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- From the Director...
- Catholic Principles in Government Policy: President Bush on Embryonic Stem Cell Research
- IRBs-Inside and Out
- Anatomy of An Ethical Debate: Mary and Jodie

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Review the Health Care Ethics USA Index of Past Publications.
The recent tragedies caused by terrorism have shocked us all. There has been an outrageous assault on our nation and social fabric. And our general well-being is under stress. At such moments our commitment to the healing ministry of Christ is more important than ever. Our Catholic ministry has a mission for the nation - to encourage healing, to offer solace, and to bring hope in the face of suffering. The many reported accounts of heroic generosity will be multiplied, quietly and steadfastly, by the dedicated personnel in Catholic health care. At this awful time in US history we humbly offer our prayers for peace and divine grace to prevail. And let us be grateful for God's abundant blessings as so many of us are able to continue our daily routine, healthy and safe with family, friends, and colleagues.

Let me also introduce this issue of Health Care Ethics USA with good news at the Center. We relocated in late summer from the School of Nursing to a newly renovated facility on Saint Louis University's health sciences campus. Our new building has the name, Salus Center - how appropriate with Salus being the Latin word for health. It will take some time to work out all the glitches that occur with every move, but we are settling well and our usual routine in the PhD program is back on track.

This year we welcome several new students to our PhD program. Patrick O'Rourke from Ireland has returned to the program after a leave of absence to be ordained for Westminster diocese, London. James Schmelzer has joined the program with his wife and family moving from the east coast. And Robert Onder, a physician in St. Louis who recently completed his JD degree at our university's Law School, has joined us. Our fourth student, Alvenio Mozol, is from the Philippines, but he will join us in January due to his delayed student visa. We welcome these new students who bring a rich diversity to our interdisciplinary PhD program, with their graduate degrees representing the fields of philosophy, theology, health administration, medicine, and law.

We opened this new academic year with a wonderful array of sponsorship affiliations with our partners in Catholic health care. We have three externally sponsored graduate assistantships (via Ascension Health, Catholic Health Partners, and the Sisters of Charity of Leavenworth Health System) and two ethics fellowships (at Ascension Health in St. Louis and at St. Thomas Hospital in Nashville, TN). The combination of these sponsorships in Catholic health care and the support we receive from our own Graduate School enables us to offer full funding for all students who need financial support. It is a blessing to be a fully funded program in this manner.

Also, we warmly welcome two faculty at the Center. First, Marian McBay, PhD, is with us for one year as a visiting professor. Her PhD degree is in interdisciplinary ethics and her specialty research area is ethics issues related to Institutional Review Boards (often referred to as "research ethics"). During the year, she will be teaching several courses, serving on Institutional Review Boards at our University Hospital and the local VA hospital, presenting research seminars, and pursuing her own research. Second, Maria Glasova is a visiting Fulbright Fellow from Bratislava. Her PhD degree is in psychology and her specialty research area is in ethics issues related to child psychology. She will be pursuing her research for several months at the Center, including work at Cardinal Glennon Children's Hospital in St. Louis.

As usual, this issue of Health Care Ethics USA has three essays addressing ethics foundations, organizational ethics, and medical ethics. The first essay by myself discusses the recent Executive Order from President Bush on embryonic stem cell research. The essay discusses the President's approval of federal funding for embryonic stem cell research from the perspective of ethics foundations - by discussing the relevance of the principle of material cooperation. The second essay, on an
increasingly important issue in organizational ethics, is by Marian McBay, PhD, the Center’s visiting professor. Marian considers emerging ethical issues that need to be addressed by institutional review boards. The third essay, on a widely discussed case in medical ethics, is by Ann Suziedelis, MA, a senior doctoral student in our PhD program who is working currently on her dissertation. The essay discusses the recent case of conjoined twins in the United Kingdom, considering alternative ethical solutions from the perspective of the Catholic tradition. I hope you enjoy the essays and I look forward to receiving suggestions for topics that we might address in future essays.

Professor Gerard Magill, PhD
Executive Director & Department Chair
Center for Health Care Ethics
Catholic Principles in Government Policy:
President Bush on Embryonic Stem Cell Research

On August 9, 2001 President Bush announced his decision on federal funding for embryonic stem cell research.\(^1\) After months of careful deliberation he took advantage of his first television broadcast to the nation to address this increasingly polarized issue in life sciences research. He had raised the policy stakes on this issue during his election campaign in Fall 2000 when he opposed the stance adopted by his predecessor, President Clinton. The science of stem cell research is complicated yet crucial to grasping the policy debate.\(^2\) And a brief chronology of the issue's emergence in policy discourse is needed to grasp the ethical conundrum that faced President Bush.\(^3\)

In 1996 the US Congress forbid the use of federal funds for research in which embryos are destroyed, discarded or knowingly subjected to risk or injury - this occurred in the Appropriations Bill for the Department of Health and Human Services. But just two years later, in November 1998, US researchers made an amazing scientific breakthrough by successfully isolating and culturing embryonic stem cells in a process that unavoidably destroyed the embryo. Because of the immense potential of stem cell research for future therapies, especially given the versatility of pluripotent embryonic stem cells, the National Institutes of Health recommended a change in the federal funding policy.

Hence, in summer 2000, President Clinton gave an executive order to approve federal funding of embryonic stem cell research, provided NIH researchers did not actually extract the stem cells from embryos.\(^4\) The purpose here was to establish a distance between the actual destruction of the embryos (unavoidably caused by harvesting the embryonic stem cells) and the NIH's funding of subsequent research on the embryonic stem cells. Although President Bush opposed this stance of President Clinton, his own position one year later in summer 2001 was surprisingly similar - seeking to establish a distance between the destruction of embryonic stem cells and approval of NIH federal funding for subsequent research on the embryonic stem cells.

At first glance, there may not appear to be a great deal of difference between the positions of the two Presidents. In reality, there is a world of a difference, ethically speaking. And that difference lies specifically in the meaning of their different quests to establish a distance between embryo destruction and subsequent embryonic stem cell research. In each case, the astute ethicist can detect an application of the *principle of cooperation*, a solid ethical principle in the Catholic tradition that is superbly nuanced for resolving intricate cases such as those faced by both Presidents. Wittingly or not, it seems that the Catholic tradition via its ethical *principle of cooperation* had a very significant role to play in these policy decisions.

**Principles**

This essay discusses the ethical difference between the policies of the two Presidents and considers the legitimacy of applying the Catholic *principle of cooperation* to the issue of embryonic stem cell research. A fundamental distinction in the ethical *principle of cooperation* is between formal and material cooperation. *Formal* cooperation involves an action distinct from the act of wrongdoing but so closely aligned that the cooperative act in reality intends, approves, or facilitates the wrongdoing. Driving the getaway car in a bank robbery is a clear example: the action of driving the car constitutes formal cooperation with the act of wrongdoing (the bank robbery). *Material* cooperation involves an action that is distinct from the wrongdoing yet sufficiently linked as to establish a material connection, but not moral complicity with the wrongdoing. Vaccine research on immortalized cell lines from previously aborted fetal tissue is such an example. The ongoing medical research for viral vaccines, while materially connected to a previous abortion via the immortalized cells lines developed from the aborted fetal tissue, is not morally complicit with the original wrongdoing of abortion - there is sufficient distance between the previous abortion and subsequent vaccine research.
The crucial distinction between formal and material cooperation requires those involved to establish a distance between their own action and that of the wrongdoer: if there is not sufficient distance (as between driving the getaway car and the bank robbery), formal cooperation is likely; if there is sufficient distance (as between ongoing vaccine research and a previous abortion), material cooperation is likely. The question, then, is whether the policy decision of Presidents Clinton and Bush are tantamount to formal or material cooperation? To answer the question requires close scrutiny of whether they effectively establish a distance between the wrongdoing (harvesting embryonic stem cells that destroys the embryo) and the subsequent research on the embryonic stem cells.

Discussion

The executive order by President Clinton approved the NIH "Guidelines for Research Using Human Pluripotent Stem Cells" in summer 2000. The guidelines permitted federal funding of embryonic stem cell research provided the harvesting of the embryonic stem cells (and hence the destruction of the embryos) occurred via non-federally funded agencies. The NIH sought to establish a distance between the destruction of the embryos and its funded research on the embryonic stem cells. The effort fails from the perspective of ethics. Indeed, there is an unambiguous difference between the act of embryos destruction (to harvest stem cells) and the subsequent act of medical research on the stem cells - but this seems very like distinguishing between the bank robbery and driving the getaway car. In other words, it is very difficult to see how scientists undertaking research on embryonic stem cells, based on the policy of President Clinton, do not cooperate formally with the ongoing harvesting of the embryonic stem cells that involves the destruction of embryos. In the getaway car the driver wants to "work with" the loot in the bags - similarly, the scientist under President Clinton's policy is driving a research agenda that wants to "work with" embryonic stem cells involving the ongoing harvesting of these stem cells. Like the loot in the bag, the embryonic stem cells have been stolen by another! This analysis suggests that the policy of President Clinton fails in the application of the ethical principle of cooperation insofar as it is tantamount to formal cooperation and therefore ethically unjustified.

Prima facie, the executive order of President Bush in summer 2001 adopted a similar approach: he sought to establish a distance between the original destruction of embryos and subsequent research on the embryonic stem cells. However, in reality there is a major difference between his policy and that of his predecessor. The difference does not lie in the President's "aggressive funding of research on umbilical cord, placenta, adult and animal stem cells which do not involve the same dilemma" to use his own words. Such support and leadership to pursue the moral high ground, as welcome as it is, could not justify an unsound ethical compromise with regard to the conundrum we have been discussing. In reality, President Bush faced the conundrum directly emphasizing that he wanted to adopt a practical policy "without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos." Here he engaged the Achilles heel in the policy of President Clinton - approving funded research that required the ongoing destruction of human embryos (albeit by non-federally funded agencies). President Bush resolutely avoided this problem.

Rather, President Bush recognized that the previous destruction of human embryos established a limited number (whose specific count remains under dispute) of immortalized embryonic stem cell lines, presenting a valuable resource for ongoing medical research. In contrast to President Clinton's policy that supported research on embryonic stem cells requiring the ongoing harvesting of such cells (necessitating the continued destruction of human embryos), President Bush approved federal funding of medical research on a limited number of immortalized cell lines, thereby avoiding research that required the continued destruction of human embryos. This approach seems very similar to the legitimacy of ongoing vaccine research on immortalized cell lines developed from previously aborted fetal tissue. That is, President Bush presented a resolution that accommodates, at least theoretically, the Catholic tradition's use of the ethical principle of material cooperation. Despite this theoretical accommodation of a renowned principle in the Catholic tradition, the Catholic Bishops demurred in their public comments about the President's decision. Hence, an explanation of this dissonance between the theoretical accommodation and the practical use of the principle is required, as follows.

From a theoretical perspective, the stance of President Bush may satisfy the requirements of the principle of material cooperation. That is, subsequent research on the embryonic stem cells does not entail ongoing destruction of human embryos (as occurred in President Clinton's decision). Moreover, subsequent research will occur not on the actual stem cells that were derived from human embryos but on the immortalized cell lines developed from those original embryonic stem cells. Hence, the
connection between the destruction of human embryos (in the process of harvesting the original embryonic stem cells) and subsequent research on the immortalized cell lines is merely material - the original wrongdoing of destroying human embryos cannot be changed or prevented, far less intended by the subsequent medical research. Given the immense benefit that such research may have on future medical therapies, there appears to be a proportionate reason to permit federal funding on these immortalized cell lines. But if this seems such a reasonable application of the Catholic principle of material cooperation, why were the Bishops so ambivalent in their public statements about the President's decision?

The reason for this ambivalence seems to lie in the shift from theoretical to practical application of this principle. While the President's decision arguably fulfills the principle's requirements theoretically, in the practical realm there remain significant difficulties that concern the Bishops. Perhaps the most obvious difficulty is the so-called "slippery slope" argument, specifically mentioned by Cardinal McCarrick from Washington, D.C., and alluded to by others, such as Cardinal George from Chicago ("runs the risk of setting us on a course "). The slippery slope the Bishops anticipate is akin to the policy of President Clinton whereby federally funded research will require an ongoing need for new embryonic stem cells and the concomitant destruction of human embryos. In other words, although President Bush emphasized he would not follow that path, the practical demands of funded research may subsequently require such an option under different leadership. And the difficulty of this problem is easy to grasp from a political perspective. For example, if President Bush decides to run for a second Presidential term, and if at that point there are new immortalized cell lines developed from the harvesting of embryonic stem cells after August 2001 (when he announced his decision), it may be very difficult for him to reject federal funding of those new cell lines - even though they involved the destruction of human embryos after his original decision this year. In other words, the Bishops see clearly that the President's decision, however justifiable from a theoretical perspective, opens from a practical perspective a Pandora's Box that seems destined to increase the destruction of human embryos in the name of medical research. Hence, as a matter of their practical prudence, the Bishops demurred about the President's decision.

**Conclusion**

The policy decisions by President Clinton and President Bush provide superb illustrations of the contribution that Catholic principles can make to government policy. Each decision represents a different application of the principle of cooperation, I suggest illegitimately by President Clinton and legitimately by President Bush. But even if President Bush met the theoretical requirements of the principle of material cooperation, the hesitation by the Catholic Bishops to support his decision reveals the complexity of this principle in the shift from theory to practice. Of course, the skepticism of the Bishops about the decision of President Bush may prove in time to be appropriate. Yet, the challenge of bold leadership is to make difficult decisions prior to the wisdom of hindsight - with the decision of President Bush, it is fascinating that an ethical principle in our Catholic tradition made such a significant contribution to government policy on embryonic stem cell research.

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2. For a comprehensive summary of the science and technology of stem cell research, see the report from the National Institutes of Health, "Stem Cells: Scientific Progress and Future Research Directions" (July 2001) at, http://www.nih.gov/news/stemcell/scireport.htm

Suggested Readings


Questions for Discussion

1. Can you explain the distinction between formal and material cooperation using practical examples?
2. Can you explain the ethical difference between the policy decisions of President Clinton and President Bush on their approval of federal funds for embryonic stem cell research?
3. Can you explain why the Catholic Bishops remain cautious about the decision by President Bush to approve federal funding form embryonic stem cell research?
Institutional Review Boards (IRBs) look very different on the inside than they do from the outside. From the outside they often appear to function as a sort of *mysterium tremendum*. Their edicts are just that, demands to be met—take the "recommendations" because leaving them is not an option. Indeed, the IRB is vested with tremendous power in the life of a research institution and over the scientists whose work must pass through it. What social principles legitimate such power and what are the aims that drive an IRB?

On the inside the mystery quickly fades. Like most operational Boards, the work of its membership is well defined by procedures, institutional policies, regulatory requirements, individual and group tasks, membership roles and politics. The vast majority of IRBs in the US at this time review cumbersome amounts of material in increasingly demanded regulatory detail. Every IRB's aims, -while not modest- are the same and can be made very clear: *the aim of an IRB is to protect human subjects of research from unnecessary or unjustified risk*. What isn't always clear on the outside is just how an IRB arrives at a decision that research is approvable by these standards of minimized and justified risk.

The truth is that it takes a competent and experienced scientist to gain IRB approval. I use the word "competent" in a very broad and yet specific sense here. A scientist, from any field, must first be able to justify the research itself. The greater the risk, particularly if a protocol involves more than minimal risk to subjects, the greater the justification and background support that is required. Scientific review, however, is rarely primary among concerns that delay an IRB review process with any given protocol. Usually, a protocol review is prolonged either by a failure to accurately justify or declare risk *in the protocol itself* or by the failure to be forthright about risks in subject consent forms. Competency regarding regulations for human subjects protections and the ability to apply these regulations in the development of one's protocol and consent forms are essential and largely gained through additional training and experience with IRB regulations and local IRB expectations.¹

**Principles**

Two overarching principles guide current IRB review requirements and thereby "frame" The Belmont Report principles (respect for autonomy, beneficence, and justice). The first could be stated this way: "*Professions are licensed, research is regulated.*" The second overarching principle involves the moral and legal requirement that *no one should be subjected to greater than minimal risk research without their permission or the permission of their representative if they are not able to give such permission themselves.*²

**Professions are licensed; research is regulated.** This statement refers specifically to research with human subjects where the professional concerned is a licensed member of a helping profession. This principle is important because it is the use of research procedures by members of the helping professions (medicine, psychology, social work, and sometimes education), that historically gave way to the need for research regulations directed at protecting human participants of research.

The dual role of care-provider and researcher is fraught with ambiguities that professionals themselves may have sorted out well in their own minds, but for which the average research participant is completely unequipped to negotiate—hence, the critical importance of forthright consent. Further, as concerns the matter of dual professional roles by members of the helping profession, conflicts of interest are difficult to sort out.

**No one should be subjected to greater than minimal risk research without their permission or the permission of their representative if they are not able to give such permission themselves.** This principle represents a monumental compromise in the history of human subjects' rights to informed consent. Where the *Nuremberg Code* strictly forbade *any medical research being carried out without competent, voluntary, informed consent, the National Commission for the Protection of Human
Subjects of Biomedical and Behavioral Research accepted the World Medical Association's claim that clinical research benefits society to the extent that every member of society ought to be potentially relied upon to further research causes at some level. What is more, non-competent populations should be afforded, and not denied, the benefits that might be gained on their behalf through research participation. The parameters imposed in order to justify acting upon both of these claims (minimal involvement, benefits for the vulnerable) are conceptualized and set forth in the regulatory threshold concept: minimal risk. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102(j)].

You will note that the regulatory definition of minimal risk, established in the context of medicine, clearly reflects the extension of this medically rooted and justified notion to the realm of psycho-social research. The conflation of medical, that is, predominantly physical, risk with that of psychological and social risk arose as the result of the overall range of the National Commission's responsibilities, clearly reflected in the Commission's title: "...for the Protection of Human Subjects of Biomedical and Behavioral Research" (emphasis mine). The Milgram experiments, perhaps more than any other, contributed to the sweeping scope of behavioral and psychological research activity that finally came under the current regulatory umbrella. Discussions regarding the meaning of minimal risk when the concept is applied across research environs is a matter of continuing discussion.

In order to understand the National Commission's intentions, in this regard, it is helpful to know that evasion of privacy, not to be mistaken for either the problems of anonymity or confidentiality, accounted in the Commission's paradigm as a risk of equal importance to a citizen as was their health. A breach of privacy was then equal to the imposition of physical risk. Anonymity and confidentiality became two procedural paradigms for minimizing, but not eliminating such risk. To further clarify these distinctions, I think of anonymity as having to do with not knowing an individual's identity, confidentiality as concealing or protecting a known or knowable identity, and privacy as pertaining to the matter of asking or inquiring at all.

Returning to the concept of a minimal risk threshold: this is the threshold at or below which research may take place strictly on the basis of the value of research itself and not as justified by a positive risk-benefit ratio such as that required when justifying "greater than minimal risk" research. The minimal risk threshold does not define "exempt" research, nor does it establish the sole parameters of "expedited" research. It only sets the first and primary parameter within which research may be ruled exempt or expeditable (45 CFR 46.101, and 110, respectively). Some minimal risk research, upon review, may be found eligible for consent waiver where consent gathering would considerably alter the validity of data or the capacity to carry out research aims [45 CFR 116.6(c)(2) or (d)(3)] and when such waiver "will not adversely affect the rights and welfare of the subjects" [45 CFR 116.6 (d)(2)]. Put simply, the intents and purposes of the minimal risk threshold was to reduce the burdens upon the research process otherwise imposed by explicit written consent practices. What is more, the threshold was developed in the context of research with children, thus further muddying the concept when applied to normal adult volunteers.

A minimal risk designation by an IRB (or by inclusion on a list of expeditable procedures) is not to be construed as providing cart blanche access to research practice in this arena. Issues pertaining to scientific merit of a protocol still inform IRB review decisions, even where minimal risk research is being considered. What is more, vulnerable populations (some with special regulatory protections, e.g. children, and some populations identified as vulnerable, e.g. the institutionalized [45 CFR 46, parts B-D]) and persons for whom legally valid consent is not possible or from whom such consent is marginally valid, are specially protected even in the face of minimal risk procedures [45 CFR 46.111(7)(b)]. Most particularly and stated again, minimal risk research does not preclude an individuals' rights to privacy, anonymity or confidentiality. Research protocols that require the gathering of identifying information at any stage of the research protocol are now generally perceived as involving risks that justify full informed consent practice and IRB review.

Discussion

Two issues loom large on the horizon of IRB review at this time and both are related to the principles above. Recently, two scientists have lost research privileges in major universities. Both the University
of Michigan and Johns Hopkins University have suspended research and researcher privileges because of failure on the part of specific scientists to undertake appropriate human subjects protections precautions. The second matter concerns the 'Office for Human Subjects Protections'(OHRP) finding that there has been an historical practice in general of IRBs assigning minimal risk status to protocols that do not meet minimal risk criteria.

OHRP is concerned first and foremost with minimizing risk to human subjects. When scientists fail to take seriously the requirements of an IRB, or the regulations an IRB must enforce, human subjects can be put at greater than necessary risk. When protocols are inappropriately assigned a minimal risk status, they receive less frequent reviews (usually the minimum required annual Continuing Review) and this may result in inadequate levels of ongoing oversight by scientists and IRBs alike. What is more, inappropriately assigned protocols become subject to waivers of consent which are far less frequently granted in greater than minimal risk experiments, and then only under much more strict criteria, particularly where vulnerable populations are concerned.

Conclusion

As frustrating as it may seem to an investigator seeking to undertake important knowledge gathering, the Office for Human Subjects Protections puts it this way: "Other people and their private information don't belong to the PI." While the privilege to practice research is well-earned through years of education and by way of institutional endorsements, the implementation of research practice skills that involves human subjects is an evolving, locally reviewed, and regulated privilege. Institutional Review Boards, by way of Multiple Project Assurances (soon to be replaced by Federal Wide Assurances), under oversight of the Office for Human Research Protections are granted authority to approve research within defined parameters.

The regulatory parameters for research practice are the same on the inside of an IRB as they are on the outside. And so, perhaps it is not so much of a mystery at all.

Marian (Shug) Yagel McBay, Ph D
Visiting Assistant Professor

1. Federal regulations for the protections of human subjects are considered minimal requirements imposed by the federal government on federally funded research and research carried out in institutions have a Multiple Project Assurance (soon to be replaced by Federal Wide Assurances). IRBs are free to impose stricter requirements where necessary to ensure subjects' protections and Institutions can require IRBs to impose stricter requirements than those required by law [45 CFR 46.102 (h)] and Penslar (Institutional Review Board Guidebook, 1993/2000).

2. Minimal risk is considered to be a "threshold" concept because it serves as a risk managing device when IRBs consider matters of informed consent requirements, qualifications of research for exempt and expeditable review (certain conditions must be met for research to fall into these categories), justifiable use of deceit, and approvability of research involving vulnerable populations. See Levine, below, for a thorough explication of "minimal risk." The National Bioethics Advisory Committee, below, also provides a critique and recommendations for clarifying the definition of minimal risk research.

3. Part C, Additional protections pertaining to prisoners includes in an additional phrase in this definition: "of healthy persons" is added to the minimal risk assessment [46.303(d)], leading to ethics discussions regarding the "incremental" meaning of minimal risk for other vulnerable populations such as children wherein the final regulatory document was codified without the inclusion of this small phrase, particularly in the case of children. Levine provides a lengthy discussion of this issue, which is also addressed by the National Bioethics Advisory Committee in their Final Report, Recommendations 2.5 and 4.2.

4. The scope of this essay does not provide for the examination of categories of exempt research.

5. Research that, upon IRB review (or other institutionally designated procedure, approved by OHRP), is found to meet the requirements of research exemption from regulatory oversight and review.

6. Research which falls in one of several proscribed categories and represents minimal risk to the subject, including risks to privacy and anonymity.

7. Research that does not qualify for exemption, but involves only minimal risk, and for which an investigator can justify to an IRB that consent gathering would significantly affect data validity,
or in which consent is virtually impossible to gain under the circumstances of a well-designed protocol, can secure an IRB approved consent waiver. Such a waiver may include all or part of the IRB process [45 CFR 46.101(c-i);116(d); and, Part D, 401(c)]. However, an IRB must still require review and oversight over some research which is otherwise exempt under regulations, if information is gathered in such a way that identifiers can be linked to individuals and the result of such linking might result in "criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation" [45 CFR 46.101(b)(1)(i)].


Suggested Readings


Questions for Discussion

1. Several arguments are offered in defense of non-regulated research. One argument is that some studies suggest that research subjects are safer from serious risks than are normal patients. Another is that scientists should be duly trained in human subjects protections and then trusted to implement these protections without such heavy handed institutional and federal oversight. Consider each of these arguments in the following contexts: conflicts of interest; changes in subject safety that would change in the absence of IRBs; and any other issues that
might come to bear on this topic such as human rights, professional scope of practice, differences between medical treatment ethics and research oriented practice.

2. If clinical research participants were enrolled in research without their consent, would they ever know? How would they know? What would be the impact of research practice on the reputation of the medical profession in light of these concerns? What would be the impact upon research practice with human subjects if the public frequently or generally discovers itself to be subjected to science without consent?
Anatomy of An Ethical Debate: Mary and Jodie

During the autumn of 2000, our imaginations were captured by the haunting image of two babies, Jodie and Mary, joined together in a tragic perversion of the human form. While Jodie's heart and lungs were strong and healthy, Mary's were virtually useless. Because of their conjoined circulatory system, Jodie's organs kept both girls alive. A Solomonic dilemma faced the adults concerned with their fate. The best medical expertise was that to separate them would mean certain death for one, but to allow them to remain conjoined would mean certain death for both. Their physicians said, "We must separate to save Jodie's life!" Their parents said, "We can't kill Mary to save Jodie!" In the end, the courts intervened, and the girls were separated. As predicted, Mary died in the surgical suite. Jodie is now home with her parents, bright and healthy.

But these are just facts. What interests us here are the ethical issues. For though we may have a gut instinct about what "should" have been done, those of us in Catholic health care cannot afford to make judgments on feelings alone. We need to understand the ethical foundations upon which such serious decisions need to be made. This case offers fascinating insight into just how such ethical analysis was carried out, even though to disparate conclusions, by a number of thoughtful minds. Since many of our sources cite double effect in their reasoning, it provides a good focal point for us here. Our discussion does not offer any conclusion about whether or not separation was ethically justifiable. It summarizes, instead, the insightful dialogue and debate.

Principles

We are told to "Do good and avoid evil." But this does not mean that no evil may be done to achieve good. It means that no moral evil may be done. The precept is not absolute in regard to physical evil, and distinguishing between moral and physical evil is facilitated through the process of double effect reasoning (hereafter, DER). It is DER that helps us determine, in a particular case, when circumstances make it morally permissible for us to allow or cause harm, and to determine moral responsibility for foreseen and unwelcome side effects of an act. It does this by helping us determine whether those effects are merely permitted as side effects of a good act (and tolerated as inevitable) or are directly willed and therefore morally evil. For example, when a parent takes a child to the hospital for an appendectomy, does that parent tolerate as inevitable the fact that the child's body will be cut open and that he or she will feel pain (physical evils), or does the parent actually will (a moral evil) the mutilation and suffering itself? If the former, DER might allow the action. The latter could never be justified.

Volumes have been written about the nuances of DER, and scholars have debated it for centuries. For our purposes, however, one standard formula will be helpful. It states that a person may licitly perform an action that he or she foresees will produce a good effect and a bad effect, provided that four conditions are verified at one and the same time: (1) that the action in itself, from its very object, be good or at least indifferent, (2) that the evil effect not be intended, (3) that the good effect not be produced by the evil effect, and (4) that there be a proportionately grave reason for permitting the evil effect. In regard to Mary and Jodie, we must ask these questions: What was the act, and was it morally good, indifferent, or evil? Though Mary's death was clearly foreseen, was it intended or merely allowed? Was the saving of Jodie's life brought about by the death of Mary, or did her living and Mary's death result in parallel fashion from the act in question? Finally, was the saving of Jodie's life proportionate to the premature ending of Mary's?

Discussion

Let's begin our analysis of the ethical discourse with the argument of Cormac Murphy-O'Connor. He wrote that, "There are those … who would argue that one might embark on such an operation without having Mary's death as part of one's aim, and that her death would then be a foreseen but unintended consequence of a morally justifiable operation aimed at saving Jodie. But what is not possible is that
one could embark on such an operation without foreseeing that it would do Mary no good but only lethal harm. And even if her death were merely foreseen, the invasion of her bodily integrity is nevertheless intended. The process of separation cannot be thought of with any plausibility as one of cutting into Jodie's body alone; Mary's body is necessarily cut into. And that violation of her bodily integrity is in the nature of the case lethal for her. It therefore cannot be justified."

Albert S. Moraczewski agrees, identifying the act in question as "the surgical procedure, especially the cutting and clamping of the artery." He argues that the surgeons unjustly brought about a lethal injury to Mary, as they knowingly and freely severed the aorta and deprived her of her source of an adequately oxygenated blood supply. The act, he believes, is therefore morally evil, because in the choice freely made, an evil (the death of Mary) is included. Though Murphy-O'Connor had written that "the life that Mary has is, because of abnormal development, dependent on Jodie's blood supply," Moraczewski concludes instead that both girls had an "equal right" to the aorta's functioning. Philosopher Alex John London argues that this was not so, and that Jodie alone had a right to what he calls the "unrestricted use of her own vital functions." He also responds to Murphy-O'Connor's argument that "no duty exists to preserve life when the only available means to do so involves a grave injustice." As Murphy-O'Connor argues that there was no obligation to save Jodie's life through a grave injustice to Mary, so London argues that there was no obligation to save Mary's life through a grave injustice to Jodie. Since other caregivers unrelated to the separation could have, but chose not to offer Mary life support or transplantation on the basis of futility, given her serious pathophysiology, London argues that it was not fair to shift that life-prolonging burden to Jodie. It was not fair to suggest that she had an obligation to provide that life-support function, especially since it would entail the sacrifice of her own life.

Catherine Dominic differs with Murphy-O'Connor and Moraczewski as well. Rather than seeing the act as "the cutting and clamping of the artery," she sees it as the restoration of Jodie's organs to her so that she might live. In this, she rejects the notion of there being any intrinsically evil lethal assault made upon Mary. Mary's death, which Moraczewski sees as included in the act itself, is seen instead by Dominic as the foreseen but unintended bad effect of the act undertaken (separation) to achieve the good effect of saving Jodie's life. Still, Helen Watt argues that DER cannot work here, since it requires that nothing the agent intends can be morally unjustified, and she likens this surgery to the removal of a heart from a living donor. "Even if the donor's death is not intended," Watt writes, and "is in no way part of the plan," what is intended is the changing of the donor's body in a fashion that she identifies as 'mutilation.' William E. May concurred in an early essay (a position he now disavows), saying that the mutilation of Mary's body takes place in the act itself, and that this act is clearly intended, even if her death is merely foreseen. Intentional mutilation would thus be intrinsic evil enough to deny the satisfaction of Condition One (DER), and the agent's intention to mutilate violates Condition Two (DER). Since Mary's fatal mutilation would be the cause of saving Jodie's life, Condition Three (DER) would also be violated. Christopher Kaczor, though, suggests that the girls had two separate bodies with some fused portion, and argues that it would thus be impossible to invade "Mary's portion" (at least in the mid-section), since that might also be equally Jodie's portion. He therefore dismisses any clear intrinsic evil of invading and mutilating Mary's body.

Kaczor also questions the premise that the surgery "brought no good to Mary." He suggests instead that it gave each girl her rightful bodily integrity and physical autonomy, fleeting as that might have been for Mary. He points out that since the surgeons took nothing from Mary's body for the benefit of Jodie's, no mutilation took place, only separation. Watt counters that no, this was indeed mutilation, since the surgeons inflicted a wound from which Mary "would not recover." But Dominic reminds us that it was not a wound from which Mary could not have recovered! Further, Kaczor adds, bodily integrity is violated for the sake "only of others" in a number of instances, as when a living person donates an organ. And to the response that that is not a fatal occurrence for the donor, he and London, again, remind Watt that Mary's surgical wounds were not fatal in and of themselves.

This discussion of mutilation is later revisited by May, when he reverses himself and concludes that the object of the surgeons was not "the surgical procedure, especially the cutting and clamping of the artery," but rather, was precisely "to separate the twins." They foresaw Mary's death, but it was outside the scope of their intention. Neither, May now argues, was Mary's death the means to obtaining or saving Jodie's life. This, May concludes, along with Dominic's contention that Mary's death was caused by her pathophysiology and not the separation, renders the act in its moral object permissible under the conditions of double effect.
Conclusion

That faithful, traditional scholars disagree about double effect reasoning in any concrete case should neither surprise us nor cause us to question its relevance as a moral principle. Sometimes the dilemmas we seek to settle may be so confounding that even the most eminent thinkers disagree. Yet the fact that the use of this subtle reasoning needs such exacting attention enhances rather than weakens its integrity. In the words of T. Lincoln Bouscaren, reasoning that can justify “the permission of even the gravest consequences, such as the death of innocent persons,” ought not be too easy to manipulate.3

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Suggested Readings


Christopher Kaczor, "The Tragic Case of Jodie and Mary: Questions about Separating Conjoined Twins," at http://bellarmine.lmu.edu/faculty/ckaczor/articles/twins.html

Catherine Dominic, "Separating the Twins Jodie and Mary," Ethics & Medics 26 (June 2001).

Albert Moraczewski, "Against the Separation of Mary and Jodie," Ethics & Medics 26 (June 2001).

Questions for Discussion

1. Does the fact that traditional Catholic scholars disagree about the application of DER to a particular case undermine its value?
2. Using the criteria of DER, how would you argue for or against the separating of Mary and Jodie?