasedmedicine.org/cam-and-the-law-part-3-malpractice/> (last updated October, 2016).
- ¹¹⁰ See, e.g., *Jones v. Chidester*, *supra*, 531 Pa. 31, 40.
- ¹¹¹ See, e.g., *Chumbler v. McClure*, 505 F.2d 489, 492 (6th Cir. 1974) (finding that a reasonable division of medical opinion is sufficient to direct a verdict for the defendant).
- ¹¹² See, e.g., California Dept. of Public Health, *supra* note 9; Massachusetts Department of Public Health, *supra* note 9.
- ¹¹³ See American Society of Addiction Medicine, *The Role of the Physician in "Medical" Marijuana* 38-39 (2010), available at http://asam.org/docs/public-policy-statements/1role_of_phys_in_med_mj_9-10.pdf?sfvrsn=0; Kevin P. Hill, *supra* note 35, at 2478-2480.
- ¹¹⁴ See Timothy Caulfield & Colin Feasby, *supra* note 14, at 200 (concluding that professional practice guidelines are likely to be viewed as powerful, although not conclusive, evidence of the legal standard of care).
- ¹¹⁵ See MARK A. HALL ET AL., *supra* note 95, at 434-435 (reviewing assumption of the risk doctrine in medical malpractice cases).
- ¹¹⁶ *Id.* at 435 (noting that a patient's waiver of liability for a physician's negligent performance of substandard care is unenforceable as contrary to public policy).
- ¹¹⁷ See generally *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), cert. den'd, 409 U.S. 1064 (1972).
- ¹¹⁸ See generally *id.*
- ¹¹⁹ See MARK A. HALL ET AL., *supra* note 95, at 214 (noting that about half of states follow a professional custom test for disclosure in informed consent cases); *Culbertson v. Memitz*, 602 N.E.2d 98 (Ind. 1992) (adopting a professional custom standard for disclosure).
- ¹²⁰ See John A. Astin, *Why Patients Use Alternative Medicine: Results of a National Study*, 279 J. AM. MED. ASS'N. 1548, 1552 (1998) (concluding from a national survey of over 1,000 respondents that "the most influential or salient factor in people's decision [sic] to use alternative health care may be its perceived efficacy"); Joshua M. Baumi et al., *Do Attitudes and Beliefs Regarding Complementary and Alternative Medicine Impact its Use Among Patients with Cancer? A Cross-Sectional Survey*, 121 CANCER 2431, 2436 tbl.3 (2015) (finding in a study of nearly 1,000 patients that expected health benefits significantly predicted the likelihood of using complementary treatments for cancer).
- ¹²¹ See Timothy Caulfield & Colin Feasby, *supra* note 14, at 193-4 (reviewing dangerous side effects of herbal remedies that many consumers are unaware of); Kah Hoong Chang et al., *Complementary and Alternative Medicine Use in Oncology: A Questionnaire Survey of Patients and Health Care Professionals*, 11 BIOMED CENTRAL CANCER 196, 196-7 (2011), available at <http://bmccancer.biomedcentral.com/articles/10.1186/1471-2407-11-196>.
- ¹²² See, e.g., Timothy Caulfield & Colin Feasby, *supra* note 14, at 195 (concluding that the proven safety, efficacy or lack of efficacy of a treatment clearly has the potential to influence treatment decisions, and as such is something a reasonable person in the patient's position would want to know).
- ¹²³ See, e.g., *Rizzo v. Schiller*, 445 S.E.2d 153 (Va. 1994) (finding that a general consent form is insufficient to satisfy the duty of disclosure); *Schneider v. Revici*, *supra* note 51, at 996 (finding that a patient may make an informed decision to seek unconventional treatment pursuant to a carefully documented consent form).
- ¹²⁴ See MARK A. HALL ET AL., *supra*, note 95, at 217 (noting that most jurisdictions apply an objective causation standard in informed consent cases).

¹²⁵ See, e.g., *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979) (holding that the jury must decide whether the plaintiff would have refused the procedure).

¹²⁶ See, e.g., Timothy Caulfield & Colin Feasby, *supra* note 14, at 200 (concluding there is a reasonable expectation on the part of professionals, patients, the public and policy makers that treatment decisions will be informed as much as possible by scientific data).

¹²⁷ See MARK A. HALL ET AL., *supra* note 95, at 221 (noting that disclosure by a physician is not required if persons of average sophistication are aware of the information or the risk is already known to the patient).

¹²⁸ See *supra* notes 76 to 77 and accompanying text.

¹²⁹ See National Safety Council Committee on Alcohol and Drugs, *Position on the Use of Cannabis (Marijuana) and Driving*, 37 J. ANALYTICAL TOXICOLOGY 47, 49 (2013) (concluding it is unsafe to drive for at least several hours after last use of marijuana); R. Andrew Sewell et al., *The Effect of Cannabis Compared with Alcohol on Driving*, 18 AM. J. ADDICTION 185 (2009) (concluding patients should be advised to have a designated driver or wait at least 3 hours after last use of marijuana before driving), available at <http://ncbi.nlm.nih.gov/pmc/articles/PMC2722956>.

¹³⁰ See Kevin P. Hill, *supra* note 35, at 2478 (noting that marijuana can worsen the treatment course for anxiety, depression and psychotic illness); Efrat Aharonovich et al., *supra* note 41, at 1511 (finding that marijuana worsens the treatment course for substance use disorders); Mohammadali Mojarrad et al., *supra* note 41, at 94 (same); M. Alvarez-Jimenez et al., *supra* note 41 (finding higher relapse rates for patients with psychotic disorders who use marijuana); Rashmi Patel et al., *supra* note 41 (same); Marcel O. Bonn-Miller et al., *supra* note 41, at 196 (finding poorer outcomes in PTSD treatment for military veterans who use marijuana); National Institute on Drug Abuse, *Marijuana 6* (Research Report Series, last revised July 2012) (noting that a significant body of research demonstrates negative effects of THC on the functioning of various immune cells), available at https://drugabuse.gov/sites/default/files/mjrrs_2.pdf.

¹³¹ See Timothy Caulfield & Colin Feasby, *supra* note 14, at 194 (recommending that physicians be sensitive to possible misconceptions held by their patients about alternative treatments and remind patients that just because a product is marketed as “natural” does not necessarily mean it is safe).

¹³² See, e.g., American Society of Addiction Medicine, *supra* note 16, at 7 (recommending that physicians counsel patients about the dangers

of accidental exposure to edible marijuana products and that marijuana precipitates relapse to addiction); Herbert D. Kleber & Robert L. DuPont, *Physicians and Medical Marijuana*, 169 AM. J. PSYCHIATRY 564, 567 (2012) (recommending on behalf of the American Psychiatric Association that physicians should inform patients clearly that marijuana is not FDA-approved or a standardized or purified medication); Kevin P. Hill, *supra* note 35, at 2478 (recommending a thorough risk-benefit discussion that includes informing patients that marijuana is not supported by leading medical organizations and is illegal under federal law).

¹³³ See MARK A. HALL ET AL., *supra* note 95, at 192-197 (discussing potential liability of physicians for failing to warn patients of foreseeable dangers to third parties).

¹³⁴ *Id.* at 195 (reviewing cases in which physicians were held liable to third parties for failing to warn patients of driving dangers associated with prescription medications).

¹³⁵ *Id.* at 192 (noting that the scope of a physician’s duty to third parties is limited by the ability to reduce risks reasonably; in many cases, simply warning the patient is adequate).



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Chair's Corner

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back to those who have sacrificed so much? Michael Clark, Chair of the Health Law Section in 2014-15, decided that we could form a Military and Veterans Affairs Task Force as part of the Health Law Section to address health issues that our active servicemen and women and our veterans currently face. The Task Force was launched last year under the leadership of our Immediate Past Chair, Bill Horton. Bill was also motivated by the lessons learned from his grandfather. When asked about his involvement in this important issue, Bill said, "My grandfather spent a lot of his adult life fighting to get veterans the support and respect they deserved. I'm proud that we were able to launch this critically important task force during my year as Chair of the Section."

The Section announced the formation and mission of the Task Force on Veterans Day last year: "In commemoration of Veterans Day, the Health Law Section is proud to introduce the Military and Veterans Health Law Task Force. The Task Force encompasses all areas of health law pertaining to active military and veterans with a particular focus on collaboration with the ABA's Military Pro Bono Center and the ABA Veterans' Claims Assistance Network (VCAN) which provide legal assistance in eight areas of Civil Law. The Military and Veterans Health Law Task Force also serves as a resource to Law School Veterans Clinics by providing a mechanism for sharing best practices, recent trends, proposed and new regulations and agency mandates, documents, policies, protocols and forms, implementation of laws and regulations, and content expertise."

Because the Task Force accomplished so much in its first year, the Section recognized the importance of the issues addressed. Accordingly, the Section made the Task Force a permanent part of the Section and re-named it the "Military and Veterans Health Law Educational/Outreach Interest Group." The Chair, Deirdre Golden, MD, JD reports that the Interest Group and its Advisory Board, chaired by Jason Vail, Esq., ABA Sr. Counsel, Director of the ABA Military Pro Bono Institute and member of the ABA's Standing Committee on Legal Assistance for Military Personnel (ABA LAMP) which supports several initiatives to deliver legal assistance and services to service members, veterans, and their families, have succeeded in reaching superior goals in helping both the military and veterans with advice, expertise, and representation. The Chair, two Vice Chairs, and many members of our Interest Group are also members of the 13 other ABA military and veteran committees, which create bridges for better communication.

The Interest Group and Advisory Board leaders, liaisons, members and law students work actively with the Department of Defense and the Department of Veterans Affairs. Also involved in this effective collaboration are members of the judiciary, the Law School Consortium, various medical academies, the Network for Public Health Law, the Centers for Disease Control and Prevention, and the Institute of Medicine. Interest Group leaders, members and the Advisory Board collaborate in representing the Interest Group on panel presentations and symposia in locations from San Diego to Washington, D.C. and all of the states in between. This draws attention to military and veteran health law issues, and it helps create ways to resolve them. The Interest Group is particularly proud of its medical-legal partnerships among the Military, the VA, and civilian physicians and lawyers.

Each leader and Advisory Board member, in turn, represents other national organizations and government entities, such as the JAG Corps and multiple veterans organizations. This creates an extraordinary network in every state.

Five Advisory Board members, the Chair of the Interest Group, and four Vice Chairs participated in the ABA's National Military & Veterans Legal Issues Summit held in Washington, D.C. in June 2016, and two Vice Chairs are members of the ABA President's 2016-2017 Commission on Military and Veterans Affairs.

As a Section, we are proud to support the efforts of our ABA President, Linda Klein, in her initiatives to promote veterans' issues. President Klein recently challenged us to get involved in veterans' issues, noting in a recent email: "The new ABA Commission on Veterans Legal Services is developing a comprehensive approach to broadening access to justice for our nation's veterans. This year, the ABA's National Pro Bono Celebration in October is being extended to Veterans Day on November 11, and we're also encouraging pro bono activities on or around Memorial Day. Please visit www.celebrateprobono.org to find a veterans pro bono event near you, to get ideas for planning an event, or to register your event. Thank you for your involvement. Together, lawyers can and will make a difference in our communities."

The Section's Washington Health Law Summit planning committee is pleased to announce that the Section will be featuring a keynote speech from President Klein, along with a panel entitled "Veterans Facing Health-Harming Legal Needs: How Medical-Legal Partnerships Can Bridge the Gap" at our upcoming Washington Health Law Summit, December 12-13, 2016, in Washington, DC.

If you are interested in being involved in this important topic, please consider joining our Military and Veterans Health Law Educational/Outreach Interest Group, chaired by Professor Deirdre Golden, MD, JD of the University of Detroit Mercy School of Law in Detroit. This group encompasses all areas of health law pertaining to active military and veterans. Visit the website for more information: http://americanbar.org/groups/health_law/interest_groups/military.html.

C. Joyce Hall
Chair

Important Mississippi tidbit: Keesler Air Force Base in Biloxi, MS, announced on October 25, 2016 that: “Keesler

Air Force Base surgeons are forging a new path in military medicine by being the first in the Air Force to use one of the most advanced robotic surgery systems available today. The Keesler Medical Center has acquired two of the newest robotic surgical systems out there, the da Vinci Xi, one for surgeries and the other for surgical training. Also, Keesler’s Clinical Research Laboratory has set up a training facility called the Institute for Defense Robotic Surgical Education, for surgeons to get their official robotic surgery credentials.”¹

¹ <http://keesler.af.mil/News/ArticleDisplay/tabid/966/Article/986014/air-forces-first-robotic-surgery-training-course-established-at-keesler.aspx>.

The Editorial Board provides expertise in specialized areas covered by the Section. Individual Board members were appointed by the Interest Group Chairs and Editor Marla Durben Hirsch. If you are interested in submitting an article to *The Health Lawyer*, you may contact one of the Editorial Board members or Ms. Hirsch. With the establishment of the Editorial Board, the Section strengthens its commitment to provide the highest quality analysis of topics in a timely manner.

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MEDICARE ADVANTAGE: FADING MISCONCEPTIONS AND REMAINING UNCERTAINTY

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Introduction

In October 2014, *The Health Lawyer* published an article entitled *Medicare Advantage Misconceptions Abound* (the “Article”), written by Humana’s former Associate General Counsel D. Gary Reed.¹ The Article explained the myriad ways that courts, lawyers, and litigants failed to appreciate that the Medicare Advantage option created by Part C of the Medicare Act (42 U.S.C. § 1395w-21 *et seq.*) really is a form of Medicare, governed by many of the same statutory and regulatory provisions as the traditional Medicare fee-for-service option created by Parts A and B of the Act.

As the Article explained, courts and litigants struggled with concepts as basic as how many “parts” the Medicare Act has; whether Medicare enrollees that select the Medicare Advantage option “opt out” of Medicare altogether; whether there is a Medicare Advantage “insurance policy;” and whether the Centers for Medicare & Medicaid Services (“CMS”) administers Part A and B “directly” or instead “by contract.” The Article also detailed how these basic misconceptions about the nature of the Medicare Advantage program had serious consequences for Medicare Advantage Organizations, who were required to endlessly re-litigate even the most basic issues in lawsuits brought by parties and/or counsel that failed to appreciate that the relevant claims arise under the Medicare Act — not under state law or a private insurance contract.

In the two years since the Article’s publication, much has changed. The gap between the version of Medicare Advantage that exists in the real world and the version that existed in the courts at the time of the Article has closed considerably. Across a range of issues, litigants and courts have recognized what is plain from the statute’s text and implementing regulations: that Medicare Advantage is an integral part of the Medicare program. This progress is due in no small part to the Article itself, which has been cited approvingly by many different courts.²

This article is intended to update and supplement the Article’s thorough analysis of the state of Medicare Advantage law as it existed in late 2014. It first offers a brief overview of both the Medicare Advantage option and the Medicare Secondary Payer (“MSP”) law. (As the original Article observed, many disputes about the Medicare Advantage program arise under the Medicare Secondary Payer law, which therefore provides necessary context for the latest Medicare Advantage jurisprudence.) It then surveys areas of Medicare Advantage jurisprudence in which federal and state courts have been coalescing around the issues set forth in the Article, including Medicare Advantage Organizations’ right to bring suit against any “primary plan” that is legally responsible for paying for a Medicare enrollee’s injury; the conclusion that Medicare Advantage Organizations’ claims for reimbursement really do “arise under” the Medicare Act and must be exhausted in the Medicare administrative appeals process and cannot be brought in state court; and federal law’s preemption of state laws that would regulate aspects of the Medicare Program governed by federal law. Finally,

this article highlights additional issues that have arisen now that courts and litigants have finally accepted that the Medicare Advantage option really is part of the Medicare Act.

Statutory and Regulatory Background

The Medicare Advantage Option

To understand the evolution of the law concerning the Medicare Advantage program, it is first necessary to understand the Medicare program and enrollees’ options for coverage. In particular, it is necessary to understand the role the Medicare Advantage option, which was created by the statutory provisions appearing in Part C of Chapter XVIII of Title 42 of the U.S. Code, plays in the overall structure of the Medicare Act.

Each year, eligible Medicare enrollees may elect between two different Medicare options.³ First, they may receive their health insurance under Medicare Parts A and B. Known as the Medicare “fee-for-service” option, Parts A and B provide hospital insurance and coverage for medically necessary outpatient and physician services.⁴ As this option’s familiar name suggests, government contractors pay for these expenses directly, on a fee-for-service basis.

Alternatively, Medicare participants may elect the “Medicare Advantage” option under Part C of the Medicare Act.⁵ Under the Medicare Advantage option — originally called Medicare+Choice⁶ — enrollees receive their Medicare benefits from a private insurance company. The insurers that administer this option are known as “Medicare Advantage Organizations” or “MAOs.”

Congress created the Medicare Advantage option in 1997 to “allow

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Medicare Advantage: Fading Misconceptions and Remaining Uncertainty

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beneficiaries to have access to a wide array of private health plan choices in addition to traditional fee-for-service Medicare,” and to “enable the Medicare program to utilize innovations that have helped the private market contain costs and expand health care delivery options.”⁷ In 2016, nearly 18 million enrollees – or approximately one-third of the Medicare population – elected to participate in a group or individual Medicare Advantage plan.⁸

Each Medicare Advantage Organization must enter into a contract with the Secretary of Health and Human Services (“Secretary”).⁹ Under that contract, the Medicare Advantage Organization generally receives a fixed (or “capitated”) amount per enrollee, and must provide at least the same level of benefits that enrollees would receive under the fee-for-service option.¹⁰ Medicare Advantage Organizations are thus incentivized to provide health insurance more efficiently than under the fee-for-service model, for example by providing opportunities for more cost-saving preventative care.

The Medicare Advantage program is funded by the same trust funds that support Medicare Parts A and B.¹¹ The Medicare Advantage Organizations, as the contractors that administer the program, are “regulated, monitored, and directly controlled by CMS.”¹² Medicare Advantage Organizations “do not issue a Medicare ‘insurance policy’ but, rather, send out a document describing the Medicare benefits that enrollees receive,” known as an “Evidence of Coverage.”¹³ Because they have no “insurance contracts” with their enrollees, Medicare Advantage Organizations “do not pay benefits pursuant to a ‘policy’ but rather under a statutory framework.”¹⁴ Moreover, Part C expressly preempts any state law inconsistent with standards established by Congress or the Secretary pursuant to her delegated rulemaking authority.¹⁵

The Medicare Secondary Payer Law

Because the Medicare Advantage option is governed by the Medicare Act statutory framework, it is governed by many of the same definitions, rules, and regulations that govern the fee-for-service option offered under Parts A and B. Many of those rules are contained in Part E of the Act, which is titled “Miscellaneous Provisions.”¹⁶ One of the most important of those “miscellaneous” provisions is the Medicare Secondary Payer law, contained in 42 U.S.C. § 1395y(b).

Congress enacted the Medicare Secondary Payer law in 1980 to help curb the rising cost of Medicare.¹⁷ Prior to that law, Medicare “paid for all medical treatment within its scope and left private insurers merely to pick up whatever expenses remained.”¹⁸ “The Act inverted that system; it made private insurers covering the same treatment the ‘primary’ payers and Medicare the ‘secondary’ payer.”¹⁹

The Medicare Secondary Payer law contains a broad definition of “primary plan” that includes “a group health plan or large group health plan” as well as “a workmen’s compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance.”²⁰ That definition covers, among other things, no-fault insurance carriers, liability insurers, self-insured tortfeasors, and workers’ compensation plans.

To ensure that these primary plans pay first, Congress prohibited Medicare from paying for “any item or service to the extent that...payment has been made, or can reasonably be expected to be made,” by a primary plan.²¹ This prohibition applies to any “[p]ayment under this subchapter,” referring to the entire Medicare Act appearing in Subchapter XVIII of Chapter 7 of Title 42 of the U.S.

Code.²² This includes the Medicare Advantage option appearing in Part C of the Act.

In the event that a primary plan (such as a tortfeasor or his liability insurer) has “not made or cannot reasonably be expected to make payment with respect to such item or service promptly,” Medicare (or a Medicare Advantage Organization) may make “conditional” payments.²³ Indeed, any-time Medicare (or a Medicare Advantage Organization) “makes a payment that a primary plan was responsible for, the payment is merely conditional” by operation of law.²⁴

The Medicare Secondary Payer law obligates primary payers to repay Medicare for any conditional payments once the primary plan’s responsibility is “demonstrated.”²⁵ “A primary plan’s responsibility for such payment may be demonstrated” in a number of different ways, including “a judgment, a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan’s insured, or by other means.”²⁶

Pursuant to her delegated rulemaking authority,²⁷ the Secretary has made clear that the ultimate responsibility for reimbursing Medicare payments rests on primary plans, and not on Medicare enrollees. Thus, even though a Medicare enrollee might receive a liability settlement large enough to reimburse conditional Medicare payments, if that enrollee fails to reimburse Medicare within 60 days of receiving settlement proceeds, “the primary payer must reimburse Medicare even though it has already reimbursed the beneficiary.”²⁸

This law has been the subject of considerable legal attention in recent years, particularly in disputes between Medicare Advantage Organizations

and primary plans that are responsible for reimbursing conditional Medicare payments under that Act. These cases show the growing consensus in Medicare Advantage jurisprudence around the notion that litigants must reimburse conditional payments made by Medicare Advantage Organizations under Part C of the Medicare Act, just as they do with conditional payments made under Parts A and B of the Act.²⁹

Growing Consensus

In the short time since *The Health Lawyer* published the *Medicare Advantage Misconceptions* Article, courts have started to coalesce around the idea that the Medicare Advantage option is part of the Medicare program after all. This growing consensus can be seen in a variety of contexts, some of which were starting to become clear at the time of the original Article. That momentum has continued – and in some cases accelerated – bringing the judicial and real-world versions of the Medicare Advantage option closer than ever.

One of the easiest places to see the evolution in Medicare Advantage jurisprudence is the context of Medicare Secondary Payer disputes among Medicare Advantage plans, their members, and/or primary payers over who is responsible for paying for the care of a Medicare beneficiary. In part this is because Medicare Secondary Payer disputes can and do arise in so many different situations; indeed, the Medicare Secondary Payer law is implicated every time a Medicare Advantage enrollee has employer-provided healthcare coverage or is injured in a car accident, a slip and fall case, or by a drug or medical device.

The relative frequency of Medicare Secondary Payer disputes also is due to the significant amount of money at stake. In a 2009 Federal Register publication, for example, CMS noted that Medicare Secondary Payer recoveries in the original

fee-for-service Medicare program totaled \$6.5 billion in 2007 (the latest year that data was then available).³⁰ Based upon the percentage of Medicare enrollees who elected Medicare Advantage coverage at the time (only 24 percent), CMS estimated that the Medicare Secondary Payer recovery opportunity in the Medicare Advantage program would approach \$2 billion by 2010.³¹

Assuming, conservatively, that the amount recovered per enrollee under the Medicare Secondary Payer law remained flat between 2007 and 2016, the recovery opportunity for Medicare Advantage Organizations today is much higher – likely in excess of \$3 billion per year – due to the growth in the overall Medicare population and the increasing percentage of enrollees who elect to join Medicare Advantage plans.

In reality, the recovery opportunity is likely much higher than that, as Congress has since amended the Medicare Secondary Payer law to require all primary payers (including liability insurers, self-insured tortfeasors, no-fault insurers, and workers' compensation plans) to "determine whether a claimant (including an individual whose claim is unresolved) is entitled to [Medicare] benefits...on any basis" – including under Part C – and then report those potential recovery opportunities to the Secretary of Health and Human services.³² Failure to file these reports subjects the primary plan to a potential \$1,000 per day penalty for each claim that went unreported.³³ CMS, in turn, makes this data available to Medicare Advantage Organizations, thereby arming them with additional information about potential Medicare Secondary Payer recoveries.

Finally, Medicare Secondary Payer disputes are disproportionately likely to give rise to litigation for another reason highlighted in the *Medicare Advantage Misconceptions* Article: many plaintiffs' attorneys

used to dealing with only fee-for-service Medicare or commercial insurance simply fail to recognize (or acknowledge) that Medicare Advantage payments are Medicare payments. Thus, Medicare Advantage Organizations' requests for reimbursement under the Medicare Secondary Payer law are not infrequently met by refusals – particularly in states where statutes or common law otherwise limit or prevent subrogation.³⁴

As explained in more detail below, these Medicare Secondary Payer disputes have given rise to a new species of Medicare Advantage jurisprudence recognizing that the Medicare Advantage option really is another form of Medicare.

Double-Damages Suits by Medicare Advantage Organizations. The Medicare Secondary Payer law contains a private cause of action. It reads:

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).³⁵

Prior to 2012, that cause of action had been successfully invoked by Medicare enrollees and even providers, but never by a Medicare Advantage Organization.³⁶ That all changed with the Third Circuit's decision in *In re: Avandia Marketing, Sales Practices & Products Liability Litigation* ("Avandia"), which held "[t]he language of the MSP private cause of action is broad and unrestricted and therefore allows any private plaintiff with standing to bring an action" — including Medicare Advantage Organizations.³⁷ The court allowed a Medicare Advantage Organization (Humana) to press forward with a suit under the Medicare Secondary Payer law against a primary payer – in that case, a drug company acting as a self-insured tortfeasor – that demonstrated its responsibility to pay for Medicare

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enrollees' care by entering into a settlement agreement to resolve thousands of claims pending in a multidistrict litigation proceeding. The *Avandia* decision was one of the first federal court decisions to clearly articulate the role that Medicare Advantage Organizations play in administering the Medicare program for those enrollees that elect to participate in the Medicare Advantage option, and sent a clear signal that any party attempting to treat Medicare fee-for-service payments and Medicare Advantage payments differently for reimbursement purposes does so at its own peril.

Although the *Medicare Advantage Misconceptions* Article referenced the *Avandia* litigation in passing, it did not discuss the case at length. At the time, *Avandia* was the only decision to have squarely addressed the question of whether Medicare Advantage Organizations can sue primary plans under the private cause of action; other courts had yet to make clear whether they would follow suit. In less than two years, however, many courts have done so, and have even extended *Avandia*'s holding into different contexts beyond a Medicare Advantage plan suing a self-insured tortfeasor.

For example, the Eleventh Circuit recently held that an assignee of a Medicare Advantage Organization could bring suit against a no-fault insurer under the Medicare Secondary Payer law to obtain reimbursement of payments made on behalf of Medicare enrollees insured by the no-fault plan.³⁸ Two federal district courts similarly held that a Medicare Advantage Organization may invoke the Medicare Secondary Payer law's private cause of action against no-fault insurers in a pair of cases brought by Humana against Farmers Insurance and its affiliated companies.³⁹ Moreover, when the defendant in one of the *Farmers*

Insurance cases attempted to bring that question to the Fifth Circuit on a petition for interlocutory review under 28 U.S.C. § 1292(b), the court refused, holding "Defendants have failed to identify a substantial difference of opinion" on that issue.⁴⁰

A federal district court in Louisiana similarly applied *Avandia* in yet another related context: disputes between Medicare Advantage Organizations and their enrollees. In *Collins v. WellCare Health Plans, Inc.*, a Medicare Advantage enrollee brought suit in state court against her Medicare Advantage Organization seeking a declaratory judgment that the Medicare Advantage Organization had no right to reimbursement from the proceeds of her settlement with a tortfeasor. The Medicare Advantage Organization removed the case to federal court and then counterclaimed against the enrollee under the Medicare Secondary Payer law's private cause of action.

The court held that the Medicare Advantage Organization could bring suit directly against its enrollee to recover the money it paid for her care, noting that the statute expressly allows the Medicare Advantage Organization to seek recovery from the settling tortfeasor and "there is no real distinction between a claim against a tortfeasor or his insurer to obtain reimbursement and a claim against a beneficiary to obtain reimbursement from a settlement *funded* by a tortfeasor or his insurer."⁴¹ The court also noted that any statutory ambiguity would require deference to the Secretary's regulations, which expressly provide that a Medicare Advantage Organization may recover from "the Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses."⁴²

Courts also have recognized Medicare Advantage Organizations' right

to sue liability insurers who settle with enrollees that, in turn, do not reimburse their Medicare Advantage Organization. In *Humana Insurance Co. v. Western Heritage Ins. Co.*, a Medicare Advantage Organization filed suit in the U.S. District Court for the Southern District of Florida against a tortfeasor's insurer after that insurer paid a settlement to an injured Medicare enrollee that refused to reimburse her Medicare Advantage Organization. Originally, the dispute arose in a posture not unlike the *Collins* case discussed above: the Medicare enrollee first filed suit in state court seeking a declaration that state law prohibited the Medicare Advantage Organization's attempt to recover funds from her tort settlement.

While that declaratory judgment action was pending in state court, Humana sent a demand letter directly to the insurer, noting that federal regulations required it to reimburse Humana "even though it has already reimbursed the beneficiary."⁴³ Western Heritage ignored the request, prompting the Medicare Advantage Organization to file suit against it in federal court under the Medicare Secondary Payer law.⁴⁴

Like the courts in the *Farmers Insurance* and *Collins* cases, the district court in *Western Heritage* held that Medicare Advantage Organizations may bring suit under the Medicare Secondary Payer law to recover conditional Medicare payments. Notably, in discussing the structure of the Medicare Advantage program the court cited the *Medicare Advantage Misconceptions* Article, even though it had not been cited in either party's brief. And, ultimately, the court entered a double-damages judgment against the liability insurer, requiring it reimburse Humana for twice what it had paid for the enrollee's care.

On appeal, the Eleventh Circuit affirmed the *Western Heritage* ruling in a published decision. Like the district court, the Court of Appeals held that “an MAO may avail itself of the Medicare Secondary Payer private cause of action when a primary plan fails to make primary payment or to reimburse the MAO’s secondary payment.”⁴⁵

Finally, the U.S. District Court for the Eastern District of Virginia recently held that a Medicare Advantage Organization may sue an enrollee’s attorney – personally – for failing to ensure that Medicare Advantage Organizations are reimbursed for conditional Medicare payments. In *Humana Insurance Co. v. Paris Blank LLP*, the district court expressly adopted *Avandia*’s holding, noting the “persuasiveness of the Third Circuit’s thorough and well-reasoned opinion.”⁴⁶ It applied a Part A/B regulation that permitted the government to seek reimbursement directly from any party that received payment from a primary plan, including an attorney (42 C.F.R. § 411.24(g)) to the Medicare Advantage context, noting that the Secretary’s regulations “dictate[] that MAOs ‘exercise the same rights to recovery from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.’”⁴⁷

Taken together, these cases demonstrate that courts now understand that Medicare Advantage is a crucial part of the Medicare Act. Courts being asked to enforce Medicare Advantage Organizations’ rights under that Act, and in particular under its Medicare Secondary Payer provisions, have had little trouble recognizing as much.

No State Court Review of Claims Arising Under the Medicare Act

There also has been a growing realization among state courts that Medicare Advantage really is Medicare, and that disputes between

Medicare Advantage Organizations and their enrollees are claims concerning Medicare benefits. Because these claims “arise under” the Medicare Act and/or pit state law against federal statutes and regulations, an increasing number of state courts have held that they either lack jurisdiction over such claims and/or that the claims are preempted by Part C of the Medicare Act.

This development is notable. As the *Medicare Advantage Misconceptions* Article indicated, many federal courts had at the time made clear that the Medicare Act’s mandatory exhaustion requirement applied to disputes over Medicare benefits, and therefore federal district courts routinely held that they lacked jurisdiction over unexhausted claims. State courts, by contrast, were a much more hostile place for Medicare Advantage Organizations to appear as defendants. In large part because of the Medicare Act’s exhaustion requirement, state judges were not as familiar with the Medicare Act, and were apt to confuse Medicare Advantage disputes with routine commercial insurance cases, particularly where one or both of the parties did little to disabuse the court of that key misperception.

Thanks to the efforts of Medicare Advantage Organizations and their counsel, however, state courts have started to realize that Medicare Advantage is not private insurance, even if it is offered by private insurers. Thus, these courts have either refused to exercise jurisdiction over claims brought by Medicare enrollees against their Medicare Advantage Organizations, and/or have held that the state laws they invoke are expressly preempted by Part C itself.

One of the first examples of this phenomenon is the Arizona Court of Appeals’ decision in *Estate of Ethridge v. Recovery Management Systems*.⁴⁸ A Medicare enrollee had died as a result of neglect, and her estate sued the nursing home that was caring for her.

After recovering a sizeable settlement, the estate did what the enrollees in *Collins* and *Western Heritage* did: it filed a state court action seeking a declaration that the Medicare Advantage Organization was not entitled to recovery from the settlement proceeds. Specifically, the estate relied upon Arizona’s anti-subrogation law to argue that recovery was legally prohibited, as would have been the case if a private, commercial insurance plan had paid for the enrollee’s care. The court rejected this claim, noting that federal regulations give Medicare Advantage Organizations an express right to bill any party that receives payment from a primary plan, which “necessarily implies payment of the amount billed.”⁴⁹

The *Estate of Ethridge* court found that these federal regulations preempt contrary state laws under the express preemption provision contained in Part C of the Act. That provision states:

The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.⁵⁰

The court found this provision to be directly relevant to the case before it: “[b]ecause this Arizona [anti-subrogation] doctrine would prevent Medicare Advantage plans from exercising their right under federal law to obtain reimbursement from plan enrollees who have received settlement proceeds that include medical expenses paid by such a plan, it is preempted.”⁵¹

Florida’s Third District Court of Appeals reached a similar conclusion in *Humana Medical Plan, Inc. v. Reale* (another case that explicitly relied upon the *Medicare Advantage Misconceptions* Article, even though it was published after argument in that case).⁵² That case, which is the

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state-court companion case to the *Western Heritage* litigation described above, likewise arose out of a Medicare Advantage enrollee's attempt to have a state court declare that state subrogation law relieved her of any obligation to reimburse her Medicare Advantage Organization out of settlement proceeds she received. The court rejected the argument that such disputes need not be exhausted through the exclusive Medicare appeals process set forth in 42 U.S.C. §§ 405(g)-(h), 1395w-22(g)(5):

Contrary to what the Reales would have us believe, courts have consistently and overwhelmingly held that disputes concerning reimbursement of conditional payments are claims for benefits that 'arise under the Medicare Act' and must be exhausted through the administrative appeals process before an enrollee invokes judicial review in a federal court.⁵³

Applying that existing, federal case law to the state court proceeding before it, the court held that "[b]ecause the Reales did not obtain a final decision from the Secretary, as required by § 405(g), their dispute is not subject to judicial review" at all.⁵⁴ "Further, if their dispute were subject to judicial review, jurisdiction would lie exclusively in the federal courts."⁵⁵ And, like the Arizona court, the *Reale* decision went on to hold that even if Ms. Reale had exhausted her claim, Florida's subrogation law would be "preempted by the broad, express preemption clause in Part C of the Medicare Act."⁵⁶

Other state courts recently have reached similar conclusions even outside the Medicare Secondary Payer reimbursement context. For example, in *Morrison v. Health Plan of Nevada, Inc.*, a Medicare enrollee that contracted Hepatitis C at an in-network gastroenterology center tried to sue

his Medicare Advantage Organization, alleging that it negligently selected the center for inclusion in its network and failed to properly supervise the providers.⁵⁷ As in *Estate of Ethridge and Reale*, the Nevada Supreme Court found that these state-law claims were really an attempt to circumvent controlling federal regulations under Part C that govern the relevant subject area (there, the selection of and contracting with Medicare providers). Thus, the enrollee's common-law negligence claims were preempted by federal law.⁵⁸

Finally – and although it's not a preemption decision – a state court in Delaware recently underscored the extent to which the *Medicare Advantage Misconceptions* Article helped educate litigants and courts on the nuances of Medicare Advantage law. In *Honey v. Bayhealth Medical Center, Inc.*, the parties disputed whether a Medicare enrollee who is a plaintiff in a personal injury case can present evidence, for damages purposes, of the amount of money that her doctors billed a Medicare Advantage Organization or, instead, only of the amount of money that the Medicare Advantage Organization actually paid (which is usually a far lower figure, at least for providers in the Medicare Advantage Organization's provider network).⁵⁹ While that case was pending, the Delaware Supreme Court held that, in cases arising under Medicare Parts A and B, plaintiffs could only offer evidence of the lower amount, so as not to inflate their damages.

In deciding whether that case⁶⁰ controlled the outcome in *Honey*, the court noted that "there exists some controversy as to whether Medicare Advantage is part of the traditional Medicare system, or, is instead, more like a private health insurer."⁶¹ But, after citing the Article, as well as the *Avandia* line of cases discussed above,

the court went on to hold that a Medicare Advantage Organization "is a federal contractor providing federal benefits, established by the federal government, to federal constituents."⁶² Thus, the court concluded, "Medicare Advantage is part of the larger Medicare system, rather than an independent, private insurance plan."⁶³ Therefore, the same rule should apply in both the Part A/B and Part C context, and plaintiffs should be prohibited from inflating their damages calculations in both instances.

Still, Questions Remain

The federal and state case law described in this article shows that courts have finally begun to coalesce around the notion that Medicare Advantage really is Medicare – and should be treated that way for legal purposes, too. In recent years, courts have consistently (and in the authors' views, correctly) held that disputes between Medicare enrollees and their Medicare Advantage Organizations do arise under the Medicare Act and must be presented in federal court, if at all. State courts have no jurisdiction to hear those claims, and any attempts to use state law to raise claims inextricably intertwined with claims for Medicare benefits are expressly preempted under the Act.

That is not to say that all Medicare Advantage case law has achieved the same level of clarity, however. There continues to be some disagreement about how disputes between Medicare Advantage Organizations and providers must be treated. In particular, courts continue to wrestle with the question of whether disputes between Medicare Advantage Organizations and providers are contract claims between those parties – which may be brought directly in state courts as contract actions – or, instead, are claims for Medicare benefits owed

under the Act, which must be presented first to the Secretary under the Medicare appeals process and then litigated in federal court (if at all).

As the original *Medicare Advantage Misconceptions* Article noted, the decisions of the Medicare Appeals Council are replete with examples of cases where Medicare Advantage providers did, indeed, exhaust claims for payment through the Medicare appeals process.⁶⁴ Some courts have continued to hold that Medicare Advantage provider-payer disputes must be brought before the Medicare Appeals Council before they may become the subject of litigation.⁶⁵ There has been some disagreement on that question, however, including in a recent case brought by a non-participating (e.g., out-of-network) provider alleging entitlement to a higher rate of payment under an implied contract theory.⁶⁶

Similarly, questions remain about whether the claims of such providers are preempted by the Medicare Act. As noted above, numerous federal and state courts have found the Medicare Advantage program regulations to preempt state laws on a range of issues, including subrogation, prompt payments, and common-law torts.⁶⁷ However, some courts have concluded that the regulations do not reach so far as to encompass certain types of payer-provider payment disputes.⁶⁸

These kinds of narrow disagreements are to be expected at some level. Indeed, they could be seen as a form of progress: now that courts have moved past the questions highlighted in the original Article — is this Medicare or something completely different? — courts must dig into the nuanced questions presented by the Medicare Act and its specific provisions. Only time will tell whether courts treat disputes between Medicare Advantage Organizations and providers like disputes between Medicare Advantage Organizations and their enrollees, or if they will distinguish these cases and instead treat

them like disputes between commercial insurance plans and providers.

Conclusion

Much has changed in the two years since the *Medicare Advantage Misconceptions* Article appeared in these pages. In large part because of the work of Humana and other Medicare Advantage Organizations, courts have come a long way toward recognizing that Medicare Advantage really is a form of Medicare. New and difficult legal questions will no doubt continue to arise in a program as large and complex as Medicare Advantage. But when courts approach those issues without the fundamental misconceptions that have plagued counsel, litigants, and the system until recently, everyone is better off. For that contribution, *The Health Lawyer* deserves everyone's thanks.



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Endnotes

- ¹ 27 *The Health Lawyer* 1 (2014).
- ² See, e.g., *Humana Med. Plan, Inc. v. W. Heritage Ins. Co.*, 94 F. Supp. 3d 1285, 1289 (S.D. Fla. 2015); *Collins v. Wellcare Healthcare Plans, Inc.*, 73 F. Supp. 3d 653, 660 (E.D. La. 2014); *Humana Med. Plan, Inc. v. Reale*, 180 So. 3d 195, 204 n. 13 (Fla. 3d Dist. Ct. App. 2015); *Honey v. Bayhealth Med. Ctr., Inc.*, No.: K13C-05-018 RBY, 2015 Del. Super. LEXIS 378, at *4 n. 3 (Del. Super. Ct. July 28, 2015). Indeed, the Article also was cited in a Spanish-language opinion issued by the Puerto Rico Court of Appeals. See *Multidisciplinary Patient Health Care v. Mmm Health Care*, 2015 PR App. LEXIS 501, *13 (P.R. Ct. App. Feb. 3, 2015).
- ³ 42 U.S.C. § 1395w-21(a).
- ⁴ *Id.* § 1395w-21(a)(1)(A).
- ⁵ *Id.* § 1395w-21(a)(1)(B).
- ⁶ As part of the Medicare Modernization Act of 2003, Congress renamed the Medicare+Choice Program as "Medicare Advantage." See Pub. L. No. 108-173.
- ⁷ H.R. Rep. No. 105-217, at 585 (1997) (Conf. Rep.).
- ⁸ See Kaiser Family Foundation, Medicare Advantage 2016 Spotlight: Enrollment Market Update (Fig. 1), available at <http://kff.org/medicare/issue-brief/medicare-advantage-2016-spotlight-enrollment-market-update>.
- ⁹ 42 U.S.C. § 1395w-27.
- ¹⁰ *Id.* § 1395w-22. Medicare Advantage Organizations also are required to perform a wide

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- variety of tasks pursuant to their contracts with CMS, including provider contracting, provider credentialing, and quality assurance activities, among others.
- ¹¹ *Id.* § 1395w-23(f).
- ¹² *Mann v. Reeder*, 2010 U.S. Dist. LEXIS 134821, at *8-9 (W.D. Ky. Dec. 20, 2010).
- ¹³ E. Kuo, Developments in Medicare Secondary Payer Law, 2013 Health Law Handbook § 12.5; see also *Collins v. Wellcare Healthcare Plans, Inc.*, 73 F. Supp. 3d 653, 664 (E.D. La. 2014) (“MAO insurance policies do not exist. MAO beneficiaries merely elect to receive a MAO plan rather than an Original Medicare plan.”).
- ¹⁴ *Id.* § 12.5.
- ¹⁵ 42 U.S.C. § 1395w-26(b)(3).
- ¹⁶ *Id.* § 1395x et seq.
- ¹⁷ See Pub. L. No. P.L. 96-499, Title IX, Part B, Subpart II, § 953, 94 Stat. 2647 (Dec. 5, 1980).
- ¹⁸ *Bio-Medical Applications of Tenn., Inc. v. Cent. States Se. & Sw. Areas Health & Welfare Fund*, 656 F.3d 277, 278 (6th Cir. 2011).
- ¹⁹ *Id.*
- ²⁰ 42 U.S.C. § 1395y(b)(2)(A).
- ²¹ *Id.* § 1395y(b)(2)(A)(i)-(ii).
- ²² *Id.* § 1395y(b)(2)(A).
- ²³ *Id.* § 1395y(b)(2)(B).
- ²⁴ *Fanning v. United States*, 346 F.3d 386, 389 (3d Cir. 2003).
- ²⁵ See 42 U.S.C. § 1395y(b)(2)(B)(ii) (“[A] primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service.”).
- ²⁶ *Id.*
- ²⁷ See *id.* §§ 1395hh(a)(1), 1395w-26(b)(1).
- ²⁸ 42 C.F.R. § 411.24(i)(1).
- ²⁹ Disclosure: the authors of this article have been involved in a number of these cases, either as in-house or outside counsel for Medicare Advantage Organizations.
- ³⁰ See 74 Fed. Reg. 54,634, 54,711 (Oct. 22, 2009).
- ³¹ *Id.*
- ³² 42 U.S.C. § 1395y(b)(8) (emphasis added).
- ³³ *Id.* § 1395y(b)(8)(E)(i).
- ³⁴ Some states prohibit subrogation of medical benefits by judicial decision. See *Estate of Ethridge v. Recovery Mgmt. Sys.*, 235 Ariz. 30, 32 n.6 (Az. App. 2014) (citing *Lingel v. Olbin*, 198 Ariz. 249 (Az. App. 2000)); *Nevils v. Grp. Health Plan, Inc.*, 492 S.W.3d 918, 920 (Mo. 2016) (a petition for a writ of certiorari is pending in *Nevils* on the issue of whether federal law preempts the anti-subrogation doctrine for Federal Employee Health Benefits Act plans). Other states partially or completely prohibit subrogation of medical benefits by statute. See, e.g., N.J.S.A. § 2A:15-97; N.Y. Gen. Oblig. Law § 5-335; 11 N.C.A.C. § 12.0319; Va. Code Ann. § 38.2-3405.
- ³⁵ 42 U.S.C. § 1395y(b)(3)(A).
- ³⁶ See, e.g., *Manning v. Utils. Mut. Ins. Co.*, 254 F.3d 387 (2d Cir. 2001) (Medicare enrollee sued employers and workers’ compensation plan under the Medicare Secondary Payer law); *Bio-Med. Applications of Tenn., Inc. v. Cent. States S.E. & S.W. Areas Health & Welfare Fund*, 656 F.3d 277 (6th Cir. 2011) (provider sued group health plan under Medicare Secondary Payer law).
- ³⁷ 685 F.3d 353, 367 (3d Cir. 2012), cert. denied sub nom., *GlaxoSmithKline v. Humana Med. Plans, Inc.*, 133 S.Ct. 1800 (2013).
- ³⁸ *MSP Recovery, LLC v. Allstate Ins. Co.*, ___ F.3d ___, 2016 U.S. App. LEXIS 15984 (11th Cir. Aug. 30, 2016).
- ³⁹ See *Cariten Health Plan, Inc. v. Mid-Century Ins. Co.*, 2015 U.S. Dist. LEXIS 126887 (E.D. Tenn. Sep. 1, 2015); *Humana Ins. Co. v. Farmers Tex. Cnty. Mut. Ins. Co.*, 95 F. Supp. 3d 983 (W.D. Tex. 2014).
- ⁴⁰ *Humana Ins. Co. v. Farmers Tex. County Mut. Ins. Co.*, No. 1:13-cv-00611, Doc. 53, p. 2 (W.D. Tex. Nov. 4, 2014). After the district court in *Farmers Texas County Mut. Ins. Co.* refused to certify its order denying the defendant’s motion to dismiss for interlocutory appeal the case settled. The *Cariten Health Plan* case similarly settled following the district court’s refusal to dismiss the Medicare Advantage Organization’s claim.
- ⁴¹ *Collins v. Wellcare Healthcare Plans, Inc.*, 73 F. Supp. 3d 653, 667 (E.D. La. 2014) (emphasis in original). Like the *Farmers Insurance* cases just discussed, the *Collins* case settled after the district court ruled that the Medicare Advantage Organization had a right of action to sue for recovery of its conditional payments.
- ⁴² 42 C.F.R. § 422.108(d)(2).
- ⁴³ *Id.* § 411.24(i).
- ⁴⁴ As noted below, the state court eventually dismissed the enrollee’s claim for lack of jurisdiction, finding that it could only be litigated in federal court after exhausting the administrative remedies afforded by the Medicare Act. See *Humana Medical Plan, Inc. v. Reale*, 180 So. 3d 195 (Fla. 3d Dist. Ct. App. 2015).
- ⁴⁵ *Humana Medical Plan, Inc. v. Western Heritage Insurance Co.*, ___ F.3d ___, 2016 U.S. App. LEXIS 14509, at *21 (11th Cir. Aug. 8, 2016). The companion state court case, *Humana Med. Plan, Inc. v. Reale*, 180 So. 3d 195, 204 (Fla. 3d Dist. Ct. App. 2015), was decided in *Humana*’s favor while the federal case was on appeal. As discussed in more detail below, Florida’s Third District Court of Appeals held that the Medicare enrollee lacked jurisdiction to seek a declaratory judgment against *Humana* in state court concerning her Medicare Secondary Payer reimbursement, and further held that any statute that would limit the amount a Medicare Advantage Organization may recover from a settlement is preempted by Part C’s express preemption provision.
- ⁴⁶ *Humana Ins. Co. v. Paris Blank LLP*, Civil Action No. 3:16CV79-HEH, 2016 U.S. Dist. LEXIS 61814, at *12 (E.D. Va. May 10, 2016).
- ⁴⁷ *Id.* (citing 42 C.F.R. § 422.108(f)).
- ⁴⁸ 235 Ariz. 30 (Ariz. App. 2014).
- ⁴⁹ *Id.* at 36.
- ⁵⁰ 42 U.S.C. § 1395w-26(b)(3). This provision was revised, and substantially strengthened, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Pub. L. No. 108-173.
- ⁵¹ *Estate of Ethridge v. Recovery Mgmt. Sys.*, 235 Ariz. at 39; see also *United Behavioral Health v. Maricopa Integrated Health Sys.*, 237 Ariz. 559, 565 (Ariz. App. 2015) (“At no point is the Secretary’s final decision reviewable by a state court.”).
- ⁵² 180 So. 3d 195 (Fla. 3d Dist. Ct. App. 2015).
- ⁵³ *Id.* at 204.
- ⁵⁴ *Id.* at 205.
- ⁵⁵ *Id.*
- ⁵⁶ *Id.* at 208.
- ⁵⁷ 328 P.3d 1165 (Nev. 2014).
- ⁵⁸ *Id.* at 1171-72; federal courts similarly have continued to find state laws that would interfere with Medicare Advantage Organizations’ recovery rights to be preempted. In *Gen. Surgical Assocs., P.A. v. Humana Health Plan of Tex., Inc.*, No. SA-14-CA-31-RP (HJB), 2015 U.S. Dist. LEXIS 54091, at *21 (W.D. Tex. Mar. 17, 2015), for example, the court held that state-law prompt pay claims are preempted by Part C. Likewise, in *South Texas Health System v. Care Improvement Plus of Texas Ins. Co.*, No. 7:14-CV-912, 2016 U.S. Dist. LEXIS 18041, at *21 (S.D. Tex. Feb. 9, 2016), the court similarly held that state prompt pay laws cannot be invoked against a Medicare Advantage Organization. And in *Pharm. Care Mgmt. Ass’n v. Rutledge*, No. 4:15CV00510 BSM, 2015 U.S. Dist. LEXIS 179440 (E.D. Ark. Nov. 25, 2015), the court denied a motion to dismiss a preemption claim challenging state law as being inconsistent with Part D standard regulating pharmacies.
- ⁵⁹ No.: K13C-05-018 RBY, 2015 Del. Super. LEXIS 378 (Del. Super. Ct. July 28, 2015).
- ⁶⁰ *Stayton v. Delaware Health Corp.*, 117 A.3d 521, 2015 Del. LEXIS 288, 2015 WL 3654325 (Del. Jun. 12, 2015).
- ⁶¹ *Id.* at *4.
- ⁶² *Id.* at *15.
- ⁶³ *Id.* at *18-19.
- ⁶⁴ See Article n. 157. As the *Medicare Misconceptions* article explained, the Medicare Appeals Council is the final step of review in an administrative appeal of an Organization Determination. That process begins with a reconsideration decision by the Medicare Advantage Organization, followed by an

appeal to the Independent Review Entity, then a hearing before an Administrative Law Judge, concluding with an appeal to the Medicare Appeals Council. *See, e.g.*, 42 C.F.R. §§ 422.560-422.626.

⁶⁵ *See, e.g., Tenet Healthsystem GB v. Care Improvement Plus S. Cent. Ins. Co.*, No. 1:15-cv-1922-WSD, 2016 U.S. Dist. LEXIS 17108 (N.D. Ga. Feb. 11, 2016); *Assocs. Rehabilitation Recovery, Inc. v. Humana Med. Plan, Inc.*, 76 F. Supp. 3d 1388 (S.D. Fla. 2014).

⁶⁶ *In Ohio State Chiropractic Ass'n v. Humana Health Plan Inc.*, No. 15-3130, 2016 U.S. App. LEXIS 8686 (6th Cir. May 9, 2016), the putative plaintiff class of non-participating providers was paid in excess of the Medicare fee schedule rate due to a "technical error" (i.e., computer glitch). After that error was corrected, the MAO recouped approximately \$1,200 from the named plaintiff in the case, who in turn filed suit, alleging that the unintentional overpayments constituted a course of dealing that implied a contractual right to receive payments at the higher amount, and

that the MAO breached that contract by recouping the overpayments. On appeal, the court held that this claim over the amount of payment due did not "arise under" the Medicare Act and therefore need not be exhausted before suit could be filed in state court. For similar reasons, the court found the claim was not preempted by the Part C pre-emption provision.

⁶⁷ *See, e.g., Estate of Ethridge; Reale; Morrison.*

⁶⁸ *See, e.g., Ohio State Chiropractic Ass'n.*

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Health Law Section Comments on HIPAA Audit Pre-Screening Questionnaire

The Health Law Section submitted comments on October 26 to the Department of Health and Human Services' Office for Civil Rights ("OCR") on the HIPAA Audit Pre-Screening Questionnaire, which is sent to certain pre-identified covered entities and business associates. According to OCR's website, the information gathered through this Questionnaire is used with other information to develop pools of potential auditees in order to select the entities that will be audited for HIPAA compliance. A special thanks to the members of the Section's *eHealth, Privacy & Security Interest Group* who contributed to these comments including **Shannon Hartsfield Salimone**,

Holland & Knight LLP; **Elaine Zacharakis Loumbas**, Zacharakis Loumbas Law LLC; and **Jennifer Mitchell**, Dinsmore & Shohl LLP.

These views are presented only on behalf of the Section. They have not been approved by the ABA House of Delegates or Board of Governors and should not be construed as representing the policy of the American Bar Association.

To view the comments, visit: http://www.americanbar.org/groups/health_law/news/2016/10/section_comments.html.

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ABA Health eSource – Our electronic monthly newsletter is a perfect place to find and publish succinct, timely articles. Generally the articles for this monthly publication are not as long as the articles in *The Health Lawyer* but are every bit as important. Susan Pachikara is the staff person in charge of the *ABA Health eSource* and can be reached at 312/988-5468 or at susan.pachikara@americanbar.org.

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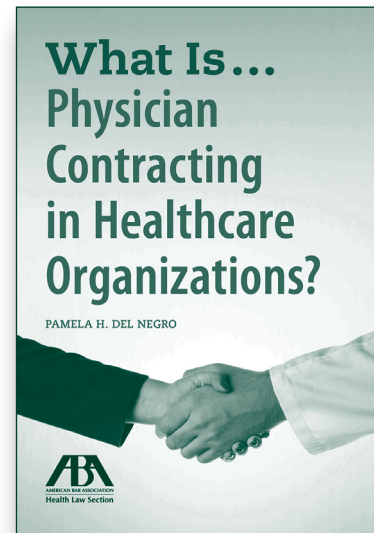
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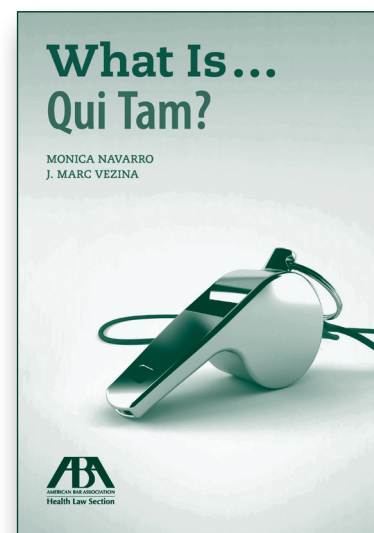
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CLARIFICATION OF THE IMPLIED FALSE CERTIFICATION THEORY UNDER THE FALSE CLAIMS ACT: THE SUPREME COURT'S DECISION IN *UNIVERSAL HEALTH SERVICES, INC. V. UNITED STATES EX REL. ESCOBAR*

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Introduction

Without question, the False Claims Act ("FCA") has been one of the most effective tools in the Department of Justice's ("DOJ") fight against fraud, particularly healthcare fraud. As disclosed by the DOJ, Fiscal Year 2015 marked the fourth year in a row that DOJ recoveries had exceeded \$3.5 billion in cases brought under the FCA. Of that sum, a large percentage, \$1.9 billion, came from companies and individuals in the healthcare industry.¹ While the DOJ has a large arsenal of criminal prosecution tools at its disposal to fight healthcare fraud – and the HEAT Task Force is devoted specifically to those efforts – the FCA is a mainstay of the government's efforts to combat healthcare fraud.²

Congress enacted both substantive and procedural amendments to the FCA in 2009 and 2010 – in the Fraud Enforcement and Recovery Act of 2009 ("FERA") and in the Patient Protection and Affordable Care Act ("PPACA").³ While these statutory amendments have touched on essentially all of the FCA's liability provisions and the definitions of key terms in the law such as "claim," "materiality," and "obligation," the DOJ and the *qui tam* bar have relied in large part upon the courts to add judicial gloss to the bare text of the statute. In fact, each year the courts, including sometimes the United States Supreme Court, consider a number of issues under the FCA and provide more guidance about how to apply this law. This year has

been no exception, and the United States Supreme Court weighed in again, handing down a much-awaited decision clarifying the scope of the theory of "implied false certification" as a basis for liability under the FCA in the case of *Universal Health Services, Inc. v. United States ex rel. Escobar*.⁴ Just as it did in last year's decision in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*,⁵ where the Court considered the application of the War-time Suspension of Limitations Act to FCA actions and the scope of the FCA's first-to-file bar, the Supreme Court issued another unanimous decision in the *Escobar* case, with Justice Clarence Thomas writing for the Supreme Court.

This article will address the "implied false certification" theory under the FCA and the clarification to the scope of that theory which the Supreme Court provided in the *Escobar* decision. Since that decision was announced in June, there has been much debate about whether, and to what extent, *Escobar* has impacted the theory of implied false certification and similar debate concerning how both the DOJ and *qui tam* litigators will respond to the ruling in *Escobar*.

Basics of Liability Under the FCA

In what is perhaps one of the most glaring anomalies or oversights in the FCA, the statute itself contains no definition of the terms "false" or "falsity" or "fraudulent." Rather, in its most recent iteration after the FERA and PPACA amendments, the FCA provides for liability for the following acts, among others:

(a) Liability for Certain Acts.

(1) In General. – Subject to paragraph (2), any person who –

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F) or (G);

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000...plus 3 times the amount of damages which the Government sustains because of the act of that person.⁶

To commit a violation of the FCA, one need not act with specific intent to defraud.⁷ This is so because the FCA defines "knowingly" to include a person who has "actual knowledge of the information" as well as one who "acts in deliberate ignorance of the truth or falsity of the information" or one who "acts in reckless disregard of the truth or falsity of the information" contained in a claim.⁸ In the simplest terms, a person incurs FCA liability when he "knowingly asks the Government to pay amounts it does not owe."⁹

What then is a "false" claim under the FCA, or what are the reasons that render a claim not payable under the FCA? Because the statute itself contains no definition of "false" or "falsity" the courts have developed two basic types of claims which are actionable under the FCA: (1) *factually false*

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claims and (2) *legally* false claims. Factually false claims are easily understood and demonstrated: they involve claims where a person misrepresents what if any goods and services were provided to the government.¹⁰ A simple example of a factually false claim would be one in which a laboratory represents that it has provided 10 units of a drug when it has only provided one unit, or where a physician represents that he has performed a panel of seven tests when he has only performed one. Such a factually false claim is not payable, and may support liability under the FCA because the claim contains inaccurate and factually false information about the product or service billed.

Legally false claims are of a different character altogether, and they arise where a person certifies compliance with a statute or regulation that is a condition of government payment while knowing that no such compliance exists.¹¹ An example of a legally false claim would be billing for services provided by unlicensed or non-licensed healthcare personnel when government regulations require a particular license or level of license for the provider, which is precisely the circumstance presented in *Esco-bar*. The claim is factually accurate in that it accurately describes the treatment or service rendered, but it is legally false because it violates a condition of payment, that condition being that the provider rendering the care be properly licensed. This is known as the “false certification” theory of liability under the FCA.

Express False Certification and Implied False Certification Under the FCA

The “false certification” version of FCA liability can also be broken down into two separate forms: express false certification and implied false

certification.¹² In the instance of an express false certification case, an entity may be liable under the FCA for expressly certifying compliance with applicable regulations in connection with its receipt of government funds.¹³ On the other hand, under the “implied false certification” theory, an entity may be liable under the FCA even though it has not explicitly certified compliance with any applicable regulations. Rather, the entity can be held liable under an implied certification theory of liability for requesting payment from the government to which it is not entitled because it has violated regulations.¹⁴

Express false certification claims were always considered somewhat clearer cases of liability under the FCA. It was generally understood that an express certification of compliance on the face of the claim with a rule or regulation provided sufficient evidence that the parties involved found the rule or regulation to be important to the claim for payment. Thus, falsely certifying compliance with a rule or regulation constituted a false claim under the FCA.¹⁵ Indeed, some courts began to treat the existence of an express certification as the *sine qua non* of liability under the FCA and the absence of an express certification as equivalent to a shield from liability under the FCA.¹⁶ Similarly, when it began to be argued that the express false certification theory of liability might reach too far – such as when a hospital had expressly certified compliance with “all applicable laws and regulations” in its cost reports – some courts began to require that the express certification at issue be tied to some condition of payment and not simply other conditions such as conditions of participation in the Medicare Program.¹⁷

While the express false certification theory of liability was being fleshed out by the courts, a separate theory, of implied false certification, began to be advanced in FCA cases.

The essence of the implied false certification theory is that the mere act of submitting a claim constitutes certification of compliance with government laws and regulations pertaining to the claim, even if the claim itself is silent as to such compliance. While some courts have been reluctant to accept either of the certification theories of liability,¹⁸ the Second Circuit was one of the first courts to discuss the implied false certification theory in detail in the case of *Mikes v. Strauss*,¹⁹ although the *Mikes* court pointed out that the implied certification theory had been applied several years earlier in an unpublished Federal Circuit case, *Ab-Tech Construction, Inc. v. United States*.²⁰ Even in adopting the implied false certification theory advanced in *Mikes*, the Second Circuit concluded that this theory of FCA liability should be given a limited reach, as the court explained:

“[W]e think a medical provider should be found to have implicitly certified compliance with a particular rule as a condition of reimbursement in limited circumstances. Specifically, implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid. (citation omitted) Liability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing – as that term is defined in the Act... that payment expressly is precluded because of some noncompliance by the defendant.”²¹

Thus, in *Mikes* the Second Circuit limited the scope of the implied false certification theory to those cases where the implied certification in question relates specifically to the government’s decision to pay or not to pay the claim because the underlying regulations expressly stated that compliance was required for payment.²²

After *Mikes*, a number of other circuits also embraced the implied false certification theory of liability under the FCA. For example, the Sixth Circuit accepted the implied false certification theory in *United States ex rel. Augustine v. Century Health Services, Inc.*²³ The Eleventh Circuit recognized the viability of implied false certification in *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*²⁴ The Tenth Circuit affirmed the dismissal of an FCA case but noted that an implied false certification theory can support FCA liability in *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*²⁵ The Ninth Circuit accepted the implied false certification theory in *Ebeid ex rel. United States v. Lungwitz*.²⁶ The District of Columbia Circuit allowed an implied certification case to go forward in *United States v. Science Applications Intern. Corp.*²⁷ The First Circuit applied the implied certification theory in *Blackstone*,²⁸ and the Third Circuit likewise adopted the theory in *United States ex rel. Wilkins v. United Health Grp., Inc.*²⁹

Other circuits were reluctant to accept the implied false certification theory. When first presented with the theory, the Seventh Circuit ruled in *United States v. Momence Meadows Nursing Center, Inc.* that the relators had waived any opportunity to rely on the implied false certification theory by failing to argue that theory to the jury.³⁰ However, in the later case of *United States v. Sanford-Brown, Ltd.* the Seventh Circuit did not accept the doctrine of implied false certification, and joined the Fifth Circuit,³¹ which, when presented with an implied certification case, declined to apply or affirm the implied certification theory, finding that no implied certification had been made by the defendant.³²

Thus, the backdrop against which the *Escobar* case reached the United States Supreme Court was this clear split of authority among the circuits on the viability and the scope of the implied false certification theory of liability under the FCA. The two questions which needed to be decided

in *Escobar* were (1) whether the implied certification theory was a viable theory of liability at all under the FCA, and (2) if so, what should be the proper scope of the theory.³³

The Background and the Lower Court's Ruling in *Escobar*

The facts in the *Escobar* case could not have presented a more compelling opportunity for the Supreme Court to determine whether implied false certification should be permitted as a foundation for liability under the FCA. The case was brought by Carmen Correa and Julio Escobar, the mother and stepfather of Yarushka Rivera. Rivera was a teenager covered under Massachusetts' Medicaid program who received counseling at Arbour Counseling Services, a satellite mental health facility in Lawrence, Massachusetts, which was owned and operated by a subsidiary of Universal Health Services. Between 2004 and 2009, Rivera received intermittent treatment from five medical professionals at Arbour. In May 2009, while Rivera was being treated for bipolar disorder, she had an adverse reaction to a medication and suffered a seizure, requiring hospitalization. After a second seizure, Rivera – who was only 17 years old at the time – died. Her mother and stepfather subsequently learned that only one of the five professionals who had been treating Rivera was properly licensed. The practitioner who had prescribed the medication to which Rivera had an adverse reaction and resulting seizures was held out as a psychiatrist when in fact she was only a nurse who lacked authority to prescribe medications without supervision. In all, it was determined that some 23 Arbour employees lacked licenses to provide mental health services, even though they counseled patients and prescribed drugs without supervision in direct contravention of regulatory requirements.³⁴

When submitting reimbursement claims, Arbour staff members misrepresented their qualifications and license

status to obtain National Provider Identification numbers and then submitted claims to Medicaid.³⁵ Armed with this information, Carmen Correa and Julio Escobar, as *qui tam* relators, filed an FCA case in 2011 under an implied false certification theory of liability.³⁶ Their basic theory was that Universal Health Services had defrauded the Massachusetts Medicaid program, which would not have reimbursed the claims had it known that it was being billed for mental health services performed by unlicensed and unsupervised staff.³⁷ The district court granted Universal Health's motion to dismiss based upon its holding that the majority of the regulations relied upon by the relators were not conditions of payment.

The First Circuit reversed in part and remanded.³⁸ The First Circuit held that a statutory, regulatory or contractual requirement can be a condition of payment either by expressly identifying itself as such or if compliance with that requirement was material to the government's decision to pay a claim.³⁹

The First Circuit further held that the regulations at issue here constituted dispositive evidence of materiality to payment because adequate supervision of nursing and counseling staff was an "express and absolute" condition of payment.⁴⁰ Universal Health then sought *certiorari*, which the Supreme Court granted to resolve the dispute among the various Courts of Appeals on the validity and scope of the implied false certification theory of liability under the FCA.

The Supreme Court's Holding in *Escobar*

At the outset of its opinion, the Supreme Court stated plainly: "We first hold that the implied false certification theory can, at least in some circumstances, provide a basis for [FCA] liability."⁴¹ This might at first blush appear to be a rousing victory for proponents of the FCA, including the government, which participated

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only as *amicus curiae* in the *Escobar* case because the DOJ had declined to intervene in the case below. A plain ruling that FCA cases may proceed under the implied false certification theory is a significant expansion of the scope of liability under the Act. As the Supreme Court noted, when “a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided.”⁴²

But the Supreme Court was not finished by simply stating that the implied false certification theory is a viable FCA theory. In accepting that the implied false certification theory is viable, the Supreme Court clarified that two basic requirements must be satisfied: “first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.”⁴³ Noting that the FCA does not define what makes a claim “false” or “fraudulent,” the Supreme Court suggested that courts should apply common law fraud and contract law principles to decide what types of “half-truths” are actionable under the FCA, but the Court offered no real guidance on how lower courts should apply these principles in FCA cases. The Supreme Court’s inclusion of the word “material” in the second of the two conditions which must be met for the implied false certification theory to apply at all is a significant clarification to the scope of the implied false certification theory, and that issue is addressed separately below. As for the claims in *Escobar*, however, the Supreme Court was satisfied that the billing codes utilized by

Universal Health in submitting its claims implied that it had qualified personnel who were adequately supervised in performing the services and that the claims represented actionable material misrepresentations.⁴⁴

Coming to the second part of its task in *Escobar*, the Supreme Court identified and addressed the question as: “whether, as Universal Health urges, a defendant should face False Claims Act liability only if it fails to disclose the violation of a contractual, statutory or regulatory provision that the Government expressly designated a condition of payment.”⁴⁵ The Court’s holding was that “the Act does not impose this limit on liability.”⁴⁶ The Court explained that “we also conclude that not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.”⁴⁷ In this respect, the Supreme Court explained that the more important question is not whether statutory requirements are labeled as conditions of payment, but rather whether compliance with the requirements is material to the government’s payment decision.⁴⁸ Although Universal Health had argued in favor of an express condition of payment limitation on the implied false certification theory, the Supreme Court rejected this argument and explained its ruling as follows:

[F]orcing the Government to expressly designate a provision as a condition of *payment* would create further arbitrariness. Under Universal Health’s view, misrepresenting compliance with a requirement that the Government expressly identified as a condition of payment could expose a defendant to liability. Yet, under this theory, misrepresenting compliance with a condition of eligibility to even participate in a federal program when submitting a claim would not.⁴⁹

Thus, instead of restricting the scope of the implied false certification theory by focusing on whether the misrepresentation at issue was tied to an express condition of payment, the Supreme Court decided instead to limit the theory by application of a materiality requirement. Moreover, the materiality requirement, which has always been a part of the FCA, focuses not on whether the actual contractual obligation about which some omission or misrepresentation is made was an express precondition to payment, but whether the misrepresentation is material to the government’s decision to pay the claim.

How then, might a relator or a defendant in an FCA case predict or conclude whether any given misrepresentation is material to the government’s decision to pay? Of course, “the Government’s decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive.”⁵⁰ Other indicia of materiality might include “evidence that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory or contractual requirement.”⁵¹ On the other hand, liability might not attach in cases where “the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, [because] that is very strong evidence that those requirements are not material.”⁵² Similarly, “if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.”⁵³

But lest one infer from these comments that *any* statutory or contractual violation *could* be material, the Supreme Court was unwilling to adopt such an expansive view which would make every possible ground on which

the government could lawfully withhold payment a sufficient basis for imposing liability under the FCA. The Court made it clear that “insignificant regulatory or contractual violations” should not be viewed as material and should not provide a basis for imposing treble damages under the FCA.⁵⁴ In this regard, the Supreme Court pointed out that the materiality standard is demanding and will not be held to have been met when the noncompliance is merely minor or insubstantial.⁵⁵ The materiality standard has always been, and remains even after *Escobar*, a rigorous one.

Questions Remaining

So what is to be made of the *Escobar* decision holding that the implied false certification theory is viable, but then reiterating that the FCA has a “materiality” requirement even under the implied certification theory under the FCA? Unfortunately, that is a question which will, again, have to be taken up and explored by the lower courts because the Supreme Court did not offer any guidance on how to weigh the various factors touching on materiality, instead leaving it to the lower courts to engage in a fact-intensive weighing process. The Supreme Court failed to provide any bright line rule for ascertaining when a statutory requirement or contractual term will be viewed as material to the government’s decision to pay. Nor did the Supreme Court explain what evidence will be required to establish that the government “consistently refuses to pay” certain types of claims or what evidence might support a finding that the government had “signaled no change in position” on various types of claims despite knowledge that requirements of a statute or contract have been violated.

Another problem left unresolved by *Escobar* is whether the weighing of these factors touching on materiality applies at the pleading stage or only at the trial stage of these FCA cases. For its part, although it offered no exhaustive discussion on the issue,

the Supreme Court rejected an argument raised by Universal Health that applying materiality to FCA cases will be too fact intensive for courts to dispose of FCA cases on a motion to dismiss or at the summary judgment stage.⁵⁶ The *Escobar* case itself was only at the pleading stage, as the district court had granted a motion to dismiss the complaint.⁵⁷ The Supreme Court was of the view that the rigorous pleading requirements of Federal Rules of Civil Procedure 8 and 9(b) are sufficient to test a FCA complaint along with the “rigorous” standard for materiality.⁵⁸

For now, the pleading stage seems to be the most immediate battleground for application of the approach adopted in *Escobar*. The Supreme Court vacated the First Circuit’s decision and remanded the case. On remand to the First Circuit, the arguments have been focused on whether the relators have alleged in their complaint representations which are sufficient to pass muster under the materiality standard addressed in *Escobar*. On remand, Universal Health argued that since Massachusetts Medicaid did not withhold or suspend reimbursement even after multiple investigations, the misrepresentations regarding staff licensure must not have been material to the decision to pay. On the other hand, Yarushka Rivera’s parents argued that having qualified mental health personnel is central to the Universal Health contract with Massachusetts Medicaid, and if that were not so then Universal Health would not have gone to such lengths to hide the lack of qualified therapists at its facilities. Alternatively, the relators argued that if the standard announced by the Supreme Court in *Escobar* has not been met by their current complaint, they should be given leave to amend to meet the contours of that standard.⁵⁹

The First Circuit issued its decision on remand on November 22, 2016, concluding that the relators had sufficiently pleaded a violation of the FCA to avoid dismissal on a 12(b)(6) motion.⁶⁰

Conclusion

While *Escobar* is one of the first cases to apply the Supreme Court’s ruling on the implied false certification theory, no doubt the acceptance of the theory will lead both the DOJ and the relators’ bar to continue advancing that theory in FCA cases. District courts and the courts of appeals will continue to struggle with how to apply the Supreme Court’s clarification that, while the implied false certification is a viable theory under the FCA, materiality is still the central consideration in any FCA case.



Robert G. Anderson currently serves as a Special Assistant Attorney General in the Public Integrity Division of the Mississippi Attorney

General’s Office, where he prosecutes cases for both the Insurance Fraud Section and the Vulnerable Adult Unit. He also has over 15 years of experience as an Assistant United States Attorney, serving as Civil and/or Criminal Healthcare Fraud Coordinator in three different districts and litigating numerous False Claims Act and criminal healthcare fraud cases. He has received on two separate occasions the U.S. Department of Health and Human Services Office of Inspector General Integrity Award for investigating and prosecuting healthcare fraud. He may be reached at rande@ago.state.ms.us.

Endnotes

- ¹ See Justice Department Recovers Over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015, available at: <https://justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.
- ² The HEAT Task Force is a cabinet-level joint task force created by the Department of Justice and the Department of Health and Human Services in May 2009. The full name of HEAT is the Health Care Fraud Prevention and Enforcement Action Team, and it operates in nine key cities to investigate and prosecute healthcare fraud cases. Those cities are: Baton Rouge, Louisiana; Brooklyn, New York; Chicago, Illinois; Dallas, Texas; Detroit, Michigan; Houston, Texas; Los Angeles, California; Miami, Florida; and Tampa Bay, Florida.

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Clarification of the Implied False Certification Theory Under the False Claims Act

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- ³ FERA made a number of changes to the FCA, including expanding “reverse” false claims liability under the FCA, expanding the definition of “obligation” under the FCA to include retention of an overpayment, eliminating the need for presentment of claims directly to the government for liability to attach under the FCA, adding an explicit materiality provision for false statements and reverse false claims under the FCA, clarifying the conspiracy provisions of the FCA, revising the anti-retaliation provisions of the FCA and expanding the DOJ’s ability to use Civil Investigative Demands under the FCA. PPACA made further amendments to the FCA, including expansion of the scope of the FCA by weakening the public disclosure bar and expanding the scope of the original source exception. PPACA also enacted a 60-day repayment requirement, after which retention of funds may constitute an “obligation” under the FCA, and added a provision specifying that claims resulting from an Anti-Kickback violation constitute false or fraudulent claims under the FCA.
- ⁴ 136 S.Ct. 1989 (June 16, 2016) (referred to herein as *Escobar*).
- ⁵ 135 S.Ct. 1970 (2015).
- ⁶ 31 U.S.C. § 3729(a)(1)(A) through (C).
- ⁷ See 31 U.S.C. § 3729(b)(1)(B).
- ⁸ 31 U.S.C. § 3729(b)(1)(A)(i) through (iii).
- ⁹ *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 438 (3rd Cir. 2004) (quoting from *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)).
- ¹⁰ *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008).
- ¹¹ *Id.*
- ¹² See *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 303 (3rd Cir. 2009), *overruled in part on other grounds by United States ex rel. Eisenstein v. City of New York, New York*, 129 S.Ct. 2230 (2009).
- ¹³ *Id.*
- ¹⁴ *Id.*
- ¹⁵ See *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 388 (1st Cir. 2011), cert. denied, 132 S.Ct. 815 (2011).
- ¹⁶ See *Mikes v. Strauss*, 274 F.3d 687, 698-699 (2nd Cir. 2001).
- ¹⁷ See *United States ex rel. Westmoreland v. Amgen, Inc.*, 707 F.Supp.2d 123, 136-137 (D.Mass. 2010) (language of Medicare Enrollment Application pertaining to compliance with “all applicable state and federal laws” was not sufficient to constitute express certification of compliance with state and federal anti-kickback statutes), *aff'd in part and rev'd in part*, 652 F.3d 103 (1st Cir. 2011).
- ¹⁸ The First Circuit spoke to this issue in *United*

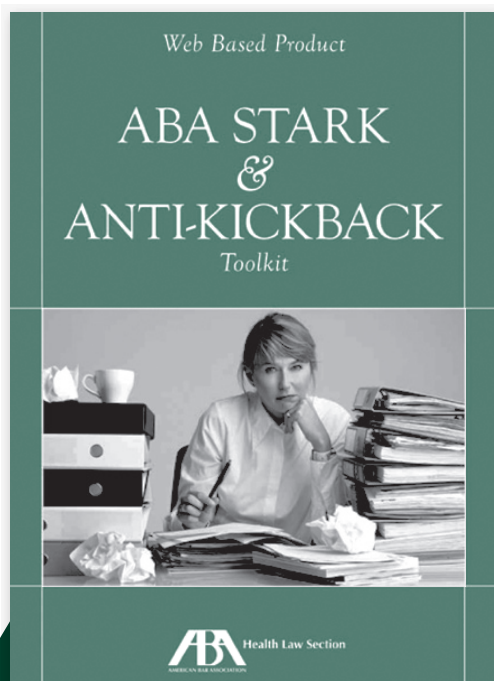
States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011), cert. denied, 132 S.Ct. 815 (2011), where the First Circuit noted:

Judicially-created categories sometimes can help carry out a statute’s requirements, but they can also create artificial barriers that obscure and distort those requirements. The text of the FCA does not refer to “factually false” or “legally false” claims, nor does it refer to “express certification” or “implied certification.” Indeed, it does not refer to “certification” at all. *Id.* at 385.

- ¹⁹ 274 F.3d 687 (2nd Cir. 2001).
- ²⁰ 31 Fed. Cl. 429 (Fed. Cl. 1994), *aff'd* 57 F.3d 1084 (Fed.Cir. 1995), cited in *Mikes*, 274 F.3d at 699.
- ²¹ *Mikes v. Strauss*, 274 F.3d at 700 (emphasis in original).
- ²² This is an issue which arose again in *Escobar*.
- ²³ 289 F.3d 409, 415-416 (6th Cir. 2002).
- ²⁴ 423 F.3d 1256, 1259 (11th Cir. 2005).
- ²⁵ 543 F.3d 1211, 1217 (10th Cir. 2008).
- ²⁶ 616 F.3d 993, 996-998 (9th Cir. 2010).
- ²⁷ 626 F.3d 1257, 1267-1270 (D.C.Cir. 2010).
- ²⁸ *Blackstone*, 647 F.3d at 387.
- ²⁹ 659 F.3d 295, 306 (3rd Cir. 2011).
- ³⁰ 764 F.3d 699, 711-712 (7th Cir. 2014).
- ³¹ 788 F.3d 696, 711-712 (7th Cir. 2015).
- ³² *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010).
- ³³ See *Escobar*, 136 S.Ct. 582 (2015) (granting *certiorari* on question whether implied certification is a viable theory under the FCA and whether, if it is viable, it is limited to cases where the certification in question relates to a condition of payment).
- ³⁴ See generally, *Escobar*, 136 S.Ct. at 1997.
- ³⁵ *Escobar*, 136 S.Ct. at 1997. For example, one Arbour staff member who treated Rivera registered for a National Provider Identifier (NPI) number associated with “Social Worker, Clinical,” although lacking the credentials and licensing required. *Id.*
- ³⁶ *Id.* at 1997.
- ³⁷ *Id.* at 1998.
- ³⁸ *Escobar*, 780 F.3d 504, 517 (1st Cir. 2015).
- ³⁹ The First Circuit said: “Preconditions of payment, which may be found in sources such as statutes, regulations, and contracts, need not be ‘expressly designated.’” *Hutcheson*, 647 F.3d at 387–88. Rather, the question whether a given requirement constitutes a precondition to payment is a “fact-intensive and context-specific inquiry,” *Amgen*, 652 F.3d at 111, involving a close reading of the foundational documents, or statutes and regulations, at issue. Cf. *United States v. Sci. Applications Int'l*

Corp., 626 F.3d 1257, 1269 (D.C.Cir.2010) (“The existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not...a necessary condition.”). 780 F.3d at 512-513.

- ⁴⁰ *Id.* at 514.
- ⁴¹ *Escobar*, 136 S.Ct. at 1999.
- ⁴² *Id.*
- ⁴³ *Id.* at 2001.
- ⁴⁴ *Id.* at 2001. As the Supreme Court ultimately held: “This case centers on allegations of fraud, not medical malpractice. Respondents have alleged that University Health misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations.” *Id.* at 2004.
- ⁴⁵ *Id.* at 2001.
- ⁴⁶ *Id.*
- ⁴⁷ *Id.*
- ⁴⁸ *Id.* at 2001 (citation omitted).
- ⁴⁹ *Id.* at 2002.
- ⁵⁰ *Id.* at 2002.
- ⁵¹ *Id.*
- ⁵² *Id.*
- ⁵³ *Id.* at 2003-2004.
- ⁵⁴ *Id.* at 2004.
- ⁵⁵ *Id.*
- ⁵⁶ *Id.* at 2004 n.6.
- ⁵⁷ *Id.* at 1993.
- ⁵⁸ *Id.* at 2004 n.6.
- ⁵⁹ The briefs after remand from the Supreme Court are filed in the First Circuit in Case Number 14-1423, along with various briefs of amici curiae including the Commonwealth of Massachusetts, the United States and the Taxpayers Against Fraud Education Fund – in support of the relators – and the National Association of Psychiatric Health Systems, the Massachusetts Hospital Association and the Chamber of Commerce of the United States in support of Universal Health. Oral argument on remand was held on October 25, 2016.
- ⁶⁰ The First Circuit’s decision on remand was filed on November 22, 2016, and appears on PACER under Case Number 14-1423. It had not yet been published as of the publication date of *The Health Lawyer*. The First Circuit specifically rejected the Universal Health claim that Massachusetts Medicaid continued to pay claims despite knowledge that UHS was not in compliance with the applicable regulations regarding the training and credentials of its personnel.



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