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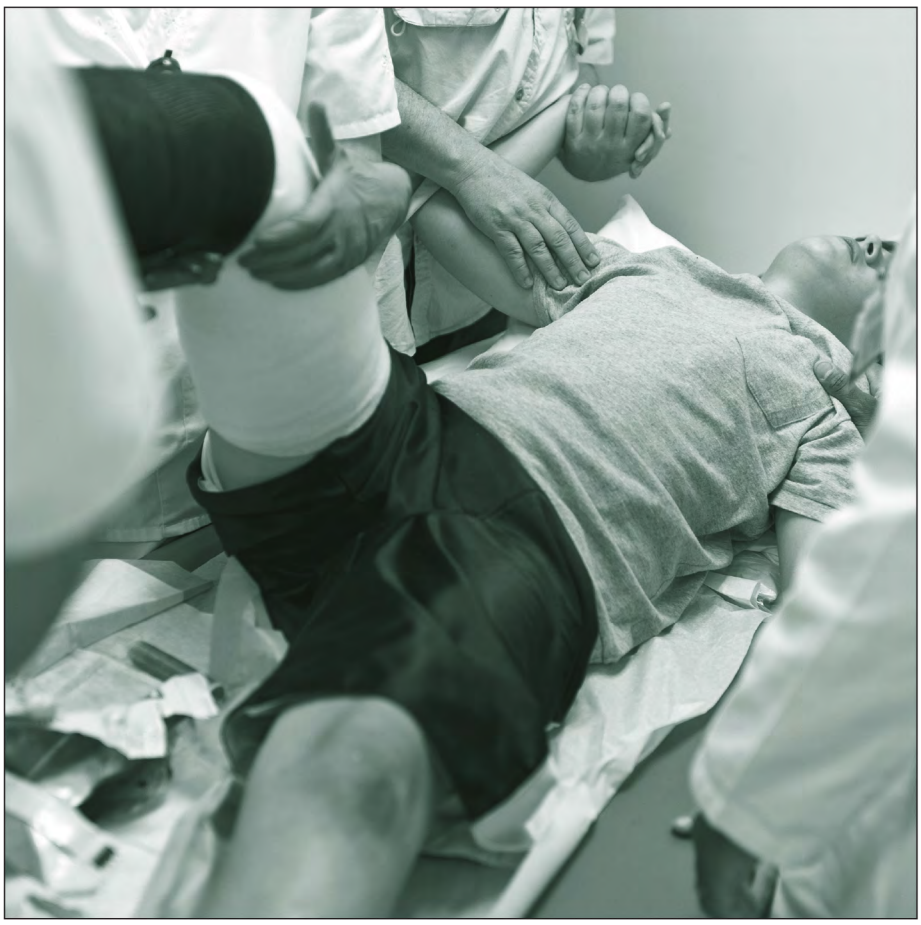

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EDITORIAL

Human Dignity: A First Principle

C. BEN MITCHELL, PHD

One of the most extended contemporary discussions of human dignity and bioethics was commissioned under George W. Bush's President's Council on Bioethics (https://bioethicsarchive.georgetown.edu/pcbe/). The council's two reports, *Being Human* (2003) and *Human Dignity and Bioethics* (2008) are the results of more than a few public meetings, thousands of pages of testimony, and the work of two scholar-chairmen, Leon Kass, MD and the late Edmund Pellegrino, MD. Notwithstanding the enormous scope of the council's work, however, in his letter to the President in March 2008, Dr. Pellegrino pointed out that as the second of the reports makes clear "there is no universal agreement on the meaning of the term, human dignity." According to Dr. Pellegrino, the discussion lacks a consensus, despite the fact that the notion of human dignity has been part of philosophical discourse at least since Greek and Roman antiquity and despite the fact that some of the best minds in the world have focused on the topic.

The work of the council provoked bioethicist Ruth Macklin to brand human dignity a "useless concept." Harvard University's Steven Pinker even assailed the notion of dignity as a "stupidity." Nevertheless, the term and the idea it stands for continues to possess significant currency not only in the popular imagination but especially in the bioethical, biolegal, and international policy literature. Roberto Andorno, Senior Research Fellow and Lecturer at the Institute of Biomedical Ethics of the University of Zurich, maintains that the notion of human dignity is so ubiquitous in intergovernmental documents in biomedicine that "It is therefore not exaggerated to characterize it as the 'overarching principle' of international biolaw."

Though a precise definition may be elusive, we should understand human dignity to be a first principle. That seems to be one of the significant uses of the term in both ordinary language and, as importantly, for the way international bodies employ the idea. This, of course, does not resolve every difficulty. We may certainly ask questions of human dignity. What sort of thing is it? Why should we believe in it? What would follow if we do? Chillingly, what would follow if we did not? But beginning with it as a properly basic notion rooted in our species membership and as the ground of human rights goes a long way toward an operational definition that helps us to make meaningful decisions about how we treat one another and what obligations we owe to whom. As Emory University legal scholar John Witte, Jr., has put it: "the current ubiquity of the principle of human dignity testifies to its universality. And the constant proliferation of human rights precepts speaks to their power to inspire new hope for many desperate persons and peoples around the world." Whether one is an atheist, Muslim, Christian, or Buddhist, there seems to be a very important overlapping consensus that what we share as a species should be the basis for solidarity, justice, and humanitarian action in every arena, including biomedicine. E&M

GREY MATTERS

Can Electronic Medical Records Make Physicians More Ethical?

WILLIAM P. CHESHIRE, JR., MD

In the second decade of the next century, it will become increasingly difficult to draw any clear distinction between the capabilities of human and machine intelligence. – Ray Kurzweil in 1999.[1]

Abstract

Electronic medical records are changing the face of communication in healthcare. These technologies, which are useful for improving efficiency, quality, and safety, also have the potential, if used wisely, to elevate the ethical standard of medical care. They can assist the morally conscientious physician by supplying legible, timely, accurate, and comprehensive data, prompts, reminders, alerts to preventable errors, and links to scholarly ethics resources and practice guidelines. As for any technology, if used carelessly, they can also introduce new harms or intrude as a distracting third presence in the examination room, diverting attention from the patient. Electronic medical records should be used in ways that connect patients to healthcare professionals rather than place a barrier between them. Vigilant human supervision of electronic medical technologies will always be needed, for automated processes, programmable rules, and digital prompts can never adequately substitute for virtue.

Introduction

Medical practices and hospitals are transitioning from paper to electronic medical record systems because they offer advantages in legibility, clear and efficient communication of clinical information, standardization of data, and verifiability of documentation required for compliance with government regulations and third party payer conditions for reimbursement. Electronic medical records not only arrange medical information but also control how that information is entered, stored, and transmitted. The electronic medical record infrastructure and programming determine what information is available at the time of clinical decision-making and, in some situations, may influence how that information is applied.

Beyond the technical questions of how electronic medical records can be used are ethical questions of how such technology ought to be used in ways that most benefit patients. Pertinent to this analysis is whether the outcomes, both intended and unintended, achievable by the use of electronic medical records are likely to support or impede the moral practice of medicine. Furthermore, if electronic medical records are useful for improving efficiency, quality, and safety, then how might they be used, not just to sustain, but also to elevate medical care to a higher ethical standard?

Ethical Advantages

Electronic medical records can support ethical clinical practice through their availability, legibility, durability, structural adaptability, and connectedness.

Electronic medical records afford access from multiple sites within a hospital or office complex, across a city or country. They also provide the option of remote access, which can facilitate the physician's conscientiousness in following up on test results when away from the practice setting. Automated prompts and reminders can further ensure that important details reach the physician's attention in a timely manner and are not overlooked.

Consistent legibility of electronic clinical documents as compared to the hurriedly handwritten notes of the past has the clear benefit of improving the integrity of communication. Electronic prescribing, order entry, and medication reconciliation systems have been shown to reduce potentially harmful prescribing errors.[2-4] Readable documentation of diagnoses, procedures, laboratory and imaging abnormalities, family and social histories, prognoses, and advance directives increase the likelihood that medical decisions will benefit without harming the patient.

Availability and legibility of information are preconditions for ethical practice wherever written words are relied upon. Ethical decision-making requires reliable and accurately transmitted factual knowledge on which to form valid moral judgments. No matter how good the user's intentions, action based on misinformation can lead to medical harm. Electronic medical records deliver this information over greater distances and at greater speed than has ever been possible with paper records. Provided that appropriate storage and backup hardware is in place, electronic medical records are also more durable and less vulnerable to fire or flood.

Electronic medical records integrated into the clinical workflow can provide structure for informed consent discussions and their documentation. Clinical templates can specify that each element of informed consent is addressed and documented, helping to ensure adherence to ethical standards.

Electronic medical records also support ethical decision-making by enlarging the knowledge base that informs clinical judgments and recommendations. Electronic prescribing systems can link directly to comprehensive drug information as well as signal alerts when the physician initiates a prescription that could potentially cross react with a drug the patient is already taking. Electronic medical records can also link to the medical literature and electronic knowledge resources that provide point-of-care guidance based on evidence-based or consensus-based best practices, such as PubMed, AskMayoExpert, UpToDate, Google Scholar, Medline, Micromedex, or MD Consult.[5,6] In these ways electronic decision support systems can guide clinical decision-making by assisting the physician in the beneficent provision of quality care and the non-maleficent provision of safe care.

Medical decision support systems that guide the scientific aspects of clinical decision-making can also be called upon to guide the ethical aspects. For example, PubMed can access more than 23 million citations from the biomedical

literature, including articles on medical ethics. Among the care process models in AskMayoExpert are consensus-based guidelines to assist clinicians in managing a range of ethical questions that arise in the practice of medicine, surgery, or medical research. Over time medical computing applications are becoming more sophisticated, and some programs can already assist in the interpretation of test results and suggest diagnoses or therapies.[7] One may speculate that future versions might submit electronically recorded clinical data to computational analysis and point the physician to a recommended ethical plan of care.

Ethical Hazards

Beneficial technologies invariably have unintended or unforeseen undesired consequences. Despite their usefulness, electronic medical record technologies also have a number of ethical pitfalls to be recognized and mitigated. These include the potential to breach confidentiality, multiply errors, misrepresent service, render authorship ambiguous, and divert attention from the patient.[8-10]

The American Medical Association Code of Medical Ethics states that, "The information disclosed to a physician during the course of the patient-physician relationship is confidential to the utmost degree."[11] Assurance of confidentiality is necessary in order for the patient to be able safely to disclose sensitive personal information essential to the medical evaluation. Electronic medical records multiply the opportunities for access to patients' confidential medical information. Unlike a paper record, which exists in one location, an electronic medical record can be accessed from numerous sites, across an institution or remotely, in private or public places, by anyone with electronic credentials to enter the system. The potential consequences of the release of sensitive medical information are further magnified if nefarious individuals acquire an opportunity to disseminate that information over the Internet or in the news media. The risk of privacy breaches can be reduced by passwords, privacy curtains, timed logoffs, access monitoring, and other electronic security measures, some but not all of which are subject to the physician's control and oversight. The increased risk of exposure of patients' electronic medical information and the complexity of the measures needed to mitigate that risk require a response of vigilant watchfulness.

When reading electronic medical notes, one should take care not to infer accuracy uncritically on the basis of legibility. In fact, electronic medical records introduce new opportunities for inaccuracy and new categories of error, such as voice misrecognition.[9,12,13] Technology-introduced errors, once entered into an electronic medical record, can potentially be multiplied by the technology through automatic report generation or by healthcare professionals' copying and pasting from note to note. Part of the solution to technology-introduced errors has been to add layers of technology to detect and mitigate these errors, which requires close attention to detect and correct misinformation that could lead to erroneous clinical decisions. One wonders whether the added layers will themselves require oversight by additional layers of technology, introducing the possibility of further errors requiring further oversight.

Electronic medical records may create the temptation for clinicians, when pressed for time, to misrepresent the level of service provided. The ability to

prepopulate notes with data can create a false appearance that the information was reviewed and considered. In an electronic milieu, completeness of documentation can no longer be taken at face value as reflecting thoroughness of review, as a few clicks of the mouse can generate the appearance thereof.

Moreover, the assembly of pastiche notes, in which information elsewhere in the record is copied and pasted into the physician's note, renders authorship ambiguous and could potentially facilitate plagiarism. Neurologist James Bernat calls these substitutions for meaningful notes "pseudohistories" and "pseudoexams," which are composed with systems that, although designed for ease of use, also encourage slipshod behavior.[8] It may be difficult to deduce the physician's reasoning from a pastiche note.[8] Greater complexity of electronic records may also make it more challenging to identify the root cause of medical error when it occurs, and whether or to what degree healthcare professionals are responsible as opposed to the systems upon which they rely.

Ambiguity of responsibility applies also in reverse. When the electronic medical record succeeds in delivering accurate information and protecting the patient's confidentiality, it may be unclear to what degree the physician deserves credit for the favorable outcome. Has the physician who purchases or whose institution uses a secure electronic medical record system earned the patient's trust in the same way as he or she did in the past, having penned notes in a paper record kept in a locked office file? What is the meaning of professional commitment to patient care once intentional acts of service are superseded by mandatory responses to automated machine prompts and thoughtful interventions replaced by standardized answers to constrained menus of options? Might systems that enforce ethical outcomes subtly, inevitably erode physicians' sense of personal responsibility? Might too much trust in electronic medical records for programmed ethical prompts cause physicians to become lax in their moral thinking or less likely to engage difficult questions with due care, attention, and effort?

Finally, the deluge of data, prompts, alerts, fields to be filled in, and labyrinthine listings that electronic medical records transmit to the physician carry the risk of diverting attention from the patient for whom the medical record was created.[14] The stream of interruptions from the electronic medical record can potentially distract the physician from the individual patient's record. Clinically meaningful alerts can become lost amid an excessive number of notifications, resulting in a low signal-to-noise ratio that can obscure important alarms in a flurry of unfiltered trivial or false alarms.[7]

Rules and Their Limits

The lines of computer code that compose the software of any electronic medical record specify the conditions and rules by which information flows into and is extracted from the record. In this way electronic medical records facilitate the standardization of clinical processes, which can include the implementation and enforcement of clinical rules. The electronic medical record thus assists the thinking of the physician to organize complex clinical information.

Miller and Goodman comment that "Sophisticated machines to assist human cognition, including decision making, are among the most interesting, important, and controversial machines in the history of civilization."[7] Despite Kurzweil's predictions,[1] electronic medical records are not at this time autonomously intelligent. They assist the clinician in the ways their programmers have designed them. The choice of information they present to the clinician depends on who has written the software or formulated the search engine. If electronic medical records influence ethical decisions in medicine, that influence reflects the presuppositions and preferences of their programmers.

The word "rule" derives from the Latin word *regula*, meaning "straight stick."[15] Rules are useful in both medicine and medical ethics. They specify, for example, the elements necessary for informed consent, which include discussion of prognosis, the nature of the proposed intervention, reasonable alternatives, relevant risks and benefits, assessment of the patient's comprehension of the information and decisional capacity, and acknowledgement of the patient's acceptance of the intervention. An electronic medical template can be constructed to require that text be entered for each of these elements in advance of any invasive medical or surgical procedure. Consistent adherence to such a rule could promote the ethical practice of medicine by decreasing the frequency of omissions from the standard of practice.

In reality, medicine is more complex than any clinical algorithm of rules can ethically accommodate. Clinicians occasionally encounter circumstances in which strict adherence to a set of universal rules could potentially harm a patient. For example, in some emergency situations it may be ethically preferable to violate the confidentiality rules in an electronic medical record if they interfere with saving a life.[16] In other situations it may be ethically obligatory to withhold or delay certain details from documentation in the medical record of a child victim of human trafficking if that information is accessible by the suspected perpetrator.[17] Such information, if shared in the usual manner, might place the child in harm's way. This is because, in their medical applications, valid principles sometimes conflict with one another in particular ways that a set of universal rules cannot resolve. An electronic medical record system designed to mandate compliance with rules could in such cases obstruct ethical behavior.

Consider the possibility that a future electronic medical record system were designed to monitor compliance with a set of rules for the rationing of healthcare services. The conscientious physician who is required to comply with the electronic directives could face a conflict of interest between the duty to the health of populations and the more immediate duty toward the individual patient.[18] On the other hand, the conforming physician who simply complies with the system may be abdicating ethical responsibility.

Miller and Goodman, in their chapter in *Ethics, Computing, and Medicine*, point out that clinical situations abound in which "standard medical care" would be inappropriate if delivered to "nonstandard individual patients."[7] They proceed to argue that,

> A robust concern for ethics in practice is not satisfied by stipulating in advance the circumstances in which a particular action would be identified

> as blameworthy or praiseworthy. Rather, practitioners should have access to a set of moral, professional, and social touchstones by which to find the way.[7]

These ethical touchstones of clinical judgment are arranged according to moral principles in the contour of a philosophical worldview.

The electronic medical record can, therefore, prompt for stipulated actions compatible with the ethical practice of medicine by ensuring, for example, that a current medication list is opened, a potential medication interaction alert is clicked, or an informed consent discussion is documented. The computer program cannot, however, ensure that the physician reasons through precautions to preempt medication interactions, listens to the patient, communicates clearly with the patient, expresses kindness, conveys comfort, with gentleness and humility considers the patient's viewpoint and preferences, weighs carefully alternative treatment options, or spends extra time reviewing and proofreading the electronic note or reflecting on the moral principles underlying a clinical encounter. In other words, the electronic medical record can supply an informational structure that promotes ethical outcomes, but it cannot produce the human motivation and depth of understanding needed for ethical behavior.

Keeping the Human Element

Electronic systems can influence what is done but not how or why, with what degree of determination, or whether with compassion. No software program can inoculate against cynicism or prevent attempts at deceit or coercion. Computers cannot compel virtue.

Elaborating on the distinction between etiquette, which for some people is no more than an outward set of learned behaviors, and the internalization of principled values, Fred Hafferty and colleagues repudiate the current trend of prioritizing "checklists ... over character."[19] It is such checklists at which electronic medical records excel. Hafferty and colleagues advocate instead for "a framing of professionalism in which virtuous behavior works itself so deeply into the marrow of the physician that it becomes 'second nature,' a teleologic *habitus*, exhibiting itself freely and easily even in challenging clinical situations."[19]

Technology in the final analysis is incapable of instilling virtue in physicians. Clinical outcomes resulting from the work of diligent, trustworthy, virtuous, compassionate and morally upright healthcare professionals will always be preferable to their imitation, no matter how thoroughly electronic prompts marshal clinical behavior. Whereas computer prompts might direct clinical personnel correctly through some of the motions, machines can never command the emotions that engender empathy, or by lines of software code replicate virtue.

Electronic medical records belong to the future of medicine. Because technology unchecked has the potential to magnify harms, virtuous human oversight will always be needed. We should welcome electronic medical record systems that add value and safety to clinical care as long as they do not displace the individual responsibility of the ethical physician.

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Medicine and the Pressure of the Marketplace: Ethical Issues Involved in Medical Research and Practice

DENNIS SANSOM, PHD

Beneficence and the Right of Self-Determination

One of the most socially compelling justifications for the practice of medicine and the advancement of medical research is the possible benefits they bring to society. People desire health, well-being, and strength, and among the several professions and industries that address these, perhaps medicine carries the heaviest burden to help society reach these goals. Medicine is never just a private or individual affair, for it involves the good of society, and in that medicine promotes this good; it fulfills one of the greatest of virtues – beneficence, the actual doing of good to others. It is one thing to wish well of others (i.e., benevolence), but it is a greater challenge and reward to do good to others. Society esteems and appreciates the work of medicine for many reasons, but perhaps the reason medicine is so esteemed is that it exemplifies the intuitively appealing and socially necessary virtue of beneficence.

Yet, beneficence is not the only virtue at play in the practice and research of medicine. People's lives are at stake. Of course, some aspects of medicine may not involve patients and their families and friends (e.g., research on animals, which is another ethical concern), but all medicine aims to impact the lives of people. Although we struggle to come up with a single, clear definition of the value of human life, whatever definition we settle on should include that people have the right of self-determination, that people must bear their own responsibility to live up to a moral purpose, and that this capacity of moral agency should not be ignored or violated by others. This struggle is never a willy-nilly act and it always involves many factors (e.g., societal traditions and influence of family and cultural norms), but at the minimum we believe people are owed respect as persons. The word *dignity* tries to capture this intuitive sense of owed respect towards others, and because medicine directly impacts some of the most important aspects of people's lives (e.g., pain, fear, dying, grief, family ties, and religious beliefs), it should always be aware that it owes respect toward the patients whom it serves and on whom it works and profits.

It would be a mistake to think these two virtues arose independently in our societal-ethical maturation and that they are stand-alone moral commitments. Although they emphasize different aspects of our moral experience (e.g., dignity is what people have and beneficence is what we do), they represent the development of the social good. It is because individuals and institutions are committed to the well-being of others, families, groups, and the whole that we come to recognize that people should be respected as moral ends in themselves and that we should avoid acting maleficently. Furthermore, we realize that when we are able actually

to benefit another person's human identity, we should learn how to do that. In this light, an argument for the respect of human dignity naturally compels us to argue for the moral duty of beneficence. And conversely, the more we understand how to act beneficently towards others, the more we understand the dignity of others.

Thus these two virtues (i.e., beneficence and respect of dignity) are not exclusive of each other, but they can conflict. For instance, they would come in conflict if researchers ever thought that it would be ethically permissible to weaken the respect owed patients in a protocol if such action would make it more likely to accomplish a successful and socially beneficial end result. If researchers are faced with the choice to conceal information from patients, to increase the risks, to indirectly coerce patients, or to explore nontherapeutic research on people so that they may move forward in new and beneficial technologies, drugs, therapies, and treatments, then the researchers are face-to-face with the conflict between these two important virtues.

Probably 99% of the time, we never have to deny completely either beneficence or dignity. Just because a research project contributes to the betterment of society does not mean we must disregard the dignity of the patients, and, moreover, just because we owe respect to the right of patients' self-determination does not mean we must stop medical research. People try to look for ways in which the project can both promote the beneficial results and protect the patient's autonomy. However, it is important to know that researchers must make this decision and know when they ought to make it. It is incumbent upon professionals to be learned and sensitive about the tension between the two virtues involved in medical research.

Brief History of Medical Codes since Nuremberg Trial

The "Medical Trials" of Nuremberg from October 1946 to August 1947 changed the practice of medical research. The trials started a process, though not always progressing forward, of code making and pronouncements that placed the patient's autonomy at the center of the ethics of medical research.

Aside from learning of the horrible and atrocious crimes committed in their medical research, the public also heard the accused defend themselves by claiming that what they had done was not all that contrary to established practices of medical research. They cited the absence of an internationally recognized code of ethics, which would have prohibited the kinds of procedures and tests they used. Nonetheless, most of the 23 accused were condemned and convicted, with 7 hanged and, surprisingly, several finding ways into American universities and military. To correct this lack of a code and to prevent further research from ignoring one, the prosecutors, with the help of the well-known scientist Dr. Andrew Ivy, came up with the ten principles of what is now called the Nuremberg Code. Its subtitle is "Directive for Human Experimentation," and its primary emphasis is on the respect owed to the people upon whom the research is conducted. Because of this respect, the Code introduces perhaps for the first time the necessity for the voluntary, informed consent of the patients before and during the research.

The court decision *United States v. Karl Brandt et al,* 1947, laid out the Code and played a legal, authoritative role for medical research. However, for the first 15 years after the trial few medical journals mentioned it, and it took the notorious

Thalidomide cases of 1961 for most of the medical establishment to realize the importance of codes to guide medical research. In fact, in the same year the Declaration of Helsinki by the World Medical Association made the patient's consent a requirement for medical research. This emphasis was repeated in the subsequent revisions of the Declaration (1975, 1983, and 1989), and separately from them, the AMA adopted its own code (*Ethical Guidelines for Clinical Research*) in 1966, also stressing the patient's voluntary consent.

As shocking as the Thalidomide cases were, what Henry Beecher revealed in 1966 was even more shocking. In the famous article, "Ethics and Clinical Research" (NEJM 274: 1354), he cited 22 examples of blatant ethical violations found in published research. Though the Nuremberg trials alerted the medical establishment for the necessity of codes that emphasize the patient's autonomy, not all researchers were recognizing and deferring to the patient's autonomy. During the 1960's and 1970's large societal events were happening (e.g., civil rights and the anti-Vietnam War movements), and common to them was the importance of individual self-determination against oppressive social practices and institutions. The famous 1965 Supreme Court decision of *Griswold v. Connecticut* on the use of contraceptives reflects this growing promotion of the personal right of self-determination.

Yet, during the 1970's several notorious cases became public that showed not all of medical science was moving in the same direction as society – the Jewish Chronic Disease Hospital, the Willowbrook study, and the Tuskegee Syphilis studies. Perhaps what upset the public the most is that these studies were so clearly against the tide of society, which was moving forward in promoting and protecting patient's right of self-determination. To curb the abuse of patients, the National Research Service Award Act was passed in 1974, led by Ted Kennedy. Its most impactful element was the requirement that all medical research receiving government funds must submit for approval their research protocols to institutional review boards before being reviewed for funding. The Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the National Commission), which in 1978 produced the influential Belmont Report.

The Belmont Report continued Nuremberg's emphasis on patients' autonomy and made explicit the requirements of informed consent, a statement of the risk/benefit assessment, and the selection of subjects for research. It put these concerns within the larger ethical framework defined by respect for persons, beneficence, and justice. Medical researchers in the view of the Belmont Report must first justify their pursuits ethically before they work on patients, and the primary motive behind this is the respect owed the dignity of patients.

Following the logic of the Belmont Report and reinforcing the societal emphasis on recognizing and securing people's right to autonomy, in 1981 the Department of Health and Human Services and the Food and Drug Administration issued the Code of Federal Regulations Title 21, which requires by law all medical research using humans to obtain IRB approval and patient's signature (or representative) on an informed consent form.

On occasions there has been pressure to set aside the necessity for informed consent (e.g., in "emergency cases"), but the ascendency from the time of the Nuremberg Code till now of the principle of protecting and promoting patients' autonomy remains central in society's estimation of medical research. Though the Nuremberg Code primarily wanted to limit the abuses of medical science upon people, its trajectory has been toward greater recognition of the patient's self-determination vouchsafed through informed consent.

Consequently, new difficulties face medical research. If the patient's autonomy is paramount, then it must be protected through the life of the protocol. IRB's make judgments in response to the documents they receive, but often the actual long-term dealings of the protocol are hard to predict and discover. Because respect is owed the patient's dignity, there will always be ambiguity about whose duty it is to protect this respect – is it the actual, hands-on researchers, the hospitals, the universities, the IRB's, or the Food and Drug Administration (FDA)? The best answer will be all-of-the-above, but in reality, the moral load is not evenly shared. The social pressures to establish predictable outcomes and to tailor research to fit quickly into the market of supply and demand come to bear on nearly all these groups not necessarily to dismiss the patient's right of autonomy and informed consent, but to lessen their primacy. In fact, William Winslade and Todd Krause, of the University of Texas Medical Branch at Galveston and of the University of Houston, have researched the influence of the Nuremberg Code on subsequent codes and commissions and, frankly, are not optimistic about the medical industry advancing this social trend. They say, "A recent change in FDA informed consent requirements clearly illustrates the dominance of scientific research over personal autonomy."[1] This struggle between the patient's autonomy and the dominance of scientific research is perhaps indicative of a comprehensive, social pressure bearing upon medical research – that is, the force of the marketplace.

The Pressure from the Marketplace upon Medical Research and Practice

In the United States the relationship between the marketplace and the practice of medicine has evolved from a "fee-for-service" transaction – in which the doctors and hospitals and patients agreed on a price to a "market-based" transaction in which large industries and bureacracies (e.g., insurance companies, technologies companies, hospitals, and the government) determine the price with the patient's financial contributions on the sideline. This move has brought the values and mechanisms of the market into not only settling the costs of actual services but also shaping the practices of health care and medical research. Because a market works with fundamental values not entirely consistent with the values of health care, this feature causes concerns for the ethical practices of medicine.

A market works by the transactions and bargaining of individuals and groups to secure desired objects and services. The objects and services become commodities whose values reflect the changing preferences of those participating in the transactions and bargaining. No doubt the word "marketplace" is comprehensive and nebulous, but generally it refers to the way profit motives determine the value of a commodity, labor, or transaction. The system of supply

and demand creates fluidity in social value, dependent upon what people at a certain time want and what others can provide. Profit in selling what others want indicates success within such a system. Since the force to succeed in the market is ubiquitous throughout society and greatly influences people's personal values, the marketplace influences medical research and practice, and when this happens, the motive for success in the market place often clashes with the respect owed to the patient's autonomy.

The market's exchange system presupposes certain norms, which the market itself cannot establish.[2] For instance the persons involved must be free, intelligent enough to engage and understand the bargaining, and have a sense of selfhood, which desires to participate in such a societal function and to accumulate the commodities. The work of the market is purely instrumental and its goals are always utilitarian – that is, the relative value of something's usefulness to maximize the bargainers' self-interests.

However, the primary aim of medicine is the care of patients, which presumes that those who provide the care are altruistic to the health needs of the patients. Altruism does not necessarily mean selfless motives and behavior towards others (which in practical terms is probably unrealistic), but it does mean the providers' *primary* motive is to treat patients beneficently because they respect the patients' self-determination of their own moral purposes. The providers, thus, must acknowledge the patient's right to be treated entirely relative to the patient's health and well-being. This commitment makes secondary (at best) what is primary in the functioning of a market transaction – the acquisitional self-interests of the health care providers. This ordering does not in principle deny some kind of juxtaposition of health care and market transactions, but it does mean that health care should not function in the same way as commodities do in the market.

To make this case, I appeal to the findings and conclusions of two sources – a series of publications by Daniel Callahan (one with Angela A. Wasunna), and a book by Carl Elliot.[3]

I. Daniel Callahan

In 1999 the *Journal of Medicine and Philosophy* publishes a series of articles analyzing the commodification of health care in the United States, and in it Daniel Callahan, of The Hastings Center, initiates a project for ethicists and health care providers to research more on the adverse effects the market has on medicine.[4] He wants to determine whether "medicine and health care [are] morally compatible with market theory, thinking and practice."[5] Market theorist have been advocating that the market can control health care cost, increase the productivity of health care, and enable poorer economies to increase their supply of health care. According to certain measurements, Callahan admits this may be true. However, he worries that such accomplishments come at a cost – health care becomes a commodity.

In the article Callahan takes on the agenda to research whether the growing influence in the United States of the market into medicine diminishes the respect owed the intrinsic value of the patient's health, the professional integrity of medicine, and ethical commitment to the solidarity of all participants in society.

In 2006, with Angela A. Wasunna, Callahan publishes his findings in the book *Medicine and the Market: Equity v. Choice*. In it he compares the practice of health care in the United States with Canada, Western Europe, and developing countries. Specifically he compares (shown in tables throughout):

1. social health insurance and tax-based systems,
2. funding sources of health expenditures, 2000,
3. life expectancy of birth and at age 65 and rank, 2003,
4. gross domestic product per capita,
5. health expenditures as percentages of gross domestic product, to 2001,
6. diagnostic technologies (per million population),
7. cardiac bypass procedures and cardiac angioplasty procedures, 2000,
8. hospital beds and lengths of stay, up to 2001,
9. number of physicians (per 100,000 populations), up to 2001,
10. standardized performance on twenty-one quality indicators in five countries,
11. citizens' views on their health care systems and general access problems, by income group, five countries, 2001,
12. citizens' overall views about their health care system, five countries, select years 1988-2001,
13. citizens' views of access to and quality of care, five countries, 2001,
14. citizens' satisfaction with their own health care system, compared with ranking by public health experts, in seventeen countries, 1998 and 2000, and 1997 per capita health spending,
15. satisfaction with their won health system among the poor and the elderly, compared with rankings by public health experts, in seventeen countries, 1998 and 2000.

From these comparisons he concludes, "As for its health care system, the United States is not the best [Western Europe's system is the best] or anywhere near the worst [rural China, India, and many African countries are the worst]."[6] Callahan and Wasunna argue that Western Europe's basic values for medicine are what make it superior – they are committed to solidarity among all citizens and equity in opportunity. These values have created an environment that does not struggle as much as the United States with the strains that the market puts on health care. Because the United States has more readily justified and applied the market to society, market-thinking engenders several expectations, which diminish the quality of health care: first, the expectation of infinite aspirations; second, unrelenting opposition against illness and death; third, reluctance to set any boundaries to medical hopes and dreams.[7] These values stem from the fundamental value that choice is more important than equity. We are free if we have the greater amount of choices, and, hence, the market is needed in medicine to create more choices for people. However, to keep securing and growing a system of choice in a market, people and services have to become more commoditized (that is, objects whose value is determine by what the market can bare), and when

this occurs the basic purpose of medicine changes from the altruistic treatment of patients to the utilitarian treatment of patients and services.

Callahan and Wasunna do not think the market should be totally removed from medicine, but it should be regulated. Five expectations should be met before the market is used – first, the plan must promote the overall population health; second, it must seek equity among all needy people; third, it should be regulated by government; fourth, its specific implementation must be based on empirical evidence, not an ideological appeal to the market per se; and fifth, society should view it as an experiment that can fail and hence can be discarded.[8] Nonetheless, according to Callahan and Wasunna, because the Western European model shows more efficiency, lower costs, and better quality of care, we should wonder why we would even experiment.

In 2009 Callahan publishes an article called "Medicine and the Market" in the book *Ethics and the Business of Biomedicine*, where he builds on his prior research to raise, almost rhetorically, the question, "What is the fruitfulness of the medicine-market debate for medicine and societal health in the United States?"[9] His findings suggest the question is already answered. He says,

> The United States ranks 1st on per capita healthcare spending; 13th among developed countries in life expectancy; many other countries perform better by some standard quality indicators; more Americans believe their system needs a complete rebuilding . . . and the US ranks 17th in its citizens' judgment of its healthcare.[10]

Moreover, Callahan sees the failure of the US system to be deeper and more costly than just these three comparisons:

> But because of its inability to embody a substantive view of the human good (other than choice and personal preference), or of health, any use of the market must, I believe, be subordinated to universal care systems. It can be used to serve them when possible, but never abandoning the value of solidarity that marks their best practice.[11]

My point is not necessarily to endorse Callahan's call for a European style health care system but to show that in light of his research and observations there is a tension between the values of the market and the ethical commitments integral to health care – beneficence and the patient's right of self-determination. The more the market influences the practice of medicine the more society becomes aware that medicine may not be totally altruistic in its approach to healthcare. Society may accept that researchers, doctors, nurses, pharmacists, hospital administrators, etc. make good salaries; and may also believe that when it comes to buying cars, homes, and the like the market works effectively; but when it comes to the medical treatments of people's lives and families, society wants and expects health care providers to be altruistic, to be committed to the patient's autonomy and to acting beneficently, rather than primarily to their financial interests.

II. Carl Elliott

Carl Elliott, a Professor of Bioethics at the University of Minnesota, endeavors to show how malleable medical practices and research are to the economical forces

of the marketplace. Elliott says in the Introduction to his 2010 book *White Coat, Black Hat: Adventures on the Dark Side of Medicine*,

> The financial stakes in medical enterprises are enormous; the center of drug research has moved to the private sector; even medical education has become big business. Like the Internet, medicine has been transformed by commerce. And just as the ethos of trust opened a window for deception on the Internet, so it opened a window for deception in medicine.[12]

This is a far-ranging charge, and he tries to support it by examining six ways the market pressures medicine to conform to the values of the economic system of supply and demand.

First, he discusses the role of paying people to join a protocol. This has created a class of people who try to make money by being research subjects. They are called *Guinea Pigs* and are used primarily in Phase I clinical trials. Because a "working group" has now emerged, they compete among themselves to sign up and consequently research teams have to pay more. Sponsors know they cannot rely only on the altruism of patients. There must be incentives to encourage people to take the kinds of risks involved in Phase I clinical trials. The problem is that though the subject consents to being researched upon, the coercive influence of making money as a research subject plays upon human weakness and diminishes the patient's dignity.

Second, medical publications have become a huge financial profit maker. For instance, from 2000 to 2005, *Reed Elsevier*, the largest publisher of scientific journals, earned nearly $10 billion in profits. Libraries often pay over $30,000 a year to keep a journal on the stacks. It becomes attractive for researchers to hire medical writers who usually are paid $90 to $120 per hour. This has created what Elliott calls the *Ghosts* – ghostwriters who write the articles for the researchers. The main problem is that the public does not know whether academic physicians or ghostwriters have written the articles, and with the pressure to publish in academic institutions and the financial attraction to publish for pharmaceutical companies, the articles' integrity becomes more suspect. After the collapse of the two drugs Zoloft and Paxil, the public found out that ghostwriters were hired to promote them. This raised the concern that too often industry presents ghostwritten articles as though they entirely originated in the universities.

Third, pharmaceutical companies can exert tremendous influence upon medical research, not only through funding specific protocols but also through what Elliott calls *The Detail Men* [and Women]. They are the drug representatives who learn the details of particular doctors, their ins-and-outs, so to tailor their sells and promotions to the doctor's interest. Although it is true that medical professionals do not receive the gifts and perks from the drug reps they once did, it is true that such gifts and perks influence doctor's decisions. To support this claim, Elliott cites two studies (JAMA, 283 (2000): 373-380 and CMAJ 149 (1993): 1401-1407). It is also true, according to the same studies, that doctors paid by a pharmaceutical company are more likely to prescribe that company's drugs. Because pharmaceutical companies are some of the most profitable businesses in the country, there is money to use to promote their products, and when doctors form close financial relationships with the companies, they appear to be part

of a vast industry aimed at increasing profits. Some doctors are more aware of this than others (for instance, the organization *No Free Lunch*), but to the public, especially after the failed and perhaps false promises of certain well publicized drugs, it has become more difficult to know the difference between the aims of the doctors and those of the pharmaceutical industry.

Fourth, in recent years pharmaceutical and medical technological companies have started to use what Elliott calls the *Key Opinion Leaders* (KOL) to promote their products. They are the leading researchers in certain fields who are hired by companies to become spokespersons for them. Both sides may approach each other with suspicion (the doctor may feel manipulated and the companies may feel exploited), and both sides are probably guided by their own professional interests, but because they are so embedded with each other, it is harder for the doctors to say that their comments and judgments are free from external influence. Even when full disclosure is given, the suspicion remains, because, whether both sides want to admit the evident fact or not, it is true that money influences people and a large amount of money influences a large amount.

Fifth, drug companies advertise to the public more now, and they use the same proven methods as with other products. Since customer empowerment induces people to be more open to products, drug advertising adopts the same approach. The people who design these marketing schemes are called *The Flacks*, and they know that it is more profitable to persuade the public to ask a doctor for a drug than it is to convince the doctors to use their products. This fact does not mean everyone's motives are cavalier or exploitive, but it does mean that the pressure of market-success influences and possibly conditions the relationship between a doctor and patient.

Sixth, in his closing chapter, *The Ethicists*, Elliott addresses the possible influence of the market's drive for success and profit upon Institution Review Boards, especially for-profit IRB's. The pressure is to quickly approve protocols so that the research can move forward, and some IRB's have become wealthy companies, which in itself is not a sign that they have lessened their scrutiny of the protocols, but it is a sign that such IRB's appear to be embedded in the vast medical industry, and that it becomes harder to distinguish their aims from those of the researchers and industry.

The upshot of Elliott's thesis (similar to Callahan's) is that medical practice and research bend to the pressures of the marketplace – to tilting the balance between economic needs and research/practice in favor of success in the market. Great benefit is still being achieved, but harm has also been done. When it appears that doctors and researchers are as driven to succeed financially as is industry, then the public wonders whether their health and well-being are the real aims of medical research.

The Conflict between the Social Values of Autonomy and Market Success

Contemporary medical research is caught in the crosscurrents of a society that values autonomy and the pressures to succeed economically. These trends are not

always compatible and can conflict with one another. If patients posses inherent dignity and the right to their own self-determination, then the primary success of a protocol should not be profit but actual medical benefit. It seems incongruent to the purpose and practice of medicine since the Nuremberg Trial to make patient's autonomy secondary to market success, but we should also recognize that medicine is part of larger social forces and, in feeling this conflict, medical practice and research express an underlying stress building in society.

The Vital Importance of Trust

Because medical research requires large amounts of money and because large amounts of money can be made in medicine by hospitals, companies, and health care professionals, medical researchers always feel the pressure of the marketplace to shape their work. Although medical science may advance and contribute great benefits to society, the patient's dignity as a self-determining moral agent must always be respected.

Because of this present tension in medical research, it is urgent that medical researchers show themselves as trustworthy enough to handle people's right of self-determination in the midst of strong market forces, which would possibly diminish the respect owed that right. For medicine and its practitioners to fulfill medicine's essential goal to cure, heal, and strengthen people, they must establish themselves as trustworthy people working in an institutional environment that assures trust.

Trust is fundamental to most of our relationships, and it is difficult to define exactly. To gain some clarity, we need to see that trust has an internal and an external dimension. The internal dimension refers to the character of the ones who assume to be trustworthy, and the external refers to the institutional assurances that research is both medically competent and also respectful of patient's dignity.

Being trustworthy does not necessarily mean that we do not make mistakes for which we have to apologize and make amends. The lack of perfection and of absolute predictability do not rule out a person's trustworthiness, but one who refuses to see errors and mistakes and does not try to rectify them indicates untrustworthiness. We make this kind of distinction because trust involves showing respect toward others. The University of Pittsburg moral philosopher Annette Baier's expresses this definition well – "For to trust is to give discretionary powers to the trusted, to let the trusted decide how, on a given matter, one's welfare is best advanced, to delay the accounting for a while, to be willing to wait to see how the trusted has advanced one's welfare."[13] That is, we trust people when we are willing to give them discretionary power over our welfare. If we think someone might misuse this welfare either maliciously or to their own benefit and our harm, then we do not trust them.

It is hard to determine to whom we should give trust. To help settle this Baier asks several questions:

> If I cannot or do not need to know the details of the other's motives for working with me, in order to judge her trustworthiness, what *would* it be good to know that I have a reasonable chance of being able to find out without

> unreasonable effort? Given that I am in shifting power relations with those on whom I depend, what sorts of power must I get, or relinquish, in order to work with them to ensure that the positions that some occupy (and that I may someday occupy) are not positions of trust-threatening powerlessness or powerfulness?[14]

It is as though we either subtly or directly ask of them, "If you were to tell me all the primary motives in your involvement with me, would I keep the same relationship?" We show ourselves trustworthy, not necessarily by telling everyone all our motives, but by determining that if we had to reveal them, then the other would see that they aim to keep and/or enhance the relationship.

Of course, we are often reluctant to reveal our motives, because the kinds of relationships we may form do not require serious exposure of our motives. However, whenever patients come to a doctor or research team, they expose to the doctors or team their weakness, illness, body, emotions, spirit, and livelihood. Their autonomy is at stake, and they need to know that, with the kind of knowledge the researchers have of them, their dignity will be recognized and respected.

Frankly, it is hard for patients to decide how much trust to give to providers. Family doctors are trusted more than specialists because they have had time to build a trusting relationship. Researchers are usually strangers to the patients, and it is difficult for them to prove to the patients that they are trustworthy enough to respect the patients' autonomy. Patients not only want to know whether the researchers are competent professionals; they want to know whether the researchers respect their dignity.

This is why the external dimension to establishing trust is vital and necessary for medical research and practice. Research must go on in an institutional environment that assures the patients and public that the researchers are competent and trustworthy. Although they may be strangers to the patient, because they are part of an institutional check system that protects the patient's autonomy, the patients are more likely to trust the researchers. For instance, because the researchers have reputable degrees, demonstrable skills and research experience, and are hired by an institution greater than the researchers' own practices, the public is more likely to trust the researchers' competence. Also, because it is required by law and authorized by the FDA that researchers must offer an uncoerced and clear informed consent form to the patients and for this form to be examined by an IRB, the public is more likely to trust the research team's motives.

Another external procedure ensuring trust would be the promise of indemnification. That is, the health care providers assure the patient and family that if a mistake is made or an unforeseen bad consequence results from the treatment, they will rectify the problem within their capabilities. In a way, malpractice insurance suggests this relationship, because it pays the damages. However, a relationship, which may experience failure and mistakes, established by trust is different than one that covers those possible failures and mistakes with malpractice insurance. Patients and families have to sue the doctor and the insurance company to receive compensation, and a lawsuit takes both parties directly into the power-structures of the marketplace and, consequently, the doctor and the patients and families remain adversarial to each other. The point

is not to dismiss the importance of malpractice insurance, but to say that this relationship hardly builds trust.

Perhaps a better comparison would be the warranties that companies sell with their products. If the failure or fault of the product lies with the company, then because of the warranty they have made a pledge to repair the problem. People would more likely trust a manufacture that gives a warranty with the product than a physician or hospital that has to be sued and legally compelled to rectify the mistake or compensate for the harm. If the only way physicians and hospitals are to correct their mistakes is under the threat of a lawsuit, then the patient knows that they are in a market-oriented relationship in which decisions are made based upon those who have the most power in the negotiations. However, if providers were to assure their patients that when the fault lies with them they would do all they are capable to rectify the problem, then patients and families would more likely trust their motives, because in such cases they would sense that the providers were acting as altruistically as possible toward them.

These external controls assure the patients that the researchers and physicians are part of a larger network of professionals, managers, and fellow citizens aware of and committed to the patients' autonomy and well-being. Researchers may on occasion think that these external controls stifle their work, but these controls further their work, because medical researchers not only advance science with their protocols and increase the benefits of medical science for society; they show how to respect the dignity of others by becoming the kinds of people who can be trusted with the well-being of others' lives.

Moreover, to build up trust medical researchers and other health care providers should affirm their own professional vocations as caregivers. It takes a certain kind of person to work toward the care of others' health – others' suffering and dying. Society recognizes this role of caring for others' health and consequently gives providers allowances denied to everyone else in society. For instance, it is illegal and we consider it a social taboo for people to maintain, store, dissect, and perform experiments on human cadavers. However, society knows that for medicine to reach its goal of health care, physicians and assistants must gain certain knowledge of the body that can be gained only by working on the dead. Also, people resist allowing their bodies and minds to become vulnerable to other people's slicing, shaping, and manipulation. The potential for harm is too great. However, society also knows that for medicine to obtain its goal of establishing health, curing diseases, and perhaps stalling death, we have to make our bodies and minds vulnerable to near or total strangers. For us to make ourselves open to potential abuse makes sense to us only because we trust the professions and the people committed to them.

These cases illustrate that society realizes medicine has a certain professional identity and that its practitioners must be the kinds of people who can live up to this identity. In this light, a way to build up trust is for practitioners to internalize in their self-understanding the relevant virtues for their profession and to show them when needed. For example, the profession should inculcate into its members through its training, its professional memberships, and its informal relationships that professional competence is more preferable than establishing a paternalistic

relationship to the patient; that loyalty to the purpose of the profession to care is more important than success in one's practice; that patience with the patient is more desirable than treating a great numbers of patients; that the practical wisdom needed to discern how to treat and not treat others is a greater skill than the intellectual skills necessary to learn the science of medicine (or other health care fields); and that the courage to face the complex, traumatic, and grievous moments of the practice of medicine is more needed for successful health care than the confidence that one can always give the correct diagnosis and treatment. Success, intellectual skills, and confidence are needed, but professional competence, loyalty, patience, and courage are virtues necessary to the practice of health care, and they should become inseparable from the self-identity of those who call themselves health care professionals. To such people, trust is readily given.

Conclusion

Market forces are straining the ethical foundations of medical research and practice. Perhaps health care in the United States will always be under this strain, which means that it is imperative for each generation of researchers, physicians, nurses, pharmacists, etc. to assure the public that they are trustworthy professionals committed to the well-being of those who call upon their services.

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The Moral Philosophical Challenges Posed by Fully Implantable Permanent Pacemakers

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Abstract

This paper reviews three philosophical constructs traditionally used to guide moral decision-making in end-of-life situations. These are: the Principle of Double Effect, the Principle of Doing versus Allowing, and the Principle of Ordinary Care versus Extra-Ordinary Care. These principles have operated in a context dominated by patient autonomy as an overarching ethical imperative. The paper argues that the three philosophical constructs and the imperative given to patient autonomy have been significantly challenged by advances in life-sustaining biotechnology. Arguments are advanced that draw on the example of the provision of fully implantable permanent pacemakers to reveal the practical inapplicability of the three Principles, as well as the over-reliance on patient autonomy as regards discontinuation of treatment. On the basis of these arguments, it is concluded that advances in biotechnology are potentially outstripping many of the premises normally applied by moral philosophy to end-of-life considerations. A process which emphasises a clear and open dialogue prior to implantation seems to be a necessary pre-requisite for moral decision-making in this context.

Introduction

This paper will firstly review the three philosophical constructs traditionally used to guide moral decision-making in end-of-life situations. These are – the Principle of Double Effect, the Principle of Doing versus Allowing, and the Principle of Ordinary Care versus Extra-Ordinary Care. We argue that advanced biotechnology is evolving at such a rapid pace that it renders these three frameworks less practically valuable in end-of-life situations than might once have been the case. This is especially true with regard to recent progress in implantable technologies, such as fully implantable permanent pacemakers (PPM). Unlike the planned cessation of antibiotic and other medical treatments, while awaiting "nature's course", PPM require active re-programming in order to cease their life-maintaining function. As well, questions arise about whether they are incorporated into the "being" or "self" of the patient, and particular concerns are raised about the autonomous rights of the patient to discontinue their use. In fact, the issue of discontinuing the use of the PPM may be addressed only in the context of some other supervening critical illness. We surmise that advances in biomedical technology may be outstripping moral philosophical underpinnings of decision-making as the end-of-life of a critically-ill patient comes into view.

We conclude that stand-alone frameworks may be increasingly less useful than a clear and open dialogue about the moral decision-making concerns that are likely to arise. This dialogue with the patient and their relatives needs to be had before implantation.

The Principle of Double Effect

The Principle of Double Effect is derived from the *Summa Theologica*: "Nothing hinders one act from having two effects, only one of which is intended, while the other is beside the intention. Now moral acts take their species according to what is intended. Not according to what is beside the intention."[1] It is applicable when a single action can have two (or more) outcomes – one (or more) good and one (or more) harmful. Examples of its use would be harming an attacker in self-defence, and wartime dropping of bombs on military targets with foreseeable but unintended civilian casualties. A commonly cited clinical example is that of minimizing suffering by giving opiate analgaesia - which foreseeably depresses spontaneous ventilation and so shortens life (however, the therapeutic margin in modern palliative care is actually not so narrow).[2] The primary outcome is to relieve suffering. The secondary outcome is ventilatory depression.

In these situations, four conditions must all be satisfied.[3,4] Appropriate doses of opiate analgaesia satisfy these criteria because: 1) opiates are not in themselves immoral; 2) opiates are used with the intention of relieving pain, although respiratory depression is a known accompaniment; 3) respiratory depression and the death of the patient are not the means that opiates employ to relieve pain; and 4) relief of severe pain is a proportionately serious reason to accept the outcome of hastened death.[5]

The Principle of Double Effect cannot be applied when sedation aimed to relieve a patient's "tiredness of life," or existential distress, does so by altering the patient's state of consciousness (unlike the action of opioids on physical pain).[6] As well, conflicted or ambiguous intentions about, for example, discontinuing home ventilation in a patient with chronic lung disease, can undermine this Principle if the intention is not to remove an encumbrance, but is in fact aimed at deliberately ending life.[7]

Nonetheless, the Principle of Double Effect is very often called upon in end-of-life settings to morally justify clinical decisions. The intention of the Principle is to pursue a morally good motive while remaining aware of the foreseeable consequence. The central distinction is "between the *intentional* causation of evil, and *foreseeing* evil to be a consequence from what one does."[8]

The Principle of Doing versus Allowing

A related concept has become known as the Principle of Doing versus Allowing.[9] It distinguishes between acting and not acting. In a non-clinical setting, this distinction applies to, for example, killing someone by actively holding their head under water versus failing to rescue a person who is drowning. A clinical example is seen in active euthanasia by lethal injection versus passive euthanasia by switching off a ventilator. Phillipa Foot distinguishes Doing from Allowing

by distinguishing initiating or continuing a sequence from allowing a sequence already in progress to complete itself.[10] James Rachels, however, argues that if the motive for action is the same and the outcome is the same, then the unqualified distinction between positively acting and negatively not acting is morally insignificant.[11]

Daniel Callahan argues that, in moral decision-making in clinical settings, there "is and will always remain a fundamental difference between what nature does to us and what we do to one another."[12] Aware of the respect many relatives and patients attach to the sanctity of human life, it is important that relatives do not see patients in ICU at any practical risk of being killed by those who see no philosophical difference between killing and letting die in terms of motive or outcome.

The Principle of Ordinary versus Extra-Ordinary Care.

This Principle distinguishes between "Ordinary" means and "Extra-Ordinary" means. The Principle is not simply about high technology or high cost treatment. To be characterised as an "Ordinary" means, a treatment option must offer some hope of benefit and be part of the normal – not experimental or unproven – standard of care, and the social situation, as well as post-intervention function, must be brought into consideration.[13] The means must also not be overly painful, anxiety-inducing, excessively expensive, dangerous, or involve travelling great distances or dislocating a family. As a guiding moral principle in clinical practice, Ordinary means are generally held to be obligatory, while Extra-Ordinary means are generally not so.

Bishop posits in this context that, if the resultant (physiological) life is overly burdensome to the patient, then the means is disproportionate and is not required.[14] An analysis of Benefit versus Burden has similarities. It aims to determine the potential benefits (utility) and the potential burdens (disutility) of a proposed treatment plan. It then derives net utility, necessarily contextualised to the individual patient, and thus aims to guide the decision as to whether interventions may legitimately be foregone - that is, withheld or withdrawn. It anchors end-of-life decision-making in the unique context of the individual patient.

Recent Challenges by Advances in Biotechnology

Recent biomedical advances, including fully implanted permanent pacemakers, render more problematic questions around withdrawal of life-maintaining support which may invoke these three Principles. Situated against a background set by these Principles, we offer some considerations for discussion.

Consider an elderly patient with a fully implanted permanent cardiac pacemaker (PPM).[15] The PPM senses whether there is a cardiac rhythm and, if there is none, it is programmed to generate an electrical stimulus. In this patient, there is no spontaneous rhythm. The PPM is required to keep the heart beating. Electrical cardiac rate is permanently set to some lower limit. The patient develops pneumonia. Neither she nor her family wishes to persist with treatment and all accept that death is the most beneficent way forward.

The first issue to consider is how the PPM is viewed from the patient's perspective. It is unclear whether fully implantable biotechnology devices are viewed by patients (or clinicians) as part of the ontology (in the sense of the nature of their being or "self") of the patient, in the same way that transplanted biological organs might be perceived. Intuitively, it seems to be part of the reality of their being-in-the-world. At a superficial level, utilising a property-law approach, Frederick Paola suggested that these devices may be viewed as similar to fixtures, rather than chattels.[16] Ruth England et al proposed that, in distinction from transplanted organs and external mechanical appliances, and located somewhere between the two, the term "integral devices" should be assigned to fully implanted devices. This reflects their status as non-organic but "integrated into the physical being" of the patient.[17]

The second issue, and the primary focus of this paper, is this: since death is considered morally evil if caused by human action,[18] on what basis might the PPM be legitimately discontinued?

The implanted battery of the PPM will last at least several years, so passively awaiting battery discharge is not a practical option. Granted it is fully implanted, to remove it would require operative intervention. There is no physical on/off switch. To non-invasively stop it functioning, it must be deliberately re-programmed by a clinician or technician so that its output is below the threshold needed to capture the heart's rhythm. If re-programmed in a patient who is dependent upon the implanted PPM, death would occur within a few moments.

Compare this to scenarios of withdrawal of antibiotic treatment, the cessation of enteral tube feeding, or a one-way trial of extubation. Each of these scenarios may result in death. However, the intention is not to cause death, and clinical experience attests to the fact that death is not always an inevitable consequence. Thus, in these scenarios, the Principle of Double Effect can be applied. Double Effect has also been invoked to permissibly allow the removal of a gravid uterus in order to remove a uterine cancer, with the foreseeable but not intended death of the foetus. We argue, however, that in the scenario of the re-programming of a PPM, the intention is not to remove or to discontinue a dysfunctional device (that is, the PPM is not the seat of cancer, or indeed any other disease); rather, the specific aim is to cease this life-sustaining technology, because death is seen as the most beneficent way forward for the elderly woman with pneumonia. Similarly, in the well-known trolley thought experiments, if the out-of-control trolley rushing toward the five workers on the track is diverted onto the side track, where stands only one worker, so that the five survive, the one on the side-track *could* conceivably jump out of the way, and so also survive. However, in the alternative scenario, pushing the fat man off the bridge on to the track, *requires* that he be hit by the trolley in order to stop it – he cannot jump out of the way and still allow the five to survive. Thus, we do not see that, in the patient whose heart rhythm is entirely dependent upon it, the Principle of Double Effect can be applied to re-programming the PPM.

Similarly, in the scenarios above, we see a valid distinction between Doing and Allowing. "Allowing" ("letting die") is only possible if there is an underlying disease which, if untreated, is fatal. Callahan cites the example of placing himself,

with healthy lungs, onto a ventilator, and then notes the significant difference between switching off the ventilator (following which nothing terminal will occur; he will simply breathe on his own again) and giving a muscle paralysing agent to prevent breathing – an active act of "doing" ("killing").[19] In trying to apply the Principle of Doing versus Allowing to actively re-programming the PPM, "doing" deliberately re-programmes the PPM so as to no longer capture the heart's rhythm. The patient's continuing life is completely dependent upon this capture. "Nature's course" has already been taken over by this technology, and so, in our view, this dramatically reduces the distinction between Doing and Allowing.

Appeal to the Principle of Ordinary versus Extra-ordinary care may well have been useful prior to implantation, but is less useful after the event, when the PPM is already *in-situ*. Considering the construct of Benefit versus Burden, the PPM treatment cannot easily be withdrawn because that would require either an operation, or re-programming with the inevitable and almost instantaneous death of the dependent patient. Additionally, even when the patient is not completely dependent upon the PPM, its re-programming would inevitably bring about the recurrence of the symptoms that mandated the insertion of a pacemaker in the first place. These symptoms are, commonly, light-headedness and a propensity to sudden episodes of loss of consciousness. This would likely re-impose a significant burden on the patient. Put another way, in the non-dependent patient, deactivation of the PPM would neither improve the patient's well-being nor hasten death. Arguably, this is an inappropriate action regardless of the intention.

In summary of our argument thus far: in situations of implantation of PPM, appeal to either of the three frameworks, traditionally called upon to guide moral decision-making as the end-of-life approaches, are seen as having troublesome deficiencies in the current context.

Another problematic concept is that of patient autonomy, or the right to self-determination. This tenet is central to clinical decision-making, serving as a virtual ethical imperative. Compare a patient with an implanted PPM with a patient with an implanted mechanical cardiac valve. Despite both being implanted, it could be argued that the patient with the cardiac valve retains their autonomy about whether to continue with this life-maintaining treatment. They can effectively withdraw their consent for this treatment by discontinuing their prescribed warfarin dose, albeit aware that, without warfarin, the valve will likely thrombose and fail. Although some suggest that, from a moral philosophical perspective, fully implantable pacemakers are no different than, for example, implanted kidneys, hearts, or other organs,[20] these implanted organs may be rendered inoperable by ceasing to take immunosuppressant medication; the patient with a PPM has no autonomy to withdraw consent for this life-sustaining treatment. Even if seeking death, it is not possible for the patient to switch off or re-programme the PPM themselves. The patient, effectively, cannot withdraw their consent for this treatment. Control over the functionality of the PPM remains entirely with the clinician or technician. Additionally, the issue of re-programming will likely only be addressed as permissible or impermissible if the patient has some other life-threatening illness. In the view of England, the special categorisation of these devices as "integral devices" means that the clinician should not deactivate the

device on the grounds of futility,[21] but that the patient can require that the device be deactivated according to their right to autonomy. Others disagree, arguing that the dividing line blurs as technology advances, and that both patient and doctor have a right to have the device deactivated.[22]

Another complicating consideration, from a moral philosophical perspective, is the fact that in the scenarios above of cessation of antibiotic treatment, of tube feeding, or of a one-way trial of extubation, the time frame for death, if it occurs, is unpredictable, albeit it is likely to be within a span of several days or weeks. Following re-programming of the PPM, the time span to death is instantaneous, or within only a few moments. The nexus between the action of deactivation and the death of the patient is so immediate that the intent to hasten death is made explicit. While this may be emotionally unsettling, time span to death does not have any moral (or legal) weight in itself. It does however offer some understanding of the moral unease in re-programming the PPM in dependent patients.

From the perspective of the patient and the clinician caring for him, as a way forward based upon respect for patient autonomy and the difficulties with the three traditional frameworks, we argue that these important issues and constraints around device reprogramming be raised with the patient and discussed in detail, with the patient and their relatives, before device implantation. This should be an inclusive, non-coercive, and self-reflective dialogue, wherein the difficulties in making end-of-life decisions should be clearly and unambiguously explained and discussed. Basing moral decision-making upon this dialogue de-emphasises moral decision-making as substantive conception - in the sense of being founded upon stand-alone frameworks - and, instead, emphasises the conception of moral decision-making as based upon a *process* involving a moral community, emphasising values and norms reached by active and reflective communicative consensus, and thus possessing both cognitive and normative force. It is reported that a majority of adult patients with congenital heart disease want to have this conversation.[23] However, a recent study of 420 patients implanted with a defibrillator found that only 30% had prepared an advanced care directive, and only 2 of these mentioned the device or its deactivation at the end of life.[24] Ensuring that there is a dialogue amongst those involved before implantation is a necessary premise upon which moral philosophical debate should be founded.

From the perspective of the clinicians actively re-programming the PPM, there remains the issue of whether that re-programming of the PPM is effectively euthanasia. Despite published arguments to the contrary,[25] in a recent survey of physicians, 19% viewed deactivation in a patient, fully dependent upon their device, as physician-assisted suicide.[26] The 2010 European Heart Rhythm Association Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy recognises that "[o]bviously, the physician asked to deactivate the ICD and the industry representative asked to assist can conscientiously object to and refuse to perform device deactivation" on these grounds.[27] Given that there is an identifiable discomfort amongst clinicians,[28] and also amongst patients and care-givers[29] in this setting, not the least of which revolves around the very short time frame between re-programming and death, there is a role both for education of clinical and technical staff, and for subsequent de-briefing.

Conclusion

Given rapid advances in biotechnology, especially fully implantable technology, a re-evaluation of the three philosophical underpinnings of end-of-life decision-making, as they might assist moral decision-making in patients with fully implanted devices, seems appropriate. Rapid advances in biotechnology have rendered the distinctions offered by these three principles less clear and less useful in practical clinical application. This advanced biotechnology also implicates the patient's autonomy itself. Clear and open communication between clinician and patient about the nature and consequences of fully implantable devices, both before implantation and when significant deterioration in health appears possible, are necessary pre-requisites to moral decision-making in this context.

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Global Bioethics and Respect for Tradition: A Response to Ruth Macklin

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Abstract

In her book Against Relativism and elsewhere, Ruth Macklin argues against what she calls "respect for tradition." While she supports cultural sensitivity and tolerance, respect for tradition, on her view, is only a secondary principle: one that does not carry the same weight as the four principles of biomedical ethics. In this paper, I argue that Macklin's conceptions of cultural sensitivity and tolerance do not carry enough weight and that respect for tradition should be treated as a universal principle on par with other important moral principles.

Introduction

As the practice of bioethics continues to expand internationally, it has encountered many challenges, especially the challenge of ethical relativism. In response to ethical relativism, Ruth Macklin argues against what she calls "respect for tradition," a maxim she thinks serves anthropologists well in the field but is not a moral principle that can justify a cultural practice. On the contrary, I will argue that respect for cultural and religious traditions is a universal principle on par with other important moral principles.

Macklin's Principle-Based Approach

Macklin's approach to ethics follows the same principle-based approach (principlism) found in Beauchamp and Childress's *Principles of Biomedical Ethics*, which has become standard reading in the field. Beauchamp and Childress elucidate four ethical principles: autonomy, beneficence, nonmaleficence, and justice. Autonomy is the obligation to respect patients as persons; beneficence is the obligation to benefit patients; nonmaleficence is the obligation to avoid harming patients; and justice means, in general, to be fair in dealing with patients.

Macklin thinks, rightly, that principlism is a better alternative than either extreme of ethical relativism or moral absolutism. According to ethical relativism, there are no moral values that apply in every case. According to moral absolutism, there are rules that apply everywhere without variation. Principlism, on the other hand, is a more tenable, flexible approach that describes principles that are normative everywhere but admit of variation depending on the context. Macklin says, "The essence of this view is that universal forms that are found as human imperatives exist in all cultures, but there are no fixed contents to be found in any of these forms."[1]

This kind of principle-based approach is based on W. D. Ross's analysis of moral obligations. Ross thinks that our moral obligations are self-evident and intuitive, and he draws a distinction between *prima facie* obligations and actual

obligations. *Prima facie* obligations are ones that are morally binding on us unless they are trumped by stronger obligations. On this view, moral obligations are universal, but they may come into conflict with one another. When conflict occurs, moral agents must use wisdom to discern which obligation is the actual obligation in the given circumstances. As Beauchamp and Childress say, "What agents ought to do is, in the end, determined by what they ought to do *all things considered*."[2]

Macklin believes that respect for tradition is *not* one of these obligations. She tells a story of teaching the principles to a group of cross-cultural workers:

> I stated and explicated the principles of nonmaleficence, beneficence, respect for persons, and prominent principles of justice. When I had finished, one participant asked: "Are these the only fundamental ethical principles?"… Turning the challenge back to them, I asked if they could provide examples of candidates for coequal principles. One person proposed "respect for tradition." Never having heard this proposed as an ethical principle, I wondered whether it should qualify as one.[3]

Macklin concludes that it should not. She claims: "'Respect for tradition' cannot serve as an ethical *justification* of an action, custom, or practice. It can only function as an explanation for why people continue to do what they have done for centuries."[4] She says that it is a "convenient injunction for people in power – usually defenders of the status quo – to keep the system that sustains their power intact."[5]

African Female Circumcision

Macklin uses the case of African female circumcision as an illustration. Female circumcision, also known as *female genital mutilation* by opponents, occurs in a number of African countries, and in some places the rate of circumcision is greater than ninety percent. Female circumcision refers to a number of different practices:

> In the "mildest" forms (type I clitoridectomy), a part of the clitoris or the whole organ is removed. In type II clitoridectomy, the entire clitoris and part of the labia minora are removed. The most severe form is total infibulation, in which the clitoris and labia minora are removed and the opening is stitched together to cover the urethra and the entrance to the vagina, leaving a small opening for the passage of urine and menstrual blood.[6]

The practice is usually carried out around puberty by older women in the community who promote and protect the tradition. It is often conducted with unsterile instruments without anesthesia. Macklin describes the negative consequences:

> Short-term consequences of the procedure include severe pain, infection, trauma, hemorrhage, and even death. If performed in an infant or child and bleeding is prolonged, severe anemia and growth retardation can result. Serious long-term consequences result from infibulations more than from the milder forms of cutting and include formation of cysts and disfiguring scars, abscesses, pain during intercourse, infertility, chronic pain, chronic

> reproductive and urinary tract infections, obstructed labor, and increased risk of HIV infection. Most (but not all) women permanently lose the ability to achieve sexual pleasure.[7]

These short and long term consequences have led to the outlawing of the practice in many western nations including the United States.

Macklin explains that anthropologists who defend (or do not adamantly oppose) the practice do so for a number of reasons: (1) out of cultural sensitivity, (2) out of concern that criticism will only more deeply entrench the practice, and (3) out of the desire to avoid appearances of cultural imperialism.[8] She says that the mutilation of female genitals is a brutal violation of women's rights, and the practice violates the principle of nonmaleficence. No appeal to respect for tradition can justify the practice.

While she is right that respect for tradition cannot justify African female circumcision, this does not prove her case against respect for tradition as a moral obligation. At most it shows that respect for tradition is not the *stronger* obligation. In the case of these traditional African practices, the protection of young girls (or nonmaleficence) trumps respect for tradition.

The Principle of Respect for Tradition

To respect tradition means to take tradition seriously. Using Stephen Darwall's helpful distinction, this kind of respect would be classified as *recognition respect*, as opposed to *appraisal respect*.[9] Recognition respect means taking the object of respect seriously; appraisal respect means evaluating the object positively. As Darwall says, "To say that persons as such are entitled to [recognition] respect is to say that they are entitled to have other persons take seriously and weigh appropriately the fact that they are persons in deliberating about what to do."[10] To respect persons in this way does not mean having to admire them or agree with what they say, but it does mean that their lives and preferences deserve consideration. In the same way, to respect tradition in the recognition sense is, in Darwall's words, "just to regard it as something to be reckoned with (in the appropriate way) and to act accordingly."[11]

Respect for tradition is illustrated in multiculturalism, the sociopolitical movement that says that diversity is natural and good. Multiculturalism militates against the human tendency to think that one's own group is the best and that one's own way of thinking is, by that reason alone, the right one.

While many forms of multiculturalism include a strong dose of ethical relativism, relativism is not necessary to the movement. The point of multiculturalism is to celebrate difference and prevent cultural imperialism, which is compatible with the existence of moral universals. In fact, multiculturalism logically entails at least two universals: (1) that cultural difference is good, and (2) that cultural imperialism is bad.

Someone who accepts multiculturalism and universal moral principles keeps the two in tension. On the one hand, she will talk about cultivating the virtue of cultural sensitivity, that is, as some authors describe, moving from an ethnocentric to an ethnorelative orientation.[12] On the other hand, she will accept that there are

universal moral principles that are normative in every culture. These principles will not be absolutes that admit of no variation, but they will be evident through empirical investigation. The discovery of these principles will come only after careful reflection because the cultural outsider will want to ensure that she is not interpreting the practices in question through her own cultural lenses. She will want to be certain she understands the practices from the perspective of the cultural insider.

The flexible features of principlism make it compatible with multiculturalism in ways that absolutism is not. Absolutism emphasizes the permanent, fixed content of moral rules. Principlism speaks of universal forms, not of fixed contents, because principles are abstract. Principles can be abstracted from concrete situations and reapplied in different ways in other situations, ways that may look entirely different on the surface. One example that shows the flexibility of principles is the obligation of gratitude. Gratitude is universal, but it is not an absolute; in other words, showing gratitude looks different in different cultures. For example, In the U.S., people say "thank you" when close friends do something nice for them. In places like Vietnam, however, saying "thank you" to close friends is insulting because you have, as they say, let the gratitude escape from your heart. In Vietnam, the one who thanks *with words* is understood as trying to avoid having to return the favor later. Both cultures value gratitude (the universal principle), but the principle manifests in different ways.

Macklin critiques a move to derive respect for tradition from the principle of autonomy or respect for persons. As she says,

> It might be argued that respect for tradition could be considered part of respect for autonomy, but that maneuver will not stand up to ethical scrutiny. Application of the principle "respect for autonomy" cannot require that any actions whatever that flow from the capacity for self-determination must be judged ethically acceptable. People who engage in political torture, commit domestic violence, and sterilize people without their consent may all be acting autonomously, but they do not deserve respect. The same is true for traditions that individuals or a cultural group autonomously accept and adhere to. Some traditional practices are harmful, even evil, some are beneficial, and others are ethically neutral. The mere fact that it is a "tradition" says nothing about the moral value that should be attached to it. Just as laws may be enacted, criticized, or overturned for ethical reasons, so too may customs and traditions be subjected to ethical scrutiny.[13]

Macklin thinks that if we link respect for tradition to the principle of autonomy, then tradition becomes an absolute. There are two responses to this. First, whether the principle of respect for tradition is, in fact, linked to the principle of respect for persons is not important, for on a Rossian account, respect for tradition would be understood as a basic, *prima facie* principle. Second, principle-based systems do not generally work this way. One of the strengths of such systems is that principles are coequal, *prima facie* obligations, which means none of them are absolute. The principle of respect for tradition can trump other principles and be trumped by others.

Macklin's Second-Tier Principles

While Macklin thinks that respect for tradition is not coequal with other moral principles, she does uphold the value of cultural sensitivity and tolerance. As she says, "Intolerance of another's religious or traditional practices that pose no threat of harm is, at least, discourteous and at worst, a prejudicial attitude. It also fails to show respect for persons and their diverse religious and cultural practices…There are rarely good grounds for failing to respect the wishes of people based on their traditional religious or cultural beliefs."[14]

Is she contradicting herself here? Probably not, for she says that intolerance of this sort does not "involve a failure to respect persons at a more fundamental level" such as "if the doctor were to deny the patient her right to exercise her autonomy in the consent procedure."[15] So, Macklin makes a level distinction here. On one level, cultural sensitivity is required, but on a deeper moral level, it is not.

Perhaps she draws a distinction between virtues and principles, saying that cultural sensitivity is a virtue of character, but not a principle of action. This is possible, but it is not clear that such a distinction would be very useful. In fact, it seems that the two are closely related: for every virtue, there is a corresponding action. For example, an honest person is one who honors the principle of honesty and someone who honors the principle is honest. So, a culturally sensitive person is one who respects cultural traditions, and one who respects cultural traditions has the virtue of cultural sensitivity. However, nowhere does Macklin explicitly make this distinction.

Perhaps she thinks the list of moral principles is quite short, that Beauchamp and Childress's set of four principles is exhaustive. Perhaps she does not want to multiply principles beyond necessity. Nevertheless, if this kind of limited principlism is her view, how will she account for the normativity of other goods such as compassion, gratitude, honesty, and forgiveness? She may attempt to subsume them under the four principles as she does in the case of compassion. She says, "Arguably, [compassion] is a specific example of a rule that falls under the general ethical principle, *respect for persons.*"[16] However, cultural sensitivity and tolerance are not treated this way; instead, they are relegated to a second class of goods: a second tier of principles that are always trumped by first-tier principles if conflict arises. She does not call the secondary goods principles, but she does call them norms.[17] So for the remainder of this paper, I will call cultural sensitivity and tolerance (and respect for tradition) second-tier principles on her account.

If my analysis of her theory of principles is correct, then the difference between us is not whether respect for tradition is a principle or not, but whether it should be given equal weight with others. As mentioned above, Macklin's second-tier principles must give way to first-tier principles when conflicts arise; for example, the principle of respect for tradition must always yield to the principle of nonmaleficence. It seems that on her account if a cultural practice entails even the slightest harm or risk, the practice should be rejected.

How would male circumcision fare under Macklin's approach? As far as I know, she has not discussed the issue, so I can only speculate. The American

Academy of Pediatrics still treats male circumcision as morally permissible, but this is only because research shows that the health benefits outweigh the risks.[18] But what if the consensus of the medical community were to change? What if the health benefits could no longer be shown on the medical evidence to outweigh the risks? This seems at least possible given the debates in the literature.[19] If this were to happen, it seems that someone applying Macklin's approach might conclude that routine male circumcision is unacceptable. The only reason then to allow religious male circumcision would be out of respect for tradition, but respect for tradition is only a second-tier principle on her account and so does not carry much weight, especially when it conflicts with a first-tier principle like nonmaleficence. It is conceivable then that someone applying Macklin's approach would conclude that even the religious kind of male circumcision is unacceptable and ought to be banned. However, this would have quite an impact on religious followers the world over, especially Jews. As Baruch Spinoza says, "I think the sign of circumcision has such great importance as almost to persuade me that this thing alone will preserve their nation for ever."[20]

The Need for a Coequal Principle

Treating respect for tradition as a coequal principle would dramatically improve Macklin's approach. First, it would promote a more serious level of intercultural communication, requiring physicians to listen more carefully to how patients interpret their illnesses. On her current approach, it seems that there is no reason to make an effort to understand the cultural backgrounds of patients, except for politeness. As she says, there is nothing that culture or tradition can say to justify harmful practices, so, if the goal is to simply uphold the four standard principles of biomedical ethics, this could be accomplished without any engagement with the patient's beliefs.

Second, compromise and accommodation should be a regular occurrence in the clinic. For example, when a patient who has capacity to make her own medical decision chooses to leave the hospital AMA (against medical advice) and the principles of autonomy and beneficence come into conflict, physicians should seek a compromise in order to honor both principles.[21] Compromise should be sought because both principles are important.

As an example of compromise in the issue of African female circumcision, the American Academy of Pediatrics (AAP) has suggested a so-called "ritual nick," which is a small pinprick that draws blood. The AAP suggested this alternative as a much less harmful practice that would not only save many lives but also show a bit of cultural sensitivity. However, all forms of female circumcision, even the ritual nick, remain outlawed in the U.S. today, and the AAP retracted its statement on the ritual nick after much criticism.

It is unclear what Macklin's stance is on the ritual nick, but she casts it in a negative light in *Against Relativism.* She says,

> Others in our multicultural society consider it a requirement of "cultural sensitivity" to accommodate in some way to such requests of African immigrants. Harborview Medical Center in Seattle sought just such a solution. A group of doctors agreed to consider making a ritual nick in the fold of

> skin that covers the clitoris, but without removing any tissue. However, the hospital later abandoned the plan after being flooded with letters, postcards, and telephone calls in protest.[22]

Even if Macklin were open to the ritual nick alternative, it is unclear whether she could justify such a position on her view for the same reason that Jewish male circumcision might be rejected: her second-tier principle of tolerance does not carry enough weight to resist the demands of the principle of nonmaleficence.

To be clear, African female circumcision is much more harmful than male circumcision, and for this reason, it should not be tolerated. However, the ritual nick is a much safer alternative, especially if it is carried out in a proper medical clinic, and it could honor, in some sense, the African values upon which the practice of African female circumcision is based. These values include both religious and non-religious ones. On the religious side, support for the tradition comes from Islam and African Initiated Churches, who use Abraham's circumcision as a model for all people, men and women. As one cultural informant says: "Since Abraham was circumcised as a sign of his faith in God, we also should emulate him if we want to be righteous before God as he was."[23] On the non-religious side, social status and marriage are given as reasons. Circumcision is a rite of passage and welcomes a young girl into the community of women. As Mary Nyangweso Wangila explains:

> It ensures female fertility, provides a source of identity, and prescribes a social status; the lack of circumcision can lead to social exclusion and shunning. Circumcision is perceived as a test of courage in preparation for the pain of childbirth, a sign of maturity, a source of respect among peers, and an honor for the girl's family. In some communities it becomes a passport to marriage.[24]

African cultural values, as well as the values of every culture, should be respected, but cultural values need to be balanced with other moral considerations, such as autonomy, beneficence, nonmaleficence, and justice. If the principle of respect for culture is not treated as a coequal principle with the rest of these, then its demands will be trivialized.

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BOOK REVIEWS

In Search of the Good: A Life in Bioethics

Daniel Callahan. Cambridge and London: MIT Press, 2012.

ISBN: 9780262018487; 232 PAGES, CLOTH, $29.00/ £19.95

Philosopher Daniel Callahan, together with his friend and neighbor, psychiatrist Willard Gaylin, began the first free-standing bioethics research institute, the Hastings Center, in 1969. *In Search of the Good* recounts the establishment of that enterprise, and gives an overview of its subsequent work. More than that, *In Search of the Good* is the story of Daniel Callahan's journey through life, told in his own voice.

The first two chapters introduce the reader to the writer. It is at once a heady experience and a realistic one. Dr. Callahan, who earned degrees at both Yale and Harvard, does not whitewash his early deficiencies. Instead, these are viewed properly from more mature and wiser eyes and, by their inclusion, encourage the reader to find in his/her own shortcomings as sources of humility as well as opportunities for redemption.

The Hastings Center chose four areas of research to pursue: "population and reproductive biology, behavior control, end-of-life care, and genetics." (58) By "behavior control," they meant *violent* behavior control by *scientific* manipulations. (58) These chosen subjects, as well as a staff that was a veritable who's who of an upstart bioethics, garnered early and sustained success for the center. The Hastings Center takes no official stands, although its research groups and published articles may reflect strong views: "We had all agreed from the start that in a field full of legal, ethical, and social disagreements, our best contribution would be as an honest broker, working to speak in a civil tone, respecting the various actors, and doing what we could to bring some illumination to murky and often impossibly hard problems." (94) Besides their prolific written output, the center was also invited to formulate ethics training for West Point cadets, as well as a code of ethics for the U.S. Senate (the latter ultimately rejecting the help they sought).

From his own study of the Socratic dialogs, Callahan learned to be "respectful, relentlessly probing, altogether civilized" in his exchanges with others. (95) That did not mean avoiding confrontation, attested by the various disparate groups he brought together in conferences. His disdain for thought experiments (including the tethered violinist), his concern about the medicalization of our lives, and his lack of trust in unbridled technology qua savior of the human race are clearly articulated. Perhaps the best surprise, found throughout the book, is Callahan's humor. He is not afraid to appreciate humor where he finds it – even in himself.

One important rule the author espouses is "that no sentence should have to be read twice." (155) Alas, this rule is challenged by the text, albeit perhaps inadvertently. Over 10% of the pages include errors; indeed, the title of the book could be *In Search of the Good English Editor.* That difficulty aside, this insider's view of the establishment and continuation of the Hastings Center is worth the read.

Reviewed by D. Joy Riley, MD, MA (Bioethics) who serves as the Executive Director of the Tennessee Center for Bioethics and Culture in Brentwood, TN, USA.

Changing Signs of Truth: A Christian Introduction to the Semiotics of Communication

Crystal L. Downing. Downer's Grove, Ill: InterVarsity Press Academics, 2012.

ISBN 978-0-8308-3966-7, 295 PAGES; PAPER, $24.

"Signs, signs, everywhere a sign…can't you read the signs?" Signs are indeed everywhere as acknowledged by the Canadian rock group, "Five Man Electrical Band," in the 1970's. But despite the frustration with authoritative signs revealed in the lyrics of the song, our human communicative existence is in fact wholly dependent upon signs, which is the topic of the book *The Changing Signs of Truth: a Christian Introduction to the Semiotics of Communication* by Crystal Downing. The stated purpose of her book is to construct a rhetorically sophisticated and persuasive apologetic for the "unquestionable essentials" of Christian faith by means of semiotics. (187) But, in the process, Downing argues for the contextual contingency of signifiers, the inadequacy of signifiers for revealing both God and Truth, the need for dialogic openness to the signs of truth expressed by others, and the need for re-signing our signs of truth to make them understandable and relevant to contemporary culture.

Beginning with a description and history of semiotics, Downing explores the development of and changes in our understanding of signs from ancient Greek thought to the present. Digging deeper into the works of Saussure and Pierce, she compares and contrasts the dyadic and triadic structures of their theories, exploring the relationship of signifier to signified and the roles of the interpretant and representamen in our comprehension of the meaning of those signs. Ultimately, she focuses her attention on the work of Bakhtin, understanding his triadic theory as a reflection of the Trinity, and appreciating his emphasis on the embeddedness of our embodiment in our perception of truth. For Bakhtin, embodiment in space and time (chronotropy) affects the way that humans perceive and communicate truth: it is the *perception* of truth that is pluralistic, not truth itself.

Throughout the book she develops the metaphor of the "coin" with its two sides as representative of many issues of our day, and calls for Christians to be "edgy," riding on the edge of the coin. Her applications, which extend to doctrine, culture, and communication are provocative and sobering. Along with Bakhtin, she issues a call to dialogism, encouraging Christians to avoid falling to one side or the other, not clinging to the traditions of the past nor discarding them while striving only for the future. We are to maintain "both/and" approach to our appropriation of truth, but are cautioned that Truth transcends all signs and signification, and that not all signs are created equal. Christians on the edge, therefore, constantly balance between God's truth and the human formulations of that truth, knowing that we understand the former through the lens of the latter: the two co-inhere. (239)

Furthermore, in developing the metaphor of the vine and branches from John 15, she encourages us to apprehend the proliferation of branches in the Church as a gift of God, providing far-reaching shade that will potentially attract a variety of seekers. We are to rest assured that it is God who guides the process of semiosis.

In the final part of her work, Downing applies Bakhtin's triadic form of semiotics to the understanding and communication of Christian truths. She first designates three non-negotiable concepts as foundational truths for Christians (although it is unclear how she singles out these three): the Trinity, the incarnation, and salvation as gift (as opposed to economic exchange). Her perception of the Bible is governed by her semiotics as well: it is a gift of the Spirit that contains signs and must be interpreted in context; it is not to be idolized in itself. With regard to other truths, she maintains that our embodiment (in the vagaries of space and time) requires that we creatively change our signs in order to adequately communicate unchanging truths, a process Jesus exemplified for us by loving the signs of the past even as He changed them (273).

True to her vocation, Downing demonstrates her affinity for linguistic signs and metaphors by coloring her writing with a plethora of puns and double entendre that delightfully intrigue and engage the reader, thereby making a complex scholarly area of study very understandable and enjoyable. It is a significant contribution to our understanding of the signs that govern our Christian lives, how to make them

understandable to those embedded in today's culture, and how to live out the command to "be one" in the midst of our plurality.

Reviewed by Susan M. Haack, MD, MA (Bioethics), FACOG, a consultative gynecologist at Hess Memorial Hospital and Mile Bluff Medical Center in Mauston, Wisconsin, USA.

Flourishing: Health, Disease and Bioethics in Theological Perspective

Neil Messer. Grand Rapids, MI/Cambridge, UK: Wm. B. Eerdmans.

ISBN 978-0-8028-6899-2; 238 PAGES, PAPER, $37.99

Neil Messer's object in this volume is not to directly address issues in bioethics, but to establish theological concepts of health and disease that will undergird and inform engagement with what we may broadly term bioethical issues. It is an essay in four chapters, proceeding from a survey and critique of "Philosophical Accounts of Health, Disease and Illness" (chapter 1) to a statement of sixteen "Theological Theses concerning Health, Disease and Illness" (chapter 4). The theological resources laid out in the third chapter enable the theses set out in the fourth to take into particular account the question of disability, which has already earned a chapter to itself (chapter 2), bridging the philosophical and theological discussion.

Operating from within what he describes as a "broadly" Reformed perspective, Messer ends his initial examination of the literature on health, disease and illness with a declaration about the proper relation of philosophical to theological criteria in attaining substantive conclusions. His governing principles will be unashamedly theological, but he will make critical use of "insights and perspectives from other approaches and disciplines." (48) He undoubtedly sticks to this. Karl Barth and Thomas Aquinas are his main, though not his only, guides. Barth supplies the framework with his view that health is "strength for human life" which God wills in giving us freedom for life; we have a corresponding responsibility to respect life, which includes cultivating "the will to be healthy." Aquinas supplies a teleological complement, studiously setting human flourishing in the context of the goal of human life. The volume concludes that human health is a penultimate good, equally honouring both the penultimacy and the goodness.

This is a solid, persuasive, informed and well-organised volume. Not only does Neil Messer navigate a safe and sure course as he maps out the right conceptual relationships between impairment and disability, illness, disease and health; he skillfully correlates the theology of the second part of the book with the questions and perspectives set out in the first. The book is a trifle repetitive and, when we come to the therapy/enhancement distinction (204-6), we might wonder whether some repetition might have been avoided in order to expand on the question of enhancement, so crucial in today's Transhumanist discussion. However, the author would doubtless respond that this would require a book in itself. The book that we have is good: a solid set of basic theological principles grounding a careful analysis of concepts and an informed engagement with the current literature on health, illness, disease and disability.

However, I have questions in one area. Neil Messer is careful to describe and adjudicate different perspectives on health and disability. Nonetheless, I think that, with fitting sensitivity, we should press gently the question here and there of whether some of the literature surveyed in this volume uses an academic framework to state the obvious. Should we really regard it as an "insight" when one of the authors whom Messer discusses concludes that "[t]o have a disease, an illness or a disorder is necessarily to have a (*prima facie*) negative condition" (31, though see the relevant footnote)? When restrictions on a person's activity on account of disease, impairment, disability or handicap are understood by another of the authors discussed as a way of *objectifying experience* (my italics, 68), are we not privileging experience over plain facts in a way which is, ultimately, unhelpful? There are just examples of how we might probe the literature discussed in a slightly different way than does the author. Let me generalize: too much academic discourse is either incoherent or, when coherent, needlessly convoluted in expression. Fortunately, Neil Messer's volume is neither.

Reviewed by Stephen N. Williams, MA, PhD, who serves on the Editorial Board of *Ethics & Medicine* and is a Professor of Systematic Theology at Union Theological College in Belfast, Ireland, UK.

Incarnational Humanism: A Philosophy of Culture for the Church in the World

Jens Zimmerman. Downer's Grove, Ill.: InterVarsity Press Academic, 2012.

ISBN 978-0-8308-3903-2; 325 PAGES, PAPER, $30.00

Humanism, defined as a system of thought that focuses on humans while simultaneously rejecting any associated metaphysical beliefs concerning human nature, has become strongly aligned with secularism and non-theistic beliefs about the meaning and purpose of human life. But secular humanism, with no goal or ground for the human dignity it advocates, has lost the "horizon of significance" to which humans might have aspired. Without a ground or horizon, we no longer know what it means to be human, to construct a culture, or to flourish. In his book *Incarnational Humanism: a Philosophy of Culture for the Church in the World*, Jens Zimmerman seeks to counter the rootlessness of our culture, which has been severed from the transcendent source of its societal values, by retrieving a form of ancient Christian humanism for our time. He accomplishes his goal through the lens of Dietrich Bonheoffer's incarnational theology, which offers a hermeneutic epistemology that encourages a dynamic, interpretive faith while maintaining the reality of the self-revelation of God in Jesus.

Zimmerman begins by arguing that Christian humanism is the very root of secular humanism despite the secularist's ignorant opposition to Christian language and ideologies. The heart of early Christian humanism was deification—becoming like God, not in substance but by participation in the divine life through communion with God and the right use of reason. It was an understanding congruent with the Platonic notion of the world as an expression of a transcendent order in which we participate and to which the human mind corresponds. This Patristic incarnational anthropology persisted through the Renaissance and provided the foundation for the educational ideal of character formation found in Western culture. Zimmerman argues that Christianity's ability to combine faith and reason with a progressive view of human nature laid the foundation for science and technological progress that later sought to eliminate the faith that engendered it. Correspondingly, as the reality of the incarnation was denied by modern and postmodern thought, the synthesis of reason and faith disintegrated. Ultimately, the Platonic notion of participation in a transcendent order gave way to a disenchanted, inert, indifferent world in which meaning is confined to the interior life of the individual. This loss of metaphysical realism, of our participation in a higher, meaningful order of things, also accounts for the modern Christian's incarnational forgetfulness—our inability to imagine our actual participation in God and discern the mystery of church and Eucharist.

Zimmerman argues that the central mystery of the Christian faith is that God has made himself a human presence without compromising his transcendence, a presence within history and time that continues among believers in the church. The heart of incarnational humanism is participation in the incarnational mode of being in which God's transcendence, justice, and otherness are intrinsically linked to the material world and brought to bear on life through human agency. God died to make us fully human; Christianity is the path to true humanity.

While this book was written for an evangelical audience, much of the material, particularly in the latter chapters, may be quite daunting for those not conversant in the ideologies and theologies of post-modern philosophers. Zimmerman expends great energy in deciphering the intricacies of their philosophical positions with respect to his argument to demonstrate their negative impact on incarnational humanism. But Zimmerman is also hopeful that several developments within post-modernism, particularly in the area of hermeneutics and epistemology will open the door to a new appreciation of the richness of an incarnational humanism with its meaning for who we are and who we can become. Only incarnational humanism takes seriously the presence of God in the believer, church, and world, synthesizing reason, faith, and science in its understanding of humanity.

Reviewed by Susan M. Haack, MD, MA (Bioethics), MDiv, FACOG, a consultative gynecologist at Hess Memorial Hospital and Mile Bluff Medical Center in Mauston, Wisconsin, USA.

God and Gadgets: Following Jesus in a Technological Age

Brad J. Kallenburg. Eugene, OR: Cascade, 2011.

Ethicist Brad Kallenberg provides a book that considers the question of technology and theology from the angle of evangelism and discipleship. He ably shows that technology has three elements that must be considered: technology as a tool, technology as a human doing, and technology as a way of being. All three of these raise questions of the Christian way of being in the world.

Kallenberg depends on a Wittgensteinian view of language to argue that "gospelizing" requires human communication, but human communication is not simply about words. It requires time, location, and bodies. When technology makes us think we can replace some of these requirements and still communicate, it is dangerous. For Kallenberg, the gospel requires not only the words that technology might help us communicate but also an embodied community's way of life that technology can actually distort.

Kallenberg also draws out the logic of instrumentalization that pervades modern reality. He lays blame for this not only at the feet of technology but also at the feet of the reduction in the understanding of causation. Because of this reduction, Christianity is tempted to operate in the logic of instrumentalization rather than the logic of gift. Kallenberg wants to reconceive technology in this logic of gift, which enables technology to be redeemed in a sense when it is brought into service of the higher ends of Christianity and doing good.

One of the strengths of the book is the way Kallenberg makes it clear that we are "social cyborgs" in the sense that technology is very close to us and changes us (he relies on Heidegger here). He likens technology to the "principalities and powers" in Scripture, arguing that some types of technology can be redeemed to some degree when they are placed within the Christian community and oriented by it (especially teologically oriented).

In the final chapter, Kallenberg provides an interesting analysis, mining the field of engineering for an analogue for discipleship. He argues that just as there are novices that depend on heuristics in engineering and other technical endeavors, discipleship and moral formation require reliance on moral heuristics (such as divine commands) that as one approaches mastery one is able to understand more clearly for what they are: not exceptionless commands but limiting practices meant to frame so much more than they do at first sight. This was a helpful and unexpected turn at the end of the book.

Overall this book is very helpful on the question of technology, especially because it deals with it so briefly and clearly. It would serve as a good entry point for Christians to think about the relationship between technology and following Christ.

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The Anticipatory Corpse: Medicine, Power, and the Care of Dying

Jeffrey P. Bishop. University of Notre Dame Press, 2011.

In this book, Jeff Bishop argues that modern medicine's epistemology (using the dead body as means to obtain curative information for living bodies) and metaphysics (rejecting formal and final causation for sole focus on material efficient causation) has created a complex set of practices that shapes the way medicine cares for dying patients and the way patients perceive their dying.

Bishop spins a pretty good yarn here, utilizing Foucault's genealogical (development through time) and archaeological (more detail at one point) approaches. He develops how power shifts into fields of medicine and the social sciences, and how they use disciplinary power to effect how death is perceived and controlled. This connects to physiological approaches, through issues of defining death, to organ transplantation and even totalizing palliative care. Bishop uses the term "biopsychosociospiritual medicine" to denote this totalizing nature, where the medical community seeks to be experts and to control all of these aspects. However, because of the limited metaphysics, this approach does not work. And because of medicine's need for the dead body for its epistemology, it becomes complicit (at the very least) in killing the body for the sake of other living bodies.

Bishop's two dominant theoretical tools are Foucault's notion of power (especially disciplinary power) and Heidegger's notion of Being, especially as related to embeddedness of purpose and relationships. Foucault is used more in his diagnoses, and Heidegger in his constructive portion.

In the end, Bishop indicates that any way forward must recognize the structural nature of the problems. Medicine must take into account Heidegger's insight about being, especially the fact that being in the world is always already caught up in relationships and purposes. Medicine cannot seek to strip these away in the course of treatment. Instead, medicine must turn to traditions—even theology—for a way forward that treats patients as particular persons. When illness is experienced, it is experienced in a way that is caught up with purposes, with people's capacities, projects, and goals; this must be taken into account on each particular case.

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Health, Healing and the Church's Mission: Biblical Perspectives and Moral Priorities

Willard M. Swartley. Downer's Grove, Ill.: InterVarsity Press Academic, 2012.

ISBN 978-0-8308-3974-2; 268 PAGES, PAPER, $24.00

Does the Bible have anything to say about medicine and health care reform in America today? In his recently published work, *Health, Healing and the Church's Mission: Biblical Perspectives and Moral Priorities*, New Testament professor Willard Swartley addresses a range of questions about healing, attempting to connect the two millennia old Bible to modern health and health care reform in America today.

Swartley is well known in New Testament and Mennonite circles. Professor emeritus of New Testament at Anabaptist Mennonite Biblical Seminary, where he formerly served as dean and president, he has published many acclaimed books and articles including *Slavery, Sabbath, War and Women* (1983) that dealt with the relationship between the Bible and these controversial issues in Christianity. Swartley has now put his hermeneutical skills to use with a different issue - health.

His current book has three main parts. The first part is entitled "Health" and the author here reclaims "the relationship between the triune God and our healing efforts, by explicating the biblical (Old and New Testaments) understandings of health and healing." (19) In these five chapters, Swartley demonstrates that the Triune God is a healing God (chapter 1), that God heals in the Old Testament (chapter 2), that God heals in the New Testament (chapter 3), that sickness and healing bring paradoxes for humans (chapter 4), and that the church is called today to be a healing community (chapter 5).

In part two, "Health Care: Biblical, Moral, and Theological Perspectives", Swartley focuses "on understanding the biblical, ethical and historical involvement of the Judeo-Christian faith in health care over the last three millennia." (19) In these 4 chapters, the author discusses health and health care from various viewpoints including the Bible (chapter 6), Anabaptist themes such as mutual aid (chapter 7), church history (chapter 8), and the experience of disability (chapter 9).

And finally, in part three, named "Toward New Paradigms," the writer tries to "connect the biblical, historical and moral perspectives with the current U.S. health care challenges." (19) In these three chapters, Swartley describes the problems of the U. S. health care system (chapter 10), the prospects for U. S. health care from the perspective of shalom and service (chapter 11), and some current models for successful health care (chapter 12).

Overall, this book is well-written and worth reading by anyone interested in Biblical perspectives on sickness and healing, in Christian attitudes toward the vocation of medicine, or in modern health care reform. Swartley interacts with great thinkers of many different disciplines including Judaic studies (Abraham Heschel), Biblical studies (Walter Brueggemann, Terrence Fretheim, Frederick Gaiser, Joel Green, Victor Furnish), Catholic Ethics (Cardinal Joseph Bernardin), Protestant Bioethics (Gilbert Meilaender, Allen Verhey, Stanley Hauerwas), Christian systematic theologians (Jurgen Moltmann, Karl Barth, Gregory Boyd), popular medicine (Oliver Sacks), and more. The many footnotes do not impede reading, but do direct the reader to further published sources in many areas. As in some of his prior works, Swartley has researched far beyond his own area of Biblical studies in an attempt to bring Biblical concerns to medicine and the health care debate today.

Not all readers will agree with Swartley's conclusions. For instance, his analysis of the Bible and the world leads him to state clearly: "I regard universal coverage for basic health care a biblical morality priority." (192) Nevertheless, with some realism, he further states, "the complexity of the U. S. system makes it hard to achieve." (192)

Overall, this book is highly recommended to those interested in the Bible and the health care debate today,

Reviewed by Thor Swanson, MD, MDiv, ThM, MA (Bioethics), who continues to practice family medicine at Siouxland Community Health Center where he is also a director, and is active at St. Luke's Regional Medical Center in Sioux City, Iowa. In addition, he is an Associate Pastor at Friendship Community Church in Sergeant Bluff, Iowa, USA.

Ethics & Medicine
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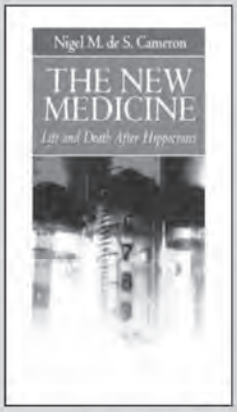
THE NEW MEDICINE : LIFE AND DEATH AFTER HIPPOCRATES

By Nigel M. de S. Cameron



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In the reprinting of a very important book for our current times, Dr. Cameron links the rise of the "new medicine" and the fall of the Hippocratic tradition to society's increased acceptance of the practices of euthanasia and assisted suicide. He states that "the medical profession is liable to follow any fundamental shift in society's values" and point to the relationship between Nazi Germany and the Nuremberg "medical crimes" as an example. In the absence of the Hippocratic prohibition against the killing of patients by their physicians, the fundamental value of protecting life is displaced. "the desire of society to avoid suffering, financial burden, and the inconvenience then lead to increasing support for physician-assisted suicide and euthanasia. The author contends that it is imperative for the medical profession to return to its Hippocratic roots.

"In the post-WWII era physicians began to water down the basic tenets of the Hippocratic tradition, and then they abandoned them. That's what this important book is all about: the rise and fall of Hippocratic medicine."
C. Everett Koop, Former US Surgeon General

"In **The New Medicine,** *Dr. Cameron has done much to earn the title of a second Hippocrates."* **Harold O.J. Brown, Professor of the Theology and Philosophy Reformed Theological Seminary**

"The New Medicine *is a persuasive manifesto that should be welcomed by those who have the courage to join a movement to reform aimed at restoring medicine to its healing mission."* **Richard John Neuhaus, Director Religion and Public Life**

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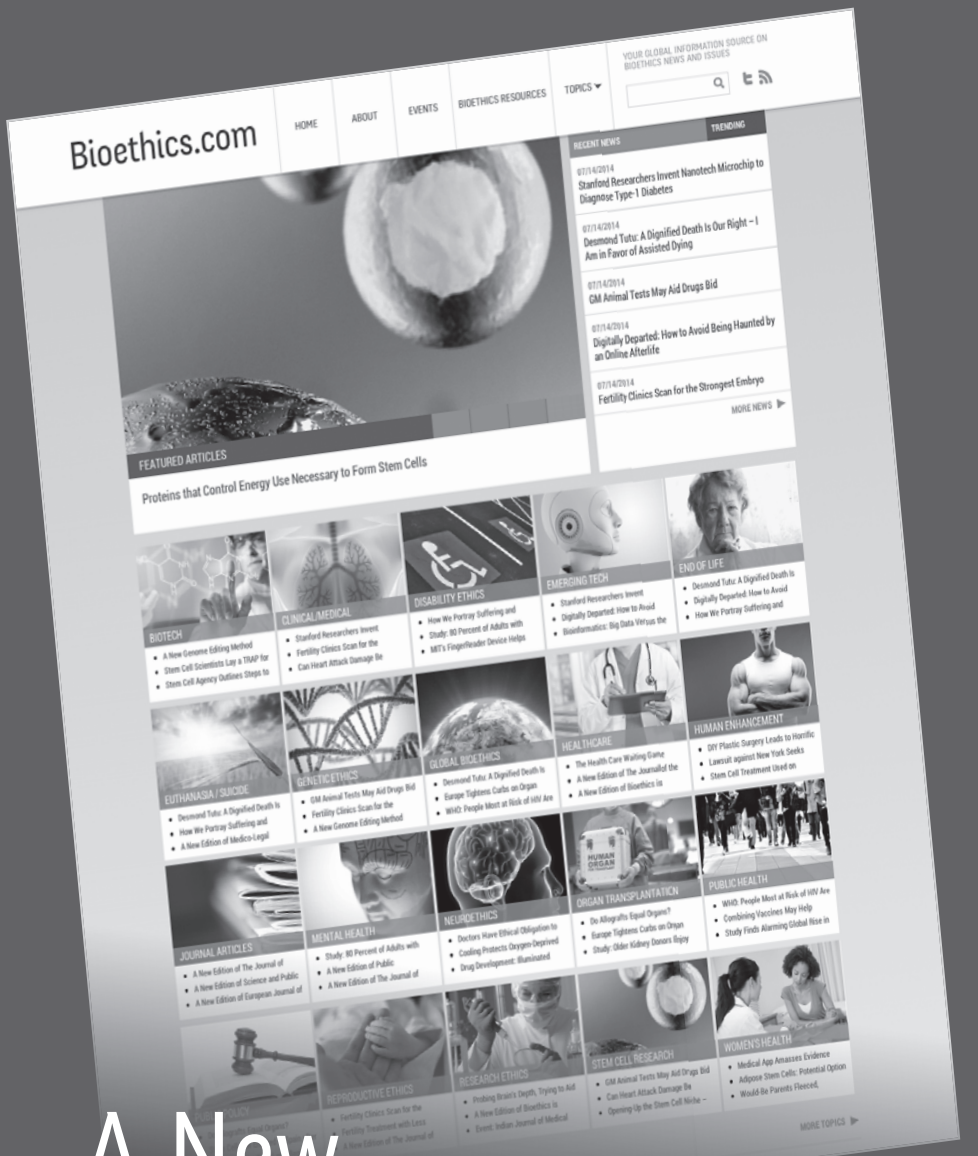

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