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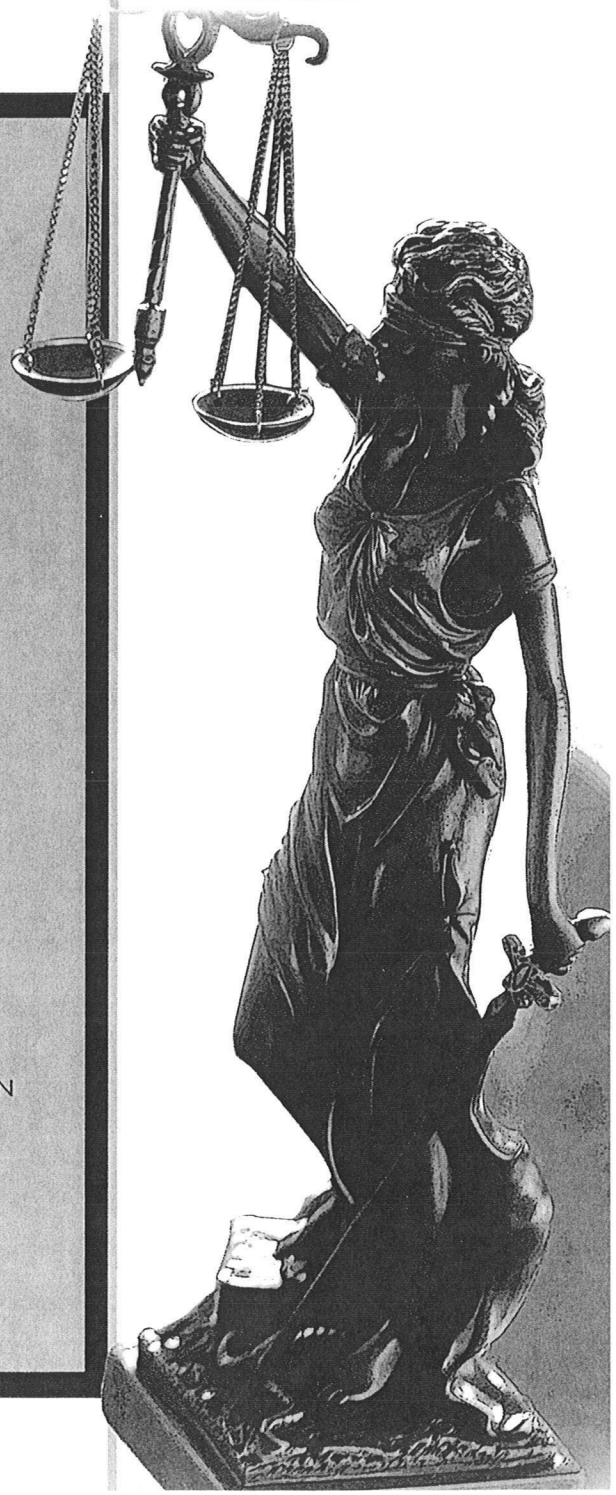

THE SURGICAL LIABILITY CASE

By Steven E. Pegalis, Megan Schnader, and Serena J. Dean

INTRODUCTION

The scope of surgical care includes pre-operative planning; disclosure of risks, benefits and alternatives to surgery so an informed consent may be obtained; intra-op skill and diligence coordinating with anesthesia and technical providers; and post-operative care.

"A lawyer shall not bring or defend ...an issue ..., unless there is a basis in law and fact for doing so that is not frivolous."[1] A lawyer's conduct is "frivolous" if it "has no reasonable purpose" ... or "... knowingly asserts material factual statements that are false."[2]

Therefore, plaintiff's legal advocate should only pursue a surgical liability case that has factual merit. If the case does have true merit and is expertly prosecuted, the defense should be revealed as "frivolous."

We include reference to a recent case involving a 21-year old who we will call Adam. We believe Adam's case had true provable merit. Why was Adam's case meritorious? How was the case proven? We hope that the answers to these questions will help legal advocates identify and successfully prosecute meritorious surgical cases.

ADAM'S CASE

Adam, age 21, though he had a spinal deformity, walked into the defendant hospital and was able to engage in all activities of daily living. He was asleep during spinal surgery. When he awoke, he was unable to move himself from the waist down and Adam remained a functional paraplegic.

What was the timing and mechanism of Adam's disabling injury? You must be able to prove, by a fair preponderance of the credible evidence, the timing and mechanism of the injury. You should not allow the fact that your client was asleep and unaware of technical medical facts to put a plaintiff at a disadvantage because there are ethical mandates requiring documentation in the patient's record and also requiring disclosure to the patient.

The code of professional conduct for surgeons requires surgeons to "...acquire and maintain competence ... scientific knowledge [and] ... the appropriate use of this knowledge ...".[3] The surgeon must serve as an effective advocate for the patient's needs and must fully disclose adverse events and medical errors.[4]

All physicians, regardless of any fear or concern of legal liability, must disclose "... all facts necessary to ensure understanding of what occurred ..."[5] Documentation is a factor in the provision of quality care and as has been stated "[I]f you didn't write it down, it didn't happen ... if the record hardly exists ... it is tantamount to an outright confession, in the eyes of the law, to careless practice."[6] The ethical mandate for all healthcare providers is to use the information learned from a bad outcome to promote safety for future cases and to promote the valid and important legal rights of the injured patient.[7]

As counsel for Plaintiff, you must inform yourself through medical experts and literature so that you can engage in a forensic process that allows you to understand what happened to your client.

FORENSIC DEDUCTIVE REASONING

The differential diagnosis methodology requires an expert to take a systematic approach, using all relevant data and contrasting all the possibilities, in an effort to identify the most likely cause of a medical event.[8] There should be enough data to establish injury timing and mechanism sufficient for logical jurors to understand what happened. That same logic should allow the jurors to understand that "risk" and "bad luck" are not evidence disputing plaintiff's case.

Harkening to the Court's reasoning in *Daubert*[9], it is not enough to "compare and contrast" clinical findings to identify "generally capable causes" of morbidity and mortality. Instead experts must use reliable scientific methods to support meritorious claims.[10] The differential diagnosis methodology is a scientifically reliable methodology to identify cause consistent with the fair preponderance of the evidence legal standard requiring a provable identification of the most likely cause of any injury.

In Adam's case, he sustained six non-symmetrical disabilities (paralysis greater on the left than the right due to non-symmetrical injuries to the front of the spinal cord; sensory deficit greater on the right than

the left and less profound than the paralysis due to non-symmetrical injuries to the back of the spinal cord; and bladder function deficit greater than bowel function deficit though the locations within the spinal cord controlling those functions are close to one another, due to non-symmetrical injuries to those spinal cord locations controlling those functions).

In Adam's case, one could extrapolate the specifics of the immediate and longer-term symptoms and disabilities with the "injured" anatomy.

Thus, the process of extrapolation and deductive reasoning is a scientifically reliable methodology used by the medical profession often to make life and death decisions.

Post-operatively, in Adam's case, the lower part of his spinal cord (the conus) was found to be swollen. The defendant spine surgeon documented that the injury was likely due to ischemia (reduced blood flow to the spinal cord). Whether the mechanism of injury was ischemia or direct mechanical trauma, the lower spinal cord was "at risk" for such an injury. What skill and precautions were required to anticipate and avoid such injuries? The question is not answered.

Adam's multiple and non-symmetric injuries would logically result from surgical drilling of the spine for a period over one hour during which time there was inadequate monitoring of the spinal cord nerve signals. The factual premise of the plaintiff's case would neatly connect like the proverbial round peg fitting in a round hole. By contrast, a defense built on vagueness and contrivances would disconnect from logic like trying to fit a square peg in a round hole.

In pursuit of the meritorious surgical liability case, we should not readily accept the idea that inadequate information, or even a cover-up, can frustrate our pursuit of justice.

QUALIFICATIONS OF THE RESPONSIBLE SURGEON

A surgeon should acquire and maintain competence that includes demonstrated proficiency. Technical skill alone is not sufficient. Skills are acquired in a context of in-depth knowledge. Informed consent is more than a legal requirement but an ethical requirement.[11]

Surgical skill and knowledge must be complemented by mindfulness, a crucial health provider attribute shown to improve safety by requiring surgeons to overcome their personal biases and to remain alert and mentally focused on the actions performed in patient care.[12]

In Adam's case, a lack of surgical skill *per se* was not the premise of liability. In considering surgical skill, the issue may relate to a lack of qualifications or, even if the surgeon is qualified, may relate to a failure to use the skill diligently and efficiently. In Adam's case, the issue would center on the failure to take and use precautions related to intraoperative neuromonitoring (IONM). With an understanding of the timing and mechanism of your client's injury, what precautions were required to anticipate and avoid that injury? Same question is asked above and neither are answered.

RISK AND INFORMED CONSENT

In Adam's case the surgeon's pre-operative office note states the following:

> "This is a major operation with significant risk of being paralyzed. The risk of paralysis can be as high as about 20-30 percent. The risk of paralysis is very real. This could be a complete or incomplete paralysis which may not recover at all. There is also the risk of bleeding, infection, malunion, implant failure, need for resurgery, need for implant removal and exchange, organ injury, vascular injury, mortality, CSF leak, back pain, shoulder imbalance, vascular injury, decompensation, pulmonary complications, deep venous thrombosis, and pulmonary embolism were also discussed. All questions were answered in detail."

The surgeon intended to cover himself legally by listing the spectrum of virtually all possible complications that may arise in Adam's or any other surgery (e.g., infection, bleeding and even mortality) and emphasizing the paralysis.

Has this surgeon's expansive documentation created a liability barrier too great to overcome? No.

If the surgeon really did discuss in "detail" each of these subjects that would take hours. Adam would be able to credibly testify that he was told and understood that during this surgery "anything could happen", but concerning the risk of paralysis he was reassured that with the IONM, the surgery was "safe".

At the deposition, the surgeon said he told the patient that while paralysis would be a risk, that with intraoperative neuromonitoring (IONM), "we will be monitoring your nerves from head to toe and if the motor, sensory, bladder and bowel signals remain OK, there is nearly a 100 percent chance you will be fine. The surgeon added that if a problem arose with the IONM "we will stop." The surgeon also acknowledged, at the deposition, that his documented estimate of "as much as" a 20-30

percent chance of paralysis was "conjecture" on his part.

Courts have held that, the mere fact that injury is a risk of a procedure, does not mean the injury is not a result from the failure to conform to the standard of care.[13] Surgeons maintain a bifurcated perspective of risk that distinguishes the risks inherent in procedures[14] from the risks that lie within the vulnerabilities (or comorbidities) of patients – factor courts have not held in favor of defendants' to deny patient access to care and as a defense to conforming to standards of care and medical judgement.[15] Occasionally, patients conceal comorbidities from their surgeons, and courts have held this to be a factor barring recovery.[16]

Surgeons may not create for their patients a unilateral dependence on the surgeon's judgement of what to disclose or not disclose. Doctors are ethically permitted to make decisions for patients, at their request through advanced directives, living wills and a growing trend in shared-decision-making. However, this should not frustrate the pursuit of justice as appropriate care and medical judgment must conform to the appropriate standard of care.[17] Lack of information about the surgical team entrusted with his or her care diminishes patient autonomy thereby impeding the spirit of true informed consent.[18]

Adam's testimony that he was reassured of safety by the surgeon's statement that if the IONM revealed a problem, the surgery would be stopped is consistent with what the surgeon concedes he told his patient.

Bleeding is a "risk" of all surgeries in which there will be cutting. The relevant "risk" issue is not bleeding *per se*, but complications from bleeding such as, for example, blood loss shock that can produce death. The anesthesiology team should monitor blood loss and vital signs.

If there would be no monitoring or inadequate monitoring of intraoperative blood loss producing shock and death, then including "bleeding" as a surgical risk would be a meaningless disclosure.

The relevant "risk" of paralysis for Adam's surgery, the issue includes the person performing the IONM. Were the personnel qualified? Adam was not told that there would be no IONM physician neurophysiologist participating.

IS AN INFORMED CONSENT CLAIM PROVABLE?

A surgical indication is a reason in the best interest of the patient to do the surgery. In Adam's case, since plaintiff's spine deformity could progress and could in the future produce paraplegia, a reasonably prudent patient would not accept an alternative option of no surgery if the surgery with proper IONM would be safe.

The issue in Adam's surgical case relates to a precaution not taken, *i.e.*, the protection related to a supervising neurophysiologist for the IONM. Failure to furnish the supervising physician neurophysiologist would be an act of negligence in Adam's case. Failure to disclose the absence of that precaution can move the case into one where informed consent becomes a viable claim.

Let us think together how we "connect" the negligence and lack of an informed consent with Adam's "injuries". During a period of more than an hour, there was drilling on the spine but no report of any IONM problem. By reporting a problem revealed by IONM changes and by stopping the drilling producing ischemia, the spinal cord can recover and the surgeon can adjust his drilling so the spinal cord is not in jeopardy.

SURGICAL RISK

A surgical risk may be thought of as a "potential danger" that the procedure will produce an "undesired result".[19]

In Adam's fact pattern, the surgeon identified paralysis, i.e., disabling injury to the spinal cord as a "significant" risk. Indeed, the surgeon documented that the risk, i.e., the likelihood that such a disabling injury to the spinal cord would occur can be "as high as about 20-30 percent."

Since the surgeon admitted at deposition that his estimate of "as high as 20-30 percent" was conjecture, is that entry in the record admissible in evidence? In a Pennsylvania case[20] the defense position was that a bowel perforation was a known risk of the surgery and therefore the injury was a complication of surgery, not negligence. The Court held that, while risks and complications evidence may sometimes be relevant in establishing the standard of care, a jury may not conclude that the risks and complications of a particular surgery demonstrated the absence of any negligence.

Surgeons are not bound to disclose every conceivable risk[21] but the surgeon is bound to disclose risks of serious bodily harm with a significant probability of occurring.[22] The court in *Canterbury* held that even a 1% chance of paralysis is significant enough to the patient to require adequate informed consent.[23] The specific issue in Adam's case was risk with a neuro-physiologist vs. risk with no physiologist. The difference of risk was not disclosed. Further, what the surgeon documented in his chart to be used to support a legal defense is not consistent with what the surgeon actually told the patient.

Even if the surgeon's conjecture is admitted into evidence with the defendant surgeon's testimony that "if the IONM data remains OK a good outcome is nearly100 percent", would the specific issue then relate to risk with skilled IONM in comparison to risk with no such supervision? What are the specific issues in your case? If surgical skill is not the issue and if the surgery truly is indicated, there must be a reason why the injury occurred.

Further, risk is not a medical event or a medical complication. Risk is information that an injury producing complication can arise. Appropriate surgical skill and appropriate precautions are required to reduce the risk of harm to as close to zero as is rationally and reasonably possible.

Medical professionals perpetuate a view of "surgical risk" as a potential negative consequence inherent in the intervention or the vulnerable state of the patient.[24] Healthcare providers must adequately evaluate patients and their vulnerabilities prior to surgery so ignorance of the vulnerability should not be an excuse.[25]

We suggest that you not accept the idea that the occurrence of an injury is a "risk of the procedure." Negligence by the surgeon and/or one of the other health care providers is always a risk for causing or contributing to a surgical injury.

IN ADAM'S CASE, WHAT WAS THE VALUE OF MONITORING AS A SURGICAL PRECAUTION?

There must be a reason why IONM was performed on Adam and for other similar cases. There must be a reason why some physicians train to become, and then are, certified as medical neurophysiologists. When we searched the medical literature, we found that IONM "... is an effective method of monitoring the spinal cord functional integrity during spine surgery and therefore can lead to reduction of neurologic deficit ...."[26] The reason for the IONM therefore was because it has been "effective" during spine surgery in the "reduction" of neurologic deficit," i.e., disabling spinal cord injury. What were the reasons in your case for relevant precautions?

In your case if there was no valid indication (i.e., no good reason in the patient's best interest to do the surgery), the case falls into place based on negligence and informed consent theories of liability. In Adam's case, there was a good reason to do the surgery provided there was proper IONM.

We found another study documenting that a focused use of IONM in 43 spine surgeries similar to Adam's used IONM to identify and promptly correct with surgical intervention IONM "alarms" reflecting spinal cord jeopardy with all 43 patients recovering with no spinal cord complication.[27] Thus, we have "proof" that with surgical skill and proper IONM, Adam's surgery would be "challenging" but "safe". If Adam's surgeons were skilled, then logically it was a problem with the IONM that was the weak link in a broken chain.

For your case, what precaution could have and should have been taken? How would each precaution reduce the risk of your client's injury that actually did occur?

We, along with judges and jurors, understand issues of human error. Establishing that an auto went through a red light is proof of negligence because it increases the risk of physical injury. One does not have to prove why that act of negligence occurred.

The evidence of causation is legally sufficient even if plaintiff's expert cannot quantify the extent to which defendant's act or omission decreased plaintiff's chance of a better outcome or increased his injury, as long as the jury may infer from the evidence that defendant's conduct diminished plaintiff's chance for a better outcome or increased his injury.[28]

WHAT EXPLAINS THE NEGLIGENCE IN ADAM'S CASE?

The literature reveals a study of data from twenty-two[29] lawsuits of "undetected" spinal cord injury caused by surgery despite IONM. The study finding was that if the testing was "administered correctly," the onset of the neuro-deficit would have been timely detected. The study found the primary reasons for failure to timely detect the onset of surgically induced neuro-deficit so as to lead to timely corrective action were related to avoidable factors such as personnel with inadequate IONM training and/or inexperience.

Be cautious about the use of medical literature as it is often written in such a way as to blame bad outcomes on "risk" or "unknown" factors. For example, the literature in Adam's case refers to "false negatives" meaning patients who post-op had neuro-deficits yet no IONM "alarm" was sounded. Yet, that meant that with due care, an "alarm" should have been called.

Sometimes the medical literature will include a study of error related to the issue in your case. Such literature can fortify your own expert that his or her profession includes medical human error as a risk of surgery. If a surgical injury may be due to error, "risk of the surgery" should not be a defense.

Negligence can seem to be illogical. A qualified auto driver could be inattentive due to texting. It

is not logical to drive and text, yet some drivers risk their own life, as well as harm to others, by doing so. Surgeons and other providers are not in harms way. Human error without intent to harm a patient can put the patient in harms way. The Institute of Medicine (IOM) in its landmark treatise discussed human error.[30] In the medical liability cases, we virtually never maintain that the defendant intended to cause harm. However, we often maintain that contrived efforts to avoid responsibility are intentional. The IOM did maintain that designing better systems for safety does not mean that individuals can be careless, as people must be vigilant and held responsible for their actions.[31]

While negligence is part of being human, so is the desire to avoid accepting responsibility.

JUDGMENT

In the *Nestorowich* case,[32] the defendant surgeon "inadvertently ligated" the renal artery supplying the patient's one remaining kidney during removal of a malignant tumor, causing the loss of that kidney. There was no dispute that surgical removal of the tumor was required and no dispute that the patient's death three years later was unrelated to the kidney loss but instead was due to the metastatic cancer. The jury found for the defendant.

The Court held that an "error in judgement" charge was erroneous as the law required skill and application of knowledge. Absent a showing that defendant considered and chose among several medically acceptable treatment alternatives, the "error in judgement" charge was inappropriate as defendant surgeon did not choose to inadvertently tie off the renal artery.

Nevertheless, the Court held that the erroneous instruction was "harmless" because of the highly unusual risks and difficulties of the procedure, *i.e.*, the "extraordinary" size of the tumor; the patient's obesity increasing the depth of the surgical cavity and impaired ability to see during the lengthy and laborious surgery. Defendant maintained that he meticulously controlled bleeding by ligating "bleeders" as he encountered them in a surgery in which the tumor, organs and vessels were encased in layers of muscle and fatty tissue.

Plaintiff's expert opined that ligation of the renal artery was not acceptable but defendant's expert maintained that although the ligation was inadvertent it was within the bounds of acceptable practice.

Even though the sole issue was negligence in ligating the renal artery (yes or no) and even though a theoretical "error in judgement" was not disclosed by the defense nor could have been disclosed to the jury, the Court ruled that the erroneous charge did not cloud the issue or negatively influence the jury's determination.

Could plaintiff's expert have focused on the need to identify the renal artery which was crucially supplying the patient's one and only kidney? Even though there were surgical challenges, and even though the surgeon characterized the procedure as "lengthy and laborious," and even though defendant's processes of ligating bleeders was "meticulous," none of that would be direct evidence to explain why an important non-bleeding main artery known to be near the surgical field was inadvertently ligated.

The reasoning by the Court is perplexing as ligating the renal artery was not because that artery was a "bleeder". The specific issue was why, with the known surgical visual difficulties, the defendant surgeon could not and did not visualize a main non-bleeding artery before "inadvertently" ligating it.

Please note that any skill including a surgical skill has been defined as a "learned ability".[33] As discussed *supra* the surgeon must be "mindful" to focus on all issues of patient safety, including specific patient vulnerabilities – surgeon distraction is a deviation from the standard of care that is gaining recognition.[34] Did the defendant in *Nestorowich,* in applying his surgical skill, learn and have a "mindfulness" that before ligating the blood vessel (that in fact was the renal artery) he must first assure himself that he is not inadvertently creating a problem? Could plaintiff's expert have explicitly explained that the surgeon should have learned that visibility difficulties required extra diligence to see what is being done before actually doing it?

The Court and jury bought into conclusory self-serving or irrelevant defense claims that the risks were "highly unusual"; that the surgery was "lengthy and laborious"; and that the impliedly skilled and qualified defendant surgeon proceeded "meticulously". The patient had serious medical problems. His "injury" (loss of kidney function for three years) was not monumental in context of his other major medical issues.

The sobering thought is that the pursuit of a surgical liability case is a "big deal" and judges and jurors will likely be supportive of a surgeon who seems to have been trying to do his or her best.

From the vantage point of pure legal justice, we wonder why the surgeon in *Nestorowich* did not see that he was ligating a major artery. We wonder why the surgeon did not pause until he could see that the artery he was about to ligate was not a "bleeder" and was supplying the patient's only remaining kidney.

From a practical vantage point, we must remain aware that proving injury due to lack of surgical skill can be challenging. In *Nestorowich,* there was a delay in identifying and trying to reverse the renal artery ligation before the kidney was irreparably injured. A negligent failure to identify and "fix" an "inadvertent" surgical "injury" may be valid and may be more easily "provable" in your case depending on the facts.

CONCLUSION

Let us all remember that the issues in the civil justice system are in a context of rights and responsibilities. The right of a patient to receive the benefits of the surgery and the responsibilities of the members of the surgical team to function in the patient's best interests to achieve the surgical goals without superimposing a new injury. The justice plaintiff attorneys seek is more than fair compensation. It includes accountability and safety for others. The IOM has maintained that unsafe care is a price we pay for a lack of accountability.[35] So, we come full circle. We cannot be entitled to accountability for an injured plaintiff and we cannot be on a mission to motivate greater safety for all other surgical patients if our surgical liability case did not have true factual merit.

BIOGRAPHY

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ENDNOTES

1 Section 1200.0 Rules of Professional Conduct, 22 NY ADC 1200.0, Rule 3.1 (a).

2 *Ibid*, subd (b) 2 and 3.

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8 See *Westberry v. Gislaved* 178 F 3d. 257 (4th CR. 1999); *Handyman v. N. Fork & WRR.* C, 243 F 3d. 255 (6th Cir., 2001)

9 See *Daubert v. Merrell Dow Pharmaceuticals,* 43 F.3d 1311 (9th Cir. 1995)

10 *Baker v. Baker Hughes Oilfield Operations Inc.* Citation (citing *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049 (9th Cir. 2003)

11 Statements on the Principles of the American College of Surgeons. Rev. 2016.

12 Erica Sibinga & Albert Wu, Clinician Mindfulness and Patient Safety, 304 JAMA 2532 (2010).

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14 2-31 Medical Malpractice Guide: Medical Issues § 31.08 [4] (2018).

15 See *Sutton v. Vee Jay Cement Contr. Co.*, 37 S.W.3d 803 (2000).

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21 *Adolphson v. U.S.*, 545 F. Supp. 2d 925 (2008).

22 AMA Code of Medical Ethics' Opinion on informing Patients, 14 AMA J. of Medical Ethics 555 (2012).

23 *See Canterbury v. Spence*, 464 F.2d 772 (1972).

24 *Dukert v. United States*, No. 14-506 WJ/WPL, 2017 U.S. Sist. LEXIS 3059 (D.N.M., Jan. 5,2016).

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31 *Ibid*, pp. 8 & 36.

32 *Nestorowich v Ricotta*, 97 N.Y. 2d 383, 740 N.Y.S.2d 668 (2002).

33 See *Hulbert v. Commissioner of Social Security* 2009 WL 2823739, citing. *Draegert v. Branhart*, 311 F.3d 468, 475 (2nd Cir. 2002

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