LEGISLATION TO PROTECT THE DECISIONALLY INCAPACITATED INDIVIDUAL'S PARTICIPATION IN MEDICAL RESEARCH: SAFETY NET OR TRAP DOOR?

> The mere mention of experimental medical research on incapacitated human beings—the mentally ill, the profoundly retarded, and minor children summons up visceral reactions with recollections of the brutal Nazi experimentation with helpless subjects in concentration camps, and elicits shudders of revulsion when parallels are suggested. Even without the planned brutality, we have had deplorable instances of overreaching medical research in this country.[1]

I. INTRODUCTION

Reports of serious abuses in medical research shock the conscience and raise the ire of most human beings when they hear of the outrageous and horrific acts medical researchers willingly inflict upon their own kind, without informed consent and in the name of medical advancement. One particularly invidious example came to light "in 1993 when the Governmental Affairs Committee conducted an investigation into the Cold War radiation experiments."[2] This investigation revealed that "from the 1940s through the early 1960s, scientists performed a series of secret, government-sponsored radiation experiments on patients who were hospitalized, institutionalized, or seeking treatment for other conditions (such as pregnancy), often without obtaining the patients' consent."[3]

Enraged citizens complain that there ought to be a law against such behavior. The good news is that there is such a law—Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, also known as the Common Rule and derived largely from various medical research codes and regulations developed since the Nuremberg trials of Nazi war criminals.[4] The bad news is that this law provides minimal protection for individuals whose decision-making capabilities are mentally or cognitively impaired.[5]

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[1] T.D. v. State Office of Mental Health, 626 N.Y.S.2d 1015, 1016 (Sup. Ct. 1995) (footnote omitted).

[2] John Glenn, *U.S. Senator John Glenn: Reply to Pat Mougey about Human Subjects Research*, (Nov. 7, 1997) (visited Sept. 20, 1999) <http://www.morethanconquerors.simplenet.com/MCF/glen-rsp.htm>.

[3] Jonathan D. Moreno, *The Dilemmas of Experimenting on People* (visited Sept. 20, 1999) <http://www.techreview.com/articles/july97/moreno.html>.

[4] *See* discussion *infra* Part II.

[5] *See infra* text accompanying notes 95-96.

Each classification of "decisionally incapacitated" individuals represents one cord of the rope in the tug-of-war raging between medical researchers who favor decisionally incapacitated individuals' participation in medical research for the advancement of science and interest groups who are concerned about the protection of decisionally incapacitated individuals' human rights. The desperation heightens on both sides because the initial rules, particularly pertaining to ethics, were unclear at the start, and new rules are proposed as the struggle continues.

Maryland recently made a failed attempt to write its own rules in a piece of legislation entitled the *Decisionally Incapacitated Research Subject Protection Act*.[6] This proposed legislation suggests an unprecedented level of altruism in medical research. If enacted, this bill could serve as a model for other states to follow in passing similar legislation. However, the proposed bill, intended for the protection of research subjects, may be more like a trap door for unsuspecting research subjects. This comment explores the ethical foundations for Maryland's policy initiative, the proposed legislation's interpretation and application of basic ethical principles in medical research, and the underlying issue of decisionally incapacitated individuals' right to bodily integrity that has gone unaddressed in Maryland's proposal.

This comment asserts that decisionally incapacitated individuals should participate in medical research only when two conditions are met: 1) the medical research is of direct medical benefit to the subjects; and 2) the medical research presents no more than minimal risk to the subjects. Part II delves into the history and development of the three basic ethical principles that form the foundation for medical research: respect for persons, beneficence, and justice. The ethical principles are traced from their roots in the *Nuremberg Code* to their later clarification and expansion in the *Declaration of Helsinki* and the *Belmont Report*. Part II also examines the loophole in the current federal regulations that provides minimal research protection for decisionally incapacitated individuals.

Part III probes Maryland's policy initiative in drafting the *Decisionally Incapacitated Research Subject Protection Act*. It details appropriate applications of each ethical principle as contemplated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the National Institutes of Health: respect for persons via informed consent, beneficence via analysis of risks and benefits, and justice via subject selection. Part III also assesses Maryland's interpretation of appropriate applications of

[6] *See* discussion *infra* Parts III and V.

the ethical principles and compares these interpretations with those contemplated by the entities mentioned above.

Part IV posits that the real issue at stake is either ill-defined or ignored by Maryland's proposed legislation. This issue involves the protection of each human being's absolute personal right to be secure in his or her body and health. This section also asserts natural law arguments, based on English common law and modern natural rights commentaries, to support the proposition that a decisionally incapacitated individual's participation in medical research may be effected by a legitimate third party only when the research poses no more than minimal risk to the individual and is of the same direct medical benefit as standard available medical treatments.

Documented abuses in medical research make clear the need for more stringent protective measures governing decisionally incapacitated individuals' participation in medical research. However, watered-down interpretations of the basic ethical principles of respect for persons, beneficence, and justice are impotent vanguards against exploitation of vulnerable research subjects. Legislation intended to protect research subjects will be effective only if it is based upon an interpretation that centers around what is best for the research subject rather than society at large. A review of the historical foundations of the ethical principles supports the premise that the focus of medical research must consider the rights of the research subject above any benefit to society, no matter how lofty and noble.

II. THE HISTORY OF ETHICAL FOUNDATIONS IN MEDICAL RESEARCH

Although ethical issues have been and continue to be inextricably intertwined with the practice of medicine, the focus of ethics was centered only upon the practice of therapeutic medicine until the middle of this century.[7] Ethics were not applied to non-therapeutic (research) medicine.[8] This focus changed in 1946 and 1947 when twenty-three Nazi physicians were tried and convicted in Nuremberg, West Germany, for crimes committed against prisoners of war, including "Jews, Gypsies, homosexuals, the mentally retarded, and others."[9] The Nazi doctors' crimes were "cruel and inhuman experiments"[10] involving exposure to extreme temperatures, mutilating surgeries, and deliberately-induced

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[7] *See* National Institutes of Health, *Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health* app. 1 (last modified Mar. 2, 1995) <http://helix.nih.gov:8001/ohsr/guidelines.phtml>.

[8] *Id.*

[9] Moreno, *supra* note 3.

[10] *Id.*

infections,[11] as well as forcing subjects to drink seawater for the purpose of "establishing the point at which lungs exploded due to atmospheric pressures."[12]

The three Nuremberg judges were so incensed by the "murders, tortures, and other atrocities committed in the name of medical science"[13] that they decided to codify the fundamental ethical standards for conducting human-subject research.[14] Their efforts produced the *Nuremberg Code*, a set of "ten conditions that must be met to justify research involving human subjects."[15] The National Institutes of Health identify the first two conditions as the most important of the ten.[16] Condition One states that "[t]he *voluntary consent* of the human subject is *absolutely essential*. This means that the person involved should have legal capacity to give consent."[17] Condition Two requires that "[t]he experiment . . . yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."[18]

Although the *Nuremberg Code* was "accepted in principle by each of the 51 original signatory nations of the Charter of the United Nations," most countries "had no mechanism for implementing" its provisions.[19]

> Despite its powerful moral influence, the code carried no legal authority. No mechanisms were created to enforce it. In fact, the very circumstances that gave the code its high moral standing— the horrors that surrounded its origins— partly account for its relative lack of influence in the postwar years: ordinary researchers found it hard to believe that the code need be applied to their own work.[20]

Physicians and medical researchers began to express concern that the *Nuremberg Code* imposed a "categorical ban on research with any subjects who could not give voluntary informed consent."[21] This strict prohibition on informed consent appeared "unduly restrictive of

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[11] *See* National Institutes of Health, *supra* note 7.

[12] Moreno, *supra* note 3.

[13] *Id.* (quoting chief prosecutor Telford Taylor).

[14] *See id.*; *see also* National Institutes of Health, *supra* note 7 (noting that during the Nuremberg trials, fundamental ethical principles governing the conduct of medical research were codified in the *Nuremberg Code*).

[15] National Institutes of Health, *supra* note 7.

[16] *See id.*

[17] *The Nuremberg Code* para. 1, *in* 2 U.S. GOV'T PRINTING OFFICE, TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (1949) (emphasis added). The full text of the *Nuremberg Code* can also be found on-line at <http://www.ncgr.org/gpi/odyssey/privacy/NurCode.html>.

[18] *Id.* para. 2.

[19] National Institutes of Health, *supra* note 7.

[20] Moreno, *supra* note 3.

[21] *Id.*

legitimate and humane research,"[22] particularly with children and psychiatric patients.[23]

Acting in response to complaints that the *Nuremberg Code* posed consent problems that were too restrictive, the World Medical Association adopted the *Declaration of Helsinki* in 1964.[24] This document codified the "philosophy of medical paternalism."[25] "According to th[e] view [of medical paternalism], the trusting, nearly sacred relationship between doctor and patient was based on the premise that the doctor knows best . . . . [D]octors were reluctant to involve patients in making decisions about their own care."[26] The *Declaration of Helsinki* reflected a tenet of the *Nuremberg Code* by maintaining "that the use of unconsenting subjects in experiments" non-beneficial to "them was a dangerous encroachment of science on personal privacy."[27] However, the *Declaration of Helsinki* guarded a doctor's therapeutic privilege to "withhold information from patients."[28]

The *Declaration of Helsinki* also lessened the strict prohibition on voluntary consent set out in the *Nuremberg Code* in two ways. First, the *Declaration of Helsinki* sharply distinguished between therapeutic and non-therapeutic (experimental) research.[29] The distinction implied that the "vast bulk of therapeutic research" did not require patient consent because "the privacy of the doctor-patient relationship was accepted as serving the public interest."[30] Second, the *Declaration of Helsinki* allowed

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[22] Laurie M. Flynn & Ronald S. Honberg, *Achieving Proper Balance in Research with Decisionally-Incapacitated Subjects: NAMI's Perspectives on the Working Group's Proposal*, 1 J. HEALTH CARE L. & POL'Y 174, 180 (1998) (footnote omitted).

[23] *See* Moreno, *supra* note 3.

[24] *See id.*; *see also* National Institutes of Health, *supra* note 7 (noting that the World Medical Association adopted the *Declaration of Helsinki* after the World Health Organization deemed the *Nuremberg Code*'s guidelines too restrictive).

[25] Moreno, *supra* note 3.

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] See WORLD MED. ASS'N, DECLARATION OF HELSINKI: RECOMMENDATIONS GUIDING PHYSICIANS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (1989) (amended 1996) [hereinafter DECLARATION OF HELSINKI], which states:

> In the field of biomedical research, a fundamental distinction must be recognized between medical research, in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

For additional detail, compare *id.* pt. II with *id.* pt. III. The full text of the Declaration of Helsinki is available on-line at <http://www.csu.edu.au/learning/ncgr/gpi/odyssey/-privacy/HelDec.html>.

[30] Moreno, *supra* note 3.

proxy consent[31] or a complete waiver of consent if the physician determined such a waiver was essential.[32] However, proxy consent was only allowed "if there [wa]s an expected *direct benefit* to the individual, not to a larger group."[33]

During the 1960s, federal funding for clinical research increased, directly resulting in an increase of "the number of individuals participating as subjects."[34] America's interest in human rights also grew due to public reports of "clinical research abuses."[35] For example, in 1963, a university team attempted to transplant a chimpanzee kidney into a human; although the experiment was federally funded in part, the research team did not conduct prior animal studies or justify the experiment as validly scientific,[36] as required by the *Declaration of Helsinki*.[37] A few years later, Harvard University's highly respected physician and investigator, Henry Beecher, alleged that "unethical or questionably ethical practices were common in the conduct of human subjects research in many of America's premier research institutions."[38] One of the incidents Beecher reported involved researchers "injecting elderly, indigent people with live cancer cells, without their consent."[39] However, the instance of research abuse that caused the most outrage was the Tuskegee Syphilis Study.[40]

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[31] See DECLARATION OF HELSINKI, *supra* note 29, pt. I, which states:

> In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject, in accordance with national legislation.

[32] *See id.* ("If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol . . . .").

[33] Michael A. Susko, *Should There Be Experimentation on "Decisionally Incapacitated" Humans?* (visited Sept. 20, 1999) <http://www.affirmationscaffe.com/aicm/gallery.htm>; *see also* DECLARATION OF HELSINKI, *supra* note 29 ("Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks, in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.").

[34] National Institutes of Health, *supra* note 7.

[35] *Id.*

[36] *See* Moreno, *supra* note 3.

[37] *See* DECLARATION OF HELSINKI, *supra* note 29, pt. I ("Biomedical research involving human subjects must conform to generally accepted scientific principles, and should be based on adequately performed laboratory and animal experimentation, and on a thorough knowledge of the scientific literature.").

[38] National Institutes of Health, *supra* note 7.

[39] *Id.*; *see also* Moreno, *supra* note 3 (stating that the purpose of the injections was to determine whether the patients' "immune systems could mount a defense against the cancer" and noting that the patients were not harmed by the injections).

[40] *See* Moreno, *supra* note 3.

> From the early 1930s to the early 1970s, U.S. Public Health Service doctors had studied more than 400 black men with syphilis in Macon County, Ala[bama]. The men were not told they had the disease, nor were they offered treatment—even after the discovery of penicillin made treatment much more effective . . . . The requirement for the "voluntary consent of the human subject" had been systematically abused right here in America, in a study that had begun just around the time the Nazis took power in Germany.[41]

The Tuskegee experiment was the "single event [that] broke the back of medical paternalism in research" set out in the *Declaration of Helsinki*.[42] Congress responded by conducting hearings on the Tuskegee experiment and other research abuses involving prisoners and children.[43] As a result of the hearings, Congress enacted the National Research Act of 1974 that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter referred to as the "Commission").[44] The Commission was charged with identifying "the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles."[45] In addition to issuing "reports on research involving pregnant women, live human fetuses, prisoners, children, the mentally disabled and the use of psychosurgery," the Commission published the *Belmont Report* in 1979.[46] The *Belmont Report* was "[a] major advancement in the development of public policy" for the U.S. Department of Health, Education and Welfare (now the U.S. Department of Health and Human Services).[47] Through the *Belmont Report*, the Commission "provided guidance for distinguishing therapeutic medicine from research, identified three fundamental ethical principles for the protection of human subjects, and illustrated how the ethical principles should be applied to the conduct of human subjects research."[48]

The Department of Health, Education and Welfare began incorporating the *Belmont Report*'s recommendations into federal

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[41] *Id.*

[42] *Id.*

[43] *See* National Institutes of Health, *supra* note 7.

[44] *Id.*

[45] The Belmont Report, 44 Fed. Reg. 23192 (1979). The full text of the *Belmont Report* is available on the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research website at <http://helix.nih.gov:8001/ohsr/mpa/belmont.phtml>.

[46] National Institutes of Health, *supra* note 7.

[47] *Id.*

[48] *Id.*

regulations in 1979.[49] Finally, in 1981, the Department of Health and Human Services gave its approval to Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects,[50] and extended the applicability of Part 46 in 1991 "to all federal agencies conducting or sponsoring human-subjects research."[51]

Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, or the Common Rule, "requires that informed consent be obtained from all research subjects, or their legally authorized representatives, regardless of whether the research is classified as therapeutic or non-therapeutic."[52] Thus, "[a]s a result of the Tuskegee scandal, *the requirement for voluntary consent in research became deeply etched in the law* and in the minds of many who had not seen the need for vigilance [in medical research] before."[53]

A. The Three Basic Ethical Principles of the Belmont Report

The *Belmont Report* "provides the philosophical underpinnings for the current laws governing human subjects research."[54] During its deliberations, the Commission noted that the best-known codes, derived largely from the *Nuremberg Code*, were guidelines or rules, some general and others specific, to direct researchers in their work.[55] The Commission also acknowledged that the rules were often "inadequate to cover complex situations," conflicted at times, and were "frequently difficult to interpret or apply."[56] In response to the alleged inadequacy of the previous guidelines and rules, the *Belmont Report* provided "[b]roader ethical principles" upon which specific rules to govern human-subjects research could be "formulated, criticized and interpreted."[57]

The most significant aspect of the *Belmont Report* was the three basic ethical principles identified by the Commission as "relevant to all research involving human subjects: Respect for Persons, Beneficence, and Justice."[58] The Commission's expression, "'basic ethical principles,' refers to those general judgments that serve as a basic justification for

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[49] *See id.*

[50] *See id.*

[51] Moreno, *supra* note 3.

[52] Flynn & Honberg, *supra* note 22, at 181 & n.32; *see also* 45 C.F.R. § 46.116 (1998) ("[N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.").

[53] Moreno, *supra* note 3 (emphasis added).

[54] National Institutes of Health, *supra* note 7.

[55] *See* The Belmont Report, *supra* note 45, n.1.

[56] *Id.*

[57] *Id.*

[58] National Institutes of Health, *supra* note 7, app. 2.

the many particular ethical prescriptions and evaluations of human actions."[59] Although the Commission recognized that other important principles sometimes apply to research, it determined that these three in particular "provide[d] a comprehensive framework for ethical decision-making in research involving human subjects."[60]

The first basic ethical principle, respect for persons, is comprised of "two ethical convictions" or "moral requirements": "individuals should be treated as autonomous agents" and "persons with diminished autonomy are entitled to protection."[61] The term, "autonomous," as applied to a person, means the "individual [is] capable of deliberation about personal goals and of acting under the direction of such deliberation."[62] In human-subjects research, "respect for persons demands that subjects enter into the research *voluntarily* and *with adequate information*,"[63] indicating a respect for their decisions and protecting them from harm. "However, not every human being is capable of self-determination"[64] and thus is not able to give voluntary informed consent. Some individuals never have the capability of self-determination or are immature in their capability to deliberate, while others "lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty."[65] In any event, "[r]espect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated."[66]

The second basic ethical principle, beneficence, "is often understood to cover acts of kindness or charity that go beyond strict obligation."[67] However, the beneficence that a researcher is required to bestow upon human subjects is understood in a much stronger sense; that is, the researcher has a *duty* or *obligation* under the beneficence principle.[68] Persons are treated ethically when researchers follow two general rules to secure their subjects' well-being: "do not harm" as well as "maximize possible benefits and minimize possible harms."[69] Read together, these two rules state that "one should not injure one person regardless of the benefits that might come to others."[70] However, therein lies the conflict in

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59 The Belmont Report, *supra* note 45, pt. B.

60 National Institutes of Health, *supra* note 7, app. 2.

61 The Belmont Report, *supra* note 45, pt. B.

62 *Id.*

63 *Id.* (emphasis added).

64 *Id.*

65 *Id.*

66 *Id.*

67 *Id.*

68 *See id.*

69 *Id.*

70 *Id.*

the principle of beneficence because "even avoiding harm requires learning what is harmful."[71] Researchers must engage in line drawing "to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks."[72] The National Institutes of Health state that "it is necessary to examine carefully the design of the study and its risks and benefits including . . . identifying alternative ways of obtaining the benefits sought from the research. Research risks must always be justified by the expected benefits of research."[73] This balancing of risks and benefits explains why "[t]he principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects."[74] For example, beneficence justifies research involving children, even when they are not direct beneficiaries of the research, because effective treatments for childhood diseases will greatly benefit children in the future.[75]

The third basic ethical principle, justice, requires that human subjects for research be treated fairly.[76] Analysis under the justice principle determines "[w]ho ought to receive the benefits of research and bear its burdens."[77] The subject selection process should be conducted carefully and fairly "to insure that certain individuals or classes of individuals—such as prisoners, elderly people, or financially impoverished people—are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so."[78] Poor selection procedures produce unjust results. "An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."[79] Examples of injustices in human-subject research include the use of poor ward patients during the 19th and early 20th centuries for the benefit of private patients; "exploitation of unwilling inmates as research subjects in Nazi concentration camps"; and use of disadvantaged, rural black men in the 1940s to study the untreated course of syphilis, a disease not confined to that population.[80] In each case, the subjects were "systematically selected simply because of their easy availability, their compromised position, or

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71 *Id.*
72 *Id.*
73 National Institutes of Health, *supra* note 7, app. 2.
74 The Belmont Report, *supra* note 45, pt. B.
75 *See id.*
76 *See* National Institutes of Health, *supra* note 7, app. 2.
77 The Belmont Report, *supra* note 45, pt. B.
78 National Institutes of Health, *supra* note 7, app. 2.
79 The Belmont Report, *supra* note 45, pt. B.
80 *Id.*

their manipulability, rather than for reasons directly related to the problem being studied."[81] When publicly-funded research results in innovative medical breakthroughs, justice requires that these advantages be extended to those who can, as well as cannot, afford them[82] and that such research not involve persons from groups who are unlikely to receive benefits.[83]

"*Each of these principles carries strong moral force*, and difficult ethical dilemmas arise when they conflict. . . . [I]t is important to understand and apply the principles, because doing so helps to assure that people who agree to be experimental subjects will be treated in a respectful and ethical manner."[84] Thus, the "philosophical underpinnings"[85] of current federal law[86] governing human-subjects research are founded upon the three broad *ethical and moral* principles of autonomy, beneficence, and justice.

B. The Belmont Report's Blurred Distinction Between Therapeutic and Research Medicine

Like the *Declaration of Helsinki*, which drew sharp distinctions between practice and research medicine, the *Belmont Report* also emphasizes the "importan[ce of] distinguish[ing] between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other."[87] The purpose of this distinction is "to know what activities ought to undergo review for the protection of human subjects of research."[88]

According to the *Belmont Report*, "'practice' refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals."[89] The *Belmont Report* distinguishes "'research' [as] an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge . . . usually described in a formal

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[81] *Id.*

[82] *See id.*

[83] *See* National Institutes of Health, *supra* note 7, app. 2.

[84] *Id.* (emphasis added).

[85] *See supra* text accompanying note 54.

[86] *See* 45 C.F.R. § 46 (1998).

[87] The Belmont Report, *supra* note 45.

[88] *Id.*

[89] *Id.* (footnote omitted).

protocol that sets forth an objective and a set of procedures designed to reach that objective."[90]

Unlike the *Declaration of Helsinki*'s sharp distinction between practice and research, the *Belmont Report* asserts that "[t]he distinction between research and practice is blurred"[91] for two reasons. First, research and practice "often occur together"—for example, "[r]esearch and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy."[92] Second, "departures from standard practice are often called 'experimental,'"[93] so they do not reach the level of research mandatorily reviewable for protection of human subjects. The Commission dissipates the gray haze created by the practice/research continuum in the following general rule: "if there is *any element of research* in an activity, that activity should undergo review for the protection of human subjects."[94]

C. The Loophole in the Common Rule: Scant Protection for the Mentally Disabled

The *Belmont Report* specifically identifies children, fetuses, pregnant women, prisoners, and people with mental disabilities as groups in need of heightened protection against medical research abuse.[95] "However, while the Common Rule contains special protections for [children, fetuses, pregnant women, and prisoners], it is virtually silent concerning special protections for individuals whose decisionmaking capabilities may, due to mental or cognitive disorders, be impaired."[96]

The Common Rule provides "two fundamental safeguards" regarding research on human subjects.[97] First, human-subjects research

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[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.*

[94] *Id.* (emphasis added).

[95] *See id.* pt. C.; *see also* 45 C.F.R. § 46 (1998); Flynn & Honberg, *supra* note 22, n.13 (stating that the Common Rule's inclusion of pregnant women, fetuses, children, and prisoners was influenced by the *Belmont Report*); Dolores Kong, *Still No Solution in the Struggle on Safeguards*, BOSTON GLOBE, Nov. 18, 1998, at A01 (noting that prisoners, children, pregnant women, and fetuses are protected by federal regulations governing medical research, but "people with mental illness have no such protection").

[96] Flynn & Honberg, *supra* note 22, n.13; *see also* Kong, *supra* note 95 (noting lack of federal regulatory protection for mentally ill individuals' participation in medical research).

[97] Diane E. Hoffmann & Jack Schwartz, *Proxy Consent to Participation of the Decisionally Impaired in Medical Research—Maryland's Policy Initiative*, 1 J. HEALTH CARE L. & POL'Y 123, 124 (1998).

must be approved by an Institutional Review Board (IRB),[98] also known as a Committee for the Protection of Human Subjects or Human Subjects Committee.[99] "An IRB has the responsibility for deciding *whether, and on what terms*, medical research that involves human subjects may be carried out. In doing so, an IRB acts pursuant to the authority and mandate of federal and state law."[100] Additionally, "an IRB is linked to an institution, and the institution's scope helps to define the IRB's responsibilities."[101] Second, researchers must obtain informed consent "from all research subjects, or their legally authorized representatives, regardless of whether the research is classified as therapeutic [practice] or non-therapeutic [research]."[102] Writers on the issue of human-subjects research agree that, outside of these two safeguards, the IRB and informed consent, the Common Rule provides little or no guidance for the decisionally incapacitated individual's participation in medical research.[103]

> These rules [the Common Rule] provide general guidelines for obtaining informed consent from research participants. The federal regulations also assign significant responsibilities to IRBs to evaluate and monitor research proposals to ensure that they comport with the requirements set forth in the rules. However, although the regulations identify "persons with mental disabilities" as a vulnerable population, they do not set forth specific guidelines or requirements for protecting the rights and welfare of research participants with these disorders. Hence, research investigators and local IRBs have generally assumed these responsibilities on an ad hoc basis.[104]

Public advertisements for free medical care, directed toward the loved ones of decisionally incapacitated individuals, evidence the great "demand for research subjects who are 'decisionally impaired'—that is,

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[98] *See id.*; *see also* 45 C.F.R. § 46.103(b) (1998) ("Departments and agencies will conduct or support research covered by this policy only if . . . the institution has certified . . . that the research has been reviewed and approved by an IRB . . . and will be subject to continuing review by the IRB.").

[99] *See* Dale L. Moore, *An IRB Member's Perspective on Access to Innovative Therapy*, 57 ALB. L. REV. 559 (1994).

[100] *Id.* at 560 (footnotes omitted) (emphasis added).

[101] *Id.*

[102] Flynn & Honberg, *supra* note 22, at 181 (footnote omitted); *see also* 45 C.F.R. § 46.116 (1998) ("[N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."); Hoffmann & Schwartz, *supra* note 97, at 124 & n.3 (noting the informed consent requirement).

[103] *See* Flynn & Honberg, *supra* note 22, at 181 ("[T]he Common Rule does not set forth specific guidelines for obtaining informed consent and protecting the rights and well-being of research subjects with mental illnesses or other brain disorders."); Hoffmann & Schwartz, *supra* note 97, at 124 ("[F]ederal regulations provide little guidance or safeguards for the conduct of research on decisionally impaired patients.").

[104] Flynn & Honberg, *supra* note 22, at 177-78 (footnotes omitted).

incapable of providing informed consent to participation in medical research."[105] The general consensus among writers in the mental health field is that the need for participation of decisionally incapacitated individuals in medical research is imperative.[106] Their justification for this "urgent need" is that more knowledge must be gained from research using decisionally incapacitated individuals to develop more effective treatments and potential cures for brain disorders, ranging from Alzheimer's disease and dementia to mental illnesses and substance abuse, and even head trauma. However, strict application of the informed consent rule, particularly as set out in the *Nuremberg Code*,[107] would disallow the participation of incapacitated research subjects, given

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[105] Hoffmann & Schwartz, *supra* note 97, at 124 & n.1 (reference is to text of advertisement entitled, "Do You Have a Loved One With Memory Loss?", printed in the Oct. 6, 1996, edition of the Washington Post, at A22). A "decisionally incapacitated individual" is one "who is at least 18 years of age and who cannot give a valid informed consent for research participation because the individual has a decisional incapacity." S. 307, §§ 20-701(D)-(E), 1999 Regular Sess. (Md. 1999). A "decisional incapacity" is defined as "a medical condition that has caused an individual to be unable to understand sufficiently the nature, extent, or probable consequences of participation in research, make a sufficient evaluation of burdens, risks, and benefits of participation in research, or communicate a decision about participation in research." *Id.* The terms, "decisionally incapacitated," "decisionally impaired," and "cognitively impaired," are used synonymously throughout this comment unless otherwise indicated.

[106] See Flynn & Honberg, *supra* note 22, at 175-76, which states:

> [R]ecent breakthroughs in understanding the etiology, nature, and treatments of these disorders [schizophrenia, manic-depressive illness, major depression] . . . have occurred through biomedical research. . . . These remarkable advances would not have occurred without the participation of individuals suffering from severe mental illnesses as human subjects in research.

See also Laurie M. Flynn, *Statement of Laurie M. Flynn, Executive Director, National Alliance for the Mentally Ill, Issues Concerning Informed Consent and Protections of Human Subjects in Research, U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on Human Resources, May 8, 1997* (visited Sept. 20, 1999) <http://www.nami.org/pressroom/testimony/imftest.html>, *available in* 1999 WL 10570907 ("The development of promising new medications for the treatment of schizophrenia and other debilitating brain disorders have occurred as a result of biomedical research. . . . These remarkable advances would not have occurred without the participation of individuals with severe mental illnesses as human subjects in research."); Miriam F. Kelty, *Expert Panel Report to the National Institutes of Health (NIH) Research Involving Individuals with Questionable Capacity to Consent: Ethical Issues and Practical Considerations for Institutional Review Boards (IRBs)* (last modified Mar. 13, 1998) <http://www.nih.gov/sigs/bioethics/reports/ exec_sum.htm> ("[T]he best hope for improving diagnosis, treatment, and preventive interventions for these disease processes [mental illness and substance abuse] requires the conduct of research involving those who experience these illnesses directly, and whose decisional abilities may be permanently or transiently impaired.").

[107] *See The Nuremberg Code*, *supra* note 17.

their inability to voluntarily consent.[108] "The existence of a hard and fast rule prohibiting research using decisionally-incapacitated individuals as subjects would have the effect of barring those who are most severely ill from participating in research which may alleviate their suffering and provide them with significant benefits."[109] An opposing concern is that researchers will not properly inform subjects of potential risks or even the true purpose of the procedure when compliance with a strict voluntary informed consent requirement would likely be difficult, if not impossible, given the subjects' decisional incapacitation.[110]

Thus, the issue of the decisionally incapacitated individual's participation in medical research has been reduced to a "*balancing* [of] the importance of maintaining a healthy climate for research with protecting vulnerable subjects who may lack capacity to fully understand the nature, risks and benefits of the research they are participating in."[111] Stated another way, the goal of researchers and bioethicists, as well as advocates for the decisionally incapacitated, should be "to retain as much autonomy as possible in research subjects, while at the same time allowing research to proceed under certain circumstances when individuals lack the capacity to provide informed consent."[112]

The Common Rule tasks the "legally authorized representative"[113] with the responsibility of ensuring this "balancing" occurs, particularly in a way that maintains the decisionally incapacitated individual's autonomy and rights. However, the definition of "legally authorized representative" is unclear and ambiguous. "The term 'legally authorized representative' is circuitously defined 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.'"[114]

Building upon the framework of guidance provided by the Common Rule, Maryland recently undertook the onerous challenge of defining the elusive character, the "legally authorized representative," and

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[108] *See* Flynn & Honberg, *supra* note 22, at 180 (stating that strict application of the *Nuremberg Code* would prohibit incapacitated individuals from participating in medical research because they are incapable of giving consent).

[109] *Id.* at 181.

[110] *See id.* at 178-79 & nn.14-18 (describing an incident at University of California, Los Angeles, in which "a former research subject . . . alleged that researchers failed to properly inform research subjects and their families about potential risks associated with the particular protocol").

[111] Flynn, *supra* note 106 (emphasis added).

[112] Flynn & Honberg, *supra* note 22, at 182.

[113] *Id.* at 181 (footnote omitted); *see supra* note 102 and accompanying text.

[114] Hoffmann & Schwartz, *supra* note 97, at 124 (footnote omitted); *see also* 45 C.F.R. § 46.102(c) (1998).

addressing other issues raised by the informed consent requirement as it relates to participation of decisionally incapacitated individuals in medical research. The next section of this comment analyzes the three basic ethical principles of the *Belmont Report* as the underpinnings of proposed Maryland Senate Bill 307 and the results of Maryland's attempt to provide research subject protection for the decisionally incapacitated.

III. THE PURPOSE OF MARYLAND'S POLICY INITIATIVE

The state of the law regarding the participation of decisionally incapacitated individuals in medical research is uncertain. Diane E. Hoffmann, Assistant Professor of Law at the University of Maryland School of Law,[115] and Jack Schwartz, Chief Counsel, Division of Advice and Opinions, Maryland Office of the Attorney General,[116] provide a comprehensive overview of the legal uncertainty in this controversial area in their 1998 article entitled *Proxy Consent to Participation of the Decisionally Impaired in Medical Research—Maryland's Policy Initiative*, pertinent parts of which follow:

> Because federal law leaves unanswered the question of who is a "legally authorized representative" for consent to research, researchers who seek to rely on this provision of federal law must turn to relevant state law for guidance. Unfortunately, little, if any, state law directly addresses this issue.
>
> The little law that is available applies primarily to *institutionalized* individuals and either prohibits incapacitated persons from participating in experimental research or significantly limits the circumstances under which these individuals can participate in research. Most of the statutes that address the issue require judicial approval or approval by a court-appointed guardian or conservator. . . . A number of states require court approval before a guardian or conservator may consent to participation in medical research by an individual lacking decision-making capacity, and the court must determine that the experimental treatment would be in the "best interests" of the ward.
>
> A few state statutes permit the parent of a child with mental retardation to consent to the child's participation in medical research, but generally statutes do not explicitly allow parents or other relatives to consent to participation in medical research on behalf of a decisionally impaired relative. Of the statutes that address the issue, none appears to permit research on cognitively impaired individuals with consent of a non-court-appointed proxy unless there are additional safeguards. In some cases, a statute may appear to allow

[115] *See id.* n.a1.

[116] *See id.* n.aa1.

> consent by a non-court[-]appointed representative with little oversight, but regulations provide additional protections.
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> . . . .
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> Without clear statutory guidance on this issue, investigators in most states who wish both to perform research on decisionally impaired individuals and to have secure legal protection would need to seek approval from the courts, probably by means of appointment of a guardian who would be authorized to make such decisions. This procedural requirement derives from the state's historical role of parens patriae, protecting incompetent individuals and ensuring that decisions for their care are made consistently with their best interests.[117]

Spurred on by the state of legal uncertainty surrounding this controversial issue, "the Maryland Attorney General's Office established . . . a 'Working Group' . . . consist[ing] of approximately 15 individuals, including lawyers, ethicists, researchers from academic and government institutions, and advocates for the mentally ill."[118] The Working Group's "mission [wa]s to develop recommendations that str[uck] an appropriate balance between the need to proceed with vitally important biomedical research and the equally important need to develop adequate protections for vulnerable individuals with brain disorders who participate as human subjects in this research."[119]

The Working Group first met in May 1995 and identified two main objectives:

> 1. To address the circumstances under which an individual with present decisional capacity might give a legally and ethically valid consent to participation in research, at a time of future decisional incapacity, through an advance directive[120][; and]
> 2. To explore whether, under carefully limited circumstances, a legally and ethically valid consent to participation in research might be

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[117] *Id.* at 125-28 & n.9 (footnotes omitted) (emphasis added) (listing state statutes that generally prohibit medical research on institutionalized mental health patients).

[118] *Id.* at 134.

[119] Flynn & Honberg, *supra* note 22, at 179.

[120] The term, "advance directive," generally refers to a document executed by a competent individual for the purpose of identifying types, limitations, extents, etc., of health care the individual is or is not willing to receive in the future when he or she may be unable to give informed consent. *See* Mark R. Tonelli et al., *Ethics in Medicine* (visited Sept. 20, 1999) <http://eduserv.hscer.washington.edu/bioethics/topics/advdir.html>. The term, "advance directive," as used by the Working Group in *The Decisionally Incapacitated Research Subject Protection Act* refers to a "*research* advance directive" wherein, *inter alia*, an individual identifies a "research agent" (the person whom the individual identifies as giving consent for the individual) and "describes, by reference to a particular medical condition, level of risk, or other pertinent factors, the research in which an individual is willing to participate if the individual is or becomes unable to give informed consent to participation in the research." S. 307, §§ 20-711(C)(1)-(2), 1999 Regular Sess. (Md. 1999) (emphasis added).

> obtained by a proxy . . . for a research subject who never had decisional capacity or who had lost decisional capacity before expressing any views about participation in research.[121]

In its quest to fill "the regulatory gap concerning decisionally impaired [research] subjects," the Working Group based its "recommendations [on] the concepts and categories embodied in federal law."[122] This means that the foundational framework for proposed Maryland Senate Bill 307 (hereinafter referred to as the "Bill") was girded by the three basic ethical principles set forth in the *Belmont Report* and later codified in the Code of Federal Regulations.[123] However, the accuracy with which the Bill actually reflects the three basic ethical principles, as set out by the authors of the *Belmont Report*, requires an in-depth analysis of the authors' intended applications of the ethical principles. Once the *Belmont Report*'s application of ethical principles is understood, a comparison of those intended applications to the principles as applied by the Working Group will determine whether the Working Group reached the *Belmont Report*'s objective.[124]

A. Application of the First Ethical Principle, Respect for Persons, via Informed Consent

"Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."[125] This formulation of the application of respect for persons by ensuring informed consent begs the following question: "[w]hat are *adequate* standards for informed consent?" The *Belmont Report* acknowledges controversy in the medical research field regarding the answer to this question, but indicates "there is widespread agreement that the [informed] consent process can be analyzed as

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[121] Hoffmann & Schwartz, *supra* note 97, at 134 (footnote omitted).

[122] *Id.* at 138.

[123] *See supra* text accompanying notes 54, 85, and 86; *see also* Dianne N. Irving, *Biomedical Research with 'Decisionally Incapacitated' Human Subjects: Legalization of a Defunct Normative Bioethics Theory* pt. I (visited Sept. 9, 1999) <http://www.all.org/abac/dni004.htm>. Irving, a critic of the Bill, acknowledges that "the bioethics principles of autonomy [i.e., respect for persons], justice and beneficence . . . , as articulated in the Belmont Report, and which ground the federal . . . regulations and Common Rule for research involving human subjects, are cited and accepted per se as the grounding of this Maryland State proposed statute." *Id.*

[124] *See* The Belmont Report, *supra* note 45 (The *Belmont Report*'s "objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.").

[125] *Id.* pt. C.

containing three elements: information, comprehension and voluntariness."[126]

According to the *Belmont Report*, the first element of informed consent, information, is comprised of a collection of "specific items for disclosure intended to assure that subjects are given sufficient information" to make an informed decision.[127] "These items generally include[] the research procedure, [its] purposes, risks and anticipated benefits[;] alternative procedures (where therapy is involved)[;] and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research."[128] The *Belmont Report* also indicates that "[a]dditional items," such as "how subjects are selected" and "the person responsible for the research," may also be appropriate for disclosure to potential medical research subjects.[129] As the *Belmont Report* points out, a listing of items gives a researcher a general idea of the essentials to include when imparting information to potential research subjects; however, a "simple listing of items does not answer the question of what the standard should be for judging *how much and what sort* of information should be provided."[130]

The *Belmont Report* does not identify the appropriate standard to use for judging the amount and type of information that researchers should give to subjects. The *Belmont Report* mentions the "standard frequently invoked in medical *practice*, namely the information commonly provided by practitioners in the field or in the locale," but rejects this standard as inadequate in medical *research* because "research takes place precisely when a common understanding does not exist."[131] The *Belmont Report* also mentions the "standard, currently popular in malpractice law, [that] requires the practitioner to reveal the information that *reasonable persons* would wish to know . . . to make a decision regarding their care."[132] However, the reasonable person standard is also rejected as "insufficient," given the fact that "the research subject, being in essence a volunteer, may wish to know considerably more about risks *gratuitously undertaken* than do patients who deliver themselves into the hand of a clinician for *needed* care."[133] Remaining very noncommittal about recommending an appropriate standard, the *Belmont Report* merely suggests that a "reasonable

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[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.* (emphasis added).
[131] *Id.* (emphasis added).
[132] *Id.* (emphasis added).
[133] *Id.* (emphasis added).

volunteer" standard should be used in determining the amount and type of information about which potential research subjects should be apprised:

> *It may be* that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, *knowing* that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should *understand clearly* the range of risk and the *voluntary nature* of participation.[134]

The second element of informed consent, identified in the *Belmont Report* as comprehension, involves "[t]he manner and context in which information is conveyed" as well as "the subject's ability to understand."[135] Researchers "are responsible for ascertaining that the[ir] subject[s] ha[ve] comprehended the information" of informed consent;[136] therefore, researchers must adapt the presentation of informed consent information to their subjects' capacities. The *Belmont Report* indicates that "[s]pecial provision may need to be made when comprehension is severely limited" and cites infants, young children, the mentally disabled, the terminally ill, and the comatose as examples of subject classes that might be considered incompetent.[137] The *Belmont Report* strongly indicates the need to consider these incompetent persons' abilities to participate in medical research decision-making by acknowledging that the ethical principle of respect for persons *requires* informed consent of these persons, either on their own terms or through third parties:

> Even for these persons, . . . *respect requires giving them the opportunity to choose to the extent they are able*, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties . . . to protect the subjects from harm. [Subjects] are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.
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> The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest.[138]

The third element, voluntariness, is so essential to informed consent, according to the *Belmont Report*, that "[a]*n agreement to participate in research constitutes a valid consent only if voluntarily*

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[134] *Id.* (emphasis added).

[135] *Id.*

[136] *Id.*

[137] *Id.*

[138] *Id.* (emphasis added).

given."[139] Voluntariness of informed consent is achieved only under "conditions free of coercion and undue influence."[140] The *Belmont Report* indicates that "[u]njustifiable pressures usually occur when persons in positions of authority or commanding influence . . . urge a course of action for a subject."[141] However, these unjustifiable pressures occur on a continuum; "it is impossible to state precisely where justifiable persuasion ends and undue influence begins."[142] Examples of undue influence given in the *Belmont Report* include "manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitle[d]."[143]

B. Maryland's Interpretation of Informed Consent

Under the proposed Bill, after an IRB approves the research protocol,[144] a researcher obtains written informed consent from the decisionally incapacitated subject's legally authorized representative[145] since the subject is incapable of deciding whether to participate in medical research. The Bill specifically cites the Common Rule as a basis for informed consent,[146] which includes, *inter alia*, such information as "[a] statement that the study involves research," "purposes of the research," "duration of the subject's participation," "procedures to be followed," experimental procedures, "reasonably foreseeable risks or discomforts," and "benefits to the subject or to others."[147] Additional information the researcher must describe to the legally authorized representative includes material risk, reasonably foreseeable direct medical benefit, whether the research involves an alternative to standard treatment as well as risk and benefit of the research compared to the alternative, and research control elements.[148] The legally authorized representative is responsible for inquiring whether the

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[139] *Id.* (emphasis added).

[140] *Id.* "Coercion occurs when an overt threat of harm is intentionally presented by one person to another . . . to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture . . . to obtain compliance." *Id.*

[141] *Id.*

[142] *Id.*

[143] *Id.*

[144] *See* S. 307, § 20-719(A)(1), 1999 Regular Sess. (Md. 1999).

[145] *See id.* §§ 20-701(I)(2), 20-724(C)(1).

[146] *See id.* § 20-724(A)(1).

[147] *See* 45 C.F.R. §§ 46.116(a)(1)-(3) (1998); *see also id.* §§ 46.116(a)(4)-(8) (listing additional information that must be provided to each subject in order to obtain informed consent).

[148] *See* Md. S. 307, §§ 20-724(B)(1)-(3).

subject's research experience is consistent with the information provided by the researcher during the informed consent process and for withdrawing the subject if inconsistency is found.[149] Thus, a comparison of the Bill's informed consent information with the specific informed consent items set out in the *Belmont Report*[150] indicates the Bill adequately covers the information element of informed consent, with the exception of a statement offering the legally authorized representative the opportunity to ask questions during the informed consent process.

The Bill infers the legally authorized representative's ability to comprehend in order to meet the comprehension element of informed consent. The Bill requires only that the legally authorized representative be at least eighteen years of age and disinterested (having no direct connection or benefit regarding the research).[151] The Bill addresses the *Belmont Report*'s concern about "manner and context"[152] by requiring the researcher to "convey all material information about the research in a *clear and understandable way*."[153]

In addition to the information given to the legally authorized representative, the researcher is required to tell the conscious decisionally incapacitated subject, in a manner appropriate to his or her capacity for understanding, the following: "the fact that [he or she] is being asked to participate in research," the nature and likely effect of the research, "the name of the legally authorized representative," and "the fact that . . . the [subject] may decline to participate in or [withdraw from] the research without penalty or loss of benefits."[154] Even though the decisionally incapacitated subject is unable to give consent, the Bill attempts to extend the comprehension element to the subject by requiring the researcher to obtain the subject's *assent*.[155] Assent is broadly defined as "an *affirmative agreement* of an individual to participate in research."[156] However, such a broad definition affords little substantive protection because it infers the subject's understanding that research participation, not therapeutic treatment, is at stake and appears to justify the interpretation of the slight nod of a head or blink of an eye as an affirmative agreement. Thus, while the Bill meets the *Belmont Report*'s recommendation[157] by inferring the legally authorized

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[149] *See id.* § 20-728.

[150] *See supra* text accompanying notes 127-28.

[151] *See* Md. S. 307, §§ 20-701(F), (L) (defining "legally authorized representative" as a "disinterested individual" and giving qualifications for "disinterested individual" status).

[152] *See supra* text accompanying note 135.

[153] Md. S. 307, § 20-702(6) (emphasis added).

[154] *Id.* §§ 20-725(A)(1)-(5).

[155] *See id.* § 20-725(B).

[156] *Id.* § 20-701(B) (emphasis added).

[157] *See supra* text accompanying notes 137-38.

representative's comprehension, informed assent by the subject appears to be nugatory because the ultimate participation decision rests with the legally authorized representative and the definition of assent makes the subject's ability to withhold assent practically impossible.

In addition to comprehension, the Bill infers voluntariness, the third element of informed consent, on the part of the legally authorized representative.[158] Informed assent also connotes voluntariness on the part of the subject. While the Bill meets the *Belmont Report*'s requirement[159] by inferring the legally authorized representative's voluntariness, the voluntariness of the subject raises concern. The subject's voluntariness appears to be perfunctory because the legally authorized representative makes the ultimate decision. Also, the subject's voluntariness in the informed assent process is subject to pressure, particularly considering that the Bill permits a researcher to "take reasonable, noncoercive steps to request a decisionally incapacitated individual to *reconsider a refusal of assent* or refusal to perform an action related to the research."[160]

In summary, while the Bill requires the appropriate substance of information to be divulged during the informed consent process, the comprehension and voluntariness required by the *Belmont Report* are merely formal exercises so far as the decisionally incapacitated subject is concerned. Appropriate substance by itself is not an effective protection during the informed consent process. Comprehension and voluntariness are also necessary. In some circumstances under the Bill, the legally authorized representative's comprehension and voluntariness are substituted for those of the subject.[161] However, in other cases, the subject's comprehension and voluntariness are not essential, even in substituted form, if the legally authorized representative determines the subject's participation in research is in the subject's medical best interest.[162]

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[158] *See supra* note 151 and accompanying text.

[159] *See supra* text accompanying note 139.

[160] Md. S. 307, § 20-725(C) (emphasis added).

[161] *See id.* §§ 20-726(A)(1)-(6). The Bill lists relevant information a legally authorized representative may take into account "[i]f a legally authorized representative is required . . . to consider *whether or not a decisionally incapacitated individual would consent to participate in research if the decisionally incapacitated individual were able to give informed consent.*" *Id.* (emphasis added).

[162] *See id.* § 20-701(M) ("'Medical best interest' means that the burden to the [subject] resulting from participation in research is determined by a legally authorized representative to be acceptable in relation to the potential medical benefit to the [subject] resulting from participation by the [subject] in research . . . .").

C. Application of the Second Ethical Principle, Beneficence, via Assessment of Risks and Benefits

"The principle of Beneficence requires [protection of research subjects] by maximizing anticipated benefits and minimizing possible harms."[163] As defined by the *Belmont Report*, "[t]he term 'risk' refers to a possibility that harm may occur,"[164] while "[t]he term 'benefit' is used in the research context to refer to something of positive value related to health or welfare."[165]

For the researcher, the IRB, and the subject, this assessment of risks and benefits involves consideration of different elements. The researcher's assessment involves determining whether the study is properly designed,[166] in light of the risks and benefits the study presents[167] and in consideration of "alternative ways of obtaining the benefits sought in the research."[168] The IRB's assessment determines whether the risks to the subjects in the researcher's proposed study are justified[169] because "[r]esearch risks must always be justified by the expected benefits of research."[170] The prospective subject's assessment of risks and benefits will help determine whether the subject should participate in the research study.[171]

Regardless of their different viewpoints in assessing risks and benefits, the researcher, the IRB, and the prospective subject consider the same risks and benefits, including those of a psychological, physical, legal, social, and economic nature,[172] although they may not give each risk and benefit the same weight in the balancing process. "[T]he most likely types of harms to research subjects are those of psychological or physical pain or injury," but other harms "should not be overlooked."[173] The *Belmont Report* notes that risks and benefits may also affect "the families of the individual subjects and society at large (or special groups of subjects in society)."[174]

According to the *Belmont Report*, "[p]revious codes and Federal regulations have required that risks to subjects be outweighed by the

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163 National Institutes of Health, *supra* note 7, app. 2.

164 The Belmont Report, *supra* note 45, pt. C.

165 *Id.*

166 *See id.*

167 *See* National Institutes of Health, *supra* note 7, app. 2.

168 The Belmont Report, *supra* note 45, pt. C.

169 *See id.*

170 National Institutes of Health, *supra* note 7, app. 2.

171 *See* The Belmont Report, *supra* note 45, pt. C.

172 *See id.*

173 *Id.*

174 *Id.*

sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research."[175] However, this interpretive statement by the authors of the *Belmont Report* is debatable. Admittedly, the *Nuremberg Code* presents the assessment of risks and benefits in very ambiguous terms, weighing the risks against "the humanitarian importance of the problem,"[176] and determining that risks should not outweigh the importance of the problem simply for the sake of solving the problem. Such a statement is wide open for subjective interpretation as evidenced by the *Belmont Report*; however, the *Declaration of Helsinki* presents the assessment of risks and benefits in very succinct terms. The risks are not weighed against the benefits to *both* the subject and society. Rather, the risks and benefits to the individual are weighed against each other, with the benefits to society added to the equation, only if the benefits outweigh the risks to the subject. The *Declaration of Helsinki* could not state this principle more clearly: "the interest of science and society should never take precedence over considerations related to the well-being of the subject."[177]

The *Belmont Report* departs from the assessment of risks and benefits presented in the *Declaration of Helsinki* and broadly interprets the *Nuremberg Code* to mean the following: research on human subjects is properly analyzed by balancing risks and benefits to both the subject and society and can be justified if the decision-maker determines that the benefit to society outweighs the risk to the subject, even in the face of no direct medical benefit to the subject. The *Belmont Report*, in pertinent part, supports this proposition:

> In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, *interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research*, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.[178]

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[175] *Id.*; *see also The Nuremberg Code*, *supra* note 17, para. 6 ("The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment."); DECLARATION OF HELSINKI, *supra* note 29, pt. III, para. 4 ("In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.").

[176] *The Nuremberg Code*, *supra* note 17, para. 6.

[177] DECLARATION OF HELSINKI, *supra* note 29, pt. III, para. 4.

[178] The Belmont Report, *supra* note 45, pt. C (emphasis added).

D. Beneficence in Maryland Senate Bill 307: Helsinki or Belmont Style?

Analysis of the beneficence principle as applied in the Bill focuses on three concerns: (1) who is a legally authorized representative; (2) what is health care as opposed to medical research; and (3) what is the appropriate standard the legally authorized representative should apply when making a research participation decision?

The Bill identifies four separate and distinct types of legally authorized representatives who perform assessment of risks and benefits for a prospective research participant, only two of whom are expressly identified by the potential research subject. The first type is the research agent who is expressly authorized by the prospective research subject, under a research advance directive,[179] "to make a decision concerning participation by [the subject] in research."[180] The second type is the health care agent who is appointed by the potential research subject through a durable power of attorney, pursuant to Maryland's Health Care Decisions Act,[181] "to make a health care decision for the [subject]."[182] The third type is the proxy decision-maker "who is designated by an IRB to consider whether to give informed consent to participation by a decisionally incapacitated individual in research."[183] The fourth type is the surrogate "who is authorized by the [Maryland] Health Care Decisions Act to make a health care decision for a [subject]" when the subject has not appointed an agent.[184]

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[179] *See supra* note 120.

[180] S. 307, § 20-701(W), 1999 Regular Sess. (Md. 1999).

[181] Addressing the durable power of attorney, one author notes that

> [w]hile most states do not have laws that expressly address consent to conduct research with decisionally impaired patients . . . , most states have passed statutes that allow individuals to consent to receipt of medical treatment on behalf of another who is cognitively impaired. These proxy consent laws are of two types: "durable power of attorney (DPA) for health care" statutes and "surrogate" statutes. A handful of states, including Maryland, have enacted comprehensive statutes incorporating both guidelines for the execution of advance directives and standards for surrogate health care decision-making for incapacitated individuals. In Maryland the law is referred to as the Health Care Decisions Act.
>
> DPA statutes allow a competent individual to execute a document appointing an "agent" to make health care decisions for the individual in the event that he or she becomes incapacitated. The agent's authority is generally defined by the [subject] in the DPA itself.

Hoffmann & Schwartz, *supra* note 97, at 130-31 (footnotes omitted).

[182] Md. S. 307, § 20-701(G).

[183] *Id.* § 20-701(S).

[184] *Id.* § 20-701(Z).

> In many states, surrogate consent statutes apply when no agent has been appointed. These statutes typically allow a family member to make medical decisions for an incapacitated patient based on an assessment of what the

While each type of legally authorized representative is required to be "disinterested,"[185] writers and experts in the field of medical research express concerns about conflicts of interests affecting the legally authorized representative's decision-making ability. For example, the research agent or health care agent, identified by the prospective research subject to make health care decisions for him or her, could potentially be the "same physician/investigator who proposes the research protocol" and "has the major control of recruiting, informing, caring [for], and interacting with patients."[186] Additionally, the IRB that reviews the proposed research protocol may fail to protect the subject from harm by appointing a proxy who is ill-equipped or unmotivated to make appropriate decisions.[187] Finally, even when the decision-maker is a member of the prospective research subject's family, as in the case of the surrogate,[188] the risk still exists that the surrogate will make a decision contrary to the subject's desires.[189]

> patient would have wanted (a substituted judgment standard) or, if that preference cannot be inferred, based upon the patient's best interests. Surrogate statutes generally include a priority ranking of those authorized to make decisions, usually beginning with a person's spouse, followed by adult children, then parents and adult siblings. Some statutes go further down the family chain, and a few include a "close friend" in the list.

Hoffmann & Schwartz, *supra* note 97, at 131 (footnotes omitted).

[185] *See supra* note 151 and accompanying text.

[186] Gregor Wolbring, *Maryland Report on Research on Non Consent Able Human Subjects: A Critique* (visited Sept. 20, 1999) <http://www.thalidomide.ca/gwolbring/mlreport.htm>. In his article, Dr. Wolbring includes the following quote from Dr. Adil Shamoo, a member of the Maryland Working Group: "[t]he physician/investigator is the one who assesses the patient's capacity to sign informed consent. This approach clearly does not resolve the past abuses of using ill-obtained informed consent . . . . Also, there is a conflict of interest of the investigator acting as the care giver." *Id.*

[187] *See* Irving, *supra* note 123, pt. II ("The reality of 'unchecked research' and of the ineffectiveness of IRB's to competently review the research and/or to protect the patients from harm and abuse has historically been demonstrated to be problematic.").

[188] *See supra* note 184 and accompanying text.

[189] The risk that the surrogate will make a decision contrary to the subject's desires became the focus of a study conducted by the University of Maryland School of Medicine:

> Dr. John W. Warren, of the University of Maryland School of Medicine, surveyed proxies about their decisions to allow nursing home residents to participate in a minimal risk study. Of the surrogates who believed the patient would have refused to be a subject, 31% consented to have the patient participate; that is, these surrogates frequently provided consent even though they believed that the consent did not represent the patient's wishes. . . . Dr. [Greg] Sachs examined the level of agreement between dementia patients and their surrogates regarding the patient's preferences for research participation in four hypothetical studies. Agreement between patients and their surrogates were [sic] modest at best. Dr. Sachs found that, overall, surrogates give consent for their relatives to participate in research more frequently than that person would have chosen. One explanation might be that surrogates are using a "best

Regardless of which legally authorized representative makes the decision, another beneficence concern arises surrounding the blurred distinction between health care and medical research.[190] The *Belmont Report* supports the implementation of beneficial treatment in conjunction with research "to evaluate the safety and efficacy of a therapy."[191] However, the Bill colors this distinction a darker shade of gray by equating beneficial health care with medical research that has the *potential* to benefit the research subject. This shading occurs by manipulating the definition of "health care" as it relates to advance directives and durable powers of attorney under Maryland's Health Care Decisions Act. The Bill's reasoning progresses as follows: (1) advance directives and durable powers of attorney permit legally authorized representatives to make health care decisions for decisionally incapacitated individuals; (2) health care refers to medical treatment intended to enhance the well-being of decisionally incapacitated individuals; (3) some forms of medical research produce beneficial results that enhance the well-being of decisionally incapacitated research subjects; (4) beneficial medical research can, therefore, be equated with beneficial health care; (5) thus, advance directives and durable powers of attorney can be used to permit legally authorized representatives to enroll decisionally incapacitated individuals in beneficial medical research studies because beneficial medical research is, in essence, health care.[192] This line of reasoning is clearly delineated by Diane Hoffmann and Jack Schwartz[193] in the following excerpt:

> [The durable power of attorney and surrogate] statutes . . . do not explicitly address consent to participation in medical research. The laws generally limit the authority of the agent or surrogate to decisions regarding health care or medical treatment. However, only a few states define the terms "health care" or "medical treatment" in their durable power of attorney for health care and surrogate consent statutes. In Maryland, the Health Care Decisions Act does not define health care; however, the Maryland Attorney General's Office stated in an opinion letter that *the term "health care" would be synonymous*

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interest" standard rather than the "substituted consent" standard that is assumed by some to underlie proxy consent.

Peter V. Rabins, *Issues Raised by Research Using Persons Suffering from Dementia Who Have Impaired Decisional Capacity*, 1 J. HEALTH CARE L. & POL'Y 22, 29 (1998) (footnotes omitted). The reader should note that Dr. Rabins appears to use the terms "proxy" and "surrogate" interchangeably, whereas they are distinguished in this comment according to the definitions set forth in the Bill.

[190] *See supra* text accompanying notes 87-94.

[191] *See supra* text accompanying note 92.

[192] *See* Irving, *supra* note 123, pt. II (setting forth a similar argument using the terms "standard medical care or treatment" and "therapeutic research").

[193] *See supra* text accompanying notes 115-16.

> *with "a procedure or course of treatment that relates to the disease state of the particular patient."* Thus, as long as the research being contemplated involves *potential* benefit, that is, *"as long as there is an articulable link between the research and a possible improvement in the patient's condition, then a 'health care' decision is possible,* and the patient's hypothesized wishes would be the basis for it."[194]

The direct result of equating beneficial health care to medical research is that "Advanced Directives for Standard Medical Care and Treatment could be convertible to Advanced Directives for Research Participation."[195] The consequence of making such an equation is that very few, if any, research protocols could be excluded from implementation, particularly if "potential" benefit is used as the standard in assessing risks and benefit. Researchers could cloak most any research protocol with characteristics of a "potential" benefit.

A final beneficence concern arises in determining the standard that a legally authorized representative should apply in making a research participation decision. Two frequently identified standards in the field of medical research are the "substituted judgment" standard and the "best interests" standard. The substituted judgment standard "requires a [decision-maker] to make a treatment decision as the [subject] would have if the [subject] could speak for him-/herself. It requires that there be sufficient evidence of the patient's preferences."[196] The best interests standard "applies when it is not possible to ascertain the [subject]'s preferences. It requires the [decision-maker] to choose a course of action that promotes the [subject]'s interests according to what a reasonable person in the [subject]'s circumstances would choose."[197]

As one author notes, the "[l]egal and ethical perspectives on substituted judgment and best interests vary, but the gold standard sought by all is honoring the [subject]'s *actual and known wishes.* The case law aspires to that goal. Advance directive laws exist for that reason."[198] If the ultimate goal is to honor the subject's known wishes, then the substituted judgment seems more appropriate than the best interests standard. The Bill, however, contemplates the use of both

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[194] Hoffmann & Schwartz, *supra* note 97, at 131-32 (footnotes omitted) (emphasis added).

[195] Irving, *supra* note 123, pt. I.

[196] Charles P. Sabatino, *The Legal and Functional Status of the Medical Proxy: Suggestions for Statutory Reform*, 27 J.L. MED. & ETHICS 52, 55 (1999). The Bill does not expressly provide a definition for "substituted judgment."

[197] *Id.* (footnote omitted). In the Bill, "'medical best interest' means that the burden to the individual resulting from participation in research is determined by a legally authorized representative to be acceptable in relation to the potential medical benefit to the individual resulting from participation by the individual in research." S. 307, § 20-701(M), 1999 Regular Sess. (Md. 1999).

[198] Sabatino, *supra* note 196, at 55 (emphasis added).

standards;[199] the substituted judgment standard is favored,[200] and the best interests standard is used in the alternative[201] if the substituted judgment standard cannot be reached[202] and if the "research presents a reasonable prospect of direct medical benefit."[203] Additionally, the Bill contemplates a hierarchy of decision-makers, beginning with the research agent,[204] proceeding to the health care agent,[205] then to the surrogate,[206] and finally to the proxy.[207] If the potential subject has identified a research agent in an advance directive, the research agent may first use the substituted judgment standard[208] and, in the alternative, the best interests standard,[209] to consent to the subject's research participation. If the potential subject has not identified a research agent in an advance directive,[210] a health care agent may step in as the decision-maker, provided the potential subject has identified a health care agent in appropriate documentation.[211] As with the research agent, the health care agent may first use the substituted judgment standard[212] and, in the alternative, the best interests standard,[213] to consent to the subject's research participation. If the potential subject has not identified a research or health care agent,[214] a surrogate may consent to the subject's research participation[215] using either the substituted judgment standard[216] or the best interests standard.[217] Finally, if no research agent, health care agent, or surrogate is available,[218] the IRB may appoint a proxy decision-maker to consent to

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[199] *See* Md. S. 307, §§ 20-732 to -735; *see also* Hoffmann & Schwartz, *supra* note 97, at 133 ("If an individual has not executed [an advance] directive, . . . a legally authorized surrogate should be able to consent to certain research protocols, using a mixed substituted judgment and best interest test.").

[200] *See* Md. S. 307, §§ 20-732(A), -733(A)(2), -734(A)(2), -735(A)(2).

[201] *See id.* §§ 20-732(B)(2), -733(B)(2), -734(B)(2), -735(B)(2).

[202] *See id.* §§ 20-732(B)(1)(I), -733(B)(1)(I), -734(B)(1)(I), -735(B)(1)(I).

[203] *Id.* §§ 20-732(B)(1)(II), -733(B)(1)(II), -734(B)(1)(II), -735(B)(1)(II).

[204] *See supra* text accompanying notes 179-80.

[205] *See supra* text accompanying notes 181-82.

[206] *See supra* note 184 and accompanying text.

[207] *See supra* text accompanying note 183.

[208] *See* Md. S. 307, § 20-732(A).

[209] *See id.* §§ 20-732(B)(1)(I), (B)(2).

[210] *See id.* § 20-733(A)(1).

[211] *See supra* note 181 and accompanying text.

[212] *See* Md. S. 307, § 20-733(A)(2).

[213] *See id.* §§ 20-733(B)(1)(I), (B)(2).

[214] *See id.* §§ 20-734(A), (A)(1).

[215] *See id.* § 20-734(A).

[216] *See id.* § 20-734(A)(2).

[217] *See id.* § 20-734(B)(2).

[218] *See id.* § 20-735(A)(1).

the subject's research participation[219] if the subject has unambiguously indicated in an advance directive his or her desire to participate in research[220] or, in the alternative, if the proxy decision-maker determines that research participation is in the subject's medical best interest.[221]

This section of the article only considers research that may have direct medical benefit for the research subject. However, it is important to note that the same decision-making hierarchy and standards of judgment also apply to research that poses a minimal risk[222] to the subject; that is, even if the proposed research protocol poses no direct medical benefit for the subject, he or she may still be enrolled in the research protocol if the research poses nothing more than minimal risk to its participants.[223] Other sections[224] of the Bill contemplate research involving no direct medical benefit and a *minor increase over minimal risk*,[225] as well as research involving no direct medical benefit and *more than a minor increase over minimal risk*.[226] It is also important to note

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[219] *See id.* § 20-735(A).

[220] *See id.* § 20-735(A)(2).

[221] *See id.* § 20-735(B)(2).

[222] *See id.* §§ 20-731(1)-(2). The Bill defines "minimal risk" as follows:

> "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in research, including psychological harm and loss of privacy or other aspects of personal dignity, are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of a routine physical or psychological examination or test.

Id. § 20-701(O)(1).

[223] Section 20-731 of the Bill applies to research involving direct medical benefit or minimal risk to the subject. *Compare id.* § 20-731(1) ("[a] reasonable prospect of *direct medical benefit* to a decisionally incapacitated individual who is a research subject; *or*) *with id.* § 20-731(2) ("[a] *minimal risk* to a decisionally incapacitated individual who is a research subject") (emphasis added).

[224] *See id.* §§ 20-738 to -746.

[225] The Bill defines "minor increase over minimal risk" as follows:

> "Minor increase over minimal risk" means that the probability and magnitude of harm or discomfort anticipated in research, including psychological harm and loss of privacy or other aspects of personal dignity, are only slightly greater in and of themselves than those ordinarily encountered in daily life or during the performance of a routine physical or psychological examination or test.

Id. § 20-701(P)(1).

[226] The Bill defines "more than a minor increase over minimal risk" in terms of an IRB determination standard.

> An IRB shall determine that a research protocol presents more than a minor increase over a minimal risk if, as a result of participation in research, a decisionally incapacitated individual would be exposed to more than a remote possibility of:
>
> (I) Substantial or prolonged pain, discomfort, or distress; or
>
> (II) Clinically significant deterioration of a medical condition.

Id. § 20-718(B)(4).

that the Bill does not identify which of these levels of risk is acceptable when the research provides a direct medical benefit to the subject.[227]

As the foregoing analysis indicates, the practical effect of the application of the beneficence principle in the Bill is skewed in favor of the researcher. First, depending on the circumstances, resort may be had to the hierarchy of four potential decision-makers on behalf of the prospective research subject. If one decision-maker is unavailable and the circumstances permit, the next decision-maker on the list may be consulted for the required informed consent. This process could be repeated until consent is obtained or the list of decision-makers is exhausted. It is also important to note that the list of decision-makers does not include the potential research subject's family members.[228] Yet, "[f]amilies are frequently in the best position to understand the wishes of their decisionally-incapacitated family member and to therefore act on their behalf."[229] As a result, "the absence of family members from the decision-making hierarchy means that individuals who may not really know the decisionally-incapacitated person may frequently be called upon to act on behalf of those individuals."[230] Second, the decision-makers are free to equate medical research with medical treatment, so long as the *potential* exists for improving the medical condition of the prospective research subject.[231] Thus, when decision-makers are performing the assessment of risks and benefits, a standard of "potential" medical benefit makes it much easier for them to give less credence to the risks in favor of potential benefits. Finally, decision-makers may resort to the very broad standard of "medical best interests" when no evidence is available to apply the "substituted judgment" standard. The absence of family members in the decision-making process, combined with application of the medical best interests standard supported by mere potential for medical benefit, particularly societal benefit as contemplated in the *Belmont Report*, opens "a gaping hole"[232] into which many decisionally incapacitated individuals will fall.

One critic of the Bill raises the issue of whether "minor increase over minimal risk" research and "more than a minor increase over minimal risk" research include "high risk" research. *See* Irving, *supra* note 123, pt. II ("[T]he lack of attempting to articulate a comparable 'high risk' category . . . would make it difficult for any one to know or understand what they were getting into, and therefore to give a valid informed consent.").

[227] *See id.*; *see also* Susko, *supra* note 33 ("In 'therapeutic research' the proposed statute does not *yet* state what level of risk for injury or death is acceptable, or even how to define levels of risk.").

[228] *See* Flynn & Honberg, *supra* note 22, at 183 ("[F]amilies are notably absent from those who are authorized to provide substitute consent.").

[229] *Id.*

[230] *Id.* at 183-84 (footnote omitted).

[231] *See supra* text accompanying notes 190-94.

[232] Kong, *supra* note 95.

This Belmont-style assessment of risks and benefits, with such low levels of protection, will inevitably and repeatedly result in the determination that the benefits to society outweigh the risks to the prospective research subject, almost without exception.

E. Application of the Third Ethical Principle, Justice, via Selection of Subjects

According to the *Belmont Report*, "the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects."[233] Justice applies to research subject selection at the individual as well as social level.[234]

> Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.[235]

The National Institutes of Health suggest that the principle of justice requires that "subjects should be carefully and equitably chosen to insure that certain individuals or classes of individuals—such as prisoners, elderly people, or financially impoverished people—are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so."[236] The principle of justice contemplates that "unless there is careful justification for an exception, research should not involve persons from groups that are unlikely to benefit from subsequent applications of the research."[237]

The *Belmont Report* cites "[o]ne special instance of injustice [that] results from the involvement of vulnerable subjects,"[238] including those at-risk subjects contemplated by the National Institutes of Health:

> Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized[,] may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved

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[233] The Belmont Report, *supra* note 45, pt. C.

[234] *See id.*

[235] *Id.*

[236] National Institutes of Health, *supra* note 7, app. 2.

[237] *Id.*

[238] The Belmont Report, *supra* note 45, pt. C.

> in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.[239]

Justice contemplates zero-tolerance for discrimination as well as abuse in research. Put very simply, the ethical principle of justice requires that research subjects be treated fairly.

F. Maryland's Justification for Condoning Research Involving Decisionally Incapacitated Subjects

The Bill states the following as a justification for its position favoring participation of decisionally incapacitated subjects in medical research:

> *Research involving a decisionally incapacitated individual may be essential* under some circumstances if science is to understand and ultimately combat diseases of the brain, including Alzheimer's Disease, severe psychiatric disorders, severe trauma, stroke, other causes of decisional incapacity, and the medical problems that are associated with these conditions and disorders.[240]

This excerpt from the Bill indicates that participation of decisionally incapacitated individuals is *necessary* for brain diseases to be understood and treated properly. This justification implies that participation by decisionally incapacitated individuals is necessary for society's benefit in obtaining data about brain diseases.

The Bill further states that

> [a] researcher should seek to enroll a decisionally incapacitated individual as a research subject only if the research is expected to yield *generalizable knowledge* important to the understanding or amelioration of the disorder or condition of the subject and related medical problems, and the knowledge can not [sic] be obtained without participation of the subject.[241]

One critic of the Bill equates the "generalizable knowledge," to which the Bill refers, with "what might benefit future generations and the greater good of society."[242] The possible "positive or negative effects on the research subject [are] not considered."[243] This critic posits that the "justification for involving people without their consent"[244] is for "societal

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[239] *Id.*

[240] S. 307, § 20-702(4), 1999 Regular Sess. (Md. 1999) (emphasis added).

[241] *Id.* § 20-702(5) (emphasis added).

[242] Wolbring, *supra* note 186.

[243] *Id.*

[244] *Id.*

good"[245] and expounds on the dangers of such a justification in the following excerpt:

> Allowing high-risk, non-benefit research on non-competent people opens the door for serious abuse. For example, parents, as substitute decision-makers for their children, might be pressured into allowing the use of their children in such research. Another danger is that people who test positive for certain genetic conditions, such as Alzheimer's, might be pressured to sign an advance research directive and thereby consent to be used later in life for high-risk, non-benefit research. Efforts like the Maryland Report do not provide sufficient safeguards. *Within the bioethics community, there is already an established notion that people have a moral obligation to volunteer for experimental research* (even high-risk, non-benefit research), which shows that the possibility of pressure as cited above is real.[246]

Considering the spirit of the proposed Bill, particularly its justification for the use of decisionally incapacitated individuals in medical research that serves no direct medical benefit to them, the Bill conflicts with the following premise set forth in the *Belmont Report* regarding the application of the justice principle: "[w]hen research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved."[247] Supporters of the Bill could argue that it fits within the exception; that is, the research proposed under the Bill directly relates to the specific conditions of the classes involved in the research. However, the categories of subjects are so broad and the types of research are so far-reaching[248] that the exception, as applied to the proposed Bill, may have already swallowed the rule.

Perhaps the Bill's most questionable affront to the justice principle is the immunity from civil and criminal liability it affords to researchers, legally authorized representatives, IRB members, and others, who

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[245] Gregor Wolbring, *Do No Harm* (visited Sept. 20, 1999) <http://www.thalidomide.ca/gwolbring/DO%20NO%20HARM.html>.

[246] *Id.* (emphasis added).

[247] The Belmont Report, *supra* note 45, pt. C.

[248] In answering the question of who would be included in research under the Bill, Michael A. Susko, M.S., Member of Coalition of Homeless Outreach Teams in Baltimore, Maryland, suggests "[a]nyone with brain 'illnesses'— a broad spectrum of Americans with *disabilities* including those diagnosed with Alzheimers, psychiatric disorders, mental handicaps— any claimed brain ailment that impairs a person's ability to give informed consent." Susko, *supra* note 33. In answering the question of what types of research would be included under the Bill, Mr. Susko suggests "[a]ny type of brain alteration including experimental anti-psychotic drugs, *challenge* drugs that induce psychiatric illness, psychosurgery, electrode implants or fetal transplants." *Id.*

comply in good faith with the Bill.[249] Regardless of whether the research was conducted without the informed consent of the decisionally incapacitated individual, liability does not accrue to researchers except for *knowing* violations.[250] One writer describes the Bill's provision for immunity from liability as a distortion of the justice principle:

> Guaranteeing total civil and criminal legal immunity for researchers, physicians, consenters, and IRB's, while legally precluding all patients from any due process when harmed or injured while participating in any research protocols, and legally precluding any follow-up medical care or compensation for harms and injuries sustained during participation in research, are clear and obvious distortions of the principle of "justice[."] Clearly the "balance" is rather heavy on the side of the benefits and interests of researchers, drug companies, research institutions, etc., over the benefits and interests of the people of the State of Maryland who will be the participants in this research.[251]

At the very least, such an immunity provision is in direct conflict with federal regulations governing the protection of human research subjects:

> No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, *or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.*[252]

The injustice that could potentially be served by Maryland's proposed Bill is not contrived, particularly in light of the fact that one member of Maryland's working group, "Dr. Adil Shamoo of the Department of Biological Chemistry at the Medical School of the University of Maryland at Baltimore"[253] has written a dissenting statement against the Bill. A pertinent portion of Dr. Shamoo's dissent follows:

> In brief, the proposed legislation does not address the major issues of the protection of vulnerable, uncomprehending human subjects from high risk non-therapeutic experiments. In other words, those human beings will continue to be used as guinea pigs for the benefit of future generations and science. In our great country and in all the civilized world, we have rejected the supremacy of science or the advancement of society over the interest of the individual human beings as enunciated by every code of ethics and declarations.[254]

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[249] *See* S. 307, § 20-758, 1999 Regular Sess. (Md. 1999).

[250] *See id.* §§ 20-758 to -759.

[251] Irving, *supra* note 123, pt. II.

[252] 45 C.F.R. § 46.116 (1998) (emphasis added).

[253] Mike Ervin, *Guinea Pigs Don't Get to Say 'No'* (visited Sept. 20, 1999) <http://www.raggededge.org/1198/b1198ft2.htm>.

[254] Wolbring, *supra* note 245 (quoting Dr. Shamoo). In his article, Dr. Wolbring quotes Dr. Adil E. Shamoo, Editor in Chief of the journal, ACCOUNTABILITY IN RESEARCH,

IV. SKIRTING THE ISSUE: WHAT IS REALLY AT STAKE?

Although Dr. Shamoo and other writers in the medical research field correctly express concern about the need for protection of "human subjects" in medical research, they either fail to recognize or refuse to define the real issue as one involving the protection of a *human being's absolute personal right to be secure in his or her body and health.*

In the first volume of his *Commentaries on the Laws of England*, Sir William Blackstone defined this common law absolute right as a residuum of human beings' natural liberty founded upon nature and reason:

> The absolute rights of man, considered as a free agent, endowed with discernment to know good from evil, and with power of choosing those measures which appear to him to be most desirable, are usually summed up in one general appellation, and denominated the *natural liberty of mankind.*[255]
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> . . . .
>
> The rights themselves . . . consist in a number of private immunities; which will appear, from what has been premised, to be . . . that *residuum* of natural liberty, which is not required by the laws of society to be sacrificed to public convenience . . . .[256]

Blackstone's use of the term "absolute rights" means "those [rights] which are so in their primary and strictest sense; such as would belong to their persons merely in a state of nature, and which every man is entitled to enjoy, whether out of society or in it."[257] Blackstone asserted that it is society's "principal aim" to protect individuals' enjoyment of these absolute rights.[258] Blackstone distilled the rights of persons into three categories: personal security, personal liberty, and private property.[259] Personal security is obviously the right at issue in this comment.

Blackstone posited that "[t]he right of personal security consists in a person's legal and uninterrupted enjoyment of his life, his limbs, his body, his health, and his reputation."[260] Regarding personal security of the body, Blackstone stated that an individual's limbs and members, as well as his body, are "entitled . . . to security from the corporeal insults of menaces, assaults, beating, and wounding; though such insults amount

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whose article entitled *A Dissenting Statement* appeared in the June 12, 1998, edition of that publication. *See* Ervin, *supra* note 253.

[255] 1 WILLIAM BLACKSTONE, COMMENTARIES *125 (emphasis added).

[256] 1 *id.* at *129.

[257] 1 *id.* at *123.

[258] 1 *id.* at *124.

[259] *See* 1 *id.* at *129.

[260] 1 *id.*

not to destruction of life or member."[261] Particularly applicable to the issue of decisionally incapacitated individuals' participation in medical research is Blackstone's premise that an individual's *health* is protected "from such practices as may prejudice or annoy it."[262]

Henry John Stephen published his own rendition of English law, entitled *New Commentaries on the Laws of England*, in which he expounded upon Blackstone's foundational principles. Regarding the preservation of an individual's body and health from harm, Stephen noted that "[i]t is to the[se personal rights'] infringement, rather than to the rights themselves, that the provisions of the laws have been in general directed."[263] In other words, the personal rights of bodily integrity and health are most appropriately analyzed as they relate to *wrongs* done to one's body or health. The following excerpt from Stephen's *Commentaries* is particularly applicable to the issue of medical research in terms of malpractice:

> [4. Injuries affecting a man's *health* are, where by any unwholesome practices of another, a man sustains any damage in his vigour or constitution, as] . . . by the neglect or unskilful management of the surgeon, apothecary, or general practitioner who attends him . . . . [For it hath been solemnly resolved . . . that *mala praxis* is a great misdemeanor and offence at common law, *whether it be for curiosity and experiment*, or by neglect; *because it breaks the trust which the party had placed in his physician, and tends to the patient's destruction.*][264]

Inherent in this right to personal security of one's body and health is a converse or reciprocal duty on the part of others. "For whatever is due *to* one man or set of men, is necessarily due *from* another."[265] Therefore, each individual's right to bodily "personal security[] implies the converse duty on the part of others not to subject him to any violence."[266] Taken to its logical conclusion, this premise indicates that decisionally incapacitated individuals' rights to be secure in their bodies and health requires a reciprocal duty from their physicians, caretakers, legally authorized representatives, and others, to do them no harm.

Having established that the right to personal security of one's body and health is indeed a natural right due from one individual to another, the legal import of this natural right to decisionally incapacitated

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[261] 1 *id.* at *134.

[262] 1 *id.*

[263] 1 HENRY JOHN STEPHEN, NEW COMMENTARIES ON THE LAWS OF ENGLAND 135 (photo. reprint 1979) (1841).

[264] 3 *id.* at 472 (photo. reprint 1979) (1841) (third and fourth emphases added). Brackets in this quotation indicate portions of Stephen's original work taken, without alteration, from Blackstone's *Commentaries*.

[265] 1 *id.* at 126.

[266] 1 *id.* at 127.

individuals must be analyzed. This analysis involves making a distinction between natural rights and positive rights. Professor Samuel Stoljar defines positive rights as those "rights institutionally recognised, either legally because backed by coercive consequences, or rights recognised as part of accepted practices."[267] A positive right "is not only an institutionally operative right, [but] it is also a right which is contained in a 'literary' source," either oral tradition or written law, and recognized by institutional operators as authoritative.[268] Natural rights, however, lack institutional dimension, "being neither legally enforceable nor part of a working practice or custom, nor emanating from an authoritative source."[269] Natural rights "nevertheless give rise to significant social censure"[270] and "connect with deep moral principles, principles of justice we simply cannot dispense with."[271]

The Bill embodies Maryland's attempt to legalize decisionally incapacitated individuals' natural rights based on the moral principles of respect for persons, beneficence, and justice. Whether it did so intentionally or even knowingly, the Working Group turned to natural rights to fill the gap in existing laws[272] intended to protect vulnerable research subjects, for the purpose of creating an institutionally recognized positive right in the form of legislation. The Working Group intuitively recognized that the right to personal security in one's body and health is one of the basic natural rights "necessary for a community to exist" and is thus a putative positive right according to Stoljar.[273]

However, talk of natural or basic rights is futile if unaccompanied by notions of equality. Equality generally ascribes to each human being "the same intrinsic worth or dignity."[274] Therefore, "the equality of individuals rests in the end on their individual human value, regardless of their personal merits or skills."[275] The idea that equality rests upon "intrinsic worth," as equality relates to natural rights, however, is not without criticism because "personal variations" of individuals' merits or

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[267] SAMUEL J. STOLJAR, AN ANALYSIS OF RIGHTS 74 (1984).

[268] *Id.*

[269] *Id.*

[270] *Id.*

[271] *Id.* at 75.

[272] *See supra* text accompanying notes 115-19; *see also Bioethics: Surrogates Could Enroll Cognitively-Impaired Subjects in Research Under Proposed Md. Statute*, BLUE SHEET, June 4, 1997, *available in* 1997 WL 20998315 [hereinafter *Bioethics*] ("Regarding the scope of the proposed statute, [Jack] Schwartz [of the Maryland Attorney General's Office] admitted it 'does not address overall inadequacies in the system. . . . The Maryland effort is intended to fulfill a particular gap in the common rule. It's not intended to rewrite it.'").

[273] STOLJAR, *supra* note 267, at 79.

[274] *Id.* at 81.

[275] *Id.* (footnote omitted).

skills are numerous.[276] Therefore, even if the argument is put forth that individuals do not have the same worth or equality because their merits or skills are greater or lesser than others' merits or skills, "there is one area in which they are, or at least have to be treated as equal, this being the area of *their actions to each other*."[277] This notion of equality that each human being must treat others as equals and must be treated as an equal in return comports with the theory of reciprocity in natural rights and duties,[278] thus placing the weak on equal footing with the strong to have their bodies and health protected.

If natural rights are to prove effective as a basis for positive rights, they must be implemented within a framework of the equality concept described above. Although grasping for a foundation in natural rights, the Bill steeps this natural rights foundation in a framework of utilitarianism rather than equality. According to utilitarian theory, the ultimate goal is to produce as much good as possible, "no matter where it is found, nor whose it is."[279] Because most actions produce both good and bad results, the utilitarian's duty is "to produce the maximum balance of [good] over [bad] in as many people as possible."[280] Underneath the Bill's stated intent to protect vulnerable subjects lurks the utilitarian mindset that using and ultimately sacrificing just a few in the name of medical advancement is acceptable and even desirable, given that society will benefit, regardless of whether the research subjects benefit. This is evidenced by the Bill's position favoring use of research subjects in high-risk studies that do not directly benefit them, as well as the Bill's stated purpose that such research is necessary to develop a body of generalizable knowledge about brain disorders.[281] Also, the Bill provides civil and criminal immunity for those who conduct medical research protocols,[282] thus widening the polarity between the weak and the strong. Little equality and even less protection of natural rights, particularly with respect to individuals' treatment of each other,[283] is achieved under such a legislative scheme.

Additionally, natural rights are "inalienable"; that is, such rights as to life, limb, health, and property are so basic to a person's ability "to pursue his life compatibly with the similar interests of others," that they

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[276] *Id.* at 82.

[277] *Id.* at 82-83.

[278] *See supra* text accompanying notes 265-66.

[279] JAN NARVESON, MORALITY AND UTILITY 14 (1967).

[280] *Id.*

[281] *See supra* text accompanying notes 240-45.

[282] *See supra* text accompanying notes 249-50.

[283] *See supra* text accompanying notes 277-78.

cannot be renounced.[284] Basic inalienable rights are protective in nature, whereas alienable rights are transactional in nature.[285] "[T]his protective role makes basic rights inalienable; we would simply not effectively protect someone as an equal and free individual in a group if his equality and freedom were merely optional."[286]

Discussion of natural rights cannot take place in a vacuum as applying only between two individuals. The community's role in protecting natural rights must be considered as well:

> Unless a community performed this task, protecting its members' rights to live, to go unharmed, to keep property, or to make complaints, there would be little or no purpose for rights: social organisation would be a form of life in which the strong control the weak, without very much occasion for talk about morality.[287]

However, there must be no misunderstanding that the importance placed on the community's role in protecting natural rights is an application of utilitarianism wherein the individual is forsaken and sacrificed for societal good. Nor should there be any contemplation that these natural rights are mutable, depending upon an individual's merits or skills. Rather, a community's survival depends upon affording protection to its citizens under a framework of immutable tenets based on natural law. Otherwise, the community will self-destruct as Stoljar elucidates in the following excerpt:

> [T]he whole point of relating the individual to a community via a notion of rights is to make society into a sort of guarantor of relatively peaceable conditions under which a person can live in relative freedom simply because he can argue as an equal amongst other individuals. Suppose we adopted . . . a decidedly meritarian policy in which only the élite, but not the so-called riff-raff, would have rights. The [élite] would now be able to dispose of all those who, because of lesser achievements, fail to measure up, and, for that very reason, are declared to be rightless. So the élite, respecting only merit, however assessed, could hunt their inferiors as farmers hunt rabbits or other undesirable pests. Nor is there, on principle, any limit to this process of selection. The merits may change as fashions do: today the *A*s may hunt or enslave the *B*s; tomorrow a section of *A*s may do the same against other *A*s suddenly declared inferior. Such total meritarianism then transpires to be a policy which, carried to its ultimate conclusion, becomes a prescription for self-destruction rather than for maintaining any sort of community. Such communities as survived would be based on preferential contingencies, and not on moral principle which is not

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[284] STOLJAR, *supra* note 267, at 90.

[285] *See id.* at 91. Examples of transactional alienable rights that may be traded or transferred include the right to waive or renounce a debt and the right to make a gift of one's money or other possessions. *See id.* at 90.

[286] *Id.* at 91.

[287] *Id.* at 88.

> liable to change in the same way, its aim being precisely to preserve a community by maintaining the equality of its members, through maintaining the rights of the non-preferred.[288]

The preceeding analysis of natural rights, particularly as they relate to the decisionally incapacitated individual's right to personal security of his or her body and health, raises the final question of whether decisionally incapacitated individuals should participate in medical research at all. If so, then the question arises of which decisionally incapacitated individuals should participate and what type of protection should be afforded to them. Recognizing that medical research is necessary to advance medical treatment and life-saving protocols, this comment should not be taken as promoting an "anti-medical-research" position. Rather, as one Bill critic succinctly stated, "it is an 'anti-*unethical* scientific research' position. There is a difference."[289] This critic "does not mean that research in mental diseases or any other mental disorders must come to a grinding halt—only that the *process* of 'scientific progress' must be ethical *as well as the intended goal*, even if it takes a little longer."[290]

Because the study of decisionally incapacitated individuals may reveal significant insight into their conditions and the best way to help them, this writer asserts that their participation in medical research may be effected by a legitimate legally authorized representative, but only when the research poses no more than a minimal risk[291] to the individual and is of the same direct medical benefit as standard available medical treatments. This caution-bearing premise is echoed by at least two writers in the medical research field—both writers are critics of the Bill, and one was a member of Maryland's Working Group.[292] "In any other research [that poses more than minimal risk or is of no direct medical benefit to the individual], participation should be authorized by a court of law."[293] A recent New York case upholds this position as evidenced by the following excerpt:

> What is most objected to are the provisions for substituted consent by surrogate decision makers. Courts tread cautiously when third parties

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[288] *Id.* at 88-89.

[289] Irving, *supra* note 123, pt. IV (emphasis added).

[290] *Id.* (emphasis added).

[291] *See supra* note 222.

[292] *See* Irving, *supra* note 123, pt. IV ("[O]nly minimal risk specified research for the direct benefit of a particular patient could be ethically consented to, and then only if the research holds out at least as much direct benefit as available standard medical therapies, and only as consented to by a legitimate legally authorized representative."); *see also* Ervin, *supra* note 253 ("Shamoo, who was a member of the working group, . . . says he personally objects only to research with decisionally incapacitated people when it presents 'greater than minimal risk' for the patient and promises no direct medical benefit.").

[293] Irving, *supra* note 128, pt. IV.

> are relied on to make decisions for an incapable patient . . . , especially where the patient's wishes are unascertainable. . . . When the proposed medical course does not involve an emergency and is not for the purpose of bettering the patient's condition, or ending suffering, it may be doubtful if a surrogate decision maker—a guardian, a committee, a health-care proxy holder, a relative, or even a parent—could properly give consent to permitting a ward to be used in experimental research with no prospect of direct therapeutic benefit to the patient himself.[294]

V. CONCLUSION

The Bill "was killed by the Maryland Senate Judicial Proceedings Committee March 22[, 1999,] following a hearing at which patient advocates characterized the [advance directive] provision[s] as 'an invitation to coercion and abuse.'"[295] At the hearing, "22 witnesses testified, with 12 against and 10 in favor of the bill."[296] The researchers seeking medical advancement and the human rights interest groups put forth their best arguments at the hearing. "[T]he bill faced opposition from those who feared it did not provide enough protection and from people who 'deemed it altogether too restrictive.'"[297]

After the Bill's 1999 defeat, Maryland's Assistant Attorney General, Jack Schwartz, prepared a revised version of the Bill for presentment to Maryland's legislature in 2000.[298] Provisions for research advance directives were removed from the Bill to improve its chances of gaining wide support.[299] "The [revised] version still maintain[ed] investigators must obtain informed consent from a legally authorized representative but no longer outline[d] legal authority with reference to risk categories."[300] According to Assistant Attorney General Schwartz, "[t]he modification [would] allow investigators and institutional review boards

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[294] T.D. v. State Office of Mental Health, 626 N.Y.S.2d 1015, 1020 (Sup. Ct. 1995) (citations omitted).

[295] *Maryland Attorney General Floats Revised Research Subject Protection Bill*, BLUE SHEET, Oct. 27, 1999, *available in* 1999 WL 10784154 [hereinafter *Maryland Attorney*].

[296] *Advance Directive Derails Decisionally Impaired Subject Protection Act*, BLUE SHEET, Apr. 7, 1999, *available in* 1999 WL 10783633.

[297] *Id.*

[298] *See* E-mail from David Brewster, Staff Member, Maryland Senator Brian Frosh's Office, to author (Mar. 22, 2000) (on file with author) [hereinafter Brewster's March 2000 E-mail].

[299] *See Maryland Attorney, supra* note 295 ("The revised bill omits earlier language stating that 'an individual . . . may execute a research advance directive' that describes 'the research in which an individual is willing to participate if the individual is or becomes unable to give informed consent.'").

[300] *Id.*; *see also supra* text accompanying notes 178-83, 197-231.

'to sort out these matters . . . without the detailed guidance' the earlier bill 'sought to provide.'"[301]

This writer fails to see how the removal of advance directive provisions, which are, according to Assistant Attorney General Schwartz, hypothetical in reality,[302] accompanied by removal of risk categories, enhances the Bill's alleged intent to protect decisionally incapacitated individuals' participation in medical research. Rather, such stated motivations smack of nothing less than intent to do whatever is necessary to get the Bill passed. The human rights interest groups' arguments were strong enough to defeat the Bill at its initial introduction and remained strong enough to make Assistant Attorney General Schwartz rethink his decision to introduce the Bill's revised version.[303] The revised Bill was not introduced in Maryland's recent legislative session.[304]

Lord Macmillan wrote that "[t]he appeal of law is in the last resort to the conscience of mankind."[305] As with so many other controversial issues such as abortion, affirmative action, animal rights, child abuse, euthanasia, military actions, and the like, the use of vulnerable subjects in medical research tugs at one's conscience as well. This comment provides support for the premise that the Bill actually dehumanizes individually incapacitated individuals rather than protecting their rights to be secure in their bodies and health, as the Bill's title claims. That dehumanization comes in the form of a hierarchy of legally authorized representatives who can enroll individually incapacitated individuals in medical research, despite the fact that those individuals' wishes may not

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[301] *Maryland Attorney, supra* note 295.

[302] *See Bioethics, supra* note 272. According to Assistant Attorney General Schwartz, "an advanced directive specifically addressing research participation . . . [is] a perfectly hypothetical document—except possibly on the campus of NIH [National Institutes of Health]. No one's seen an advanced directive specifically addressing research participation." *Id.*

[303] Maryland Senator Brian Frosh sponsored Senate Bill 307. According to David Brewster, a member of Senator Frosh's staff:

> SB 307 wasn't introduced this year. The Maryland AG's office did much of the work on the legislation. The Assistant AG responsible for the project, prepared a streamlined version of SB 307 for introduction this year. But the new version really didn't crack the wall of opposition we ran into last session. Faced with what he thought w[a]s certain defeat in Committee, he advised against introducing the bill.

Brewster's March 2000 E-mail, *supra* note 298.

[304] *See* E-mail from David Brewster, Staff Member, Maryland Senator Brian Frosh's Office, to author (Aug. 16, 2000) (on file with author). Mr. Brewster states that the Bill "was introduced in 1999. Nothing similar that [he knows] of was introduced during the recent session." *Id.*

[305] LORD MACMILLAN, *Law and Ethics, in* LAW & OTHER THINGS 36, 42 (photo. reprint 1997) (1937).

be known or may be contrary to the legally authorized representative's ultimate decision. "The exploitation [of decisionally incapacitated individuals] deemed to be inferior [is] condemned [no] more [in the Bill] than the killing of steers in a slaughterhouse."[306]

Lord Macmillan suggests that "[t]here is nothing more detrimental to the moral order of society than that its laws should not commend themselves to the conscience of the people."[307] In support of his premise, Lord Macmillan memorialized the words of "Dr[.] Nicholas Murray Butler, the courageous and outspoken president of Columbia University, [who] declared that 'The law whose infraction calls out the overwhelming disapproval of public opinion is a good law. The law that does not call out that disapproval is a bad law. When conduct and the law are at odds the fault may be with the law.'"[308]

The conduct proposed by the Bill is at odds with the law of natural rights as well as the human conscience. Thus, the logical conclusion is that the fault is with the Bill. The Maryland Senate Judicial Proceedings Committee properly refused presentment of the Bill's original version, and Assistant Attorney General Schwartz wisely refrained from introducing the revised Bill a second time. A return trip to the drafting desk is in order for the Bill if Maryland's true intent is to protect decisionally incapacitated individuals' participation in medical research.

Kendall Ann Desaulniers

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[306] HERBERT SCHLOSSBERG, IDOLS FOR DESTRUCTION 288 (1990).

[307] MACMILLAN, *supra* note 305, at 44.

[308] *Id.* at 45.