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PLURALISTIC CASUISTRY

MORAL ARGUMENTS, ECONOMIC REALITIES, AND POLITICAL THEORY

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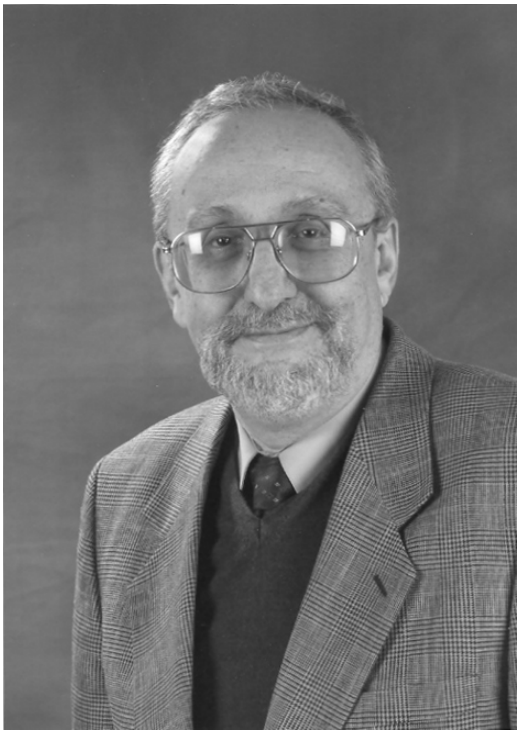

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The volume is dedicated to the life and work of our teacher: Professor Baruch A. Brody, a true scholar among scholars, whom we thank for granting us permission to prepare this festschrift in his honor.

CHAPTER 1

MORAL CASUISTRY, MEDICAL RESEARCH AND INNOVATION, AND RABBINICAL DECISION-MAKING

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I. A PHILOSOPHICAL INTRODUCTION

> The scope of bioethics has expanded over the years from its original emphasis on questions arising out of clinical encounters and biomedical research to an increasing emphasis on questions about health policy and health care reform. I have long been convinced, however, that even this expanded scope is still conceived far too narrowly. While few technological advances in medicine take place without public commentary by bioethicists, major structural changes in the delivery of health care or in the conduct of biomedical research often go unnoticed by the bioethics community, despite the fact that these changes often raise profound moral and social issues (Brody, 1996, p. 5).

The impressive range and depth of Baruch Brody's writings in biomedical ethics and the philosophy of medicine illustrate his deep appreciation that thorough and critical scientific research and philosophical analysis are central to reigning in the untutored human desire to ameliorate pain and suffering so that medical treatments and health care policy do more good than harm. On the one hand, medicine must abandon the presupposition that customary or accepted treatments are good simply because they are customary and accepted.[1] Nor, should medicine assume that new pharmaceuticals and medical technologies constitute the best practices simply because they are new. And, on the other hand, well-meaning but heavy handed paternalistic and moralistic public policy, frequently given social political credence through the endorsement of bioethicists, has at times failed to protect the long term interests of persons. For example, if medical practice is to advance, if there is to be development of more efficient and effective pharmaceuticals and medical devices, there must be significant incentives to stimulate innovation: medical advancement requires

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an engine for innovation. Yet, as Brody recognizes, one must both overcome the usual chronic menace to innovation—the interests of the status quo in suppressing change[2]—and correct for the ill consequences resulting from the all too human impulses to increase professional status and income, wield social political authority, and to help those in need. As the history of medicine pays witness, the human suffering caused by ill-founded, but well-meaning interventions—both medical and political—have been significant.

As the contributions to this volume consistently illustrate, few who work in biomedical ethics are as well aware of the moral and political challenges that medical research and bioethical policy represents as Baruch Brody. He has recognized, where others have failed adequately to do so, the intimate connection between bioethics and other areas of philosophy: e.g., political theory, metaphysics, epistemology, axiology, and the philosophy of religion. His appreciation of the importance of such connections has led to his critical exploration of core questions, which others have failed to appreciate. This skillful analysis time and again permitted the fields of bioethics, the philosophy of medicine, and health care policy to see seemingly intractable problems in a new light. Such philosophical insights frequently led to very practical solutions to medical and political challenges. Indeed, Brody has called for bioethical reflections to be deeply philosophical *so that* they can be practical (Brody, 1989).

Contrary to a common stereotype of philosophy professors, philosophical analysis does not inevitably lead to abstract insights and utopian recommendations. Instead, done well, philosophical work can clarify complex issues, facilitate creative problem solving, and lead to real-world solutions to difficult situations. Brody's work exemplifies the ways careful philosophical examination of biomedical issues can help generate practical solutions. He has been one of the most important voices in bioethics over the last several decades, asking new and challenging questions about a range of problems, examining recalcitrant issues in novel ways, always with the goal of offering practical solutions to complex problems. A number of contributors to this volume address Brody's epistemological and methodological contribution to bioethics, namely his normative moral theory—pluralistic casuistry (Kelley, Wildes, Malek, McCullough)—and his discussions of Jewish medical ethics (Engelhardt, Lustig). Others critically reflect on many of the areas he has addressed or employ his model of bioethical analysis to analyze particular issues, including human embryo transfer (Brakman), medical futility (Arnold), life and death decisions in pediatrics (Zoloth), euthanasia and end-of-life decision-making (Kamm, Kopelman), the obligations of clinical researchers toward study participants (Morreim), and professional integrity (Parker). Brody also has made important contributions to discussions of philosophy of law, philosophy of medicine, philosophy of religion, metaphysics, epistemology, abortion, access to health care and justice.

In this brief introduction to Brody's contributions to the field of bioethics, we draw the reader's attention to two areas in which he has made especially important contributions—human research ethics and end-of-life decision-making—to illustrate the relationship among Brody's normative moral theory, his careful analytic work,

and the crafting of practical solutions to complex bioethical problems. Thereafter, we encourage readers to address the chapters throughout this volume, as each carefully and critically assess in greater detail Brody's philosophical thought and bioethical research.

II. RESEARCH ETHICS

> These observations are about research in developing countries in general, and not just about research on vertical transmission [of HIV]. Three lessons have emerged. The standard for when a placebo group is justified is a normative standard (what they should have received if they were not in the trial) rather than a descriptive standard (what they would have received if they were not in the trial). Coercion is not a serious concern in trials simply because attractive offers are made to the subjects. Legitimate concerns about exploiting subjects should be addressed by ensuring their future treatment, rather than by asking what will happen in their community at large (Brody, 2002a, pp. 2857–2858).

Throughout much of the 20th century, concerns emerged about the ethical conduct of biomedical, behavioral, and social sciences research on human beings, often because of specific practices and problematic cases that became widely known.[3] Research ethics has become a major sub-field within bioethics, and Brody has made significant contributions to a number of debates, often identifying issues and questions not previously addressed or creating pathways for resolving disagreements over what is and is not permissible. Some of the most important issues he has addressed include ethical issues regarding controlled clinical trials in general (e.g., Brody, 1995 and 1998a) and placebo controlled trials in particular (1997a; 2003), including trials that call for placebo surgery (Moseley et al., 2002); research in developing nations (2002a and b); emergency research (1997b); informed consent (2000; 2001); research on vulnerable subjects (1998b); and the recruitment of human subjects (2002c). Brody also has helped us understand and evaluate the regulation of biomedical research, the drug approval process (1995), and intellectual property and technology transfer law in the United States (2006), as well as research ethics guidelines and regulations from around the world (1998a). Here we consider his contributions to the field regarding consent for emergency research and conflicts of interest, where he has made extraordinarily important contributions to the literature and where the rigor of his philosophical insight combined with his commitment to resolving conflicts and crafting practical solutions are evident.

To provide safe and effective medical care, interventions must be evaluated and tested using research methods, and to use humans in research generally requires the consent of the research subjects, or, in the case of non-competent humans, permission of their legal guardians or representatives. For many years, the need for research coupled with the importance of consent or permission made it nearly impossible to conduct research on emergency treatments. Observing that overall it is not in the public interest that new treatments for life-threatening emergency medical conditions either not be developed or not be tested prior to widespread use, in 1996 the Food and Drug Administration (FDA) issued regulations that

would allow institutional review boards (IRBs) to waive or alter informed consent requirements for some emergency research under specific, narrow conditions (FDA, 1996). Controversy surrounded and continues to surround such waivers (see, for example, Kipnis, King, and Nelson, 2006; Carnahan, 1999; Fost, 1998; Biros et al., 1998; Karlawish and Hall, 1996). In the wake of the new regulations, Brody offered one of the most cogent defenses of waivers of consent for emergency research and he predicted accurately some of the areas that would pose the most difficulty in interpreting and applying the regulations (Brody, 1997b). As with so much of his work, Brody focused his analysis of the ethics of emergency research on the non-ideal nature of medicine and the statistical nature of medical knowledge, on the need to make decisions and promote the good of individuals and society in an imperfect world, and on the multiplicity of values that ought to be respected:

> (a) the desperate social need for research in the emergency setting to test promising treatments for patients presenting with acute crises such as strokes and closed head injuries for which there are few treatments of proven value that can limit the damage; (b) the potential benefit to some patient-subjects (those in the treatment group) who receive promising new therapies if those therapies fulfill their promise; (c) the need to protect these individuals from being exploited and harmed by researchers when (as often happens) promising new therapies do not fulfill their promise and turn out to be harmful; (d) the right of all individuals not to be used as research subjects without their consent or the consent of those who speak for them (Brody, 1997b, p. 7).

In ideal circumstances, it would be possible to respect all of these values, but, Brody argues, emergency circumstances sometimes make it impossible to do so. Furthermore, he holds, these values cannot be rank-ordered in an absolute fashion. Instead, their significance in individual cases or circumstances must be assessed and a judgment made. The moral world, Brody has long argued, is not governed by absolute values but by a series of independent, non-absolute values. He argues that the FDA regulations reflect the importance of pluralism as well as of assessing and comparing the significance of competing values. Sound ethical judgment requires that we consider competing values when it is not possible to respect them all fully. The FDA regulations on emergency research, Brody argues, reflect just such a consideration competing values. They acknowledge the importance of research subject consent but recognize that sometimes it is not possible to fulfill the need for certain types of biomedical research and grant individuals access to potentially beneficial interventions, if one must obtain consent. The regulations also acknowledge the possibility of exploitation and the need to protect persons from exploitation by requiring community consultation.

Brody's assessment of the ethical issues regarding research in emergency settings reflects his emphasis on the importance philosophical analysis has for generating practical solutions to serious issues. Brody defends the FDA regulations on emergency research by returning to his philosophical account of the moral world according to which multiple values are relevant and at stake. The consideration of competing values relevant to emergency research justify the FDA regulations permitting waivers of consent in some cases, Brody argues. At the same time, those regulations leave open important questions that also must be addressed, such as

the permissibility of conducting placebo-controlled trials with waivers of consent. Resolution of these concerns will require careful deliberation using the same process of identifying the competing underlying values and assessing their relative significance. Ethical concerns emerge because there are multiple values that, in an ideal world, all would be fully respected. In our non-ideal world, we must identify those values and assess their relative significance. Doing so, Brody has demonstrated, allows us to build practical and ethically sound solutions.

Failure adequately to analyze the nature of ethical controversies puts us at risk for trying to solve the wrong problem, leaving undiscovered related ethical concerns, ignoring morally significant dimensions of issues, and missing potential mechanisms for resolving controversies. Understanding the nature of ethical controversies is a necessary first step toward crafting sound and practical solutions. In examining conflicts of interest in research, for example, Brody's analysis demonstrates that the scope of issues related to conflicts of interest are much broader than typically acknowledged. Much of the literature on conflicts of interest in research focuses on financial conflicts of interest, such as stock ownership and consulting/speaking fees, which may affect investigators' decisions to enroll subjects into studies and the integrity of data, potentially compromising subject safety and the validity of results. These issues are, according to Brody, both real and significant. But they hardly represent the full range of concerns raised by conflicts of interest in research. Conflicts of interest, Brody argues, can affect a number of other decisions, including:

> (1) Which treatments will be tested in the proposed trial, and which will not be tested?; (2) Will there be a placebo control group as well, or will the treatments be tested against each other or against some active control group?; (3) What will be taken as the favorable endpoint (the result constituting the evidence of the dangerousness of the treatment)?; (4) What will be the condition for inclusion or exclusion of subjects from the trial?; (5) What provisions will be made for informed consent?; (6) Under what conditions will the trial be stopped or modified because there have been too many adverse endpoints in one or more arms of the trial or because the preliminary data have shown that one of the treatments is clearly the most efficacious treatment?; (7) Under what conditions will the trial be stopped or modified because of the newly available results of other trials?; (8) Which patients who meet the criteria will actually be enrolled, and which ones will not? (Brody, 1996, p. 409).

Until we acknowledge the full range of sources of conflicts of interest and the many ways in which such conflicts can affect the research enterprise, it will remain impossible to manage such conflicts appropriately or to understand the impact they may have on research results (Brody, 1996, p. 407).

Brody's analysis of the scope and impact of conflicts of interest in trials of various thrombolytic agents demonstrates that to focus strictly on stockholding and other financial relationships between investigators and sponsors will lead one to miss important areas of conflict and thus to propose inadequate solutions (Brody, 1996, p. 408). Much of the anxiety over conflicts of interest typically concerns financial conflicts that, some fear, will result in fraud. This, Brody argues, is not where our energies should be focused. Instead, he says "the concern should be with how conflicts of interest may lead investigators, perhaps unconsciously, to make

inappropriate decisions about the design and conduct of clinical trials" (Brody, 1996, p. 408). Fraud, he argues, can be managed relatively well through a number of mechanisms, such as double-blinding and independent data analysis. As noted, the focus of concerns to control for potential conflicts of interest should be the many decisions about trial design and study implementation that can affect the outcome of a study. Once we understand the multiple ways in which conflicts of interest can affect research, we might find ourselves convinced that the obvious solution is to abolish them or to require disclosure of conflicts so as to alert readers that they should be cautious in their reading and interpretation of study results. He argues that the various "obvious" solutions that have been proposed are flawed because they focus on commercial relationships, such as stock ownership and consulting or speaking fees, rather than on broader conflicts, such as those generated by the importance of grantsmanship and of grant/sponsorship income for physician practices, departments, and institutions (Brody, 1996, pp. 413–414). They reflect an incomplete analysis of the problem. Thus, Brody argues, we need more data on how much profit grants/sponsored studies generate so that we can develop "detailed guidelines for avoiding conflicts of interest from grant income" (Brody, 1996, p. 416). In evaluating approaches to conflicts of interest in research, we should heed Brody's call to identify and assess the multiple values relevant to ethical analysis of an issue and refrain from treating our interest in avoiding the difficulties associated with conflicts of interest as absolute.

If one applied Brody's framework for analyzing competing values, in developing such guidelines one would want to consider the value of a research enterprise free of conflicts of interest as well as relevant values, such as the importance of an efficient and effective research enterprise. We would need critically to assess the relative significance of each of those values and consider how different proposed responses to conflicts of interest in research would respect such competing values. Brody is careful to point out that to craft a solution requires empirical evidence we lack; to attempt to solve a problem without acknowledging the multiple values at stake and without facts about the current circumstances and thus the ways in which different proposals might affect those values is irresponsible.[4]

III. END-OF-LIFE CARE

> There is, moreover, a practical reason for such an approach. The varying criteria for brain death were developed in response to the emergence of life support systems and transplantation technology. Three basic clinical questions emerged. One question is old: When is a patient ready for the services of the undertaker rather than those of the clinician? Two questions are new: When is it appropriate to *unilaterally* stop supporting patients (as opposed to stopping support at the request of a patient or surrogate)? and When can organs be obtained for transplantation? (Halevy and Brody, 1993, p. 523).

As Brody is aware the determination of "death" is not merely descriptive, as if it straightforwardly described an objective fact of the world; but is in addition both evaluative and performative. The now classic fourth edition of *Black's Law Dictionary* defined death as "the cessation of life; the ceasing to exist; defined by

physicians as a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereon, such as respiration, pulsation, etc." (4th ed., rev., 1968). This description of whole body death emphasizes the presence of circulatory and respiratory functions. The advent of intensive care units and respirators capable of sustaining brain-dead but biologically alive bodies and the significant costs that such treatment engendered, placed whole body definitions of death under intense conceptual scrutiny. Developments in kidney transplantation in the 1950's and heart transplantation in 1967 further underscored a perceived need conceptually to place the death of the person over against the death of the human body—i.e., a need for a brain oriented definition of death. As the transplantation community well understood, brain dead, but otherwise biologically alive, human bodies could be excellent sources of transplantable organs. In 1981, the *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research* endorsed a change that would incorporate the importance of brain stem function for the life of persons into its definition of death: "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem is dead. A determination of death must be made in accordance with accepted medical standards" (1981, p. 3). With brain death whatever is distinctly personal in the organism is dead. Both *Black's Law Dictionary* and the *President's Commission* point to physician judgment and medical standards for the declaration of death.

The determination of death is a performative judgment: it changes the social significance and place of the human body. Dead bodies are not treated as living persons. Thus, as Brody notes, controversies regarding defining the moment that "death" occurs turn on how little life activity, and of what kind, may remain before the person may appropriately be declared dead. To be alive is to be able to gear into the world of experience and action, where death is characterized by the irreversible loss of those characteristics that are essential and necessary to be so engaged. Yet, the debate among whole-body-oriented, whole-brain-oriented, and neocortical-oriented definitions of death turns on this very question of how much life activity, and of what type, is essential to sustain the life of a person. As Brody lays out these three competing definitions: Death can be understood as the 1) "permanent cessation of the flow of vital bodily fluids" (whole-body death); 2) "permanent cessation of the integrative functioning of the organism as a whole" (whole-brain death); or 3) "permanent loss of what is essential to the nature of humans" (neocortical-oriented or higher-order brain death) (Halevy & Brody, 1993, p. 520). The President's Commission, Brody notes, chose to focus on whole-brain death, in part because of the brain's primacy in integrative functioning and partly because the brain is the sponsor and location of human consciousness.

While many continue to urge the adoption of a higher-order brain death criterion, Brody has argued that the challenge of a neocortical-oriented brain criterion is that there is no wide-spread consensus on what portions of the brain are required for

cognition and consciousness; moreover, even when such sites can be found, their cessation often cannot be assessed with the certainty that a legislative and statutory definition requires (1993, p. 519). Here, the challenge even to whole-brain death, Brody concludes, is a set of adequate medical tests:

> A review of published reports about brain death shows that many patients who meet the standard clinical tests for brain death still maintain some brain functioning and therefore do not satisfy the whole-brain criterion of death. Three areas of persistent functioning are neurohormonal regulation, cortical functioning as shown by significant nonisoelectirc electroencephalograms, and brain stem functioning as shown by evoked responses (1993, p. 520).

A difficulty with the standard definition of whole-brain death is that it treats the line between life and death as if it were a sharply defined physical moment, and then attempts to identify that moment with the lose of brain function. However appealing, Brody argues, such an attempt fails to recognize the complexity of the dying process:

> The data we have presented challenge this consensus by showing that different aspects of brain functioning cease at many different times. Thus, any sharp dichotomy between life and death based on brain functioning, although convenient and appealing, is biologically artificial (1993, p. 523).

What is needed is more careful philosophical appreciation of the types of questions that are being asked and the appropriate physical and medical context for answering them. If death is appreciated as a process, such as irreversible cessation of conscious functioning, satisfaction of clinical tests for brain death, and asystole, then particular concerns, such as unilaterally withholding treatment, harvesting organs, and burying the body, can be addressed separately with more careful nuance. The implications of such an approach to understanding death and the dying process are significant.

Consider, for example, its implications for the allocation of scarce health care resources to patients in a permanently vegetative state (PVS). While some have argued that care can be withheld from permanently vegetative patients because it is futile, as Brody has noted, if the goal of the patient's family or surrogate decision-maker is the extension of mere biological life, then care of a permanently vegetative patient that accomplishes this goal is not futile.[5] Others have argued that patients in PVS may, at least sometimes, be permissibly euthanasized.[6] Others argue that PVS patients should simply be understood as dead and thereby be so declared. Life-sustaining therapy can be unilaterally withheld from patients who have died, without the need for any elaborate decision-making process. The challenge is that PVS patients remain living human beings, and do not even have a terminal illness in the usual meaning of the term, since they can go on living for many years if they are given certain types of medical care, such as artificial nutrition and hydration. Unless consensus is reached regarding higher-order brain death criteria, which is unlikely, PVS patients may not permissibly be declared "dead" without straightforwardly begging the question.

Here Brody argues that it is unnecessary fully to resolve the controversies regarding medical futility, permissible euthanasia, or higher-order brain death,

adequately to address the issues which the care of PVS patients raises: "Because PVS patients are not persons, in any plausible account of personhood, society should give their life-prolonging care a very low priority as it develops priorities for the allocation of health care resources, and individual providers should give them a very low priority in clinical triaging decisions" (1992, p. 104). If care of PVS patients is seen as regarding the allocation of resources, rather than a definition of death issue, then given scarce medical resources:

> appropriate use of social resources should serve as the justification for the unilateral withholding or withdrawing of care. For example, irreversible cessation of conscious functioning is a point on the continuum where the need to rationally use societal resources outweighs the desires of some persons for unlimited care. In such cases, the question of the unilateral withholding or withdrawing of care can be answered without any appeal to a criterion for death (1993, p. 524).

While this position may give rise to further questions regarding the appropriate use of scarce health care resources and whether individuals may permissibly purchase additional care for PVS patients utilizing private resources, the discussion is more appropriately focused on the permissible use of public resources verses private resources as well as on maintaining the integrity of the medical profession.[7] Whereas some hold that PVS patients constitute among the most vulnerable members of society and that their basic dignity requires that they be kept alive more or less indefinitely, even on artificial nutrition and hydration, it may still be appropriate to place limits on the use of public funds to care for PVS patients, leaving such extended and potentially very expensive care to private resources, if available.[8]

Consider also organ harvesting. Some commentators have begun arguing in favor of utilizing higher-order brain criterion of death because it would enable the harvesting of a greater number and healthier vital organs for transplantation.[9] Here Brody argues that the question of when it is appropriate to harvest human organs should not be confused or conflated with the very different question of how to conceptualize death. What really is at stake, he argues, is a balancing of the public acceptance of organ harvesting with encouraging the availability of organs for transplant to save lives:

> The shortage of available organs has led to the consideration of using organs from vegetative patients and to the proposal that we use organs from anencephalic infants. It might be suggested that organs can be obtained from such patients if we adopt a new criterion for death. We rejected that argument above. *But we also feel that the criterion for death is not where the discussion should be centered*. For us, it should center around the attempt to balance the advantage of lives saved through increased organ availability (which argues for harvesting in such cases) against the need for public acceptance of organ donation (which may require forgoing harvesting organs in such cases). We feel, in view of these considerations, that the combination of irreversible cessation of conscious functioning with apnea is the appropriate point on the continuum for organ harvesting. This is, in fact, close to the point at which we currently harvest organs, using the whole-brain criterion and the standard clinical tests (Halevy and Brody, 1993, p. 524, emphasis added).

The attempt to redefine death so as to be able to harvest organs from living humans is deeply to misunderstand—or even culpably to misrepresent—this core metaphysical and moral issue. If we begin taking internal organs from living humans, then the proximate cause of death is not the underlying disease or infirmity, but the act of taking the vital organs. It is, in effect, an attempt to side-step the dead donor rule, by broadening the definition of who is considered to be dead. Still, it may make sense to rethink the dead donor rule, and to permit the earlier harvesting of vital organs, at least with the consent of the individual or surrogate decision maker, and the transplant team.

Similar, very practical questions can be raised about when to call the undertaker. We might be comfortable with declaring death once the criteria for whole-brain death are met, and even unilaterally to withdraw and to withhold care. Some might even be comfortable with the higher-order brain death criterion. But, are we comfortable calling for the undertaker? "Little is to be gained in terms of conserving social resources by using the services of the undertaker before the classic criterion [whole-body death] is met because the social costs of minimal care are relatively low and do not outweigh respecting the intuitive social feeling that breathing bodies should not be cremated or buried" (Halevy and Brody, 1993, p. 524). Since in each case we are asking quite different questions (when unilaterally to cease care, when to harvest organs, when to call the undertaker) it is not unreasonable to believe that we will reach quite different moments on the continuum from life to death as plausible answers.

IV. PHILOSOPHICAL AND BIOMEDICAL IMPACT

A. Pluralist Moral Casuistry

> The tremendous scientific and technological advances of the second half of the twentieth century have given physicians and other health-care providers the ability to keep patients alive who would have died relatively quickly in the past. Successful techniques for resuscitating patients whose cardiopulmonary functioning has ceased, for monitoring and responding to major organ failures in the intensive care unit, and for transplanting kidneys, livers, and hearts all exemplify the advances in medical knowledge and technology that have enabled patients to survive for a considerable period of time. …Physicians and other health-care providers, patients and their families, and the general public eventually came to accept the idea that the technological imperative which urges the use of these techniques on all occasions should be resisted. Out of that recognition arose one of the fundamental problems of modern biomedical ethics; when to strive to preserve the life of the patient and when to simply allow the patient to die (Brody, 1988, p. 3).

The first brace of chapters articulate, explore, and critically assess Brody's foundational moral theory: pluralistic moral casuistry. As Laurence McCullough argues, Brody's articulation of a pluralistic moral theory is not premised on the assumption that single-component moral theories, such as those that appeal uniquely to consequences, or to rights, or to virtues, and so forth, are necessarily false. Rather, each failed adequately to account for the complexity of the moral world because

it recognized only one of the many legitimate and core moral appeals; i.e., each appealed to only a portion of the truth. Brody's theory underscores the complexity of the fundamental philosophical questions regarding the moral world, including his willingness to acknowledge, at times, the existence of deep moral ambiguity, Kevin Wm. Wildes, S.J. notes; it thereby "…provides a sharp challenge to the desire for simplicity and sound bite answers" (p. 39). It is, as McCullough makes the point, by combining each of the various moral appeals that Brody has been able critically to articulate and defend the use of his moral theory. It is the theory's ability to capture important elements of our moral experience and to utilize those various elements, through the careful consideration of different appeals, in the resolution of moral controversies and moral decision-making, that the defense of Brody's pluralistic moral casuistry is found.

McCullough argues, for example, that the core professional virtues of physicians include integrity, compassion, self-effacement, and self-sacrifice. Such virtues, however, are not sufficient in themselves to provide comprehensive guides for care in the medical clinic or while engaged in medical research—additional moral guidance is necessary. He argues:

> Here the key insight of Brody's pluralistic moral theory comes to bear powerfully. Rather than adding what could be, at worst, endless or, at best, unmanageable specification to virtues to make them do all of the work needed to fulfill the commitments to competence and protection of the patient's health-related interests, a pluralistic professional medical ethics recognizes the need for complementary action guides based on specified ethical principles such as beneficence, respect for persons, and respect for autonomy. These ethical principles, when specified to the demands of clinical practice or research, provide concrete guides to and the basis for critical assessment of clinical judgment, decision making, and behavior (McCulllough, p. 31).

For example, while the professional virtues direct physicians to address the patient's health related concerns, the ethical principle of respect for patient autonomy reminds physicians that patients bring a much broader array of interests and values to the clinical encounter than just health-related concerns. Such attention deepens our appreciation of the clinical encounter as well as of the physician/patient relationship. As Wildes makes the point, unlike those who lament the empirical reality of moral pluralism, Brody offers bioethics a positive account of moral pluralism—a richer understanding of the phenomenological and ontological world of biomedical ethics.

Maureen Kelley and Janet Malek each raise important objections to Brody's theory and method of pluralistic casuistry. Malek notes, for example, that Brody's moral theory relies on an account of moral intuitionism. In *Life and Death Decision Making* (1988), Brody posits the existence of a fundamental cognitive capacity "…which enables us to recognize the moral value of individuals, actions, and social arrangements" (p. 12). Here a central question regards whether there is reason to believe that such intuitions ever reveal objective moral truths. Kelley's suggestion is that a detailed account of the training for moral judgment and expertise is needed further to develop the theory. We ought to consider, she argues, issues in social moral psychology and seek to develop the virtues of an expert casuist: courage, mental flexibility, integrity, and emotional sensitivity. Yet, as Malek argues, at the

heart of the theory of conflicting appeals is human judgment on which there are constraints imposed by our moral cognitive faculties. Her questions: Do natural cognitive constraints exist? And, if so, is there reason to believe that those constraints lead us to moral truth?

B. Jewish Medical Ethics

> I must confess that I have little sympathy for the parents' decision. Coming from a Jewish theological background, I find their position objectionable on theological grounds. The objection was best put by Rabbis Akiva and Ishmael when they said: 'just as one does not weed, fertilize, and plow, the trees will not produce, and if fruit is produced but is not watered or fertilized it will not live but die, so with regard to the body. Drugs and medicines are the fertilizer and the physician is the tiller of the soil.' It is strange to find people actively intervening through natural means to produce desired results in all areas but matters of life and death, and insisting that in those areas alone man should merely pray and leave himself in the hands of God (Brody, 1981, p. 10).

The second section, with chapters authored by Laurie Zoloth, H. Tristram Engelhardt, Jr., and B. Andrew Lustig, turns to an exploration of Brody's robustly Orthodox Jewish bioethics, especially his forthright use of halakhic material and traditional Jewish casuistry to offer insight into modern biomedical moral controversies, such as life and death decision making, suicide and euthanasia, abortion, and even gender reassignment surgery (see Brody, 2003, chapters 16, 17, and 18). For example, Lustig explores Brody's comments on the status of the Noahide commandments, the Bnai-Noah, the commandments of God for Gentiles. Lustig considers whether such commandments should be characterized as a Jewish version of natural law conclusions. His exploration includes, in turn, Brody's arguments regarding: 1) Maimonides' statement that the appropriate motives for the observance of these commandments is because God has commanded them—not because they are inherently reasonable; 2) that central details concerning interpretations and application of these commandments are derived from biblically or Talmudically based arguments, rather than from "pure reason"; and 3) that not all of the given commandments comport with natural law accounts based on considerations of practical reason.

Zoloth highlights Brody's ability to draw on Jewish casuistry for understanding and appreciating the moral complexities of cases, including the often conflicting commitments of the moral decision makers. In pediatric cases, for example, medical teams often forget that parents of critical ill children may have deep and important duties to other members of their families:

> This is perhaps an idea more theological than philosophical, but here too Brody is a teacher, for his moral philosophy is never far from the Jewish tradition itself, in which the actor is never completely alone…It was Brody who stressed work in justice, impressing a graduate student (this author) with his argument that families in the clinical realm were more than adjuncts to the ill child, but persons with obligations to other children outside our view, and with the capacity to organize and order their lives for those children as well as the ill one we knew (p. 105).

Within the hospital setting we often forget that parents exist in a deeper more complex family context. Zoloth notes that Brody's scholarly familiarity with the narrative stories that illuminate and expand the discourse of the Talmud adds depth to his moral analysis, for he appreciates the case-based examples of halakhic legal decisions as well as the Midrash, the narratives that surround the legal decisions, which in all of their complexity give insight into complex modern cases, including euthanasia and the treatment of PVS patients.[10]

Engelhardt develops Brody's insights into the often stark differences between the assumptions and content of general secular morality and the halakhic requirements for right behavior. As Engelhardt explores Brody's arguments, he appreciates Brody as advancing at least the following three claims. First, that "secular morality does not exhaust the halakhic requirements for right behavior"; second, that "there are conflicts between secular morality and halakhic requirements"; and third, "that the first two points have force in part because Orthodox Jews, and for that matter Orthodox Christians, do not have a morality, a moral philosophy, or a theology, as these practices have come to be understood in Western European culture, especially after the first millennium" (p. 110). Or, to state the point in another fashion, "though Orthodox Judaism and Christianity have a morality in the sense of norms of behavior, and a theology in the sense of a recorded reflection on the experience of God, neither has a morality or theology as a practice independent of the religious life" (p. 110). Moreover, as Engelhardt argues, Orthodox Jewish bioethics affirms one bioethics for Jews and another for Bnai-Noah (non-Jews), and neither of which is compatible with the dominant accounts of secular bioethics. As a consequence, while there are real tensions between the requirements of God, on the one hand, and the requirements of secular morality, on the other, such tensions are not problematic because these two separate sets of requirements are framed by incompatible moral life-worlds. The moral philosophical world of secular bioethics is unable to claim governance over Talmudic argument—the disparate paradigms are incommensurable.

C. Biomedical Public Policy and Clinical Medical Ethics

> An infant born with multiple congenital abnormalities that rendered survival unprecedented required high-dose vasopressors to maintain blood pressure. After several days, gangrene developed in the extremities, and the parents sequentially demanded amputations of several limbs in an attempt to "do everything." The surrogate decision maker for a comatose woman dying of multisystem organ failure in an intensive care unit (ICU) was her estranged husband; they separated because of repeated spousal abuse. Despite many conferences with the husband recommending comfort measures and a do-not-resuscitate order, the husband demanded that the medical staff "do everything to my wife." A public hospital serving an indigent community of several hundred thousand had a full ICU, and 3 patients were being kept in the emergency department on ventilators. One of the patients in the ICU was a gentleman who had been ventilator dependent and unresponsive for 4 ½ months after a cardiac arrest; his daughter insisted on full support because she was hoping for a miracle.

> Common to all 3 cases was a health care team that believed that continued aggressive support was inappropriate or futile and a surrogate decision maker who insisted on "everything" being done for the patient (Halevy and Brody, 1996, p. 571).

The next two sections—*Biomedical Public Policy* and *Critical Application and Analysis*—compass a brace of essays concerned with the deployment of Brody's argument on a variety of fronts: from the fashioning of public health care policy to clinical medical ethics decision-making. While Robert Arnold proves critical of the Texas Advance Directive Act of 1999, a state law modeled after the Houston policy crafted by a interdisciplinary committee of which Brody was a chair and central mover, E. Haavi Morreim's analysis of research ethics echoes Brody's rejection of simple mandates and restrictions on research, in favor of working towards reasonable judgments and the consideration of various public interests and moral appeals to fashion non-mechanical conclusions. Loretta Kopelman critically assesses the claim that the removal of artificial nutrition and hydration from PVS patients constitutes active euthanasia. She argues that the burden of proof is on those who wish to forbid guardians of PVS patients from removing such care with the advice and consent of the medical team. Kopelman argues against Brody's conclusion that the delivery of artificial nutrition and hydration to PVS patients is basic care akin to keeping someone warm and dry, and that it is obligatory to provide it.

J. Clint Parker, Sarah-Vaughan Brakman, and Frances Kamm each consider the implications of Brody's arguments for the care and treatment of patients. Parker, for example, applies Brody's pluralistic moral casuistry to an oncology case involving a female elderly patient, to illustrate the explanatory power of Brody's theory to resolve real world cases. And, Brakman's analysis of human embryo adoption echoes Brody's work in clinical ethics as she seeks to couple clinical reality and medical knowledge, with clear analysis and philosophical rigor. Kamm, in turn, explores Brody's views on passive euthanasia and active euthanasia as a way of deepening our understanding of the significance of the moral difference (if any) between killing and letting die.

V. CONCLUSION: A PERSONAL POSTSCRIPT

Some time ago, a first year philosophy graduate student enrolled in a seminar on ethics taught by Professor Brody. The syllabus was daunting: several major articles each week, often an entire book, drawn from the classic works in the history of philosophy and their modern philosophical colleagues. In addition, extensive reading questions were to be completed prior to class and reworked with corrections and revisions after class. Classroom discussion began each week in much the same fashion: What is the author's position? Where is his argument for the position? Can we put it in numbered steps? What criticisms can legitimately be raised to the position? ("I just disagree" never being acceptable, absent extensive further argument, which would also likely need to be put into numbered steps.) What are the alternative positions? Answering each question led to significant, detailed,

and philosophically robust discussions, as well as extensive training in sustained philosophical rigor. Brody insisted that we learn the development of philosophically rigorous arguments, drawn from both the history of philosophy and contemporary philosophical analysis, as well as how carefully and critically to assess such positions. Later seminars with Professor Brody would include Philosophy of Law, Ancient Philosophy, and Political Philosophy—each course similarly constructed. Indeed, each semester would inevitably include a couple of extra classes—with extra readings and questions—in the evening at Professor Brody's home, over food and drink, seminars *par excellence*.

Beyond being an inspired and engaging teacher, Brody took a real interest in his students. At a cross-road in graduate school, needing to choose a dissertation specialty, he encouraged me (Mark Cherry) to sit in on his seminar in bioethics for medical students at Baylor College of Medicine. His expressed view: at worst, I would read a series of very interesting and important books in bioethics; at best, I would choose a philosophical career path. Many years later, having nearly finished my dissertation in bioethics and entered the job market, Brody insisted that we meet routinely to hone interview skills and to develop pedagogy for teaching undergraduates. Philosophy has the reputation of being esoteric and isolated from the real world, he pointed out, in large measure because of the behavior of philosophy professors. The challenge is making philosophical insights and challenges interesting and important for the daily lives of our students—a lesson he himself drew on daily as he consulted with physicians, nurses, families, and colleagues in biomedical ethics. Careful and critical philosophical analysis was important for gaining insight into the deep challenges of human life.

What was my philosophy of teaching? He asked one day. A question I had never considered. After much consideration, and gentle but significant prodding, I responded: great books and great ideas. Students should read the great works in the history of philosophy and contemporary philosophy, always guided along with reading questions: What is the author's position? Where is the author's argument….

With the publication of his book *Taking Issue: Pluralism and Casuistry*, we were struck with the extent to which his scholarship had shaped the national and international bioethical debate. This was particularly clear at many of the major professional meetings, where the influence of the method of pluralistic casuistry, as well as his particular insights into complex biomedical cases is always evident in a significant proportion of the papers and presentations. None of the chapters in this volume are merely laudatory; instead, each addresses, explores, and critically assesses the last decade or so of Brody's scholarship from both senior scholars as well as from his former students, individuals whom he has mentored into scholars in their own rights. As is clear from his response to these essays, sometimes he agrees, other times he disagrees but adds depth to his own analysis in his reply. This result is as it should be for a philosopher who has had such an influence. Our hope in presenting this volume to the international world of bioethics is to celebrate a distinguished career marked by a singular depth and breath of scholarship, as well as by exceptional teaching, and generosity to his students and colleagues.

Mentioned here are just a few examples among many gifts of generosity and kindness. We, the editors of this volume, as well as many of the contributors (including Maureen Kelley, J. Clint Parker, Sarah-Vaughan Brakman, Frances Kamm, Kevin Wm. Wildes, S.J., and Janet Malek), have had the distinct honor of being Baruch Brody's students, philosophically engaging with him through classroom lectures and discussions, medical clinical encounters with patients and professional mentoring; it is with sincere honor and, indeed, personal affection that we refer to him as "Professor."[11]

NOTES

[1] Consider his work within the multi-disciplinary community of the Texas Medical Center in patient based research to demonstrate that particular treatments are likely ineffective. For example, patients often report symptomatic relief after undergoing arthroscopy of the knee for osteoarthritis; yet, it is reportedly unclear how the procedure produces this desired result. Indeed, in a randomized, placebo-controlled trial, Brody and colleagues demonstrated that for patients with osteoarthritis of the knee, the outcomes after arthroscopic lavage or arthroscopic debridement failed to be any better than those after a placebo procedure for reported relief of pain and return of level of function (Moseley et al., 2002). Brody's efforts in the testing of thrombolytics presents another excellent example of such critical analysis, see section II.

[2] As Rosenberg and Birdzell make the point: "The diffusion of authority to initiate innovations served also as the West's way of guarding against a chronic menace to innovative change—the interests of the status quo in suppressing innovation. An innovation will seldom be authorized or financed by government or corporate officials whose careers would be adversely affected by the success of the proposal" (2002, p. 22).

[3] Here, in addition to the World War II cases that led to the crafting of the Nuremberg Code, and the Tuskegee syphilis experiments, consider also the cases of Thomas Parham and Jesse Gelsinger. In the case of Thomas Parham, his physician allegedly encouraged him to participate in a clinical trail of a pharmaceutical designed to shrink enlarged prostates. While Parham had not had any previous prostate difficulty, his physician allegedly argued that the drug might prevent future problems. A year earlier, Parham had been hospitalized for a chronic slow heart rate, which should have likely disqualified him for participating in the study. However, his physician sought an exemption from the drug company. After he began taking the study drugs, Parham evidently experienced fatigue, a symptom of a slow heart rate. Eventually, Parham was hospitalized and a pacemaker was implanted. What became clear only after the fact was that Parham's physician was receiving $1,610 for each patient he enrolled in the study. While the pharmaceutical company designed the fee to cover study expenses, it was allegedly sufficient to provide the recruiting physician with a profit per enrolled patient (Goldner, 2000).

In a similar case, Jesse Gelsinger, an 18-year-old, died following his participation in a gene transfer study at the University of Pennsylvania's Institute for Human Gene Therapy. Gelsinger suffered from a rare liver disorder that he managed with drugs and a special diet. Food and Drug Administration (FDA) investigators concluded that researchers placed him on the scientific protocol and gave him an infusion of genetic material, even though his liver was not functioning adequately to meet the minimal level required under study criteria. FDA investigators criticized the study for failure properly to notify the FDA of severe side effects experienced by prior subjects that may have been sufficient to halt the study, failure to notify the FDA of the deaths of four monkeys that were tested using similar treatments, failures in Gelsinger's consent form to notify him of such potential harms, as well as the inability to document that all research subjects had been informed of the risks and benefits of the protocol. Eventually, the FDA suspended all gene therapy studies at this Institute. It emerged that the director of the Institute, James M. Wilson, owned stock in Genovo, the company financing the research. Moreover, Wilson and the former dean of the medical school owned patents on aspects of the procedure. Wilson admitted that he would gain $13.5 million in stock from a biotechnology company in exchange for his shares of

Genovo and that the University has some $1.4 million in equity interest in Genovo. In their agreement, Genovo would receive any rights to gene research discoveries at the Institute in exchange for financial support (Goldner, 2000).

[4] Brody argues, for example, that "…one major role of empirical studies is to help identify the ethical issues that actually arise in the practice of medicine and to find out how they are currently treated. Such findings present ethicists with the opportunity to confront actual questions and to propose defenses of, or alternatives to, current procedures for dealing with these actual questions. This is not, however, the only role of such empirical studies. They can also discover the consequences of alternative ethical policies, and that discovery can provide at least part of the basis for a moral evaluation of the alternatives. Even if one is not a consequentialist, one can at least agree that consequences are morally relevant and are part of the basis for evaluating policies. In this way, then, discoveries about what is the case are relevant for deciding what ought to be the case" (1993, pp. 211–212).

[5] The judgment that a treatment is "futile" is a performative judgment designed to defeat a putative duty to provide the requested healthcare (see Halevy, Neal and Brody, 1996). Part of the difficulty of such judgments, though, as Brody notes is adequately defining "futility". Consider four possibilities: "physiologic futility (the intervention does not have its intended physiologic effect), imminent demise futility (the patient will die before discharge regardless of the intervention), lethal condition futility (the patient has an underlying disease that is not compatible with long-term survival, regardless of the intervention, even if the patient could survive to discharge from this hospitalization), and qualitative futility (the resultant quality of life is too poor)" (Halevy and Brody, 1996, p. 571; see also Halevy and Brody, 1995).

[6] John Harris has argued, for example, that since patients in a PVS state can no longer experience and benefit from their existence that we do them no harm when we cease to support their lives, or indeed to take it from them: "Thus John's critical interest in a further thirty years of life in PVS would give way to the significant critical interests or preferences of any actual persons, persons to whom the satisfaction, or not, of their desires can continue to matter. … We would not, I imagine, think that someone who could no longer benefit from, or appreciate, the life he was leading should have that life sustained when to do so would cost the lives of others who could appreciate, and benefit from, their existences" (Harris, 1995, p. 19).

[7] It is worth noting that the Society of Critical Care Medicine has argued that PVS patients should not be admitted to the intensive care unit, even if beds are available. "Examples of patients who *should* be excluded from the ICU, whether beds are available or not, include those who competently decline intensive care or request that invasive therapy be withheld; those declared brain dead who are not organ donors; and those in a persistent vegetative or permanently unconscious state" (1994, p. 1202). Their statement appreciated such care as an inappropriate use of scarce health care resources, both physical resources as well as professional expertise.

[8] This viewpoint, for example, was the focus of Pope John Paul II's statement "To the Participants in the International Congress on 'Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas"' of March 20, 2004. He urged: "I should like particularly to underline how the administration of water and food, even when provided by artificial means, always represents a *natural means* of preserving life, not a *medical act*. Its use, furthermore, should be considered, in principle, *ordinary* and *proportionate*, and as such morally obligatory, insofar as and until it is seen to have attained its proper finality, which in the present case consists in providing nourishment to the patient and alleviation of his suffering" (para. 4). Here, John Paul II brought together his longstanding claims regarding personal dignity and the value of human life to bear on a very particular judgment regarding the moral obligation to continue artificial nutrition and hydration for patients—even those patients in a permanently vegetative state. There has been sustained and significant debate about the meaning of John Paul II's statement. See, for example, *Christian Bioethics* 12(1), 2006: "Judgments at the Edge of Life and Death: Artificial Nutrition and Hydration" and Cherry (2006).

[9] Consider Robert Veatch: "The relationship of the dead donor rule to the definition of death is complex and not always well understood even by experts in the field. Consider the position of those who believe that organs should be procured from irreversibly comatose persons who still have some residual brain function or from those in a persistent vegetative state. Such patients currently are classified as