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Conflicts of Interest in Medicine, Research, and Law: A Comparison

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Abstract

Several of the remarks and articles presented in this symposium have addressed conflicts of interest arising during the provision of legal counsel to individuals who are elderly, including specific conflicts of interest implicated by estate planning, retirement planning, and long-term care planning. Topics examined thus far include conflicts of interest with respect to the application of rules of confidentiality within state rules of professional conduct to elderly clients with impaired decision-making capacity; conflicts of interest involving representative payees for Social Security benefits; conflicts of interest in distributions when parents enter into marriages that are unprotected by law; and conflicts of interest inherent in powers of attorney, among others.[1]

This article will diverge slightly from the prior articles and focus instead on conflicts of interest present in the involvement of individuals who are elderly with impaired decision-making capacity in clinical and experimental medicine when legal counsel and advanced health care and research participation planning have not taken place. More specifically, Parts I and II of this article will identify conflicts of interest that arise in the contexts of clinical medicine and human subjects research when an elderly patient with impaired decision-making capacity has not executed

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1. *See* Katherine C. Pearson, Introduction to Symposium Issue, *Capacity, Conflict, and Change: Elder Law and Estate Planning Themes in an Aging World*, 117 PENN ST. L. REV. 979 (2013) (highlighting the issues presented in this symposium edition).

an advanced health care directive, an advanced biomedical or behavioral research directive, or other similar document, and for whom a guardian has not been appointed. Parts I and II also compare and contrast illustrative state approaches for identifying and managing these conflicts to determine whether one state's approach to managing such conflicts is preferable to another.

Part III of this article compares and contrasts approaches taken by illustrative state rules of professional conduct for managing conflicts of interest in the context of legal representation. Part IV compares the approaches used in legal representation to the approaches used in clinical medicine and human subjects research. One purpose of these comparisons is to identify options for managing conflicts in different professional settings and to determine whether the approach of one professional setting is superior to another. Part IV finds that the law imposes more stringent duties on attorneys regarding the identification and management of conflicts of interest with respect to their clients as opposed to physicians with respect to their patients and researchers with respect to their human subjects. Part IV also finds that the conflicts of interest that can arise due to the lack of advanced health care and research participation planning are as substantively concerning, if not more so, than the conflicts of interest that arise during the provision of estate planning, retirement planning, and long-term care planning.

For these reasons, this article joins the already robust law review and other literatures that urge advanced health care and advanced research participation planning to minimize conflicts of interest that could arise when a surrogate, in the absence of a formally appointed agent or guardian, would like to consent to the administration, withholding, or withdrawal of treatment or consent to research participation on behalf of an elderly individual with impaired decision-making capacity. As such, this article hopefully serves as a nice capstone to the other pieces in this symposium by providing yet another reminder that legal planning, even with the conflicts of interest identified by the other authors in this symposium, is almost always superior to the lack of planning. This article also, however, proposes a novel solution for health care and research-related conflicts: state laws governing conflicts of interest in clinical medicine and human subject research should consider borrowing approaches to conflicts management that are set forth in state rules of attorney professional conduct.

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I. CONFLICTS OF INTEREST IN CLINICAL MEDICINE

The involvement of individuals who are elderly and have impaired decision-making capacity in clinical medicine can create conflicts of interest that require identification and proper management.[2] As background, in the context of clinical medicine, *decision-making capacity* refers to an elderly patient's cognitive and emotional capacity to consider information relating to the risks and benefits of a proposed diagnostic examination, medical treatment, or surgical procedure; the ability to make a decision to consent or refuse to consent to such examination, treatment, or procedure; and the ability to communicate that decision.[3] Neurologists, psychiatrists, geriatricians, and emergency

2. The introductory material in text accompanying notes 1-8 is taken with permission and with only technical changes from Stacey Tovino, *A 'Common' Proposal*, 50 HOUS. L. REV. 787, Part I (2013).

3. *See, e.g.*, Gregory L. Larkin et al., *Emergency Determination of Decision-Making Capacity: Balancing Autonomy and Beneficence in the Emergency Department*, 8 ACAD. EMERGENCY MED. 282, 282 (2001) ("Decision-making capacity includes the ability to receive, process, and understand information, the ability to deliberate, the ability to make choices, and the ability to communicate those preferences."); Roy C. Martin et al., *Medical Decision-Making Capacity in Cognitively Impaired Parkinson's*

medicine physicians, among other clinicians, frequently treat elderly patients with impaired decision-making capacity.[4] Some of these patients may be in a coma or vegetative state and have no present decision-making capacity.[5] Other elderly patients may have mild, moderate, or severe neurological disorders, including Parkinson's disease, Alzheimer's disease, and related dementias that may restrict their decision-making capacity.[6] Still other elderly patients may have severe mental illnesses, such as schizophrenia with disturbance of thought and perception, which limit their decision-making capacity.[7] As

Disease Patients Without Dementia, 23 MOVEMENT DISORDERS 1867, 1867-68 (2008) (defining medical decision-making capacity as the cognitive and emotional capacity to accept a proposed treatment, to refuse treatment, or to select among treatment alternatives).

4. *See, e.g.*, Edmund Howe, *Ethical Aspects of Evaluating a Patient's Mental Capacity*, 6 PSYCHIATRY 15, 15 (2009) (noting that non-psychiatrist physicians frequently consult with psychiatrists to help make determinations regarding patients' decision-making capacity); James M. Lai & Jason Karlawish, *Assessing the Capacity to Make Everyday Decisions: A Guide for Clinicians and an Agenda for Future Research*, 15 AM. J. GERIATRIC PSYCHIATRY 101, 101 (2007) (noting that competency assessments are a common and necessary part of caring for older patients with cognitive impairments and that geriatricians face considerable challenges in accurately and reliably identifying impaired competency); *id.* at 103 (explaining that discharge planners, case managers, and clinicians in hospitals, skilled nursing facilities, and emergency departments frequently must decide whether patients with functional impairments are capable of making decisions). *See generally* Grant V. Chow et al., *CURVES: A Mnemonic for Determining Medical Decision-Making Capacity and Providing Emergency Treatment in the Acute Setting*, 137 CHEST 421, 421-27 (2010) (addressing the evaluation of decision-making capacity in the emergency context).

5. *See, e.g.*, Rowan H. Harwood, Robert Stewart & Peter Bartlett, *Safeguarding the Rights of Patients Who Lack Capacity in General Hospitals*, 36 AGE & AGEING 120, 120 (2007) ("Many people . . . in coma are admitted to hospital, but lack the capacity to consent to admission."); Sheila A. M. McLean, *Permanent Vegetative State and the Law*, 71 J. NEUROLOGY, NEUROSURGERY & PSYCHIATRY i26, i26-i27 (2001) (noting that patients in a vegetative state lack capacity to consent to treatment).

6. *See, e.g.*, Jason Karlawish, *Measuring Decision-Making Capacity in Cognitively Impaired Individuals*, 16 NEUROSIGNALS 91, 91-98 (2008) (reviewing studies of the capacity to consent to treatment and research in the context of Alzheimer's disease and related dementias; noting that individuals with Alzheimer's disease and related dementias frequently experience losses in decision-making capacity); Martin et al., *supra* note 3, at 1867-74 (assessing decision-making capacity in patients with Parkinson's disease (PD) compared to healthy older adults and suggesting that impairment in decision-making capacity is already present in cognitively impaired PD patients without dementia, and that such impairment increases as these patients develop dementia); Jennifer Moye et al., *Neuropsychological Predictors of Decision-Making Capacity Over 9 Months in Mild-to-Moderate Dementia*, 21 J. GEN. INTERNAL MED. 78, 78-83 (2006) (examining rates and neuropsychological predictors of decision-making capacity among older adults with dementia; finding that some patients with mild-to-moderate dementia develop clinically relevant impairments of decision-making capacity within a year).

7. *See, e.g.*, Delphine Capdevielle et al., *Competence to Consent and Insight in Schizophrenia: Is There an Association? A Pilot Study*, 108 SCHIZOPHRENIA RES. 272, 272-73 (2009) ("Data from studies of treatment decision processes by schizophrenic

these examples show, an elderly individual's decision-making capacity is not always conclusively present or absent, but occurs along a continuum that depends on the nature and severity of the patient's physical and mental health conditions and the timing of the patient's symptom occurrence.[8] Neurological, psychiatric, and other health conditions do not invariably impair an elderly individual's decision-making capacity, and patient-specific assessments are always necessary.[9]

If an elderly individual does not have impaired decision-making capacity, the elderly individual can receive information regarding a proposed diagnostic examination, medical treatment, or surgical procedure and make an informed decision regarding whether to consent to that procedure. Assuming (for the moment) that the health care provider does not have an interest, such as a financial stake, in the proposed treatment that would result in the recommendation or performance of a treatment that is not in the patient's best interests,[10]

patients have suggested that, as a group, these patients perform significantly worse on many measures in comparison to those suffering from depression, other medical illnesses (such as heart disease, HIV infection) or healthy control subjects."); John H. Coverdale, Laurence B. McCullough & Frank A. Chervenak, *Assisted and Surrogate Decision Making for Pregnant Patients Who Have Schizophrenia*, 30 SCHIZOPHRENIA BULL. 659, 659 (2004) (explaining that "[s]chizophrenia can chronically and variably impair a woman's decisions concerning the management of her pregnancy," including decisions regarding pregnancy continuation).

8. Joseph E. Beltran, *Shared Decision Making: The Ethics of Caring and Best Respect*, 12 BIOETHICS F. 17, 17 (1996) (noting that decision-making capacity for individuals with disabilities occurs along a continuum); Larkin et al., *supra* note 3, at 282. Larkin et al. state:

> [Decision-making capacity] is a dynamic . . . and changing talent; in practice it may be assessed on a non-dichotomous spectrum of capacity, pertaining to the particular health care decisions at hand. Often, impairment is situational; the same patient may be competent for one decision and not another, depending on the gravity and consequences of the decision and the potential for harm.

Id.

9. *See, e.g.*, THE MACARTHUR RESEARCH NETWORK ON MENTAL HEALTH & THE LAW, THE MACARTHUR TREATMENT COMPETENCE STUDY (2004), *available at* http://bit.ly/laRQnc. The study notes:

> Most patients hospitalized with serious mental illness have abilities similar to persons without mental illness for making treatment decisions. Taken by itself, mental illness does not invariably impair decision making capacities. On the other hand, a substantial percentage of hospitalized patients—up to half in the group with schizophrenia when all four types of abilities are considered—show high levels of impairment.

Id.

10. Certainly, this assumption does not always hold. Any physician who receives payment directly from a patient or indirectly through insurance for performing a procedure on a patient has a financial interest in the performance of that procedure. If the procedure is not in the patient's best health interests, then a conflict of interest exists. Many physicians also use, prescribe, or recommend health care items and services provided, manufactured, or otherwise made available by companies with which the

conflicts of interest are not front and center in the treatment of elderly individuals with intact decision-making capacity.

On the other hand, if an elderly individual does have impaired decision-making capacity, the elderly individual may not be able to comprehend information regarding a proposed examination, treatment, or procedure, or make an informed decision whether to consent to such examination, treatment, or procedure. In this case, if the elderly individual did not execute an advanced health care planning document when competent, such as a directive to physician (also called a living will)[11] or a medical power of attorney (also called a health care power of attorney),[12] governing law typically allows—as a default—certain classes of persons to provide what is known as "surrogate" consent to treatment on behalf of the individual.[13]

The problem, of course, is that the surrogate decision maker may have interests that conflict with the interests that the elderly individual would or could identify if competent. For example, the surrogate may stand to inherit money or property upon the death of the elderly individual and, therefore, may wish to withhold or withdraw life-sustaining treatment from the individual even though the individual, while competent, may have desired to have been maintained for as long as possible in the event of a medical cure or for another reason. In this case, the surrogate's interests would conflict with those of the elderly

physician has a financial relationship, such as an ownership interest or compensation arrangement. If even one reason the physician uses, prescribes, or recommends the item or service is for compensation or other financial reward, a conflict of interest exists. These are just two examples of conflicts of interest that are present in everyday clinical medicine involving patients with intact decision-making capacity. In order to focus on the conflicts of interest that exist in clinical medicine involving elderly patients with impaired decision-making capacity and for whom no planning has taken place, this article recognizes, but must set aside, these basic conflicts.

11. Under many state laws, a directive to physician, sometimes called a living will, is a document that contains a directive from a patient to a physician declaring the types of treatments that will be administered, withheld, or withdrawn from the patient in the event the patient has a terminal or an irreversible condition. *See, e.g.*, ARIZ. REV. STAT. ANN. §§ 36-3261–36-3262 (1992) (codifying Arizona's provisions governing living wills); TEX. HEALTH & SAFETY CODE ANN. § 166.031 (West 2012) (codifying Texas's provisions governing directives to physicians).

12. Under many state laws, a medical power of attorney, sometimes called a health care power of attorney, is a document in which an individual (the principal) appoints a second individual (the agent) to make decisions regarding the administration, withholding, or withdrawing of life-sustaining treatment in the event that the first individual has a terminal or an irreversible condition. *See, e.g.*, ARIZ. REV. STAT. ANN. §§ 36-3221–36-3224 (2008) (codifying Arizona's provisions governing health care powers of attorney); TEX. HEALTH & SAFETY CODE ANN. §§ 166.151-166.166 (West 2012) (codifying Texas's provisions governing medical powers of attorney; *id.* § 166.002(11) (defining medical power of attorney under Texas law).

13. *See infra* Part I.B.1-3.

individual. By further example, the surrogate, including a surrogate related to the elderly individual by blood, such as a parent or child, may have religious or cultural views regarding the withholding or withdrawal of life-sustaining treatment that conflict with the views that were held by the elderly individual while competent. In this case, again, the interests of the surrogate would conflict with those of the elderly individual. By still further example, a surrogate who was romantically linked with the elderly individual may develop a new romantic interest and, therefore, may wish to minimize future ties to and care obligations associated with the former romantic interest. Here, again, the interests of the surrogate would conflict with those of the elderly individual with whom the surrogate formerly had a romantic interest. By final example, a physician or other health care provider of the elderly individual who serves as the individual's surrogate may have a financial interest in administering treatment to the individual if the individual is a paying or otherwise well-insured patient or, alternatively, in withholding or withdrawing treatment from the individual if the individual happens to be a non-paying or uninsured patient. Here, too, the physician or other provider's interests would conflict with those of the elderly individual.

Part I begins by describing federal law, as well as three sets of illustrative state laws, that address the identification and management of these types of conflicts of interest in the context of surrogate consent to treatment on behalf of elderly individuals who have impaired decision-making capacity. In particular, laws from Pennsylvania, Arizona, and Nevada are used to illustrate an extremely comprehensive, a moderately comprehensive, and a bare-bones approach, respectively, to the identification and management of conflicts of interest in the context of surrogate health care decision-making. Using these state laws as examples, this Part highlights statutory features that are desirable due to the assistance they provide with respect to identifying, managing, and minimizing conflicts of interest. This Part concludes that, although it cannot eliminate all conflicted decision making, Pennsylvania has a very good model for the identification and management of conflicts of interest in the context of surrogate health care decision making. Arizona and Nevada, on the other hand, leave elderly individuals with impaired decision-making capacity susceptible to conflicted surrogate decision making.

A. Federal Law

Other than general references to the doctrine of informed consent to treatment and state law provisions regarding legal representatives, federal health law does not specifically address impaired clinical

decision-making capacity, first-person consent to treatment, or surrogate consent to treatment.[14] For example, federal regulations that establish requirements applicable to Medicare-participating hospitals simply provide:

> The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.[15]

Federal regulations governing Medicare-participating hospices, which provide palliative care to patients with terminal conditions, similarly give hospice patients a general right to be involved in the development of their own hospice plans of care, as well as the right to refuse unwanted care.[16] If a hospice patient has been adjudged incompetent under state law by a court of proper jurisdiction, federal regulations provide that "the rights of the [hospice] patient are to be exercised by the person appointed pursuant to state law to act on the patient's behalf."[17] "If a state court has not adjudged a [hospice] patient incompetent," federal law provides that "any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law."[18] Federal regulations governing Medicare-participating nursing homes also are general in nature: "[u]nless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, [patients have the right to] participate in planning care and treatment or changes in care and treatment."[19]

B. State Law

Unlike federal law, most states have enacted laws that do some or all of the following: (i) define *competency*, *decision-making capacity*, or *incapacity*; (ii) establish the process for obtaining the informed consent of patients with capacity; (iii) establish the process for following advanced health care planning instructions under a directive to physician or medical power of attorney in the event a patient lacks capacity; (iv) establish the process for obtaining surrogate consent in the event a patient lacks capacity and has not executed an advanced health care

14. The text in this Part I.A and accompanying notes 14-18 is taken with permission and only technical changes from Tovino, *supra* note 2, Part II.
15. 42 C.F.R. § 482.13(b)(2) (2012).
16. *Id.* § 418.52(c)(2)-(3).
17. *Id.* § 418.52(b)(2).
18. *Id.* § 418.52(b)(3).
19. *Id.* § 483.10(d)(3).

planning document and for whom a guardian has not been appointed; (v) identify the persons in priority order who are eligible to serve as a surrogate for health care decisions in the absence of an advanced health care planning document and guardian-made decision; and (vi) identify the standard that such surrogate should use in deciding whether to consent to the administration, withholding, or withdrawal of medical treatment on behalf of the patient.[20] Three illustrative state laws are examined below.

1. Pennsylvania

Pennsylvania has enacted a comprehensive Health Care Agents and Representatives Act ("Pennsylvania Act")[21] that allows certain "health care representatives" to make a health care decision for an individual whose attending physician has determined is incompetent if the individual does not have a health care power of attorney and a guardian has not been appointed for the individual.[22]

Under the Pennsylvania Act, there are two different methods for identifying a health care representative.[23] First, "an individual of sound mind may, by a signed writing or by personally informing the attending physician or the health care provider, designate one or more individuals to act as health care representative."[24] Because many individuals, including many elderly individuals, will not have identified in writing or through another means of communication a representative before they become incompetent, the Pennsylvania Act also allows any member of the following classes, in descending order of priority, who is reasonably available, to act as a health care representative: (i) the individual's spouse, unless an action for divorce is pending, and the adult children of the individual who are not the children of the spouse; (ii) an adult child; (iii) a parent; (iv) an adult brother or sister; (v) an adult grandchild; and (vi) an adult who has knowledge of the principal's preferences and values including, but not limited to, religious and moral beliefs, to assess how the individual would make health care decisions.[25] The

20. *See generally* UNIF. HEALTH-CARE DECISIONS ACT (1993).

21. 20 PA. CONS. STAT. ANN. §§ 5451-5465 (West 2012).

22. *Id.* § 5461(a)(1)-(3). Health care representatives are authorized to make health care decisions under the Pennsylvania Act if the individual's health care agent under the power of attorney is not reasonably available, or has indicated an unwillingness to act, and no alternative health care agent is reasonably available. *Id.*

23. *Id.* § 5461(d)(1).

24. *Id.*

25. *Id.* § 5461(d)(1)(i)-(vi). Under Pennsylvania law:

(1) If more than one member of a class assumes authority to act as a health care representative, the members do not agree on a health care decision and the

Pennsylvania Act allows an individual, by signed writing, to provide for a different order of priority,[26] and to disqualify one or more persons from acting as the individual's health care representative.[27]

Keeping in mind potential conflicts of interest, the Pennsylvania Act establishes several limitations on the persons who may serve as an individual's health care representative. First, unless the person is related by blood, marriage, or adoption to the individual, the following persons may not serve as an individual's health care representative: (i) the individual's attending physician; (ii) another health care provider to the individual; and (iii) anyone who owns, operates, or is employed by a health care provider in which the individual receives health care.[28] These provisions are designed to ensure that a physician, other health care provider, or owner or operator of a health care-providing institution who may have a financial interest in providing additional treatment to a paying or otherwise well-insured patient or, alternatively, declining additional treatment to a non-paying or otherwise uninsured patient, will not be placed in that conflicted position.

Second, an individual of sound mind, including an elderly individual who regains "sound mind," "may countermand any health care decision made by the [individual's] health care representative at any time and in any manner by personally informing the attending physician or health care provider."[29] And, regardless of the individual's mental or physical capacity, the individual "may countermand a health care decision made by the [individual's] health care representative that would withhold or withdraw life-sustaining treatment at any time and in any manner by personally informing the individual's attending physician."[30]

> attending physician or health care provider is so informed, the attending physician or health care provider may rely on the decision of a majority of the members of that class who have communicated their views to the attending physician or health care provider.
>
> (2) If the members of the class of health care representatives are evenly divided concerning the health care decision and the attending physician or health care provider is so informed, an individual having a lower priority may not act as a health care representative. So long as the class remains evenly divided, no decision shall be deemed made until such time as the parties resolve their disagreement. Notwithstanding such disagreement, nothing in this subsection shall be construed to preclude the administration of health care treatment in accordance with accepted standards of medical practice.

Id. § 5461(g)(1)-(2).

26. *Id.* § 5461(d)(2).
27. 20 PA. CONS. STAT. ANN. § 5461(e) (West 2012).
28. *Id.* § 5461(f).
29. *Id.* § 5461(i)(1).
30. *Id.* § 5461(i)(2).

The Pennsylvania Act also establishes the standard of decision making for health care representatives by adopting the standard of decision making that applies to health care agents under health care powers of attorney.[31] That is, except as otherwise provided in a health care power of attorney, a health care representative shall have the authority to make any health care decision and to exercise any right and power regarding the individual's care, custody, and health care treatment that the individual could have made and exercised, including the authority to make anatomical gifts, dispose of remains, and consent to autopsies.[32]

To assist the health care representative in making a treatment decision that would be in the individual's best interests, the Pennsylvania Act does require the health care representative to gather information on the individual's prognosis and acceptable medical alternatives regarding diagnosis, treatments, and supportive care.[33] In the case of health care decisions regarding the end of life of an individual with an end-stage medical condition, the information shall distinguish between curative alternatives, palliative alternatives, and alternatives that will merely serve to prolong the process of dying.[34] The information also shall distinguish between the individual's end-stage medical condition and any other concurrent disease, illness, or physical, mental, cognitive, or intellectual condition that predated the principal's end-stage medical condition.[35]

The Pennsylvania Act is designed to assist the health care representative in following any instructions left by the individual and, if there are no instructions, making decisions in accordance with the individual's preferences and values. That is, after consultation with health care providers and consideration of the information described in the previous paragraph, the Pennsylvania Act requires the health care representative to make health care decisions in accordance with the health care representative's understanding and interpretation of the instructions, including any clear written or verbal directions that cover the situation presented and that were given by the individual at a time when the individual had the capacity to understand, make, and communicate health care decisions, if they exist.[36] In the absence of instruction, which is a common occurrence among elderly individuals with impaired decision-making capacity, the health care representative

31. *Id.* § 5461(c) (adopting generally the standard applicable to health care agents, codified at *id.* § 5456).
32. *Id.* § 5456(a).
33. 20 PA. CONS. STAT. ANN. § 5456(c)(1) (West 2012).
34. *Id.* § 5456(c)(3).
35. *Id.*
36. *Id.* § 5456(c)(4).

shall make health care decisions that conform to the health care representative's assessment of the individual's preferences and values, including religious and moral beliefs.[37]

If the health care representative does not know enough about the individual's instructions, preferences, and values to decide accordingly, the health care representative shall take into account what the representative knows of the individual's instructions, preferences, and values, including religious and moral beliefs, and the health care representative's assessment of the individual's best interests, taking into consideration the goals and considerations of: (i) the preservation of life; (ii) the relief from suffering; and (iii) the preservation or restoration of functioning, taking into account any concurrent disease, illness, or physical, mental, cognitive, or intellectual condition that may have predated the individual's end-stage medical condition.[38]

In the absence of a specific written authorization or direction by an individual to withhold or withdraw nutrition and hydration administered by gastric tube or intravenously or by other artificial or invasive means, the Pennsylvania Act does specify that the health care representative shall presume that the individual would not want nutrition and hydration withheld or withdrawn.[39] However, this presumption may be overcome by the previously clear expressed wishes of the individual to the contrary.[40] In the absence of such clearly expressed wishes, the presumption may be overcome if the health care representative considers the values and preferences of the individual and assesses the factors set forth in the previous paragraph, and determines it is clear that the individual would not wish for artificial nutrition and hydration to be initiated or continued.[41]

Without a written advanced health care planning document, such as a directive to physician or medical power of attorney, that specifies an elderly individual's preferences and instructions regarding future health care decisions, we can never be sure what the now incompetent elderly individual would want, and surrogacy legislation is always going to be the second best option. However, the Pennsylvania Act does as good a job as possible of attempting to minimize conflicts of interest by preventing certain classes of persons from serving as a surrogate and by establishing a detailed process that attempts to assist the surrogate in

37. *Id.* § 5456(c)(5)(i).
38. *Id.* § 5456(c)(5)(ii)(A)-(C).
39. 20 PA. CONS. STAT. ANN. § 5456(c)(5)(iii)(A) (West 2012).
40. *Id.* § 5456(c)(5)(iii)(B).
41. *Id.*

making a decision that would be in alignment with the elderly individual's preferences and values.

Unfortunately, it is possible even under the carefully drafted Pennsylvania Act for a health care representative to make a decision that is not in accordance with the individual's preferences and values by simply claiming that "it is clear" that such a decision is consistent with the elderly individual's preferences and values. Stated another way, it is still possible, even under the comprehensive and detailed Pennsylvania Act, for a surrogate who stands to inherit money or property from an elderly individual, or a surrogate who was formerly romantically linked with the elderly individual but has developed a new romantic interest in a second person, or any other surrogate whose interests diverge from those of the elderly individual, to hide those interests and make a decision to administer, withhold, or withdraw treatment from the individual when such decision would not be consistent with what the individual would have wanted.

In addition, note that the Pennsylvania Act prioritizes spouses over children, children over parents, parents over siblings, siblings over grandchildren, and grandchildren over other individuals who have knowledge of the individual's preferences and values in terms of persons who may serve as a surrogate. This scheme works extremely well for elderly individuals who are in traditional, heterosexual, legally-recognized marriages and whose spouses have interests that converge with their own. The Pennsylvania General Assembly may have codified this priority list of surrogates due to its belief that more state residents would be in interest-convergent, legally-recognized, and heterosexual marriages and, therefore, that the default provision giving highest priority to a spouse would serve more Pennsylvanians than any other default provision. Of course, we must recognize that this default provision will not serve every Pennsylvanian. If an elderly individual does not have a spouse and, instead, has a domestic partner or significant other whose interests converge with the elderly individual's interests, that partner or significant other may not have a chance to make a decision that would be in the elderly individual's best interests because another person would have priority over the partner or significant other. If that other person has interests that diverge from the interests of the elderly individual, the Pennsylvania Act essentially allows the conflicted individual to serve as the surrogate over the unconflicted partner or significant other.

In summary, the Pennsylvania Act does a good job of attempting to manage conflicts of interest in the context of surrogate health care decision making, but the Act does not completely remove the possibility of conflicted decision making.

2. Arizona

Under Arizona's Surrogate Decision Makers Act ("Arizona Act"),[42] if an adult individual is unable to make or communicate a health care treatment decision, a health care provider shall make a reasonable effort to locate and follow an advanced health care planning document or to locate and consult the individual's appointed guardian, if any.[43] If the individual has not executed an advanced health care planning document and does not have a guardian, then certain classes of persons may serve as surrogate decision makers for the individual if the individual is found "incapable,"[44] although the Arizona Act does not appear to define "incapable."

In priority order, the Arizona Act lists six classes of persons who may serve as a surrogate decision maker for an "incapable" individual, including: (i) the individual's spouse, unless the individual and spouse are legally separated; (ii) an adult child of the individual or, if the individual has more than one adult child, a majority of the adult children who are reasonably available for consultation; (iii) a parent of the individual; (iv) if the individual is unmarried, the individual's domestic partner; (v) a brother or sister of the individual; and (vi) a "close friend" of the individual, with "close friend" defined as "an adult who has exhibited special care and concern for the [individual], who is familiar with the [individual]'s health care views and desires and who is willing and able to become involved in the [individual]'s health care and to act in the [individual]'s best interest."[45]

In terms of the standard of decision making, the Arizona Act simply provides that the surrogate has "the authority to make health care decisions for the [individual] and . . . shall follow the patient's wishes if they are known."[46] The Arizona law does not clarify the standard of decision making that should apply if the individual's wishes are not known, other than to state that a surrogate who is not the individual's agent or guardian is not permitted to make decisions to admit the individual to certain behavioral health facilities under certain conditions.[47]

If the health care provider cannot locate any of the persons who are eligible to serve as a surrogate, the individual's attending physician may make a health care treatment decision for the individual after the

42. ARIZ. REV. STAT. § 36-3231 (LexisNexis 2012).
43. *Id.* § 36-3231(A).
44. *Id.* § 36-3231(A), (D).
45. *Id.* § 36-3231(A)(1)-(6).
46. *Id.* § 36-3231(A).
47. *Id.* § 36-3231(D)-(E).

physician consults with and obtains the recommendations of an institutional ethics committee.[48] If a consultation with an institutional ethics committee is not possible, the physician may make a decision after consulting with a second physician who concurs with the physician's decision. Unlike the comprehensive Pennsylvania Act, the Arizona Act provides no further detail regarding surrogate health care decision making in the context of adults, including elderly persons, with impaired decision-making capacity.

The Arizona Act is less desirable than the Pennsylvania Act for several reasons. First, unlike the Pennsylvania Act, the Arizona Act does not do a good job of attempting to minimize conflicts of interest by preventing certain classes of persons from serving as a surrogate. The only conflict recognized by the Arizona Act is the possibility that a surrogate might want to admit an elderly individual to a behavioral health facility when such admission might not be in the interests of the elderly individual. In addition, the Arizona Act actually allows the elderly individual's physician to make a health care decision for the elderly individual as long as the physician consults with an ethics committee or, if an ethics committee consultation is not possible, if the elderly individual consults with a second physician. Because the first physician or the second physician may have an interest in administering, withholding, or withdrawing treatment based on whether such administration, withholding, or withdrawal would be in the physician's, hospital's, or someone else's financial or other interest, it is possible that the decision made by the physician will not be in the health interests of the elderly individual.

Second, the Arizona Act does not establish a detailed process, or really any process at all, that would help the surrogate in making a decision that would be in alignment with the elderly individual's preferences and values. If the surrogate does not know what the elderly individual's wishes are, then the surrogate appears to be able to make any health care decision for the elderly individual, regardless of whose interest the decision is in, and there appears to be no oversight of that decision by any type of independent or third-party monitor.

Third, the Arizona Act suffers from the same problem that the Pennsylvania Act does in that the Arizona Act prioritizes certain individuals who may have interests that diverge from the interests of the elderly individual, over other individuals whose interests may be more

48. ARIZ. REV. STAT. § 36-3221(B) (LexisNexis 2012). An "institutional ethics committee" is defined as a "standing committee of a licensed health care institution appointed or elected to render advice concerning ethical issues involving medical treatment." *Id.*

closely aligned with those of the elderly individual. In particular, note that the Arizona Act prioritizes spouses over children, children over parents, parents over domestic partners, domestic partners over siblings, and siblings over close friends. Again, this scheme works extremely well for elderly individuals who happen to be in legally-recognized marriages and whose spouses have interests that converge with their own. The Arizona State Legislature may have codified this priority list of surrogates due to its belief that more state residents would be in interest-convergent, legally-recognized marriages and, therefore, that the default provision would serve more Arizonans than any other default provision. However, the default provision will not serve everyone. Again, if an elderly individual does not have a spouse and, instead, has a domestic partner or close friend whose interests converge with the elderly individual's interests, that partner or friend may not have a chance to make a decision that would be in the elderly individual's best interests because another person would have priority over the partner or friend. If that other person has interests that diverge from the interests of the elderly individual, the Arizona Act essentially allows the conflicted person to serve as the surrogate over the unconflicted partner or friend.

In summary, the Arizona Act does not do a good job of identifying potential conflicts of interest, attempting to minimize such conflicts, or assisting surrogates in making decisions that would serve the interests of the elderly individual.

3. Nevada

Nevada is unique in that it does not even have a default provision identifying the classes of persons who may provide surrogate consent to the *administration* of treatment in the absence of an advanced health care planning document. That is, if an elderly individual with impaired decision-making capacity has not executed an advanced health care planning document and has no guardian, Nevada law simply does not address whether, or how, a surrogate can consent to the affirmative provision of health care, whether such care is a medically necessary diagnostic examination, medical treatment, surgical procedure, or prescription drug.

However, Nevada does have a default provision that identifies the classes of persons who may provide surrogate consent to the *withholding* or *withdrawal* of life-sustaining treatment from the individual if the individual has not executed an advanced health care planning document

called a "declaration"[49] and a guardian has not been judicially appointed for the individual.[50] Codified within Nevada's Uniform Act on Rights of the Terminally Ill ("Nevada Act"),[51] the provision gives a surrogate the authority to consent to the withholding and withdrawal of life-sustaining treatment from an individual who does not have an effective declaration and for whom a guardian has not been appointed if the individual has been determined by the individual's attending physician to be in a terminal condition[52] and is no longer able to make decisions regarding the administration of life-sustaining treatment.[53]

The following classes of persons, in the following order of priority, may serve as surrogates in Nevada: (i) the spouse of the individual; (ii) an adult child of the individual or, if there is more than one adult child, a majority of the adult children who are reasonably available for consultation; (iii) the parents of the individual; (iv) an adult sibling of the individual or, if there is more than one adult sibling, a majority of the adult siblings who are reasonably available for consultation; or (v) the nearest other adult relative of the individual by blood or adoption who is reasonably available for consultation.[54] The only other relevant provision in the Nevada Act provides that a decision made by a surrogate to consent to the withholding or withdrawal of life-sustaining treatment on behalf of an individual must be made in "good faith" and that such consent would not be valid "if it conflicts with the expressed intention of the patient."[55]

The Nevada Act is the least helpful of the three state statutes surveyed. Because the affirmative administration of health care, including the performance of medically necessary diagnostic

49. A "declaration" is the name given under Nevada law to the document that an individual may sign that would appoint another person to withhold or withdraw life-sustaining treatment from the individual in the event the individual is in an incurable and irreversible condition. *See* NEV. REV. STAT. §§ 449.610-449.611 (2011). Nevada's "declaration" is the functional equivalent of other states' medical powers of attorney or health care powers of attorney; *cf. supra* note 12.

50. NEV. REV. STAT. § 449.626(1)(b) (2011); *id*. § 449.613(2).

51. *See id*. §§ 449.535-449.690.

52. Nevada defines a "terminal condition" as an "incurable and irreversible condition that, without the administration of life-sustaining treatment, will, in the opinion of the attending physician, result in death within a relatively short time." *Id.* § 449.590.

53. *Id.* § 449.626(1)(a)-(b); *see also id.* § 449.617 (stating that the declaration becomes operative when "the declarant is determined by the attending physician to be in a terminal condition and no longer able to make decisions regarding administration of life-sustaining treatment").

54. *Id*. § 449.626(2). "If a class entitled to decide whether to consent is not reasonably available for consultation and competent to decide, or declines to decide, the next class is authorized to decide, but an equal division in a class does not authorize the next class to decide." *Id.* § 449.626(3).

55. *Id*. § 449.626(4).

examinations, treatments, and surgical procedures, will be in the interests of many elderly individuals who are or may be ill, the fact that the Nevada Act fails to provide legislative authority for a surrogate to consent to such health care is troubling.

Although the Nevada Act does provide legislative authority for surrogate consent to the withholding or withdrawal of life-sustaining treatment, it does so in a manner that, like the Arizona Act, fails to identify possible conflicts of interest, barely makes an attempt to minimize such conflicts, and fails to assist surrogates in making withholding and withdrawal decisions that will serve the interests of the elderly individual. The criticisms applicable to the Arizona Act apply with equal force to the Nevada Act.

The only evidence that the Nevada Act contemplated a conflict of interest might occur is through the statutory provision that provides that a surrogate, when making a decision to consent to withhold or withdraw life-sustaining treatment, shall make the decision in "good faith" and that consent will not be valid "if it conflicts with the expressed intention of the patient."[56] Stated another way, the Nevada Act recognizes that some surrogates may act in bad faith, and the Nevada Act technically would invalidate a bad faith decision, although the Act provides no guidance to a physician, third-party monitor, or other individual with oversight regarding how to determine whether a surrogate is acting in bad faith. The Nevada Act also recognizes that, if the elderly individual happened to have expressed a preference for the maintenance of life-sustaining treatment, a decision by a surrogate to withhold or withdraw such life-sustaining treatment would constitute a conflict of interest. However, the Nevada Act completely ignores the fact that many elderly individuals with impaired decision-making capacity will have failed to express a past preference regarding the desirability of life-sustaining treatment and will have insufficient capacity to express a current preference. In these cases, the Nevada Act opens the door for a surrogate to make a decision to withhold or withdraw life-sustaining treatment when such decision could conflict with the unexpressed preferences of the elderly individual.

56. NEV. REV. STAT. § 449.626(4) (2011).

II. CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

The previous Part compared and contrasted illustrative state laws governing conflicts of interest in clinical medicine (or, *treatment* for shorthand) involving elderly individuals with impaired decision-making capacity. This Part will compare and contrast illustrative state laws governing conflicts of interest in human subjects research (or, *research* for shorthand). First, however, the concepts of *treatment* and *research* must be distinguished.

Treatment and *research* are intrinsically different concepts.[57] *Treatment* may be defined as "the provision, coordination, or management of health care and related services by one or more health care providers" to a particular individual.[58] The definition of *treatment* is based on the concept of *health care*, which has been defined as care, services, and procedures related to the health of a particular individual.[59] *Health care* is frequently defined to include preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care that is provided to a particular individual, as well as counseling, assessments, and procedures that relate to the physical or mental condition or functional status of a particular individual.[60] Activities are thus classified as treatment when they involve a health care service provided by a health care provider that is tailored to the specific preventive, diagnostic, therapeutic, or other health care needs of a particular individual.[61]

Research, on the other hand, is defined as a systematic investigation—including research development, testing, and evaluation—that is designed to develop or contribute to generalizable knowledge.[62] Knowledge is considered *generalizable* when it can be applied to either a population inside or outside of the population served

57. The introductory text in Part II and accompanying notes 58-75 is taken with permission and with only technical changes from Tovino, *supra* note 2, Parts I, IV.

58. *See, e.g.*, 45 C.F.R. § 164.501 (2012) (definition of *treatment* set forth in the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule).

59. *See, e.g.*, *id.* § 160.103 (definition of *health care* set forth in the federal HIPAA Privacy Rule).

60. *See, e.g.*, *id.*

61. *See, e.g.*, Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,626 (Dec. 28, 2000) [hereinafter HIPAA Privacy Rule] ("The activities described by 'treatment,' therefore, all involve health care providers supplying health care to a particular patient. While many activities beneficial to patients are offered to entire populations or involve examining health information about entire populations, treatment involves health services provided by a health care provider and tailored to the specific needs of an individual patient.").

62. *See, e.g.*, 45 C.F.R. § 46.102(d) (definition of *research* set forth in the federal Common Rule); *id.* § 164.501 (definition of *research* set forth in the federal HIPAA Privacy Rule).

by the institution conducting the research.[63] The purpose of research, then, is to collect data that will lead to the creation of generalizable knowledge that may result in the production of new therapies or the improvement of existing therapies.[64]

Compared side by side, the differences between treatment and research become clear. First, the primary purpose of treatment is to maintain or improve a particular patient's health, whereas the primary purpose of research is to gain knowledge that will result in the creation of new treatments for a class of future patients.[65] Second, physicians providing treatment frequently adjust, substitute, and change therapies to meet the specific health needs of particular patients.[66] Investigators conducting research, however, must follow approved research protocols and are not permitted to adjust, substitute, or change the experimental intervention in response to the wants or needs of a particular participant.[67] Third, a treating physician has a primary duty of loyalty to

63. *See, e.g.*, HIPAA Privacy Rule, *supra* note 61, at 82,625.

64. *See* Rebecca Dresser, *The Ubiquity and Utility of the Therapeutic Misconception*, 19 SOC. PHIL. & POL'Y 271, 272 (2002) ("Although some research participants may receive a health benefit, research is designed to generate data that could lead to improved care for future patients."); *id.* at 285 ("[I]nvestigators in the research setting focus primarily on the need to obtain valid scientific data."); Gail E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLOS MED. 1735, 1737 (2007) ("[T]here is consensus that the defining characteristic of research is to create generalizable knowledge through answering a scientific question."); *id.* ("Clinical research is designed to produce generalizable knowledge and to answer questions about the safety and efficacy of intervention(s) under study in order to determine whether or not they may be useful for the care of future patients.").

65. *See, e.g.*, Dresser, *supra* note 64, at 285 ("[P]hysicians in the medical setting seek solely to benefit the patient. In contrast, investigators in the research setting focus primarily on the need to obtain valid scientific data.").

66. *See id.* at 272 ("After treatment begins, medication dosages may be increased if the patient fails to respond to the standard dosage, or decreased if the patient experiences unwanted side effects. Patients who fail to improve when taking one medication may be switched to another one.").

67. *See, e.g.*, Paul S. Appelbaum, *Clarifying the Ethics of Clinical Research: A Path Toward Avoiding the Therapeutic Misconception*, 2 AM. J. BIOETHICS 22, 22 (2002) (explaining that the use of randomization, double-blind procedures, adherence to strict protocols, and administration of placebos in research studies "may be undertaken because they advance the scientific validity of the research study, rather than because they serve the subject"); Paul S. Appelbaum, Charles W. Lidz & Thomas Grisso, *Therapeutic Misconception in Clinical Research: Frequency and Risk Factors*, 26 IRB: ETHICS & HUM. RES. 1, 1 (2004) (explaining that researchers are required to protect the validity of the data they generate by using techniques such as randomized assignment, placebo control groups, double-blind procedures, and fixed treatment protocols, which often preclude personalized decisions from being made); Dresser, *supra* note 64, at 272 ("Research methods that minimize ambiguity and bias in data collection rule out the individualized approach that is the hallmark of clinical care. In research, the intervention an individual receives is usually determined by random assignment instead of a physician's clinical judgment."). Although research participants have a legal right to

his or her patients and is charged with recommending treatments that the physician believes to be in each patient's best interests.[68] On the other hand, researchers who do not also have a treatment relationship with their research participants are not considered to have a fiduciary or primary duty of loyalty to their research participants.[69] In theory,

withdraw from a research study at any time, they do not have the right to adjust, substitute, or change an experimental intervention. 45 C.F.R. § 46.116(a)(8) (2010).

68. *See, e.g.*, AM. MED. ASS'N, CODE OF MEDICAL ETHICS: OPINION 10.015 (2001), *available at* http://bit.ly/10pFfMq. The American Medical Association opines:

> The relationship between patient and physician is based on trust and gives rise to physicians' ethical obligations to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare. Within the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount.

Id.; *accord The Hippocratic Oath*, NAT'L INSTS. OF HEALTH (last visited Mar. 28, 2013), http://1.usa.gov/sx5h5 (pledging that the physician will "benefit [his or her] patients according to [his or her] greatest ability and judgment"); TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 173 (5th ed. 2001) (explaining that the goal of medicine is to promote the welfare of individual patients).

69. *See, e.g.*, Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 429 (S.D.N.Y. 2005) (refusing to find a fiduciary duty running from the sponsor of an independent research study to the individuals who participated in the research); Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003) (refusing to find a fiduciary duty running from Canavan disease researchers to their research participants); Moore v. Regents of Univ. of Cal., 793 P.2d 479, 486 (Cal. 1990) (explaining that the regents of the defendant university and its affiliated researchers were not physicians and therefore did not owe the plaintiff patient a fiduciary duty), *cert. denied*, 499 U.S. 936 (1991); Dresser, *supra* note 64, at 292 (recommending that researchers explain to participants as part of the consent-to-research process that their primary loyalty is to future patients, not current research participants). Notwithstanding these cases, some attorneys who represent research participants continue to assert that the researcher-participant relationship constitutes a fiduciary relationship. *See, e.g.*, Alan C. Milstein, *Research Malpractice and the Issue of Incidental Findings*, 36 J.L. MED. & ETHICS 356, 358 (2008). Milstein states:

> Once the research subject or the guardian for a minor subject signs the informed consent document, a fiduciary relationship is formed between the [principal investigator] and the research subject. The very nature of scientific research on human subjects creates special relationships out of which fiduciary duties arise, similar to the physician/patient relationship. The fiduciary relationship is formed not only by the informed consent agreement between the parties, but also by the trust the subject necessarily places in the researcher. In the context of human subjects research, a special relationship is created between the human subject and those responsible for the design, approval, and implementation of the experiment because the latter have a duty to protect human subjects both under the Common Rule and common law.

Id. In addition, some courts have found that researchers have "special relationships" with their research participants that can give rise to unspecified tort-like duties. *See, e.g.*, Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 846 (Md. 2001) ("[S]pecial relationships, out of which duties arise, the breach of which can constitute negligence, can result from the relationships between researcher and research subjects."). *See generally* Stacey A. Tovino, *Incidental Findings: A Common Law Approach*, 15

investigators design, and research participants consent to participate in, research protocols with the understanding of the differences between treatment and research[70] and with the knowledge that research participation may not directly benefit the participant and may pose personal health and other risks to the participant.[71]

Human subjects researchers, also called investigators, whose research is designed to improve clinical practice in the areas of neurology, psychiatry, geriatrics, emergency medicine, and critical care, among other specialties, frequently design research protocols that involve elderly individuals with impaired decision-making capacity.[72] Some of these protocols involve the neuroimaging of elderly individuals who have disorders of consciousness, including coma, vegetative state, and minimally conscious state.[73] Other protocols are designed to

ACCOUNTABILITY RES. 242, 250-54 (2008) (discussing the concepts of fiduciary duty and fiduciary relationships in the context of neuroimaging research).

70. *See, e.g.*, 45 C.F.R. § 46.116(a)(1) (2012) (requiring research participants to be informed that they are participating in research); *id.* § 46.102 (defining *research* as a systematic investigation—including research development, testing, and evaluation—that is designed to develop or contribute to generalizable knowledge). As discussed in more detail below, some research participants and researchers may be operating under a therapeutic misconception.

71. *See* 45 C.F.R. § 46.116(a)(2) (2010) (requiring research participants to be informed of reasonably foreseeable risks and discomforts before they may consent to participate in the research).

72. *See, e.g.*, B. Lynn Beattie, *Consent in Alzheimer's Disease Research: Risk/Benefit Factors*, 34 CAN. J. NEUROLOGICAL SCI. S27, S27 (2007) (noting that research in Alzheimer's disease is complicated by the disease itself, which affects the subject's decision-making capacity for participation in research); Scott Y. H. Kim et al., *Assessing the Competence of Persons with Alzheimer's Disease in Providing Informed Consent for Participation in Research*, 158 AM. J. PSYCHIATRY 712, 712 (2001) (noting that even relatively mild Alzheimer's disease can significantly impair consent-giving capacity in the research context and that research in the field of Alzheimer's disease therapeutics requires participation by subjects with relatively mild Alzheimer's disease); Ukamaka M. Oruche, *Research with Cognitively Impaired Participants*, 13 J. NURSING L. 89, 89 (2009) (noting that research involving individuals with cognitive impairments is necessary to improve understanding of illnesses such as Alzheimer's disease, Huntington's chorea, cerebrovascular disease, psychiatric disorders, chronic alcoholism, and AIDS dementia complex).

73. *See, e.g.*, Martin R. Coleman et al., *Towards the Routine Use of Brain Imaging to Aid the Clinical Diagnosis of Disorders of Consciousness*, 132 BRAIN 2541, 2541-52 (2009) (describing the functional brain imaging findings from a group of 41 individuals with disorders of consciousness who undertook a hierarchical speech processing task and concluding that functional neuroimaging has the potential to inform the diagnostic decision-making process for persons with disorders of consciousness); Davinia Fernandez-Espejo, *Combination of Diffusion Tensor and Functional Magnetic Resonance Imaging During Recovery from the Vegetative State*, 10 BMC NEUROLOGY 1 (2010) (using functional magnetic resonance imaging to investigate cortical responses to passive language stimulation as well as task-induced deactivations related to the default-mode network in one patient in the vegetative state at one month post-ictus and twelve months later when he had recovered consciousness); Joseph J. Fins, *Neuroethics, Neuroimaging,*

investigate the safety and efficacy of experimental drugs and other interventions for elderly individuals who have mild, moderate, or severe dementia or mental illness and may have restricted or limited decision-making capacity.[74] Still other protocols, especially those designed to improve clinical practice in the emergency room, may involve experimental interventions for elderly individuals with mild, moderate, or severe traumatic brain injuries.[75]

If an elderly individual has intact decision-making capacity, the elderly individual, in theory, can receive information regarding a research protocol, including the nature of the research and its risks and possible benefits, and make an informed decision regarding whether to

and Disorders of Consciousness: Promise or Peril, 122 TRANSACTIONS AM. CLINICAL & CLIMATOLOGICAL ASS'N 336, 339-43 (2010) (reviewing research using functional magnetic resonance imaging and positron emission tomography to elucidate brain states); Olivia Gosseries et al., *Disorders of Consciousness: What's in a Name?*, 28 NEUROREHABILITATION 3, 5-9 (2011) (summarizing research studies designed to investigate the residual neural capacity of individuals with disorders of consciousness); Luaba Tshibanda et al., *Neuroimaging After Coma*, 52 NEURORADIOLOGY 15, 15-24 (2010) (summarizing research studies using magnetic resonance spectroscopy, diffusion tensor imaging, and functional magnetic resonance imaging to assess patients with disorders of consciousness); Audrey Vanhaudenhuyse et al., *Default Network Connectivity Reflects the Level of Consciousness in Non-Communicative Brain-Damaged Patients*, 133 BRAIN 161, 161 (2010) (using functional magnetic resonance imaging to investigate default network connectivity in individuals with disorders of consciousness, including coma, vegetative state, minimally conscious state, and locked-in syndrome).

74. *See, e.g.*, Linda Beuscher & Victoria T. Grando, *Challenges in Conducting Qualitative Research with Persons with Dementia*, 2 RES. GERONTOLOGICAL NURSING 6, 7 (2009) (discussing consent to research and other challenging issues raised by the conduct of qualitative research involving individuals with dementia); Sabina Gainotti et al., *How Are the Interests of Incapacitated Research Participants Protected Through Legislation? An Italian Study on Legal Agency for Dementia Patients*, 5 PLOS ONE 1, 1 (2010) (noting that research involving individuals with compromised mental ability can be ethically challenging due to their impaired ability to give free and informed consent); Scott Y. H. Kim et al., *Surrogate Consent for Dementia Research: A National Survey of Older Americans*, 72 NEUROLOGY 149, 149 (2009) [hereinafter *Surrogate Consent*] (noting that research in novel therapies for Alzheimer's Disease (AD) rely on persons with AD as research subjects); Robin Pierce, *A Changing Landscape for Advance Directives in Dementia Research*, 70 SOC. SCI. & MED. 623, 623 (2010) (noting that one of the primary challenges to conducting research on dementia is the gradual loss of the capacity to consent to research participation by individuals with dementia).

75. *See* Je Sung You et al., *Use of Diffusion-Weighted MRI in the Emergency Department for Unconscious Trauma Patients with Negative Brain CT*, 27 EMERGENCY MED. J. 131, 131 (2010); *see also* Wusi Qiu et al., *Effects of Unilateral Decompressive Craniectomy on Patients with Unilateral Acute Post-Traumatic Brain Swelling After Severe Traumatic Brain Injury*, 13 CRITICAL CARE R185, R185 (2009) (finding that unilateral decompressive craniectomy (DC) lowers intracranial pressure, reducing the mortality rate and improving neurological outcomes over unilateral routine temporoparietal craniectomy; also finding that DC increases the incidence of delayed intracranial hematomas and subdural effusion, some of which need secondary surgical intervention).

participate in the research. Unlike treatment, however, research involving even healthy individuals with intact capacity is fraught with conflicts of interest. Many researchers have financial and other interests in their research—including sponsorship by pharmaceutical companies—that result in their recommendation of research studies and aggressive research recruitment strategies vis-à-vis individuals for whom such research may not be in their best health interests. As discussed above, remember that a researcher's primary purpose in conducting research is to generate statistically significant data that will produce knowledge that will contribute to the creation of new treatments for a class of future patients, not to treat current patients. Also, remember that investigators conducting research must follow approved research protocols and are not permitted to adjust, substitute, or change the experimental intervention (other than to allow the research participant to discontinue participation) in response to the wants or needs of a particular elderly individual. Further, remember that, although a treating physician has a primary duty of loyalty to his or her patients and is charged with recommending treatments that the physician believes to be in each patient's best interests, researchers generally are not considered to have a fiduciary or primary duty of loyalty to their research participants. In theory, investigators design, and research participants consent to participate in, research protocols with the understanding of the differences between treatment and research, and with the knowledge that research participation may not directly benefit the participant and may pose personal health risks to the participant. However, as discussed elsewhere, it is unclear the extent to which research participants and researchers understand the differences between treatment and research, as well as the nature and extent of health risks proposed by research experiments.[76] To summarize thus far, conflicts of interest, especially between researchers and research institutions on the one hand and research participants on the other hand, are inherent in research protocols, even when only healthy individuals participate.

In research protocols involving elderly individuals with impaired decision-making capacity, the risk of conflicts is even greater. An elderly research participant with impaired decision-making capacity may not be able to comprehend information provided about the nature of a research protocol, as well as its risks and benefits, and may not be able to make an informed decision regarding whether to consent to research participation. In this case, if the elderly individual, when competent, did not execute an advanced research participation document establishing the

76. *See* Tovino, *supra* note 2, Part IV.

elderly individual's preferences and providing instructions with respect to future research participation, federal law and some state laws allow—as a default—certain classes of persons to provide what is known as "surrogate" consent to research participation.[77]

The problem, of course, is that the surrogate decision maker may have interests that conflict with the interests that the elderly individual would identify if competent. For example, the surrogate may have a risk-seeking personality and might wish to enroll the elderly individual in a physically risky research protocol that has some prospect of direct therapeutic benefit for the elderly individual even though the individual, while competent, would have taken a more risk-averse or risk-neutral approach and would only have participated in low-risk research protocols, even if such behavior meant missing out on the prospect of therapeutic benefit. In this case, the surrogate's interests would be in conflict with those of the elderly individual. Alternatively, the opposite scenario might be the case. That is, the surrogate might have a risk-averse personality and might wish to exclude the elderly individual from participation in a risky research protocol even though the individual, while competent, would have wished to take on a risk associated with research that held out the prospect of direct therapeutic benefit. In this case, too, the surrogate's interests would be in conflict with those of the elderly individual.

Research involving elderly individuals with impaired decision-making capacity can involve many other types of conflicts of interest. For example, a surrogate might receive some type of benefit from enrolling an elderly individual in a research study, such as recruiter or researcher attention, relief of care-taking responsibilities during the time that the research experiment takes place, and even small financial or other incentives or benefits. In all of these cases, the surrogate might have an incentive to enroll the elderly individual in the research study even though enrollment might not be in the elderly individual's health interests.

Of course, all of the conflicts of interest that apply to research involving healthy individuals with intact capacity also apply to research involving elderly individuals with impaired decision-making capacity. For example, a researcher might be receiving financial compensation for conducting the research from a pharmaceutical company and, therefore, may have an incentive to minimize the health risks associated with the research during informed consent conversations, even though it would be in the interests of the elderly individual or the surrogate to be made fully

77. *See id.* Part II.

aware of such risks. By further example, researchers have an incentive to enroll as many participants as possible in their studies in order to improve their chances of producing statistically significant results even though the research experiment might not be in the health interests of all those who are encouraged to enroll.

This Part begins by describing the patchwork of federal and state laws[78] that address the identification and management of these types of conflicts of interest in the context of surrogate consent to research participation on behalf of elderly individuals who have impaired decision-making capacity. In particular, laws from California, Virginia, and Nevada are used to illustrate an extremely comprehensive, a moderately comprehensive, and a nonexistent approach, respectively, to the identification and management of conflicts of interest in the context of surrogate research participation decision making. This Part concludes that, although not all conflicts of interest can be eliminated, California and Virginia do a very good job of attempting to assist in the identification and management of conflicts of interest in the context of surrogate research participation decision making. Nevada, on the other hand, leaves elderly individuals with impaired decision-making capacity susceptible to conflicted surrogate decision making.

A. Federal Law

In a previous article, I detailed three decades of policy uncertainty and failed attempts by the federal government to regulate human subjects research involving adults with impaired decision-making capacity.[79] As noted in that article, the federal government teetered back and forth for several decades between the competing goals of fostering cutting-edge biomedical and behavioral health research and protecting vulnerable human subjects.[80] One result is that federal law still does not contain specific regulations governing human subjects research involving adults with impaired decision-making capacity.[81]

Particular issues on which federal and state policymakers (as well as researchers and research participant protectionists) disagree include the following: (i) whether researchers should be required to demonstrate that

78. *See infra* Part II.A-B; *see also* Oruche, *supra* note 72, at 5 (summarizing gaps in federal and state regulation of human subjects research involving individuals with cognitive impairments).

79. *See* Tovino, *supra* note 2, Part I. *See generally Surrogate Consent*, *supra* note 74, at 149-50 ("[P]olicy uncertainties have continued for three decades . . . [b]ecause policy discussions regarding surrogate-based research have continued for three decades without a clear resolution.").

80. *See* Tovino, *supra* note 2, Part I.

81. *See id.* Part I.A.

a research study classified as minimal risk[82] relates to an individual's psychiatric, neurological, or other condition before an individual with the condition is permitted to be enrolled in the research; (ii) whether it is ever permissible to enroll individuals with impaired decision-making capacity in research classified as greater than minimal risk and, if so, (A) whether the greater-than-minimal risk research intervention must hold out the prospect of direct benefit to the individual, (B) whether the individual is required to have executed an advance research directive through which the individual gave prior consent to research participation, (C) whether a surrogate may consent to the individual's research participation in the absence of an advance research directive, and (D) whether a special standing panel or other similar body that has expertise in research involving individuals with impaired decision-making capacity also should be required to review and approve the individual's research participation.[83]

Today, most of these questions remain unanswered at the federal level. The federal Department of Health and Human Services (HHS) does have regulations that generally govern the conduct of human subject research. Known as the "Common Rule,"[84] the regulations contain a "Basic Policy for the Protection of Human Subjects" ("Basic Policy"), which is codified at Subpart A of the Common Rule,[85] as well as special provisions governing human subjects research involving three sets of vulnerable populations: pregnant women, fetuses, and neonates ("Subpart B");[86] prisoners ("Subpart C");[87] and children ("Subpart D").[88]

The Common Rule does not, however, contain a special Subpart governing research involving adults in general or elderly individuals in particular with impaired decision-making capacity. As a result, proposed research that would involve adults with impaired decision-making capacity must satisfy only the general provisions set forth in the Basic Policy. One of these general provisions does relate to surrogate consent to research participation and provides that the institutional review board

82. 45 C.F.R. § 46.102(i) (2012) ("[M]inimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.").

83. *See, e.g.*, *Surrogate Consent*, *supra* note 74, at 149 (noting that policies for surrogate consent for research remain unsettled after decades of debate).

84. *See* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44, 512, 44,512 (July 26, 2011).

85. 45 C.F.R. §§ 46.101-46.124 (2012).

86. *Id.* §§ 46.201-46.207.

87. *See generally id.* §§ 46.301-46.306.

88. *See generally id.* §§ 46.401-46.409.

(IRB) must ensure that informed consent to research participation has been obtained from each prospective subject or the subject's legally authorized representative (LAR),[89] defined elsewhere in the Basic Policy as "an individual or judicial or other body authorized under *applicable law* to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."[90] The phrase *applicable law* is generally thought to refer to state law, although, as discussed in more detail in Parts II(B)(1)-(3) below, state law on this topic varies widely when it exists.

In light of the Common Rule's lack of specific guidance regarding research involving individuals with impaired decision-making capacity, several national commissions and federal agencies have issued non-binding recommendations and responses to frequently asked questions relating to the conduct of research involving individuals with impaired decision-making capacity.[91] As of this writing, however, HHS has yet to incorporate these informal recommendations and responses into formal federal regulations. As a result, the conduct of human subject research involving elderly individuals with impaired decision-making capacity remains legally and ethically murky, especially in the context of multi-state clinical trials, where more than one state law could govern different parts of the trial.[92]

B. State Law

Although the federal government has yet to issue regulations governing research involving adult or elderly individuals with impaired decision-making capacity, some states do have relevant laws, although these laws vary widely in their application, scope, and regulation when they exist.[93] Below, laws from California, Virginia, and Nevada are used to illustrate the variety of approaches to surrogate consent to research

89. *Id*. §§ 46.111(a)(4), 46.116.

90. *Id.* § 46.102(c) (emphasis added).

91. *See* Tovino, *supra* note 2, Part II.A.

92. *See* Scott Y. H. Kim et al., *Proxy and Surrogate Consent in Geriatric Neuropsychiatric Research: Update and Recommendations*, 161 AM. J. PSYCHIATRY 797, 797 (2004) ("Despite a wave of initiatives in the late 1990s to clarify policy, surrogate consent for research continues to be a murky legal area and incapable subjects in the United States still lack clear regulatory protection.").

93. *See id.* at 798 ("Previous reviews of state laws and regulations on proxy or surrogate consent for research have revealed tremendous heterogeneity. . . ."). *See generally* Elyn R. Saks et al., *Proxy Consent to Research: The Legal Landscape*, 8 YALE J. HEALTH POL'Y L. & ETHICS 37, 37-39 (2008) (surveying state laws governing consent to research by legally authorized representatives on behalf of individuals with impaired decision-making capacity).

participation and to highlight desirable and undesirable statutory features.

1. California

California's Protection of Human Subjects in Medical Experimentation Act ("California Act")[94] allows a surrogate to consent to research participation on behalf of an elderly individual who is unable to consent, does not have an agent under a health care power of attorney, and does not have a conservator or guardian, but only if certain criteria are satisfied.[95] First, the surrogate must have "reasonable knowledge of the subject."[96] Second, the surrogate must be selected from the following priority-ordered list of persons: (i) the spouse of the individual; (ii) an individual as defined in Section 297 of the Family Code (a domestic partner); (iii) an adult son or daughter of the person; (iv) a custodial parent of the person; (v) any adult brother or sister of the person; (vi) any adult grandchild of the person; and (vii) an available adult relative with the closest degree of kinship to the person.[97] Third, the elderly individual must not express dissent or resistance to research participation.[98] Fourth, the research must relate to the cognitive impairment, lack of capacity, or serious or life-threatening disease and condition of the individual.[99] Finally, the surrogate may not receive financial compensation for consenting to the elderly individual's research participation.[100]

If these criteria are satisfied, the surrogate shall, in making a decision whether to consent to research participation on behalf of the elderly individual, "exercise substituted judgment, and base decisions about participation in accordance with the person's individual health care instructions, if any, and other wishes, to the extent known to the surrogate decision maker."[101] If the elderly individual did not leave any instructions and the surrogate does not know the elderly individual's wishes, then the California Act provides that the surrogate shall "make the decision in accordance with the person's best interests."[102] In determining the elderly individual's best interests, the surrogate is required to consider the elderly individual's "personal values and his or

94. *See* CAL. HEALTH & SAFETY CODE §§ 24170-24181 (West 2012).
95. *See id.* § 24178(c).
96. *Id.*
97. *Id.* § 24178(c)(3)-(9).
98. *Id.* § 24178(c).
99. *Id.* § 24178(b).
100. *Id.* § 24178(i).
101. CAL. HEALTH & SAFETY CODE § 24178(g) (West 2012).
102. *Id.*

her best estimation of what the [individual] would have chosen if he or she were capable of making a decision."[103]

Finally, prior to making a research participation decision on behalf of the individual, the surrogate shall be fully informed of several matters, including the name of the sponsor or funding source, if any, of the research study,[104] as well as the existence of any material financial stake or interest that the investigator or research institution has in the outcome of the medical experiment.[105] The California Act defines "material" as $10,000 or more in securities, assets, salary, or other income.[106]

Without an advanced research participation planning document that specifies an elderly individual's preferences or instructions regarding participation in medical experimentation, we can never be sure whether an elderly individual would want to participate in research. Surrogacy legislation, such as the California Act, is always going to be second best. However, like the Pennsylvania Act in the context of clinical medicine, the California Act does as good a job as possible of attempting to minimize conflicts of interest in the context of human subjects research by prohibiting certain persons, including individuals who receive financial compensation, from serving as surrogates and by establishing a detailed process that attempts to assist the surrogate in making a research participation decision that would be in alignment with the elderly individual's preferences and values. In particular, if an elderly individual with impaired decision-making capacity dissents or even expresses resistance to a medical experiment, the surrogate would be prohibited from enrolling the individual in a research study, essentially forcing an alignment of the individual's and the surrogate's interests. Additionally, the California Act, in theory, requires the surrogate to make a decision that would be in the elderly individual's best interests and forces the surrogate to consider the elderly individual's values and what the individual would have chosen if he or she were capable of making a decision.

Also note that the California Act requires the research to relate to the cognitive impairment, lack of capacity, or serious or life-threatening disease and condition of the elderly individual.[107] The theory here is that an elderly individual might be more inclined to participate in research about the condition from which he or she actually suffers. For example, if the reason the elderly individual has impaired decision-making

103. *Id.*
104. *Id.* § 24173(c)(9).
105. *Id.* § 24173(c)(11).
106. *Id.*
107. CAL. HEALTH & SAFETY CODE § 24178(b) (West 2012).

capacity is because the individual has severe Alzheimer's disease, then the theory is that the individual might be more inclined to participate in research relating to Alzheimer's disease because she could both empathize with those who have the disease and wish to help others with the disease and because there is a possibility that she could directly benefit from the research. On the other side, the California provision requiring alignment between the research participant's own health condition and the topic of the research also prohibits a surrogate who is personally interested in, for example, dermatology or plastic surgery research, from enrolling an elderly individual with Alzheimer's disease in such research when the research likely would not be in the individual's interests.

Unfortunately, it is possible even under the carefully drafted California Act for a surrogate to make a research participation decision that is not in accordance with the elderly individual's preferences and values. This can happen if the elderly individual did not express her wishes regarding research participation prior to her incompetency, in which case all the surrogate would have to do is claim that research participation would be in the elderly individual's "best interests" and that participation would be what the individual would choose if capable of doing so. For example, if a risky research protocol held out some prospect of direct medical benefit to the elderly individual, the surrogate might be able to assert that the prospect of direct medical benefit is in the individual's "best interests" and that the elderly individual would have chosen to take on the risks associated with the research in exchange for the possible benefit. This could occur even if the elderly individual, at heart, was a risk-averse or risk-neutral person and would have had an interest in avoiding any risk, even if such behavior meant losing out on a chance to benefit medically from the experiment. Note that the California Act does not clarify who oversees a surrogate's determination that research participation would be in the elderly individual's best interests. If it is the research team, which obviously has an interest in conducting the research and enrolling as many participants as possible, then further conflicts are introduced.

Notwithstanding this flaw, which is the same flaw that exists in the detailed Pennsylvania Act governing conflicts of interest in clinical medicine, the California Act also does a good job of requiring information to be disclosed to surrogates to assist them in identifying potential conflicts. For example, the California Act requires the surrogate to be notified during the informed consent process of the names of sponsors and funding sources, and of the researcher's financial interests that exceed $10,000. These provisions attempt to make the surrogate aware that the researcher has a financial interest in conducting

the research and that this financial interest may conflict with what would be in the elderly individual's best interests. Perhaps the California Act could go further by requiring this conflict to be expressly stated to the surrogate, for example: "You should know that a researcher who receives material financial incentives in exchange for conducting research has an interest in conducting such research that may conflict with the best interests of the prospective human subject."

Like the Pennsylvania, Arizona, and Nevada Acts governing conflicts of interest in clinical medicine, the California Act establishes a priority-ordered list of persons who are eligible to serve as an elderly individual's surrogate. The list set forth in the California Act is perhaps superior to the lists discussed in the previous Part for a couple of reasons, including the fact that the California list requires the person selected to have "reasonable knowledge of the subject."[108] Although most children, parents, siblings, and grandchildren would have reasonable knowledge of the elderly individual for whom they are making a research participation decision, not all families are close-knit, and the California Act appears to be attempting to ensure that estranged relatives with interests that diverge from the elderly individual do not make conflicted decisions.

In addition, note that the list set forth in the California Act places domestic partners immediately after spouses instead of at the bottom of the list after a number of other family members, including children, parents, siblings, and grandchildren. Because an elderly individual could not legally have both a spouse and a domestic partner, this provision does result in an elderly individual who has a domestic partner with convergent interests being at the top of the list of persons who could serve as the individual's surrogate. Of course, domestic partners, just like spouses, can have interests that diverge from those of their legal partner, in which case the statutory scheme would produce conflicted decision making. At least, however, the statute allows homosexual elderly individuals the same nondiscriminatory default—good or bad—that heterosexual and married elderly individuals have. To make the default completely nondiscriminatory, I would change the first class of persons on the list to "spouses or domestic partners" instead of having "spouses" listed first and "domestic partners" listed second.

Again, the list is not perfect. Any time a person in a higher class has interests that diverge from the elderly individual when a person in a lower class has interests that converge with the elderly individual, the statute could force conflicted decision making. California is assuming that spouses and domestic partners are more likely to have convergent

108. *Id.* § 24178(c).

interests compared to children, parents, siblings, and grandchildren, and that may be true for many people, but it will not be true for all.

In summary, the California Act does a good job of attempting to manage conflicts of interest in the context of surrogate research participation decision making, but does not remove the possibility of conflicted decision making entirely.

2. Virginia

Under Virginia's Human Research Act ("Virginia Act"),[109] consent to research participation generally must be obtained from the elderly individual who will be participating in such research.[110] However, if the elderly individual is incapable of making an informed decision regarding research participation, the Virginia Act does allow a legally authorized representative (LAR) to consent to research participation on behalf of the elderly individual.[111] In the context of elderly individuals who do not have an agent under a medical power of attorney and for whom a guardian has not been appointed, the Virginia Act allows the following priority-ordered list of persons to serve as LARs: (i) the spouse of the individual, except where a suit for divorce has been filed and the divorce decree is not yet final; (ii) an adult child of the individual; (iii) a parent of the individual; (iv) an adult brother or sister of the individual; or (v) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research.[112]

The Virginia Act does an excellent job of recognizing the possibility that the LAR and elderly individual might have conflicting interests regarding research participation. For example, the Virginia Act clarifies that "[n]o official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a[n] [LAR],"[113] which is an attempt to ensure that the financial and other benefits to the institution of conducting research do not influence the elderly individual's research participation. The Virginia Act also clarifies that, "[n]otwithstanding consent by a[n] [LAR], no person shall be forced to participate in human subjects research if the investigator conducting the research knows that the participation in the research is

109. VA. CODE ANN. §§ 32.1-162.16–32.1-162.20 (2013).
110. *Id.* § 32.1-162.18(A)(i).
111. *See id.* § 32.1-162.18(A)(ii).
112. *Id.* § 32.1-162.16 (referring to definition of "legally authorized representative," criteria (iii)-(viii)).
113. *Id.* (referring to the definition of "legally authorized representative").

protested by the prospective subject"[114] Moreover, the Virginia Act prohibits an LAR from consenting to research participation if the "[LAR] knows, or upon reasonable inquiry ought to know, that any aspect of the research is contrary to the religious beliefs or basic values of the prospective subject, whether expressed orally or in writing."[115] Finally, the Virginia Act prohibits an LAR from consenting to research on behalf of an elderly individual if the research would involve nontherapeutic sterilization, abortion, psychosurgery, or admission for research purposes to certain hospitals and other health care facilities.[116] Although sterilization and abortion might not be entirely relevant in the context of elderly individuals, psychosurgery and inpatient admissions certainly could be.

The Virginia Act also recognizes that the LAR and the elderly individual could have divergent views regarding the level of acceptable research-related risk. To this end, the Virginia Act prohibits an LAR from consenting to nontherapeutic research on behalf of the elderly individual unless a human research committee determines that such nontherapeutic research will present no more than a minor increase over minimal risk to the elderly individual.[117]

The Virginia Act, although less detailed than the California Act, does a nice job of attempting to recognize some of the most important conflicts of interest between research institutions and surrogates on the one hand, and prospective human subjects who lack capacity on the other. As discussed above, the Virginia Act recognizes four different situations in which the LAR and the elderly individual might have divergent views regarding research participation, including when the research institution itself wants to be an LAR; when the individual is protesting research participation; when the research is contrary to the individual's known religious views; and when the research involves controversial interventions such as psychosurgery and inpatient psychiatric hospital admission. The Virginia Act also does an excellent job of identifying the concern associated with risk-seeking LARs attempting to enroll elderly individuals in risky, nontherapeutic research,

114. *Id.* § 32.1-162.18(A). The Virginia Act clarifies:

> In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force.

Id.

115. VA. CODE ANN. § 32.1-162.18(B) (2013).

116. *Id.*

117. *Id.*

and essentially prohibits LAR consent in such situations, unless the research presents only a minor increase over minimal risk.

The Virginia Act could be critiqued on the usual grounds. That is, (i) the Virginia Act's priority-ordered list of persons who may serve as a surrogate will not always ensure that the person who is highest on the list has interests that are convergent with those of the elderly individual; (ii) the Virginia Act's priority-ordered list does not include some persons, such as domestic partners, whose interests may converge with the elderly individual's interests; and (iii) because surrogacy legislation is always less preferential than advanced health care and research participation planning, the Virginia Act leaves the door open for unscrupulous LARs to consent to research that is not in the best interests of elderly individuals who cannot protect themselves due to impaired decision-making capacity.

3. Nevada

Many states do not have any laws that thoroughly govern the conduct of human subject research, including laws that thoroughly address whether and how a surrogate may consent to research participation on behalf of an elderly individual with impaired decision-making capacity when advanced research planning has not taken place and a guardian has not been appointed for the individual.[118] Nevada, for example, has one extremely short provision that simply prohibits a physician from "performing, without first obtaining the informed consent of the patient or the patient's family, any procedure or prescribing any therapy which by the current standards of the practice of medicine is experimental."[119] Of note, the provision would appear to allow any family member to consent to research participation on behalf of an elderly individual with impaired decision-making capacity when advanced research planning has not taken place and if the individual does not otherwise have a guardian, regardless of whether the family member has interests that conflict with those of the elderly individual. Of course, given the ethical and legal consequences of such consent, it would be unwise for an attorney to rely on such a short statutory provision, which

118. *See, e.g.*, SEC'Y'S ADVISORY COMM. ON HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH & HUMAN SERVS., RECOMMENDATIONS FROM THE SUBCOMMITTEE. FOR THE INCLUSION OF INDIVIDUALS WITH IMPAIRED DECISION MAKING IN RESEARCH (SIIIDR) (2009) [hereinafter SIIIDR RECOMMENDATIONS] ("Very few states specifically define legally authorized representatives (LARs) for research, and most state's laws are silent on the topic. Virtually no state laws address the many ethical issues that arise when LARs are involved in research decision-making, leaving it to IRBs and institutions to invent solutions.").

119. NEV. REV. STAT. § 630.306(6) (2012).

suggests a lack of knowledge by the Nevada Legislature regarding the complex ethical and legal issues associated with human subject research.

As discussed elsewhere, in states that lack research-specific laws, like Nevada, some researchers and research institutions rely on state laws that govern consent to treatment,[120] including laws like the Pennsylvania Act, the Arizona Act, and the Nevada Act discussed earlier in this article. Moreover, it is the current policy of the federal Office of Human Research Protections (OHRP) to permit a surrogate to consent to research if the surrogate is authorized under state law to consent to the "procedures involved in the research" under state laws governing consent to treatment.[121] In addition, a federal Subcommittee for the Inclusion of Individuals with Impaired Decision Making in Research (SIIIDR) currently recommends, in the absence of a specific state law governing consent to research, that a surrogate who is designated to make non-research health care decisions be ranked second in the priority-ordered list of persons who are eligible to make research participation decisions.[122] Elsewhere, I argued that legislation governing consent to treatment should not be used to answer research-related questions due to the inability of research subjects, surrogates, and sometimes even researchers to distinguish between the concepts of treatment and research, resulting in a problem known as "therapeutic misconception," and, more generally, the conflicts of interest that are inherent in human subject research. I incorporate those arguments herein. That is, I critique states such as Nevada that fail to have proper legislation governing surrogate consent to research participation because I believe the lack of such legislation opens the door for elderly individuals with impaired decision-making capacity to be the subjects of conflicted and dangerous decision making.[123]

120. *See, e.g.*, Tovino, *supra* note 2, Part I; *see also* OFFICE OF EXTRAMURAL RESEARCH, NAT'L INSTS. OF HEALTH, RESEARCH INVOLVING INDIVIDUALS WITH QUESTIONABLE CAPACITY TO CONSENT: POINTS TO CONSIDER (Nov. 2009), *available at* http://1.usa.gov/X4GvWt ("In most jurisdictions, LAR [legally authorized representative] appointment processes are not specific to the research setting and institutions rely on the laws governing the use of LARs for clinical care.").

121. *See, e.g.*, SIIIDR RECOMMENDATIONS, *supra* note 118, at 8(b) (explaining that, "[i]n states with laws or regulations that address consent to treatment but do not specifically consider consent to research, current OHRP [Office for Human Research Protections] interpretation permits consent to research by individuals authorized under laws that allow consent to the 'procedures involved in the research.'").

122. *See id.* at 9(a)(ii)(b) (recommending, in the absence of applicable state law, that a person who is designated to make non-research health care decisions be ranked second in the priority-ordered list of persons who are eligible to make research participation decisions).

123. *See* Tovino, *supra* note 2, Part IV.

III. CONFLICTS OF INTEREST IN LEGAL REPRESENTATION

This final Part compares and contrasts approaches taken by state rules of professional conduct for managing conflicts of interest in the context of legal representation and compares these approaches to the approaches used in clinical medicine and human subject research. One purpose of these comparisons is to identify options for managing conflicts in different professional settings, including clinical medicine, human subjects research, and law, and to determine whether one professional setting's approach is superior to another.

A. Model Rules of Professional Conduct

The American Bar Association's *Model Rules of Professional Conduct* ("Model Rules") strictly govern conflicts of interest between attorneys and clients, including elderly clients with impaired decision-making capacity.[124] As explained previously in this symposium issue, the general Model Rule is that an attorney is prohibited from representing a client if the representation involves a concurrent conflict of interest.[125] Under the Model Rules, a concurrent conflict of interest exists if the representation of one client will be directly adverse to another client or if there is a significant risk that the representation of one or more clients will be materially limited by the attorney's responsibilities to another client, a former client, or a third person, or by a personal interest of the attorney.[126] For example, an attorney generally could not represent both an elderly individual with impaired decision-making capacity and the elderly individual's estranged son who is contesting the elderly individual's will because he was not included in it.

Notwithstanding the existence of a concurrent conflict of interest, the Model Rules do allow an attorney to represent a client if the following criteria are satisfied: (i) the attorney reasonably believes that he or she will be able to provide competent and diligent representation to each affected client; (ii) the representation is not prohibited by law; (iii) the representation does not involve the assertion of a claim by one client against another client represented by the attorney in the same litigation or other proceeding before a tribunal; and (iv) each affected client gives informed consent, confirmed in writing.[127]

124. MODEL RULES OF PROF'L CONDUCT (2012), *available at* http://bit.ly/dPaBGm.
125. *Id.* R. 1.7(a).
126. *Id.* R. 1.7(a)(1)-(2).
127. *Id.* R. 1.7(b)(1)-(4).

In addition to these general rules, and as explained previously in this symposium issue, the Model Rules also provide specific guidance for particular situations in which conflicts are especially likely. For example, the Model Rules prohibit an attorney from entering into a business transaction with a client or knowingly acquiring an ownership, possessory, security, or other pecuniary interest adverse to a client unless: (i) the transaction and terms on which the attorney acquires the interest are fair and reasonable to the client and are fully disclosed and transmitted in writing in a manner that can be reasonably understood by the client; (ii) the client is advised in writing of the desirability of seeking and is given a reasonable opportunity to seek the advice of independent legal counsel on the transaction; and (iii) the client gives informed consent, in writing, to the essential terms of the transaction and the attorney's role in the transaction, including whether the attorney is representing the client in the transaction.[128]

By further example, the Model Rules prohibit an attorney from soliciting any substantial gift from a client, including a testamentary gift, or preparing on behalf of a client an instrument giving the attorney or a person related to the attorney any substantial gift unless the attorney or other recipient of the gift is related to the client.[129] This rule would of course prohibit an attorney who is representing an elderly client with impaired decision-making capacity and who is not related by blood to such client from preparing a will for the client that gives to the attorney substantial money or property upon the client's death.

By still further example, the Model Rules prohibit an attorney from accepting compensation for representing a client from one other than the client unless: (i) the client gives informed consent; (ii) there is no interference with the attorney's independence of professional judgment or with the client-attorney relationship; and (iii) information relating to representation of a client is protected as required under Model Rule provisions relating to confidential client communications.[130] This rule, of course, would prohibit an attorney who is representing an elderly client with impaired decision-making capacity from accepting payment for the legal services provided to the elderly client from the client's estranged son, who is seeking to be added to the client's will.

Note that the Model Rules take a different approach to conflicts in legal representation than the state laws discussed in Parts I and II of this article take in regards to conflicts in clinical medicine and human subject research. That is, the default in the practice of law is that an attorney

128. *Id.* R. 1.8(a)(1)-(3).
129. *Id.* R. 1.8(c).
130. MODEL RULES OF PROF'L CONDUCT R. 1.8(f) (2012).

cannot take on a representation when there is a conflict of interest, unless several criteria, including client consent, have been satisfied. With few exceptions, the default in clinical medicine and human subject research, on the other hand, is that a surrogate can consent to the administration, withholding, or withdrawal of treatment and research participation as long as the surrogate has considered the individual's preferences and values and believes that the surrogate's decision is in accordance with those preferences and values. Stated slightly differently, the default in law is that the activity, i.e., legal representation, cannot take place when a conflict exists, whereas the default in medicine and research is that the activity, i.e., consent to treatment or research, can take place because it is assumed that a conflict of interest does not exist, absent the existence of a limiting factor, such as an advanced health care or research planning document or other express statement that the individual did not want to do what the surrogate is contemplating doing. Stated yet a third way, the law governing conflicts of interest in the context of legal representation, at least as set forth in the Model Rules, appears to be more stringent than the illustrative state laws examined in Parts I and II that govern conflicts of interest in clinical medicine and human subjects research.

B. State Law

Although most state rules of professional conduct relating to conflicts of interest are modeled (with some changes) after the Model Rule provisions governing conflicts of interest, three sets of state rules will be quickly examined for the purpose of completeness.

1. Texas

The Texas Disciplinary Rules of Professional Conduct ("Texas Rules") are similar to, but more stringent and detailed, and organized slightly differently, than the Model Rules with respect to the topic of conflicts of interest. Under the Texas Rules, the general rule is that an attorney shall not represent opposing parties to the same litigation[131] and that an attorney shall not represent a person if the representation of that person: (i) involves a substantially related matter in which that person's interests are materially and directly adverse to the interests of another client of the attorney or the attorney's firm; or (ii) reasonably appears to be or become adversely limited by the attorney's or law firm's responsibilities to another client or to a third person or by the attorney's

131. TEX. DISCIPLINARY RULES OF PROF'L CONDUCT R. 1.06(a) (2012), *available at* http://bit.ly/UpovTq.

or law firm's own interests.[132] However, the Texas Rules permit an attorney to represent a client in the circumstances described in the second clause of the preceding sentence if: (i) the attorney reasonably believes the representation of each client will not be materially affected; and (ii) each affected or potentially affected client consents to such representation after full disclosure of the existence, nature, implications, and possible adverse consequences of the common representation and the advantages involved, if any.[133]

Like the Model Rules, the Texas Rules also contain specific provisions governing particular situations that are likely to give rise to conflicts of interest, including situations involving attorneys who wish to act as intermediaries between clients,[134] attorneys who wish to enter into business transactions with clients,[135] and attorneys who wish to represent new clients in matters adverse to previous clients.[136]

2. New Jersey

The New Jersey Rules of Professional Conduct ("New Jersey Rules") are almost identical to the Model Rules governing conflicts of interest with just a few technical changes. That is, the New Jersey Rules generally prohibit an attorney from representing a client if the representation involves a concurrent conflict of interest.[137] Under the New Jersey Rules, a concurrent conflict of interest exists if: (i) the representation of one client will be directly adverse to another client; or (ii) there is a significant risk that the representation of one or more clients will be materially limited by the attorney's responsibilities to another client, a former client, or a third person, or by a personal interest of the attorney.[138] Notwithstanding the existence of a concurrent conflict of interest, the New Jersey Rules allow an attorney to represent a client if: (i) each affected client gives informed consent, confirmed in writing, after full disclosure and consultation; (ii) the attorney reasonably believes that he or she will be able to provide competent and diligent representation to each affected client; (iii) the representation is not prohibited by law; and (iv) the representation does not involve the assertion of a claim by one client against another client represented by

132. *Id.* R. 1.06(b)(1)-(2).
133. *Id.* R. 1.06(c)(1)-(2).
134. *Id.* R. 1.07.
135. *Id.* R. 1.08.
136. *Id.* R. 1.09.
137. *See* N.J. RULES OF PROF'L CONDUCT R. 1.7(a) (2012), *available at* http://bit.ly/ZuhUXw.
138. *Id.* R. 1.7(a)(1)-(2).

the attorney in the same litigation or other proceeding before a tribunal.[139]

Like the Model Rules, the New Jersey Rules contain specific rules governing particular situations in which conflicts are particularly likely to arise, including, for example, situations in which attorneys are considering entering into business transactions with clients; situations in which attorneys are considering preparing, on behalf of a client, an instrument giving the attorney a substantial gift; and situations in which attorneys are considering accepting compensation for representing a client from a person other than the client.[140]

3. Nevada

The Nevada Rules of Professional Conduct ("Nevada Rules") are also almost identical to the Model Rules and the New Jersey Rules governing conflicts of interest with just a few technical changes. That is, the Nevada Rules generally prohibit an attorney from representing a client if the representation involves a concurrent conflict of interest.[141]

Under the Nevada Rules, a concurrent conflict of interest exists if: (i) the representation of one client will be directly adverse to another client; or (ii) there is a significant risk that the representation of one or more clients will be materially limited by the attorney's responsibilities to another client, a former client, or a third person, or by a personal interest of the attorney.[142] Notwithstanding the existence of a concurrent conflict of interest, however, the Nevada Rules, similarly to the Model Rules, permit an attorney to represent a client if: (i) the attorney reasonably believes that he or she will be able to provide competent and diligent representation to each affected client; (ii) the representation is not prohibited by law; (iii) the representation does not involve the assertion of a claim by one client against another client represented by the attorney in the same litigation or other proceeding before a tribunal; and (iv) each affected client gives informed consent, confirmed in writing.[143] The Nevada Rules also contain specific rules governing particular situations in which conflicts are particularly likely to arise including, for example, situations in which attorneys are considering entering into business transactions with clients; situations in which attorneys are considering preparing, on behalf of a client, an instrument

139. *Id.* R. 1.7(b)(1)-(4).
140. *Id.* R. 1.8(a), (c), (f).
141. *See* NEV. RULES OF PROF'L CONDUCT R. 1.7(a) (2012), *available at* http://bit.ly/114SWmu.
142. *Id.* R. 1.7(a)(1)-(2).
143. *Id.* R. 1.7(b)(1)-(4).

giving the attorney a substantial gift; and situations in which attorneys are considering accepting compensation for representing a client from a person other than the client.[144]

IV. CONCLUSION: CONFLICTS IN MEDICINE, RESEARCH, AND LAW COMPARED

This final Part compares and contrasts the approaches taken by illustrative state laws in identifying and managing conflicts of interest in the context of legal representation to illustrative state laws in the contexts of clinical medicine and human subject research. One purpose of these comparisons is to identify options for managing conflicts in different professional settings and to determine whether one professional setting's approach is superior to another.

As discussed in more detail below, this Part finds that the law imposes more stringent duties relating to the identification and management of conflicts of interest in the context of legal representation compared to the contexts of clinical medicine and human subjects research.

Let us begin by examining whether state laws in each professional context actually recognize and explicitly refer to the concept of "conflict of interest." The three state laws discussed in Part III addressing legal representation all recognize that attorneys may have interests that conflict with their clients. Each state law has a separate rule or rules (i.e., Texas Rules 1.07, 1.08, and 1.09; New Jersey Rules 1.7 and 1.8; and Nevada Rules 1.7 and 1.8) governing conflicts of interest that identifies the concept of a conflict of interest, that defines the activities and relationships that constitute a conflict of interest, and that generally prohibits an attorney from taking on any representation when a conflict of interest exists. On the other hand, the state laws discussed in Parts I and II relating to clinical medicine and human subject research do not do this. Without using the language of "conflict of interest," a few of the state laws discussed in Parts I and II, including the Pennsylvania Act, the Arizona Act, the California Act, and the Virginia Act, implicitly recognize that certain individuals may have a financial or other interest that diverges from those of the patient or human subject. However, note that even the comprehensive Pennsylvania Act, Arizona Act, California Act, and Virginia Act do not use the language of "conflict of interest." These state laws do not have separate provisions identifying, defining, listing, or describing the possible conflicts of interest. Instead, they simply (and quietly) identify a few situations in which certain classes of

144. *Id.* R. 1.8(a), (c), (f).

persons cannot serve as another individual's surrogate. The trained health law professor or health care attorney will recognize the statutes for what they are: an understated attempt to limit conflicted surrogate decision making. To the untrained eye, however, the statutes do not specifically recognize, highlight, or otherwise make the reader aware that the relationships between and among physicians and investigators, surrogates, and patients and human subjects are fraught with potential conflicts of interest.

Second, with the exception of the California Act discussed in Part II, which does require disclosure by the researcher to the surrogate of certain financial interests (although these are not labeled *conflicts* of interest), note that the illustrative state laws discussed in Parts I and II do not require express disclosure and waiver of conflicts of interest. For example, the Virginia Act does not require a prospective human subject or a surrogate to be given a document that contains a section called "Conflicts of Interest" that identifies or lists all of the situations in which a researcher or research institution might have interests that diverge from those of the elderly individual whose research participation is being encouraged. Without such a disclosure, an unsophisticated human subject and/or surrogate might not make the connection between the receipt of financial compensation by a researcher from a pharmaceutical company and the creation of an incentive on the part of that researcher to enroll human subjects into the research sponsored by the pharmaceutical company, even though such research might not be in the subject's best health interests.

Third, note that the illustrative state laws discussed in Parts I and II of this article take a different approach to the management of conflicts of interest. That is, the default in the practice of law is that an attorney cannot take on a representation when there is a conflict of interest, unless several criteria, including labeling and disclosure of the interest as a "conflict of interest" and client consent to the conflict of interest, confirmed in writing, have been satisfied. With few exceptions, the default in clinical medicine and human subject research, on the other hand, is that a surrogate can consent to the administration, withholding, or withdrawal of treatment and research participation as long as the surrogate has considered the individual's preferences and values and believes that the surrogate's decision is in accordance with those preferences and values. Stated slightly differently, the default in law is that the activity, i.e., legal representation, cannot take place when a conflict exists, whereas the default in medicine and research is that the activity, i.e., consent to treatment or research, can take place because it is assumed that a conflict of interest does not exist unless there is an advanced health care or research planning document or other express

statement that the individual did not want to do what the surrogate is considering doing.

Finally, note that the conflicts of interest that can arise due to the lack of advanced health care and research participation planning in the contexts of clinical medicine and human subjects research are as substantively concerning, if not more so, than the conflicts of interest that arise during the provision of estate planning, retirement planning, and long-term care planning. Elsewhere in this symposium, an author has expressed concern that Social Security benefits may be paid to a representative whose interests diverge from the interests of the actual Society Security beneficiary.[145] A second author has expressed concern that, when elderly parents enter into marriages that are unprotected by law, conflicted distributions may be made.[146] Concerns relating to inappropriate Social Security payments and unintended distributions are no laughing matter. However, concerns relating to the inappropriate withholding or withdrawing of life-sustaining treatment, or consent to a risky medical experiment, which may result in serious injury or death, are at least equally concerning.

For these reasons, this article joins the already robust law review and other literatures that urge advanced health care and advanced research participation planning to minimize conflicts of interest that could arise when a surrogate, in the absence of a formally appointed agent or guardian, would like to consent to the administration, withholding, or withdrawal of treatment or consent to research participation on behalf of an elderly individual with impaired decision-making capacity. As such, this article hopefully serves as a nice capstone to the other pieces in this symposium by providing yet another reminder that legal planning, even with the conflicts of interest identified by the other authors in this symposium, is almost always superior to the lack of planning.

This article also, however, proposes a novel solution for health care and research-related conflicts: state laws governing conflicts of interest in clinical medicine and human subject research should consider borrowing approaches to conflicts management that are set forth in state rules of attorney professional conduct. Such approaches include, but are not limited to, the establishment of: (i) special statutory provisions specifically governing "conflicts of interest," much like those set forth in

145. *See* Reid K. Weisbord, *Social Security Representative Payee Misuse*, 117 PENN ST. L. REV. 1257 (2013).

146. *See* Lynne Marie Kohm, *Why Marriage Is Still the Best Default in Estate Planning Conflicts*, 117 PENN ST. L. REV. 1219 (2013). For a discussion of the other articles in this symposium issue, see Pearson, *supra* note 1.

Texas Rules 1.07, 1.08, and 1.09; New Jersey Rules 1.7 and 1.8; and Nevada Rules 1.7 and 1.8; (ii) content within such statutory provisions that requires identification and description of the types of conflicts of interest that can arise in clinical medicine and human subjects research; (iii) content within such statutory provisions that explains in lay terminology why such conflicts of interest can be harmful to the health (including death, serious injury, and illness) and other interests of the patient or human subject; and (iv) content within such statutory provisions that requires disclosure and waiver of such conflicts, as appropriate.