

**The International Organization
for Judicial Training (IOJT)**

**The UNESCO
Chair in Bioethics (Haifa)**



Casebook on Bioethics for Judges



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Casebook on Bioethics for Judges

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First edition

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Foreword

Judges today face bioethical dilemmas in a host of situations once barely imaginable, and the modern age has increased the issues presented many-fold. The internet (along with internet abuse) and social networking has allowed public access to information once in the sole and protected domain of health care providers. Age-old expectations of privacy are being eroded. Notions of informed consent are being reshaped. Paternalism on the part of physicians is no longer acceptable.

Further, it is well established that medical malpractice claims are a function of poor bedside manner, an area of physician training that until recently has received short-shrift. But a positive bedside manner, along with reducing malpractice claims, also fosters good care and a better doctor-patient relationship. To adequately and properly address patient's concerns, the doctor must be sensitive to bioethical issues in addition to purely medical ones, including safeguarding the patient's dignity, privacy and autonomy. When conflicts over proper medical conduct under these bioethical constraints are brought before the judiciary, it is critical that some mechanism is available to help sort out these thorny issues, many of which are novel questions without precedent.

'The Casebook on Bioethics for Judges' offers this much needed and comprehensive tool to help judges address a variety of medical-legal questions. The fact patterns that are presented are based on real cases that perplexed real judges. The discussion and questions following each vignette are based on the wealth of experiences and deep insights of the contributors and the Editor-in-Chief, Professor Amnon Carmi. Along with sensitizing judges to critical medico-legal and ethical issues, the Casebook introduces Judges to important and relevant provisions and principles of the UNESCO Declaration of Human Rights. Prof. Carmi, the holder of the UNESCO Chair of Bioethics and Deputy President of the International Organization for Judicial Training (which embraces 125 member-institutions from 76 countries) provides his unique perspectives as he frames the issues for discussion and sets out the bioethical considerations. Moreover,

the natural link between these two international organizations will, no doubt, promote the spread of knowledge presented in this book among judges and judicial educators world-wide.

I have no doubt that 'The Casebook on Bioethics for Judges' will be a major contribution to the knowledge of judges and lawmakers and aid their decision-making abilities when dealing with these critical and sensitive issues, and I am honored to present The Foreword for this important book.

Prof. Eliezer Rivlin, President

International Organization for Judicial Training (IOJT)

Introduction

Judges have to make various health care decisions. Many of the legal resolutions have ethical values built into them. Moral experience is universal, but some moral perceptions and legal judgments vary. A better understanding of the relationship between law, ethics and medical practice is required.

In their development through history, the disciplines of ethics and medical law that are founded on the ideas of duty and obligation have known different approaches. This book will offer an opportunity to examine and critically evaluate the different ethical and legal concepts in order to capture the valuable insights of many of these approaches. It will inquire the interaction and tension between morals and law and will analyze new trends concerning their causes and effects.

Special attention is paid to the phenomenon of patients' rights, especially in the context of health care. More specifically, the book will examine the various aspects of medical "paternalism" and judicial "imperialism", the content and scope of informed consent, the confidentiality rules, the end of life dilemmas, as well as additional issues such as medical research, the human genome project, assisted reproduction, the vulnerable patients, malpractice and risk management, and benefit and harm considerations. The new technologies that are currently introduced to the clinical practice require courts and legislators to reconsider certain rationales underlying the existing regulatory framework. The UNESCO Universal Declaration on Bioethics and Human Rights will be thoroughly discussed throughout the book.

The Judges Book on Bioethics is edited and published by two international organizations: The International Organization for Judicial Training (IOJT), and the UNESCO Chair in Bioethics (Haifa).

The IOJT was established in 2002 in order to promote the rule of law by supporting the work of judicial education institutions around the world. The mission of the IOJT is realized through international and regional conferences and other exchanges

that provide opportunities for judges and judicial educators to discuss strategies for establishing and developing training centers, designing effective curricula, developing faculty capacity, and improving teaching methodology.

The UNESCO Chair in Bioethics was established by UNESCO in 2001. The Chair was authorized to build and activate an international network of Units and to develop an up-to-date syllabus for medical ethics education which will satisfy the requirements of medical schools in the world. During the first fifteen years the Chair has established about 120 Units in five continents, and produced ten guiding books on ethics education.

The Constitution of UNESCO, adopted on the 16.11.46 stated that the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the dignity of man and constitute a sacred duty which all the nations must fulfill in a spirit of mutual assistance and concern.

On 19 October 2005, the 33rd Session of the General Conference of UNESCO adopted the Universal Declaration on Bioethics and Human Rights. The Declaration embodies a set of bioethical principles that has been agreed upon by 191 Member States of UNESCO, and that provides a common global ethical platform.

The Universal Declaration states (article 18) that professionalism, honesty, integrity and transparency, in a decision-making process, should be promoted. This basic ethical principle should be followed by the judicial community all over the world, and should be a cornerstone in the study of bioethics in law schools and in the judicial training institutes. The Declaration states (article 23) that in order to promote the principles set in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, States should endeavor to foster bioethics education and training at all levels.

Ethical dilemmas arise where judges confront two or more conflicting ethical principles. Each case has its own special circumstances. Judges should be trained to cope with

ethical issues and taught how to handle such difficult cases.

The educational message for judges is not easy and simple. On one hand, the Declaration provides them with ethical principles. On the other hand, the wording or the phrasing of the articles leaves them open for interpretation. The ball returns back to the judge, who is expected to cope with the specific circumstances of the individual case while following the general guidelines.

For example: Article 9 of the Universal Declaration deals with the ethical principle of privacy and confidentiality. The privacy of persons concerned and the confidentiality of their personal information should be respected. However, this commitment is not absolute, as the Declaration clarifies that the information should be kept to the greatest extent POSSIBLE. Moreover, in order to respect the prerogatives of States, the original text of the Declaration was changed, the word must has been replaced by should be: The privacy *should be* respected, instead of must be respected.

In practice, the rights and freedom of individuals are in conflict with the exigencies of the 'common good' and with the potentialities of information technology. The confidentiality of medical data is confronted with a set of legal and factual situations that could limit its scope, such as identification of potential offenders, codes of public health, or preventive medicine. Another example: The Universal Declaration states (Article 16) that the impact of life sciences on future generation, including their genetic constitution, should be given DUE REGARD. The Declaration emphasizes that our generation have to consider not only ourselves but also our global community and members of future generations. However, the Declaration does not fix unlimited or absolute requirements, but prefers to use the term of "due regard". The word due means – giving attention to a matter, but not an absolute duty or obligation. Same applies to Article 17 of the Universal Declaration that states that Due Regard should be given to the interconnection between human beings and other forms of life. As shown above, the Universal Declaration states (article 18) that professionalism, honesty, integrity

and transparency, in medical decision-making, should be promoted. However, the Declaration does not require to use absolute measures, but rather to make endeavor to use the best AVAILABLE scientific knowledge. Moreover, the Declaration does not use the term shall, but prefers the word should: the above mentioned values should be promoted. The Declaration represents a compromise of all the Member States. It was left to each State to express in its domestic law the desired degree of flexibility or rigidity in implementing the stipulations of the Declaration (P.Tandon,Henk&Jean,p.262).

Article 4 of the Universal Declaration emphasizes that in applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefit to patients, research participants and other affected individuals should be maximized, and any possible harm to such individuals should be minimized. Article 4 follows from Article 3 that refers to “Human Dignity and Human Rights”. Both articles treat dignity as an inherent property of being human. Recognition of the central place of dignity in human rights and ethics takes into account the obligations of the human species for other human beings.

In health care practice it is important to evaluate benefits and harm. An assessment has to be made between risk of harms and potential benefits. This is particularly important for resource allocation, when time and material resources are scarce. Conformity to the obligations of Article 4 requires a combination of prudential judgments and technical competence. Estimates of probability and projections of the expected impact on the individual patient and the society of a proposed treatment must be made.

The book possesses heuristic and pedagogical characteristics, thus translating complicated ethical dilemmas and conveying their messages in an easy and clear manner. The editors of this book have collected and chosen cases as the tool to teach ethical concepts. While as a teaching tool the use of cases may have its detractors, they are commonly used to convey in a few paragraphs the central elements of a case and to demonstrate in practice the application of concepts. The cases are collected from many

countries worldwide and reflect a universal perception. The problems that the vignettes depict are similar everywhere, and judges have to grapple with them no matter where they practice. The cases in this book cover large segments of issues and topics that most often bedevil the medical practice, and on occasions become a matter of public debate about the appropriateness of medical interventions.

Following the presentation of each case a binary approach has been used to indicate the possibilities of at least two opposite answers to the problem. Of course, judges are invited to develop their own favored ethical choices for the resolutions of these case studies. While this approach may be considered too simplistic, the idea is to provide judges with alternatives in thinking ethically, without encumbering them with deep ethical concepts for which texts and other books have been specifically written. The cases are drawn from real-life experiences. They are based on simple fact situations, so that the judges can address their ethical elements, rather than evade ethical engagements by resort to technical means or development of additional facts. Through case studies, judges will learn, firstly, to develop sensitivity for ethical problems and to describe an ethical conflict; secondly, to identify and analyze the underlying ethical principles and values which are relevant to the case, and, thirdly, to stimulate ethical decision-making in the practice of health-care. This book should be considered as just a "primer" in ethics with no pretense to be a scholarly text. The editors do not profess to solve all the ethical issues, but rather to inspire the readers to think about all of them more closely and more carefully.

Last but not least, I would like to express our gratitude to the UNESCO Headquarters, especially to Dr. Dafna Feinholz, Chief, Bioethics Section, Division of Ethics of Science and Technology, Social and Human Sciences Sector for the support in the production of this book.

Prof. Amnon Carmi

Preface

“The sanctity of life is not disputed and I would say that it is so well-known that it does not call for evidence. Everywhere, irrespective of religion or nationality, human life is regarded as a treasured possession to be guarded at all costs. The trouble is, however, that this supreme consideration is not the only one which we must bear in mind.... As in most problems of law and of life in general, it is not the choice between the good and the bad which makes decision difficult. The difficulty lies in the choice between different considerations all of which are good and worthy of attention but inconsistent among themselves and in respect of which we must determine an order of priority.”

Zim Israel Navigation Co. LTD. v. Shoshana Maziar CA 461/62

With this backdrop in mind, The Judge’s Book on Bioethics and the unique training program devised by Professor Amnon Carmi is offered as a framework to assist judges in sifting through bioethical considerations (as enumerated in the UNESCO Universal Declaration on Bioethics and Human Rights (2005)) that may present themselves in the course of litigation. I have been honored and privileged to work with (and learn from) Professor Carmi in the production of this book.

In developing this work, we relied on the work of many volunteer contributors (as well as UNESCO employees and contractors) without whose efforts this book would not have been born. We thank them heartily. The midwives of this work came from around the world, and coordinating their activities became a joy and a challenge, most especially for Prof. Carmi who spent endless hours pouring over and trying to organize comments that came from widely disparate time zones with accompanying differences in legal and bioethical sensitivities, and later for me in trying to reconcile different legal systems, jurisdictional approaches, terminology, and choice of language that brought along with it differing understandings of various case holdings.

To make the most of this work, the reader should understand that the legal fact

patterns are presented to “humanize” the ethical dilemmas addressed in the UNESCO Declarations and to make the discussions more relevant, meaningful and memorable. While the fact patterns are based on real cases, they are not necessarily identical with those as reported. In all cases the facts have been sharpened to highlight the particular issue raised in each unit; in some cases facts may have been omitted, in others facts may have been changed – again to allow focus on the bioethical issue raised for study and avoid distraction by facts which may be important– albeit extraneous from this vantage point. In some cases, these facts – some heart-rending – may have influenced the judges’ decision, and the reader is urged to refer back to them in cases of interest. The same caveat holds true for the judicial decisions. In some of these cases the latest appellate decision in the chain may have been given short shrift (or may not have yet even occurred) in order to focus on more interesting and illustrative passages from intermediate opinions.

We recognize (and hope) that this book will be used by judges in jurisdictions the world over. Consequently, we tried to use “legally neutral language” where possible. Words with particular legal connotations in some jurisdictions (such as for example “infringe on”) were eschewed in favor of other less legally loaded terms (e.g., “impinge on”), perhaps in the process sacrificing some precision. In other cases, the reader will be asked to bear with us, as words such as “affirmed, sustained, upheld” which may have different connotations in different jurisdictions –could not easily be “homogenized”.

An important word of thank you. I wish to express my extreme gratitude to Elizabeth Wasson, of Suffolk University Law School for her invaluable assistance.

Barbara Pfeffer Billauer

UNIT 1: Human Dignity

Article 3

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

1. *“Human dignity, human rights and fundamental freedoms are to be fully respected.*
2. *The interests and welfare of the individual should have priority over the sole interest of science or society.”*

Introductory Discussion:

Dignity and Individual Interests

All human beings are equal in dignity, irrespective of gender, age, social status or ethnicity. Recognition of a person's dignity presupposes an active respect for his or her human rights, self-esteem and self-determination. The notion of ‘dignity’ is used to mark a threshold, a level of respect and care beneath which the treatment of any human being should never fall.

As Justice William Brennan noted in the United States Supreme Court case, *Furman v. Georgia*, 408 U.S. 238 (1972): "Even the vilest criminal remains a human being possessed of common human dignity."

The concept of human dignity provides the necessary conceptual background for responding to the concerns about respect in clinical and research settings.

Against this backdrop, we must recognize that treating people equally need not - and should not- mean treating them identically. Exceptional circumstances may arise where the balancing of interests is extremely delicate. In some cases the interests of others (or the community as a whole) may be so important or compelling that impinging upon the interest(s) of an individual is both unavoidable – and justifiable -- to avoid serious harm to others or the community.

This dilemma poses especially poignant questions in the area of health-care and provider-patient relations. Some aspects of concern which address dignity and human rights include the phenomenon of paternalism, the treatment of children, elderly persons and the mentally handicapped, palliative treatment of terminal patients and treatment of embryos and fetuses.

FACT PATTERN 1:***Dignity in Death and Dying:***

Based on Pretty v. UK (England, 2002).

The applicant, who is paralyzed from the neck down, is suffering from a degenerative motor neuron disease, which is incurable and progressive. She has virtually no decipherable speech and is fed through a tube. Her life expectancy is very poor, measurable only in weeks or months. As she is frightened and distressed at the suffering and indignity she will endure if the disease runs its course, she wants to be able to control how and when she dies. The applicant's solicitor sought assurance from the Director of Public Prosecutions (DPP) not to prosecute the applicant's husband should he assist her in committing suicide in accordance with her wishes. The DPP denied the husband's petition and the husband appealed.

Issue: Should the applicant's husband be granted immunity from prosecution if he assists his wife in committing suicide?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The husband would be carrying out the wishes of his beloved wife, and he is the only one who can help fulfill her wishes to die with dignity.

2: Yes.

The husband has demonstrated his respect for the state and its laws by seeking legal permission to carry out an action which he morally supports.

3: No.

The State has an interest in protecting life and no person may take the life of another innocent person.

4: No.

Assisting in the death of another person is inhumane and cannot be seen as a remedy for an otherwise undignified death.

Court Decision:

The court upheld the denial of the husband's petition.

The court stated that the very essence of the Convention for the Protection of Human Rights and Fundamental Freedoms is respect for human dignity and human freedom. However, it rejected the applicant's claim, holding that the right not to suffer inhumane or degrading treatment should be read in harmony with the right to life, which does not confer on an individual a right to require a State to permit or facilitate his or her death.

Bioethical Considerations:

The DPP's refusal to grant immunity from prosecution and the prohibition on assisting suicide may, indeed, foster inhumane and degrading treatment, thereby failing to protect patients (especially terminal patients), from suffering. The Court's reading of the right not to suffer inhuman treatment grants primacy to the latter, and in this sense reflects a moral judgment which is not necessarily evident from the Convention.

The UNESCO Declaration on Bioethics and Human Rights, Article 3, states that "fundamental freedoms are to be fully respected." Thus we can say that life is a right, not an obligation. The second part of this article states that "the interests and welfare of the individual should have priority over the sole interest of science or society."

We may ask: what are the interests of society in this case?

Let's look at one example: Assume a terminal patient is taking up a bed which might be better used by someone with a better prognosis, and assume further that there is a scarcity of hospital resources, including beds. In this case keeping a terminal patient alive against his or her wishes is detrimental to both patients: Keeping the first patient alive is against his or her right to die with dignity and also deprives the second (non-moribund) person of a chance to fully - or at least more quickly - recover and enjoy a productive life.

Looking at the matter from a different perspective, we must remember the holistic definition of ‘quality of life’ in the Constitution of the World Health Organization (WHO). WHO defines ‘quality of life’ as an “individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." It is a broad-ranging concept which is affected in complex ways by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment. In this case, the husband feels his wife is not meeting any criteria contemplated by this definition. The judge's decision (denying the husband's petition) is based on legal constraints. However, it is important to consider the bioethical concerns, as well.

It is interesting to note that some bioethical principles are in conflict here: the Respect for Human Dignity is in conflict with the State's legal obligation to protect and preserve human life and with the imperative to do no harm. Even the respect for human dignity is in conflict with the respect for the value of human life.

For Further Discussion:

1. Is it of interest that the husband is seeking legal protection without indication of the wife's preferred timing of the anticipated suicide, either objective (e.g., when her liver fails), or expressed (such as when she sends her husband a written note) or subjective (for example, when she no longer has moments of joy). Under this scenario, one may argue the husband is given power over the timing of the wife's decision – which, without written evidence that she confers on him this right, impacts on her right of autonomy.
2. If the husband is the decision-maker, one may argue there is a potential conflict of interest – or that one might arise in the future: Thus, for example, assume the wife clearly wants to end her life – but only at some future undetermined date. One may question whether the husband's interests might be the driving force in – or at least influence - his carrying out the initiative prematurely (for example: would a husband be inclined to hurry a wife's death so he can remarry?). Alternatively, might he procrastinate effectuating her death, delaying it to a point long after the wife would have desired such an end (e.g., because the husband is psychologically conflicted about performing his wife's request).
3. Akin to question #2: If judgment or subjective considerations are involved – in

other words, the wife says she wants to die when she no longer can experience joy –could other personal considerations such as financial interests cloud the husband’s judgment? What about his religious or social interests?

4. In the event the wife’s preferred timing is unclear - is there some way to effectuate the wife’s desire without the dangers of enabling her husband to do both the ‘the doing’ and the deciding. Would this separation of responsibilities (via e.g., an independent panel of doctors, a court-appointed committee or guardian ad litem), relieve some of the concerns?
5. It is not very clear what counts as assistance. There have been a number of Dutch cases on this issue. The general line is that for ‘assistance’ there must be more than mere information given to the patient, although some claim that even the husband’s travelling with his wife could be objectionable.

FACT PATTERN 2:

Individual Interest and Discontinuation of Life Support:

Based on: ‘Plaintiff v. Yonsei University’ (South Korea, 2009).

A request for discontinuing life-support was brought by the family of an incompetent patient who suffered widespread brain edema, loss of cognition, reduction in cerebral function and inability to maintain breathing without an artificial respirator. The family inferred that the patient would have wanted to have her life-sustaining support removed from three facts:

1. as a Christian the plaintiff kept clean appearance by wearing long-sleeve clothing after she had a scar caused by traffic accident;
2. a remark by the plaintiff while watching a television program that she wants to leave this life without becoming a burden to others, and
3. she rejected a tracheotomy operation for her husband, saying she does not believe in extending life by machine.

The plaintiff’s attending physician was of the opinion that the patient was not brain dead but in a vegetative state with less than a 5% possibility of recovering consciousness. The medical practitioner evaluating her records and the doctors who examined her were of the opinion that she was beyond a vegetative state, and was, in fact, near brain

death, with no chance of recovery.

Issue: Should the attending physician be permitted to comply with the family's request?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons:

1: Yes.

The family is best equipped to know the best interests of the patient, which includes more than just artificially keeping her alive.

2: Yes.

The family better knows the patient's wishes and feelings which should be considered in the decision-making.

3: Yes.

Preference should be given to the patient's right to dignity and autonomy (fulfilled through her guardian) over preserving her life.

4: Yes.

Complying with the family's request saves public resources that might otherwise be wasted.

5: No.

The patient or her family's request pertaining to medical treatment should be subject to medical evaluation concerning the possible risks and benefits of such a treatment.

6: No.

There is no certainty of the patient's wishes and feelings regarding her death before the accident, and therefore causing her death may not be in accord with her desires.

7: No.

Complying with the family's request requires medical intervention which amounts

to killing an innocent person.

8: No.

Complying with the family's request violates both the doctor's Hippocratic Oath (i.e., first, 'do no harm') and is a violation of the Bioethical Imperative of non-maleficence (non-maleficence).

Court Decision:

The court ruled that where there is no possibility of recovering consciousness, the irreversible process of death had already begun. If a life-extending treatment, such as medically futile invasion of the body, is forced upon the patient, his or her human dignity and values may be compromised. In such a situation, protecting the patient's dignity and values as a human being corresponds to social norms and does not violate the spirit of the Constitution.

Bioethical Considerations:

In this case, on the one hand, the poor medical prognosis helps the court accept the family's request which both promotes the patient's best interests and protects societal interests concerning public resources. In such a situation protecting the patient's dignity and value as a human being is accomplished by respecting the patient's decision to face death. This argument corresponds to accommodating prevailing social norms.

On the other hand, the Court does not attribute much weight to the nature of the requested action by her family, namely actively discontinuing life-support and to other personal values of a Christian person, especially her beliefs regarding the value of life and the conditions for their preservation.

For Further Discussion:

1. In the absence of a written or express declaration or designation of a particular person as a surrogate, must the surrogate's conflicts-of-interests be carefully examined? In the absence of a designated surrogate, even implicit, where issues of autonomy are concerned, is a court-appointed guardian-ad-litem a better way to proceed?
2. If any treatment is forced on a patient, bioethical concerns arise: The court, here, is co-mingling two distinct issues: a. the use of arguably futile of treatment (which further triggers the question of how we establish whether any treatment is futile? What standards we will use: case reports? epidemiological studies?) and, b. forcing

or imposing treatment on a patient who is incompetent to consent (which, in some cases, can be considered a battery).

3. What constitutes futile treatment? Prolongation of life by a month? By a week? By day? Who decides?
4. Concerning her reaction to extending the life of her husband: Does her desire not to prolong his life mean she had the same view for herself?

UNIT 2: Individual Interests

FACT PATTERN 3:

Removal of Artificial Nutrition and Hydration:

Based on 'The case of Eluana Englaro' (Italy, 2008-2009).

A twenty-one year old woman was involved in a devastating car accident that placed her in a coma. She was paralyzed from the neck down and unable to swallow. The patient did not leave any advance directive concerning treatment, although her friends reported that she had told them that if she ever had an accident and entered a vegetative state, she would rather die than be kept alive artificially. A commission established by the Ministry of Health concluded that withdrawal of nutrition and hydration for permanently comatose patients can be legitimate, and the patient's guardian, her father, petitioned the Court for removal of his daughter's artificial nutrition and hydration.

Issue: Should a patient's guardian be granted the authority to request removal of artificial nutrition and hydration?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons:

1: Yes.

As her guardian, the patient's father is given the legal right to determine her best interests, which includes artificially feeding and hydrating his daughter and determining the time of their cessation.

2: Yes.

Preference should be given to the patient's right to dignity and autonomy (through her guardian) over artificial feeding and hydration.

3: No.

Feeding and hydration are not considered "medical treatment" and cannot be subject to the discretion of a guardian. These represent elemental needs of any human being

and must be administered without exception.

4: No.

Complying with the guardian's wishes amounts to inhumane and degrading treatment, including causing pain and possibly leading to death.

5: No.

The patient's treatment was not medically futile, and therefore cannot be withdrawn.

Court Decision:

The lower Courts refused to be bound by the Commission's report and rejected all legal grounds to withdraw treatment. Although there was sufficient evidence to find that the young woman had repeatedly stated that it would be better to die than surviving in a state of complete unconsciousness, the court ruled there was a conflict of interest between the patient and her father, who treated her as if she were already dead, according to testimony of nuns who cared for her.

The patient's father filed a new petition to the Court, seeking to appoint a curator speciale to share decision-making. The petition was rejected both by the lower court and the Court of Appeals. However, in a dramatic turn of events, the Supreme Court held that nutrition and hydration are considered medical treatment that, in principle, can be withdrawn.

(The decision was issued on November 13, 2008 and was met with immediate criticism from the Roman Catholic Church. On February 2, 2009 after all rights of appeal were exhausted, the patient's father moved her to a private nursing home and feeding was discontinued. On February 6, 2009 Prime Minister Berlusconi issued a decree that would have forced the continuation of the treatment of the young woman. This action thrust Italy into a constitutional crisis when the President of the Republic refused to sign the decree. The woman died on 9 February 2009.)

Bioethical Considerations:

Instead of determining who has legal authority to make end-of-life decisions the various tribunals involved in this case focused on the best interests of the patient. The case pivoted on the fundamental question of whether artificial feeding and hydration are considered "medical treatments" such that a guardian may be authorized to request their withdrawal.

From an ethical perspective it is not clear why the removal of any "treatment" is less inhumane or degrading than removal of other actions performed on a comatose or terminal patient. Both removals may involve either increased suffering or hastening of death, which is contrary to the primary principle in medical ethics: first, do no harm to the patient. Therefore, one must ask if the critical question should turn on whether the patient has a right (expressed via her guardian) to remove artificial feeding and hydration (even where no explicit wishes are made by her when she was competent).

Another issue to be considered is whether the Executive Branch of the government (here the Prime Minister, in the case of Terry Schiavo, the Governor) should have the right to intercede in a legal issue that is fully resolved (or resolvable) in the courts. It can be argued that courts, at least, have some capacity to investigate bioethical issues, or at least distinguish the personal interests (and religious beliefs) of the Executive from the best interests and the rights of patient and his or her guardian.

For Further Discussion:

1. By definition can 'autonomy' ever be fulfilled through another person without a detailed advanced directive?
2. Where there is no specific advanced directive, is the appointment of a totally impartial (non-related) guardian more protective than allowing someone who may have personal interests make these decisions?
3. If the guardian's wishes are not carried out – what is the purpose of a guardian?
4. Does a guardian have the authority to consent to withdrawal of non-medically futile treatment? What safeguards are in place to prevent personal interests (financial, emotional) from affecting the decision?
5. Assume the father is the sole heir to his daughter's estate – would that affect one's decision?
6. Is this a case where the duty to avoid malfeasance or maleficence conflicts with the patient's right to autonomy? How should such a conflict be resolved?
7. Is this an issue that should be determined based on the social concerns or religious mores of the majority of the country?

FACT PATTERN 4:***The Right to Abortion:***

Based on R.R. v. Poland (Poland, 2008).

An 18-week pregnant woman underwent an ultrasound and was told by her treating physician that the possibility her fetus was affected with either Edwards* or Turner Syndrome** could not be ruled out. The woman told her physician she wished to have an abortion if the suspicion was confirmed. Following more scans confirming one of these diagnoses and after consultation with a geneticist, the woman sought referral for a genetic testing. Her physician refused her request because he determined the fetus' condition did not legally qualify for an abortion. Subsequently, the woman and her husband visited the treating physician and demanded the termination of the pregnancy. The doctor refused, but instead proposed that a panel of doctors would review the case. The woman and her husband rejected this proposal and went to a public hospital, seeking genetic testing and an abortion if warranted. The woman was admitted on an emergency basis. An amniocentesis performed during the 23rd week of pregnancy confirmed Turner Syndrome. The woman asked the hospital on three separate occasions - and in writing - to terminate her pregnancy, but received no response. Her geneticist felt that under the provisions of the law performance of the abortion legally could be undertaken. Yet, the hospital refused on the grounds that the fetus was viable, that the law in the country allowed abortion only before the 22nd week of pregnancy - and only where the pregnancy endangers the mother's health or life or where there is an indication the fetus will be severely or irreversibly damaged or will suffer a life-threatening ailment. A few weeks later the woman gave birth to a baby girl suffering Turner Syndrome.

The woman and her husband brought an action against her treating physician and the hospital for delay in performing the genetic testing, thereby depriving her of the option of having a timely abortion. The Regional Court dismissed the woman's claim, holding that her rights had not been breached. The court ruled there was no actionable procrastination since her visit to the hospital (where the tests were performed) occurred when she already was in 23rd week of pregnancy. Her appeal to the Court of Appeal was dismissed and the matter was brought before the Supreme Court.

Issue #1: Should the pregnant woman have been given an opportunity to have an abortion?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Decisions relating to pregnancy are the most intimate and private and should be decided by the individual and not the State or physicians.

2: Yes.

The pregnant woman expressed a legitimate wish to terminate the pregnancy in a timely manner at a point when such a termination was legal.

3: No.

By week 23 of the pregnancy, the fetus is a person and has an independent right to life according to the laws of the country of the patient's domicile.

4: No.

Complying with the woman's wishes sends a message to society that people suffering from Edwards, Turner Syndrome (or any other such diseases) are not worthy of living. Such a message may legitimize discriminatory actions towards people with disabilities (raising the 'slippery slope' argument).

5: No.

The pregnancy is not-life threatening to the mother and the severity of the genetic disease to the child is not known at the time the decision needs to be made.

Issue # 2: May a screening program of fetal diseases be offered to women if abortion is prohibited?

1. Yes.

The parents will be better prepared to cope with their child's defects at birth if these exist, should they decide (or be forbidden) to terminate the pregnancy.

2. Yes.

This may facilitate timely abortions to address life-threatening defects.

3. No.

Ultrasound taken before the 22nd week of pregnancy is not accurate.

4. No.

The issues are the same as without a screening program and such a program may only increase psychological harm to the parents.

Court Decision:

The Supreme Court reversed the Appellate Decision.

The court held that the doctor was obliged to refer the pregnant woman for genetic testing, which derived from her right to obtain adequate information about the health of the fetus. The court commented that if the doctor had moral objections to such a referral, he should have informed the applicant and referred her to another practitioner. Moreover, the obligation to refer the applicant for genetic testing did not end when abortion of a fetus was no longer legal in that country (that is, after 22nd week). Hence, the court held the doctors had breached the applicant's rights. In the court's view, the tests should have been carried out immediately after the suspicions arose.

Bioethical Considerations:

A woman's right to terminate or continue her pregnancy due to medical or social reasons is one of the most intimate and private rights protecting her autonomy and dignity. While the State may have an interest in protecting the life of the fetus, it nonetheless should exercise such interests with great sensitivity, albeit in accordance with social beliefs and norms in that locality as to when life begins. These latter beliefs may be affected by religious or spiritual conventions that, at times are derived from the characteristics of the State, e.g., a Catholic state or a state where religion and State are separated.

On one hand, one could argue that to fully respect an adult's right to autonomy, a woman's right to choose to continue or to terminate her pregnancy should not be dependent on the stage of pregnancy or (any legally-protected) societal values. Just as women should not be forced to follow a specific life-style because they are pregnant, they should not be forced to carry a fetus they do not desire. On the other hand, the freedoms of every

individual could be outweighed by serious and constitutive societal norms and values along with the interests and rights of other individuals, especially those who cannot protect themselves. The State's interest in protecting the life of the fetus at a certain age may represent an example of such a compromise.

For Further Discussion:

1. Does it matter what the diseases are that the fetus may be suspected of having? See below for definitions of Edwards and Turner Syndrome.
2. Is the fact that the doctor procrastinated in referring the woman for genetic testing relevant? Should the hospital have followed the geneticist's advice and terminated the pregnancy – or sought leave to do so?
3. If the life of the fetus enjoys a primacy, then the doctor may have deprived the pregnant woman of a right to terminate the pregnancy- but should it affect the court's ruling as to the legitimacy of the hospital's failure to perform the abortion?
4. Would the mother have a civil action against the doctor (for malpractice) if the law affords the fetus the right to life?
5. While ultrasound may be a useful screening tool, should the fact that it is not a perfect tool affect one's decision? In other words, does the existence (and incidence) of false positive or false negative results impact on one's decision?
6. Is it useful to consider the high suicide rates of mothers in countries where access to abortion is unavailable or severely limited vs. the suicide rates of countries where abortion is easier to secure?
7. Is it important to consider the claim that women who have abortions are said to suffer an increased rate of post-traumatic stress syndrome?
8. Does it matter whether the child has Edwards syndrome or Turner syndrome?

Edwards syndrome is a chromosomal abnormality caused by the presence of all, or part of, an extra 18th chromosome. The majority of fetuses with the syndrome die before birth. The syndrome has a very low rate of survival, and severe retardation is prevalent in those who do survive. (Merck Manual, 14th edition. P. 1925) “Of those that survive to birth, around half will die within two weeks and only around one in every five will live at least three months. Around one in every 12 babies born with Edwards' syndrome

survives beyond one year, and they will live with severe physical and mental disabilities. Some children do survive to early adulthood, but this is very rare.” N.H. S. Website, last accessed Nov. 27, 2015. <http://www.nhs.uk/conditions/edwards-syndrome/Pages/Introduction.aspx>

Turner syndrome (TS) also known as Ullrich–Turner syndrome, is a condition in which a female is partly or completely missing an X chromosome and is associated with an absence of secondary sex characteristics. (Merck Manual 14th edition p. 1600) Generally, girls with Turner syndrome are unable to have children. Many have troubles with spatial visualization such as that needed for mathematics although, otherwise intelligence is generally normal. “Nearly all girls and women with Turner syndrome need ongoing medical care from a variety of specialists. Regular checkups and appropriate care can help most girls and women lead relatively healthy, independent lives.” (From the Mayo Clinic web page; last accessed Nov. 27, 2015, <http://www.mayoclinic.org/diseases-conditions/turner-syndrome/basics/definition/con-20032572>), See also NIH National Human Genome Research Institute, <https://www.genome.gov/19519119>, last accessed Nov.

Difficulties with ultrasound accuracy and reliability: In one study, prenatal ultrasonography diagnosed congenital anomalies in 289 (63.2%) patients, 257 (56.2%) of which were confirmed after birth, exhibiting 96% sensitivity and 79% specificity. See Alex Sandro Rolland de Souza², Olímpio Barbosa de Moraes Filho³, Adriana Mota Bione Noronha, Validation of ultrasound diagnosis of fetal anomalies at a specialist center Carlos Noronha Neto^{1*}, *Rev Assoc Med Bras* 55(5): 541-6, (2009) http://www.scielo.br/pdf/ramb/v55n5/en_16.pdf.

References:

United Nations 1981 Convention on the Elimination of All Forms of Discrimination against women <http://www.un.org/womenwatch/daw/cedaw>

UNESCO Gender Mainstreaming Resource Centre at UNESCO/Section for Women and Gender Equality/Gender Focal Points/Passport to Equality <http://www.unesco.org/women>

FACT PATTERN 5:***The Right to Enjoy IVF (In Vitro Fertilization)***

Based on Artavia Murillo et al. v Costa Rica (Inter-American Court of Justice, 2012).

A young woman (we will call her Amy) is an infertile Costa Rican resident who wants to use in-vitro-fertilization (IVF) in order to become a parent. However, IVF is no longer permitted in Costa Rica. The Inter-American Commission on Human Rights brought an action against the State of Costa Rica on behalf of the woman, claiming that this prohibition constituted an arbitrary interference in the right to private life and the right to found a family. It further alleged that the prohibition violated the right to equality of those seeking treatment, inasmuch as the State denied them access to treatment that would have enabled them to overcome their biological disadvantage and incapacity to have biological children. It also argued that this ban has a disproportionate impact on women.

Issue: Is there an ethical justification for the (legislative) prohibition of IVF such that Amy may legally be deprived of the opportunity to become a parent?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

In the course of IVF, human embryos are created, some of which are unavoidably destined to die or used for experimentation which some may find morally reprehensible. Hence, the practice of IVF negatively affects the right to life and dignity of the human being.

2: No.

Amy has rights to privacy, family and the right to pursue happiness, including equal access to treatment which might enable her to become a parent, and the State should not be allowed to limit these rights.

3: No.

Amy's well-being will be affected by the opportunity to take advantage of IVF and the possibility of becoming a parent.

Court Decision:

The court observed that the decision to have one's own biological children using assisted reproduction techniques (ART) forms part of the right to personal integrity and the right to family, and concluded that the Constitutional Chamber failed to consider these other competing rights when prohibiting IVF.

Accepting the WHO definition of infertility as a disease, the court also held that the prohibition of IVF amounts to disability-discrimination due to the financial hardship of costs associated with travelling outside Costa Rica to access these services. In addition, the court ruled that such a prohibition has a detrimental effect on women.

Finally, in distinguishing between fertilization and implantation of embryos, the court held that it is only after completion of implantation that conception has occurred. In the court's view, un-implanted embryos are only human cells or tissues and they should not be granted the status of a person with incident human rights, specifically, the right to life.

Bioethical Considerations:

This case involves the question of when life begins and when one becomes a "person" entitled to its own rights, including the right to life and dignity.

Along with the interests or rights of un-implanted embryos one must consider the rights (and responsibilities) of their genitors. Unlike the maternal-fetal conflict where one may have to balance competing interests, and then only at certain stages of pregnancy, in the case of un-implanted embryos, the rights of genitors should receive the highest weight and prevail over any and all other interests. This does not only derive from the status of un-implanted embryos, but from the very nature of the IVF procedure itself.

For Further Discussion:

1. Is the embryo considered a 'being' entitled to a right to dignity as distinct from a right to life?
2. Since there is no guarantee IVF will work- does the petitioner have a right to the potential for parenthood?

3. How should one decide whether un-implanted embryos are to be regarded as persons? Is this a religious decision? Does it turn on the state of the art- of-science which may enable the embryo to attain personhood? Should it be based on a vote of the majority of the population?
4. The court ruled that only upon implantation does the embryo begin to have some personal identity, a condition necessary for securing 'moral status. Is there a right to 'moral status'? How is that defined? What is the benchmark? Who makes that determination?
5. Assuming *arguendo* (for the sake of argument) that embryos do not enjoy 'personhood', should un-implanted embryos be regarded as property of their genitors? What distinguishes them from other human cells or tissues?
6. Should genitors be allowed to maintain some level of control over their management and fate? Should both contributors to the genetic component of the embryo be afforded equal rights? (i.e., mother and father equally?) Should they be responsible for their disposal?
7. Would a child born from IVF in this country be stigmatized if the case became public?
8. Should persons choosing IVF, which entails a host of physical and emotional risks, be responsible for all outcomes?
9. If there is a conflict between the potential right to life of an embryo and the bioethical rights of a potential parent – whose rights are paramount? (See UNIT 3, Balancing of Interests).

References

International Federation of Gynecology and Obstetrics 2009 Recommendation about ethics themes in Obstetrics and Gynecology.

UNIT 3: Risks and Benefits

Article 4

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.”

Introductory Discussion:

Maximizing Benefits and Minimizing Risks

In the health care practice it is important to evaluate and balance benefits and harm. Estimates of probability and projections of expected impact of a proposed treatment on the individual patient and the society-at-large must be carefully scrutinized – based on multiple considerations, including accuracy (reliability), validity and legitimacy.

Benefits can be of many kinds, such as advancing the welfare of a patient or the interests of society or producing new knowledge of value to future patients. Risks are defined as estimates or probabilities (or even possibilities) of harming a patient or a society. Benefits and harm may be physical, psychological, or social/economic. At times the possibility of harm may be morally acceptable if maximization of benefits and minimization of harm have been achieved.

FACT PATTERN 6:

Surgical Separation of Conjoined Twins:

Based on: Re A (Children) (United Kingdom, 2001).

Jaye and Em (not their real names) were twins-girls who were born joined at the pelvis. Jaye sustained Em's life as Em's heart and lungs did not function. Evidence showed that if they were not separated, Jaye's heart would fail and both would die within a few months. The hospital sought to perform separation surgery - which would allow Jaye to live a relatively normal life although Em would die immediately. The twin's parents refused on religious grounds. They seek a declaration that the separation surgery would

be unlawful, lost at the High Court and appealed.

Issue: Should doctors be permitted to perform the separation surgery contrary to the twins' parents' view?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Without such a surgery both babies would die, while following it (it is expected that) one of them would live a normal life. The separation surgery thus maximizes benefit and minimizes harm as much as possible.

2: Yes.

Complying with the parent's request is tantamount to killing an innocent person (Jaye) who, it is expected, would otherwise live a normal life.

3. No.

In this country, the doctors' duties toward their infant patients are subordinated to the wishes (and autonomy) of their parents or guardians, even if complying with such wishes will lead to an infant's death. In this case, the twins' rights to oppose surgery (on religious grounds) or refuse life-saving treatment are represented by their parents as guardians.

4: No.

Performing the surgery is tantamount to killing an innocent person (Em).

Court Decision:

The Court of Appeals affirmed the High Court ruling, holding that an operation to separate the twins would be in the best interests of each child. The purpose of the operation would be to give Jaye a reasonably good prospect of a long and normal life. Furthermore, although Em's death would be an inevitable consequence of the surgery, it would not be the purpose of it. The separation surgery would give Em, even in death,

bodily integrity as a human being. To the contrary, continued life would hold nothing for Em except possible pain and psychological trauma. In fact, the same would hold true for Jaye.

Bioethical Considerations:

It might be argued that this case raises similar considerations to those where the medical team is asked to consider discontinuing medical treatment which prolongs the life of a patient. In such scenarios, we evaluate the quality of life of the patient receiving treatment, her prognosis and the possible benefit associated with the proposed treatment (in terms of quality of life, human dignity, costs, etc.).

However, this case is more complicated from an ethical perspective because there are four individuals to whom doctors owe both the duty to do no harm and the duty to do good (both parents and the two twins). Performing the separation surgery may benefit Jaye, but will also immediately lead to the death of Em. Although this is not the intention of the medical team, it is highly expected.

The court did not attribute much weight to the interests and rights of the twins' parents and decided the case mainly by focusing on the net benefit achieved by the surgery. The court also raised the distinction between 'intention' and 'expectation' upon which the doctrine of 'double effect' is based, although one can question its validity and relevancy. (In ethics, the doctrine of 'double effect' addresses the issue of under what conditions one may perform an act that has both good and bad consequences).

Additional Legal Considerations:

In the U.S, at least, in this case the parent's rights (autonomy) would be terminated, as the State is given an imputed co-right to decide the best interests of the children as *parens patriae*. Thus, it is important to recognize this issue may well be inapplicable to certain jurisdictions and may be resolved differently in different places. Nevertheless, satisfying the procedural requirements necessary to designate the State as *parens patriae* would probably entail convincing a judge as to the probability of saving at least one child's life.

For Further Discussion:

1. What if Jaye's chance of survival was not guaranteed and she only had a 75% chance of life? Would that make a difference? What about a 50% chance of life?

2. Since there is a conflict of interest between the interests of each of the two children, should each child have a separate surrogate?
3. Is the religious preferences of the surrogate (the parent) automatically imposed on the child (or incompetent)?
4. Does it matter whether Jaye would live a 'healthy' life? What if she will live, but will suffer some infirmity? Would that affect the decision-making?

FACT PATTERN 7:

Rights of Genetic Material:

Based on: Evans v. Amicus Healthcare Ltd. (United Kingdom, 2004) and Evans v. United Kingdom (2006).

Following her diagnosis of ovarian cancer, a woman harvested a number of eggs via assisted reproductive technology (ART), had them fertilized with the sperm of her partner and stored the embryos with the clinic. A year later, the relationship between the woman and her partner broke down and he sought to destroy the embryos by revoking his consent to fertilization and storage. The woman attempted to prevent the destruction, arguing her partner should be estopped from revoking his consent. Alternatively, she argued that permitting such revocation would violate her right to privacy and family life under the European Convention on Human Rights. The woman brought suit in the U.K. courts seeking an injunction against her former partner's attempt to destroy the embryos, arguing, inter alia, that if the embryos had already been implanted the boyfriend would have no rights to terminate the pregnancy.

Issue: Should the revocation and withdrawal of the ex-partner's consent be permitted?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes

Joint consent is required for the creation, managing and use of embryos in the clinic.

2: Yes.

The woman's ex-partner does not want to be responsible of a child after a broken relation and has the right to be released from the possibility of his being saddled with this responsibility later on.

3: No.

Revocation should not be permitted regarding irreversible actions that lead to the discarding of human life.

4: No.

Preference should be given to the woman who, due to her illness, initiated the medical procedure with the expectation of using the resulting embryos in the future.

Court Decision:

Case dismissed.

Rejecting the woman's arguments, the court ruled that the clear policy of the Human Fertilization and Embryology Act is to require continuing consent from commencement of treatment to the point of implant. Hence, the claimant's partner was entitled to withdraw his consent. Since the court has no point of reference to evaluate the consent of each of the parties and determine whose deserves greater priority, such a balance must be struck by Parliament.

The woman appealed the ruling to the European Court of Human Rights. On 10 April 2007 the Grand Chamber of the ECHR ruled that there had been no breach to the right of Human Rights and no breach to the right to life in a unanimous verdict. On the issue of the right to respect for private and family life and the prohibition of discrimination, the court also ruled against the woman, but by a divided court, holding that the requirement of joint consent was the law of the United Kingdom which they were obliged to follow.

Bioethical Considerations:

The woman's argument against her ex-partner's revocation of consent turned on the language of the contract which stated: "...You may vary the terms of this consent at any time except in relation to sperm or embryos which have already been used." The woman claimed that the sperm had already been used and so he should not be allowed to withdraw his consent.

The case raised multiple difficult questions: factual, legal and bioethical. In addition to considering whether the sperm had already been used, courts need to consider whether the consent of both parties in ART cases should receive similar weight. Usually, the legal view in matters pertaining to sexual intercourse is that a man's procreative liberty ends with the donation of sperm and that in light of the woman's unique role in gestating the embryo/fetus, she should have the right to determine its fate and management. The court could have followed this view.

Deciding on the primacy of one party's autonomy as it pertains to rights and values which may impact on others may have far-reaching implications. Rather than interpreting the Human Fertilization and Embryology Act as requiring a determination whether joint (and continuing) consent is necessary, a more substantial decision concerning the nature of the right to continue ART versus the right to discontinue such procedure (i.e., the right not to parent), might have been a better approach.

For Further Discussion:

Should the fact that the woman has ovarian cancer, with an invariably prognosis, usually leading to death should affect the decision?

FACT PATTERN 8

Compelling a Pregnant Woman to Bed Rest:

Based on: Samantha Burton v. State (Florida, U.S.A., 2010).

A 25 week pregnant woman sustained premature rupture of the membranes and displayed signs of premature labor. She was not in labor, however, but nevertheless was ordered to remain on bed rest. Her obstetrician refused to allow her to leave the hospital (to seek a second opinion) and applied for a court order seeking to compel her submission to any medical treatment he deemed necessary, including hospital detention for enforcement of bed rest, administration of intra-venous medications and anticipated surgical delivery of the fetus. An action was initiated in the Circuit Court by the State Attorney (under the procedure described in *In re Dubreuil*, 629 So. 2d 819 (Fla. 1994) which provided that after the State Attorney received notification from a health care provider that a patient refused medical treatment, the State Attorney may exercise his discretion to determine that a sufficient state interest was at stake to justify legal action).

The Circuit Court found that the woman failed to follow the doctor's instructions and

recommendations, rendering her pregnancy "high risk," and that there was a substantial and unacceptable risk of injury or death to the fetus and sustained the obstetrician's petition. As ordered, the woman submitted to hospital confinement, medical treatment and surgical delivery. A few days later she was delivered of a deceased fetus by Cesarean section.

Issue: Should a physician be allowed to compel a pregnant woman to submit to unlimited medical procedures in whatever manner he requests/orders, or to otherwise compel her to limit her activities and restrict her freedom?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The obstetrician has a duty to save the life of a fetus, especially in advanced stages of pregnancy.

2: Yes.

The pregnant woman's autonomy, freedom (and rights to refuse medical treatment) is subordinate to the fetus' right to life and the State's interest in protecting fetal life.

3: No.

The fetus' right to life is subordinate to the pregnant woman's right to autonomy and freedom.

4: No.

The doctor has only one patient, i.e., the pregnant mother, and he owes primary responsibility to promote and protect her liberties including her right to refuse medical treatment.

5: No.

Hospitals are not prisons and premature delivery is not a cause for enforcement of the physician's wishes or limitation of the mother's freedom.

6: No.

No one can force a person (male or female) to undergo medical treatment. One must consent to treatment for it to be lawful. In the absence of such consent doctors may violate the duty and doctrine of 'informed consent' and may be held liable for assault and battery.

Court Decision:

Reversed.

Holding that "[t]he state's interest in the potentiality of life of an unborn fetus becomes compelling "at the point in time when the fetus becomes viable," defined as "the time at which the fetus becomes capable of meaningful life outside the womb, albeit with artificial aid, the Court of Appeals ruled that the appellant suffered a significant deprivation of her physical liberty and personal freedom.

The appellate court ruled that the trial court had erroneously focused its ruling on the best interests of the child (determined forced treatment was indicated for this purpose) instead of determining whether the State had a compelling interest in overriding the mother's right to refuse medical treatment, While the balancing tests employed by the trial judge may be appropriate in other circumstances (such as the competing rights of a parent and an already born child), the Court of Appeals ruled this application of the State's *parens patriae* authority to override the appellant's right to refuse medical treatment for the unborn child was in error. Upholding the woman's right to privacy, the court ruled that there was no competing right-to-life for the fetus as there was no showing that the fetus had reached a sufficient stage of viability required to withstand the State's threshold.

Although the court did not hold that the State could never intervene in a woman's pregnancy, it limited such intervention to situations in which the State proves that the fetus is viable (not necessarily by the gestational age), and further, that the State must demonstrate the proposed intervention is the least intrusive available.

Finding most of the issues moot, a situation in which most courts would refuse to insinuate themselves, the court nevertheless ruled that mootness does not preclude appellate review if the issue is "capable of repetition yet evading review," as in the case of medical issues which require immediate resolution. Hence it proceeded to evaluate the actions involved so as to aid other courts facing similar emergency decisions.

“The trial court found that the appellant had failed to follow the doctor’s instructions and recommendations, rendering her pregnancy ‘high-risk,’ and found a ‘substantial and unacceptable’ risk of severe injury or death to the unborn child if the appellant continued to fail to follow the recommended course of treatment. The trial court stated the rule that “as between parent and child, the ultimate welfare of the child is the controlling factor,” and concluded that the State’s interests in the matter “override [the mother’s] privacy interests at this time.” The court ordered the mother to comply with the physician’s orders including, but not limited to “bed-rest, medication to postpone labor and prevent or treat infection, and eventual performance of a cesarean section delivery.” The appellate court disagreed, holding that: “This fundamental right to privacy encompasses a person’s “right to the sole control of his or her person” and the “right to determine what shall be done with his own body.” The Florida Supreme Court has specifically recognized that “a competent person has the constitutional right to choose or refuse medical treatment, and that right extends to all relevant decisions concerning one’s health.” *Browning*, 568 So. 2d at 11. “The state’s interest in the potentiality of life of an unborn fetus becomes compelling “at the point in time when the fetus becomes viable,” defined as “the time at which the fetus becomes capable of meaningful life outside the womb, albeit with artificial aid.” *Roe v. Wade*, 410 U. S. 113, 163 (1973); *In re T. W.*, 551 So. 2d 1186, 1193 (Fla. 1989).

According to the court, the Legislature had defined “viability” as “that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb.” § 390.0111(4), Fla. Stat. No presumption of viability is provided in the statute. Because there is no statutory or precedential presumption of viability, in terms of the stage of pregnancy or otherwise, there must be some evidence of viability via testimony or otherwise. The holding in *M. N. v. Southern Baptist Hosp. of Florida*, 648 So. 2d 769 (Fla. 1st DCA 1994), ‘that as between parent and child, the ultimate welfare of the child is the controlling factor,’ does not apply to this case. Unlike this case, in *M.N.*, the parents refused consent for a blood transfusion and chemotherapy for their 8-month-old infant.”

The appellate court further noted: “No privacy rights of a pregnant woman were involved. The test to overcome a woman’s right to refuse medical intervention in her pregnancy is whether the state’s compelling state interest is sufficient to override the pregnant woman’s constitutional right to the control of her person, including her right to refuse medical treatment [cites omitted]. In addition, where the state does establish

a compelling state interest and the court has found the State's interest sufficient to override a pregnant patient's right to determine her course of medical treatment, the State must then show that the method for pursuing that compelling state interest is "narrowly tailored in the least intrusive manner possible to safeguard the rights of the individual."

Bioethical Considerations:

This is an extraordinary case in which an obstetrician seeks to severely restrict the freedom and privacy of his patient and forcibly compel various medical procedures in order to maintain her pregnancy. It raises the question of whether, in such cases, there is only one patient, namely the pregnant woman, or two patients, the pregnant woman and the fetus. If so, the question emerges at which stage of pregnancy does the second patient become a viable entity. The trial court had difficulty dealing with this issue, although it was clearly addressed by the appellate court, who ruled that the applicable point of time arises at "some inchoate date at which the fetus is capable of maintaining permanent viability outside the womb."

The competing interests:

"The law in Florida is clear: Every person has the right "to be let alone and free from government intrusion into the person's private life." Art. I, sec. 23, Fla. Const.

"A patient's fundamental constitutional right to refuse medical intervention "can only be overcome if the state has a compelling state interest great enough to override this constitutional right." *Singletary v. Costello*, 665 So. 2d 1099, 1105 (Fla. 4th DCA 1996).

Thus, the threshold issue in this situation is whether the state established a compelling state interest sufficient to trigger the court's consideration and balance of that interest against the appellant's right to refuse to submit to the medical intervention the obstetrician prescribed." If what motivated the lower court's decision is the right to life of a potential human being, the case may also have worrisome implications for any action that endangers sperm, egg cells, embryos or fetuses in a non-pregnancy environment. Will we want to go this far to balance of a set of interests, which may, at times, lead to restricting the freedoms of competent adults? From a bioethical point of view, this would be an infringement of autonomy; from a legal point of view this would be considered a violation of the duty of the physician to elicit informed consent

– without which it could be said that the physician committed assault, battery and/or is liable for false imprisonment.

While the court's decision balances competing interests and rights, it nevertheless raises questions as to whom doctors owe ethical obligations, especially when the State has an interest. Nevertheless, the appellate court was clear that “where the state does establish a compelling state interest and the court has found the state’s interest sufficient to override a pregnant patient’s right to determine her course of medical treatment, the state must then show that the method for pursuing that compelling state interest is narrowly tailored in the least intrusive manner possible to safeguard the rights of the individual.”

For Further Discussion:

1. Does the physician (as opposed to the State), have a personal duty to the unborn fetus?
2. Is bed rest considered medical ‘treatment’ such that it can legally be imposed?
3. Why should the prospective mother be compelled to be restrained in the hospital? If her rights are to be tampered with, shouldn’t it be done in the most minimally invasive fashion, i.e., at home?
4. Does it matter what is the medical evidence that enforced bed rest has a reliable impact on the viability of the fetus? If it is only a possible 5% improvement in outcome – for example, should the pregnant woman be forced to submit?
5. Are there competing considerations? Can enforced bedrest be harmful to the pregnant woman?
6. Why should the court be compelled to listen to this one obstetrician?
7. Shouldn’t the right to a second opinion be given paramount consideration as it benefits both the prospective mother and the fetus – and the State?
8. Does the civil doctrine of ‘false imprisonment’ of the pregnant woman supersede the ethical rights the fetus may have- assuming it was viable.

It is important to note that many medical authorities hold that 23 weeks is the cut off for viability. However, it must be understood that this is the cut-off used to determine whether the expensive special premie care is warranted such as to decide to save

the life of the pre-mature infant. The question here is the reverse: At what point can we be sure - not that the fetus has a probable chance at life – but at what point the fetus has a probable chance of death?

9. Even assuming that the fetus right to life has priority, there is no independent showing that bed rest will increase the likelihood of birth. The treatment options the obstetrician seeks to impose are “blunderbuss” i.e., anything and everything he feels like it. Yet, it managed to convince the trial court – is this troublesome?

10. May a pregnant vegetarian be compelled to eat meat if it might benefit the fetus?

11. May a pregnant woman be compelled to give up a kidney for the sake of the fetus?

12. Should the Hospital Bioethics Committee be called in to consult with the pregnant woman if she is not in favor of this? Would involving them - against her wishes -- be a violation of her privacy? After all, she has a relationship with her doctor, not with a group of outsiders who are there to advise the hospital – and patients – but at their request.

13. If the physician is allowed by the hospital to implement his orders, would this be grounds for a civil suit of ‘false imprisonment’ against the hospital?

References

Casebook on Benefit and Harm, Bioethics Core Curriculum Casebook Series, No. 2, UNESCO: Paris, 140pp. (2011) Casebook on Human Dignity and Human Rights, Bioethics Core Curriculum Casebook Series, No.1, UNESCO: Paris, 144pp.

UNIT 4: Respect for Personal Autonomy

Article 5

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.”

Introductory Discussion:

Protection of the Right of Personal Autonomy

A person's basic rights derive from the recognition of his or her human status, the inviolability of his or her life and the fact that s/he was born with the inalienable right to freedom (liberty). The autonomy of every person is recognized as an important and protected right and value. This principle affects making or participating in decisions concerning one's own body or health, decisions which may not be acceptable to or accepted by others. Nevertheless, respect for the values and wishes of every individual is a duty owed to him or her by others. This duty becomes even stronger if the individual becomes vulnerable.

FACT PATTERN 9:

Right of the Mentally Ill to Commit Suicide:

Based on ‘X v. Health Directorate of Zurich’, (Switzerland, 2006).

A 53 year old Swiss national suffering from a bipolar disorder had attempted suicide twice. Eventually he joined the organization Dignitas and expressed the desire that this association should do what was necessary to terminate his life, as his condition and his incurable disease did not allow him to live a dignified life. The man was advised to obtain 15 grams of sodium Phenobarbital which could only be obtained by prescription via a licensed physician, and which he was unable to do. He then contacted various authorities in an attempt to obtain that substance, invoking his right to end his life in a dignified manner without risk and without danger to others. Both the Federal Office of

Public Health and the Directorate of Health of the Canton of Zurich refused his request. The man then appealed to Federal Department of the Interior and the Administrative Court of the Canton of Zurich.

Issue: Should the person's right to autonomy have been respected and thus should he have been allowed to obtain a doctor's prescription for the drug in order to end his life with dignity?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Every person, including one suffering bipolar disorder, has a right to die. As long as the person was able to make a clear wish, his wish should have been respected.

2: No.

This person suffers from mental illness – which by definition impairs his ability to be fully autonomous. Hence, his wish to die could not be respected unless supported by a physician.

3: No.

Allowing a man to take his own life is immoral and cannot be justified under any circumstances.

Court Decision:

The court found that sodium pentobarbital is a psychotropic substance giving rise to dependence. It is obtainable only with a medical prescription from a licensed medical practitioner. Licensed medical practitioners may only prescribe such substances on condition that they comply with the medical and pharmaceutical ethical rules. Under the national legislation, it was therefore impossible to obtain the desired substance without a medical prescription. Contrary to the appellant's opinion, the applicable provisions allowed for no exception in situations like his.

The appellant invoked Article 8 ECHR and Articles 10.2 and 13.1 of the Federal

Constitution and claimed that the law must be interpreted consistently with the Constitution and the Convention. He maintained that those provisions include the right to commit suicide, and imposed an obligation on the State to allow suicide without risk or pain.

“Article 10.2 of the Federal Constitution guarantees personal freedom and the free development of the personality. Likewise, Article 8.1 ECHR gives the right to respect for private life, allowing the individual to develop his personality without intervention on the part of the State. While the individual has a right over his or her own death, that does not mean that he is entitled to the assistance of the State or of third parties to end his life. Such a right does not follow from the constitutional and Convention rights on which X. relied. The State's primary task is to protect life. There is no positive obligation to provide a person wishing to commit suicide with the substances and the instruments required for that purpose. The right to life within the meaning of Article 2 ECHR does not entail a corresponding negative freedom and Article 3 does not require States to grant immunity for assistance to suicide". The State was thus not required to make available the substances that would allow X. to end his life.

“On the assumption that there was an interference with the guarantee laid down in Article 8.1 ECHR and Article 10.2 of the Federal Constitution, the obligation to be in possession of a medical prescription in order to obtain sodium pentobarbital would be covered by Article 8.2 ECHR and Article 36 of the Federal Constitution. When examining that question, it was necessary to strike a balance between public interests and private interests. The obligation to have a medical prescription is intended to protect the health and safety of people and to prevent ill-considered decisions. A lethal substance must not be supplied by a pharmacist without further formality, but requires an examination and a diagnosis by a doctor who is subject to ethical rules and who gives the appropriate and necessary information. Switzerland's rules on assisted suicide are relatively liberal; it is possible that, after carrying out an examination and in accordance with the ethical rules, a doctor will provide a person wishing to end his life with a prescription for sodium pentobarbital. Where the person is suffering from a psychiatric disease, then, according to the case law of the Federal Court, a prescription for the substance was possible only to a very limited extent".

In the light of those considerations, the legal requirement to be in possession of a medical prescription in order to obtain a lethal dose of sodium pentobarbital was

compatible with constitutional and Convention law.

Case dismissed.

Bioethical Considerations:

While in many instances we tend to equate mental illness with physical illness, whether the wish to die and the request for end-of-life assistance should be regarded the same way is still controversial. Indeed, perhaps decisions of a person who suffers physical pain and a reduced quality of life should be questioned as carefully as that of a mentally disabled individual. Nevertheless, society tends to pay more attention to the former's wishes and confers more vigilance on the latter's. This approach is, at times, unjustified and reflects prejudice towards mental illness. Courts should develop an independent standard to decide these issues.

In addition to the questions surrounding the autonomy afforded a mentally ill person, this case also introduces an evolving ethical concern regarding whether doctors or other parties should be allowed to help patients with serious mental illness take their own lives.

For Further Discussion:

Most people suffer from varying degrees of neurosis and other psychological difficulties, at times worse than others. At what point along the continuum is a person deemed "severely" psychically ill such that a doctor's intervention would be needed? Would this include someone severely depressed for a short time? Someone moderately depressed for a month? Someone mildly depressed for six months?

References:

<http://www.codices.coe.int/nxt/gateway.dll/CODICES/precis/eng/eur/sui/sui-2007-1-003>

FACT PATTERN 10:

Responsibility for Preventing the Mentally Ill from Committing Suicide:

Based on: Rabone v. Pennine Care HNS Trust (United Kingdom, 2010, 2011).

Doctors and a hospital staff allowed a two-day home visit for a 24 year-old voluntary mental patient who was known to be suicidal. During the home visit, the patient committed suicide. The parents of the deceased brought a claim against the medical

institution, doctors and the State (as custodians of the Health Care System), claiming negligence and violation of the patient's right to life.

Issue: Should the doctors and the medical institution have allowed the home visit of a voluntary mental but suicidal patient?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes .

The person was a voluntary mental patient and not dangerous to others. Hence, the doctors did not have any right to restrict her freedom and prevent her from enjoying her rights, including home visitation

2: No.

The patient was suicidal and doctors owe a special duty of care to the vulnerable patient.

Court Decision:

The Court of Appeals ruled that Article 2 of the European Convention on Human Rights protecting the right to life does not impose upon the State an operational obligation towards all persons who are at real and immediate risk of death. Since the deceased was a voluntary patient and not detained under the Mental Health Act, the defendants had no such operational obligations to her.

Bioethical Considerations:

This case challenges the State's authority and duty to protect the lives of voluntary psychiatric patients. One may question whether the duty to protect life requires additional or greater precautionary measures when medical authorities know or should know (knew or should have known) that there is a real and immediate risk of suicide. This question must be asked separately whether the patient is voluntarily or involuntarily detained. One can argue that the duty to save the life of a schizophrenic patient with suicidal intentions should not be less than to a patient who undergoes major heart

surgery. In both cases, the medical team should recognize dangers to a patient's life, and thus have a duty to protect his/her life using all reasonable measures.

It appears that in this case, the court gave greater weight to patient autonomy, exempting care-givers from the duty of due care to act in the best interests of the patient.

For Further Discussion:

1. The court dealt with a patient who was known to be suicidal. Should this diagnosis require greater specificity to determine the obligation on the part of the medical institution? Would it matter if the patient already attempted suicide? Merely had suicidal ideation? Was the patient on drugs known to potentiate or increase the risk of suicide?
2. What was the intended scope of services expected from the medical institution/doctor?
3. Did the patient have a right to rely on the hospital to determine his readiness to leave?
4. Does the patient's family have a right to rely on the hospital to determine their daughter's readiness to leave such as to enable them to sustain a lawsuit against the hospital and Health Care System?

FACT PATTERN 11:

Protecting the Infant's Interests:

Based on: Wyatt v. Portsmouth NHS Trust (England, 2005).

The parents of a prematurely born daughter suffering chronic respiratory and kidney problems and profound brain damage requested that their child be ventilated if she sustained antibiotic-resistant infection that might lead to a collapsed lung. The doctors felt that ventilation would not improve the child's condition and might even kill her, thus depriving the child of a peaceful death.

Medical evidence suggested that it was 'virtually inevitable' some respiratory crisis would arise, and [that the daughter] would not survive such an event, whatever aggressive invasive treatment was tried; further medical evidence drew attention to improvement in [the child's] condition and suggested that, in the event of infection, ventilation would be justified, particularly in view of the fact that the parents wanted

everything possible to be done. The parents argued that their daughter had continued to survive against expectations with evidence of improvement, and brought suit seeking mandatory intervention.

Issue: Should the doctors ventilate the baby at the parents' request?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The patient's parents know what is best for their child.

2: Yes.

All efforts should be made to save the child's life and improve its quality.

3: No.

Complying with the parent's wishes has no medical benefit, and may lead to unnecessary suffering and undignified dying for the child.

4: No.

The child's profound brain damage and along with the compromise to her airways and kidneys heralds a very poor quality of life if she survives.

Court Decision:

The appellate court confirmed that a seriously ill baby should not be resuscitated if she stops breathing.

The Court of Appeals ruled that courts are obliged to consider the child's best interests from the point of view of the patient. The term "best interests" encompasses medical, emotional and all other welfare issues. The court must undertake a balancing exercise weighing all relevant factors on the basis of comparative benefit and harm on a case by case basis.

The court ruled that "there were two questions to be answered in the light of the 'best interests' test: (1) in the event of an overwhelming respiratory infection, whether it

would be right to attempt or refrain from aggressive intervention by way of intubation, transfer to a tertiary center and ventilation; and (2), if the indications were that such treatment should be withheld, should that decision be made now or should it await the crisis and then be resolved at that time.

The presiding judge decided “that, on the issue of resuscitation of a seriously ill child and notwithstanding the conflict of medical opinion, in the event of the child surviving after such medical intervention, the resulting deterioration caused by the treatment would make life for her intolerable on a day to day basis,” and denied the parents’ request.

Bioethical Considerations:

In this case one must discern the best interest of the patient who cannot express her own views and thus choose her course of treatment. In many cases, deciding the "best interests" of an incapacitated patient may involve evaluation of specific values promoted by surrogate-decision makers. Nevertheless, the court must analyze the situation from an objective perspective. Determining an objective, universal and justifiable sets of ‘best interests’ may nevertheless be illusory, and in some cases, it is perhaps better that the judge or ethicists acknowledge their own position. This case also suggests that the "best interests" test should be applied differently to children than to incompetent adults, a position not supported by the literature. Ethical discussion addressing the moral significance of issues involving children is warranted before courts proceed down this route.

References

United Nations 1989 Convention on the Rights of the Child.

United Nations High Commissioner for Refugees UNHCR 2008 Guidelines on Determining the Best Interests of the Child.

FACT PATTERN 12:

Protecting the Interests of the Incapacitated Child:

Based on: NHS Trust v. MB (United Kingdom, 2006).

Moby (not his real name) was an 18 month old boy who suffered from spinal muscular atrophy. He was completely paralyzed and reliant on ventilation. Some level of mental

capacity was attributed to the child, along with acknowledgement of his deriving pleasure from listening to stories or watching DVDs. The doctors asked to discontinue treatment in the best interests of the child, claiming that his quality of life had become very poor and the burden of living too great. The boys' parents, however, favored continuing life-prolonging treatment and insisted that treatment continue.

The NHS Trust (British Health Service) applied for a declaration that it shall be lawful, and in the boy's best interests for medical staff to withdraw all forms of ventilation from him, notwithstanding his parents' refusal to consent, and instead to furnish palliative care. The Trust considered that the child's quality of life was so low, and the burdens of living were now so great, that it was unethical or 'cruel' to continue artificially to keep him alive. Much expert opinion attested to the fact that it was in the boy's best interests that the ventilation be withdrawn and he be allowed to die, probably 'very quickly'. Furthermore, the child's own guardian supported the Trust. Shortly before the hearing, the parents issued a cross-application in which they sought a declaration that it shall be lawful and in their son's best interests for a tracheostomy to be performed to enable long-term ventilation to be carried out.

Issue: Should the doctors be allowed to discontinue Moby's treatment?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Doctors are in the best position to evaluate the best interests of the patient, having the entire medical record at their disposal along with the expertise to evaluate his wellbeing and prognosis.

2: No.

The patient's best interests include more than the determination of well-being by medical evaluation.

3: No.

The patient is an infant and all efforts should be made to save his life and improve its quality.

4: No.

The parents are in the best position to determine what's in the best interests of their child.

Court Decision:

Stressing that this was a very fact-based ruling, the court held that it was unlawful to discontinue or withdraw breathing assistance from the child, siding with the parents on the basis of the specific circumstances at the time the request was made.

The judge noted that he believed that "this was the first case in which the court was being asked to approve that, against the will of the child's parents, life support may be withdrawn or discontinued, with the predictable, inevitable and immediate death of a conscious child with sensory awareness and assumed normal cognition and no reliable evidence of any significant brain damage." Finding that, despite the child's short life expectancy, the judge said it was impossible to say that the child was 'in the dying process', and there were sufficient benefits in not making the declaration at this time as to outweigh the burdens.

Applying a "balance sheet" approach to determining the best interests of the child, the court asked the parties to prepare a list specifically identifying the benefits or advantages and the burdens or disadvantages of continuing the treatment in question. The court ruled that it is impossible to put a quantitative value on the benefits, but held the benefits are precious and real and should outweigh routine discomfort, distress and pain the doctors ascribed to the treatment.

See generally (Family Law Week (15 March 2006)) <http://www.familylawweek.co.uk/site.aspx?i=ed2067>.

Bioethical Considerations:

The judge determined that there was no legal distinction between withholding or withdrawing life-support and that the 'best interests' test applied equally to both situations. On the issue of deterioration, he noted that where such deterioration was

inevitable, continuous and relatively rapid, it was unrealistic to leave it out of the overall balance, although it was not a determining factor in this case.

In this case, a balancing test evaluating the patient's best interests was suggested by the court. One can argue that tabulating advantages and disadvantages in order to infer the best interests of a patient is not morally neutral, because one still must identify the relevant risks and benefits and assign relative weights to them. Nevertheless, the court eschewed a purely quantitative approach, recognizing that joy and simple pleasures may outweigh the pain of moderately invasive medical procedures.

This exercise in itself is subjective and obviates the court's intention to objectify decision-making. On the other hand, what more can be done since there is no objective list for the determinants of quality of life? It must be noted, however, that some philosophers do support an objective list theory although others disagree.

For Further Discussion:

1. Can an objective (or semi-objective) list be drawn up as determinants of quality for life?
2. Should people be asked, when preparing advanced directives to compile such a list, perhaps weighting those factors they consider more important (i.e., create an algorithm).
3. Even if such a list could be created, can it be objectively applied? In other words, at the end of the day even if we knew what a person found valuable or pleasurable – wouldn't interpreting how much pleasure they derived from a particular activity be a subjective determination?
4. Does it matter what was the treatment in question? Does it matter if it was removal (e.g., of ventilation) or administration (e.g., drugs, food)?

FACT PATTERN 13:

Protecting the Interests of an Adolescent:

Based on: Re Bernadette (Australia, 2011) (see also 2010 decision).

The parents of a transsexual adolescent sought medical treatment for their child which involved administration of puberty-suppressing drugs in order to induce expression of

the child's female secondary sexual characteristics. The doctors refused to provide the treatment without a court order. The parents contended that decision about treatment was part of their parental responsibility such that an order of the court was not required. They also argued that the proposed treatment was neither 'special, irreversible nor non-therapeutic,' as required to sustain a court's jurisdiction.

Issue: Should the doctors provide the requested treatment without a court order?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The proposed treatment falls under the exclusive parental discretion; it also reflects the autonomy of the patient, as expressed by her parents.

2: Yes.

Even if the doctors oppose treatment for ethical/religious/moral reasons, they should refer the parents to other doctors.

3: No.

This is a rare and unique request and the proposed treatment may harm the patient.

4: No.

The patient is almost an adult. To fully respect her autonomy, a third party must evaluate the patient's supposed wishes.

Court Decision:

The court held that one of the major questions in this case is whether or not transsexualism is a malfunction or a disease or a natural variation to be found in human beings where brain sex and genitalia are different. The argument of the applicants is that such a situation does not occur as a result of disease or malfunction, and accordingly should not be treated as such. And the judge noted that "in this case I am not satisfied that the medical evidence was clear cut so as to enable me to say precisely what was the cause

of transsexualism or gender dysphoria.”

After a review of the numerous contentions, the court found that the child believed herself to be female; lives as such since 2004 (from the age of 12) and noted “that the child in this case clearly wishes to proceed.... [and that] I am satisfied on the evidence I have heard that so far that is possible this has been done in an appropriate and age appropriate fashion, [although acknowledging] that ... undergoing the therapy will result in her losing the ability to produce biological children. Nonetheless, I am satisfied her views are well formed and have been strongly held over an extensive period of time. I am satisfied that she has worked competently and sensibly with those assisting her to obtain that which she seeks to achieve.”

However, while the court ratified the past treatment, the ultimate issue presented was: “Is this a case where I should permit the parents to authorize the treatment for a child [in the future] with there being no need for the court to be in any way involved in this decision?”

The court answered the question in the negative:

I am not satisfied that the evidence before me establishes that there has been such a change in the state of medical knowledge ... to disregard the views of the High Court.... The risk of making a wrong decision [is] ... a primary factor As conceded by the Director General, orders for phase 1 and 2 for [the girl] were made by consent. However, that which is appropriate in one case has no necessary general application. As I have said to the point of boredom, it is the intention of the applicants to obtain to what appear to be findings that would have a general application. However, as a matter of general application, a number of issues may arise, for example, parents may have competing interests and concerns. I am satisfied there still remains grave dispute within the medical community as to the best treatment that can be offered. I am satisfied that until there is a clear cut line of authority within the medical profession, it would be difficult for parents to reach an informed conclusion in every case.... To try and make any form of order or declaration that would be seen as enabling any parent or guardian to authorize treatment of the type involved in this case could be to expose children, the subject of such authorizations, to unwarranted risks. It would not, I am satisfied, be in the best interests of every child to enable parents or guardians to give such consent.

Accordingly, I am satisfied that in the best interests of children it is necessary for the court to retain the power to authorize treatment in respect of a particular child when treatment of this kind is contemplated. The court may in appropriate cases, being satisfied on evidence put before it, find that in that particular case it is appropriate to permit the parents or guardians in that particular case to authorize treatment. However, that remains a matter for determination on a case by case basis.

The court summed up the issue and presented its holding as followed: “Does the parent of an adolescent minor and/or such minor (provided that such minor has a sufficient understanding and intelligence to enable him or her to understand fully what is proposed) have the authority to lawfully authorize medical treatment of that adolescent minor to arrest the onset of the minor’s puberty (“Phase 1 Treatment”) in the course of the medical treatment of the condition of transsexualism (also called gender identity disorder) without an Order of a Court?”

The court answered in the negative.

In 2011, the case was appealed. At this point the ‘child’ had turned 18. The court held that it did not have jurisdiction once the patient reached the age of 18 and that relevant law concerning treatment decision-making applies only to persons under 18. As an adult, the appellant no longer requires court intervention or parental approval to consent or oppose any medical treatment. The appeal was therefore rejected on the jurisdictional grounds.

Bioethical Considerations:

In principle, the closer a child or an adolescent is to becoming an adult, more weight should be given to their desires and values, and less to their surrogate’s. Although the law in many places opts for a single decision-maker, it may be argued that a joint decision made by the surrogate and the child/adolescent is preferable. This is especially true when the proposed medical treatment/intervention is irreversible, has social sensitivity or may be harmful. While doctors are usually not expected to express their own views on the morality of the requested treatment, they may be more active in clarifying the medical aspects of a controversial treatment to better equip decision-makers choose the right course of action.

For Further Discussion:

1. Does it matter if the treatment is irreversible?

2. Does it matter if the child and her parents both agree on the proposed treatment?

References:

<https://www.humanrights.gov.au/re-bernadette-2008>

<http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/cth/FamCA/2010/94.html?stem=0&synonyms=0&query=re%20bernadette>

<http://guides.sl.nsw.gov.au/content.php?pid=316240&sid=3770404>

UNIT 5: Informed Consent

Article 6

UNESCO Universal Declaration on Bioethics and Human Rights(2005)

1. *“Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.*
2. *“Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.*
3. *“In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives or the group or community may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.”*

Introductory Discussion

Informed Consent

The informed consent rule states that it is the duty of a doctor to ensure that the patient is well informed about the treatment to which s/he consents, so that s/he knows to what s/he is committing her/himself.

The purpose of the informed consent rule is to achieve several objectives, amongst them that:

1. It asserts the patient's autonomy and status as a human;
2. It satisfies the need and the wish of most of the patients to know what is being done to or for them;
3. It helps prevent coercion, fraud, duress and deception;
4. It encourages the doctor's self-criticism and truth telling;
5. It supports the process of rational decision-making;
6. It improves physician-patient relationship by fostering trust and open communication;
7. It protects the physician from claims of assault and battery;
8. It educates the public at large.

The objective of disclosure of information is to enable the patient to make an informed decision whether s/he should consent to (i.e., accept or reject) the proposed treatment. In ordinary circumstances the decision is solely that of the patient.

The term 'informed consent' implies cognition, willingness, consideration, intention and understanding on the part of the patient, as well as the willingness, consideration and ability to properly convey the information to the particular patient on the part of the health professional. Thus, after the information is conveyed, the patient should understand the nature of the proposed treatment, its risks and benefits, including the various economic, social, administrative and psychological implications.

The patient also should be able to comprehend the meaning of the information given and be able to balance the pros and cons against each other, to draw inferences from the information with reasonable rationality, to assess the situation at hand sufficiently well to guide this choice and thus to finally to make a deliberate decision on the basis of all information reasonably available.

FACT PATTERN 14:

Informed Consent: Generally:

Based on: Foo Fio Na v. Dr. Soo Fook Mun (Federal Court of Malaysia, 2007).

Following an open reduction of her spinal column to stabilize her spinal cord during which the doctor inserted a wire loop, the patient (who we will call Sophia) suffered paralysis

of both arms and legs. Additional testing procedures revealed that the wire loop was pressing on her spinal cord. Not long after the first surgery, the neurosurgeon performed another surgical procedure to remove the wire loop, after which the patient was able to move her hands, although she remained unable to move her legs. In addition to alleging the surgeon was negligent in performing the surgeries which caused her paralysis, Sophia alleged that the risk of possibly needing a second surgery was not explained. Further, she alleged that she specifically asked about the dangers of the operation and that had she known the risks, she would not have given her consent. Sophia brought suit and the lower court ruled in her favor. The doctor appealed.

Issue: Should the doctors have informed the patient that risks of the first surgery included a risk of paralysis and the possibility of a second operation?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Although the second surgery was not anticipated it was still connected to the first surgery.

2: Yes.

Spinal surgery presents important risks and patients must be informed of all possible risks, no matter how remote.

3: No.

The second surgery was not anticipated. Informing of its risks would have wasted time and resources and caused the patient unnecessary stress.

Court Decision:

The Malaysian Federal court accepted the trial judge's findings that the patient was not warned of the risk of paralysis from the first procedure or of the possibility that a second surgery may be necessary, and held that if she had been so warned, she would not have undergone it. It also ruled that the trial judge had sufficient evidence to determine

causation. Endorsing a patient-centered approach to the duty of disclosure of risks, the court emphasized the need for members of the medical profession to admit wrong doings, as is the case in other professions. In this way, people involved in medical negligence cases would obtain better professional advice.

Bioethical Considerations:

The doctors performed the operation without proper consent of the woman, which included informing her of the possibility of both paralysis and the possibility of a second surgery in the event the first was not successful. This constitutes a clear violation of her autonomy and dignity as a person as well as a violation of the legal standard of care. This paternalistic approach to clinical relations demonstrates ethical faults in the practice of medicine which must be recognized and addressed.

The circumstances when doctors may not inform their patients are well defined by both bioethics and law: unconsciousness, immaturity, incapacity to understand. These situations represent greater vulnerability on the part of the patient and the need for more protection from doctors and representatives. This is not the present case. The obligation of providing a full and complete informed consent – including disclosures of all risks that would enable a reasonable and prudent person to make decisions is a violation of her autonomy and dignity.

There are, however, situations where the medical team must perform additional procedures that cannot be reasonably anticipated. When the probability of these procedures is remote, it may be justifiable to exempt doctors from informing the patient of their possible risks.

Legal Considerations:

The case presents the question whether the information to be disclosed is determined by reference to a) the specific patient, b) a reasonable patient, or c) the views of the medical profession, generally.

One can argue that a court's use of the more subjective test of disclosure rests on an inclination to "punish" doctors for their wrongdoing rather than acknowledging a substantial patient-right-to know with full information regarding medical risks.

For Further Discussion:

1. If, in the cases of people who are incompetent or unable to make decisions, the

physician is relieved of the duty to give informed consent — then could it not be inferred that where the patient is fully capable of making decisions, the physician's non-disclosure was done in an abundance of concern for the patient's well-being, similar to that which would be required in the case of the vulnerable patient?

2. On the other hand, does the failure to give informed consent when the physician thinks the patient is incapable or incompetent to exercise it (albeit where the patient has not been adjudicated incompetent, such as perchance a hyperemotional person, or where the doctor in fact has reason to know the patient can't – or would not want to cope with making these decisions), reek of paternalism?

FACT PATTERN 15:

Disclosing Treatment Alternatives:

Based on: Birch v. University College London NHS Foundation Trust (United Kingdom 2008).

The patient suffered a stroke in the course of a catheter angiography, which is considered a mildly invasive diagnostic procedure. In this case, the patient did not receive an MRI scan, which was a viable medical alternative to the angiography (although she was initially scheduled for such test), because the equipment was booked by other patients. The patient brought suit alleging damages stemming from the lack of informed consent, arguing that although she had been informed of this one percent risk from angiography, she should have been told of the comparative risks of using MRI-imaging - which carried no risk of stroke.

Issue: Where the risk of harm suffered from the procedure was remote, should the patient have been informed of comparative risks of an alternative procedure which was risk-free but not immediately available?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Patients should be told of all alternatives, especially those which carry no or minimal risks. It is up to patients to choose whether and how to access these alternatives, should they desire.

2: No.

There is no ethical obligation to inform patients of alternatives which the patient cannot access.

3: No.

When the harm is quite remote, there is no requirement to afford the patient of options which have a lower (or no) risk of harm.

Court Decision:

The court ruled that the duty to inform a patient of significant risks would not be discharged unless she is made aware that fewer, or no, risks are associated with another procedure. The court acknowledged that the decision regarding informing the patient of alternatives with lower or no other risks is difficult to delineate and raises legal uncertainty. However, given that both the MRI and angiography were available - although not necessarily immediately, the patient's physician should have explained the comparative risks.

Bioethical Considerations:

This case raises the question of the obligation to disclose treatment alternatives with fewer or no other risks and comparative risks. This question is more delicate when some alternatives are expensive, difficult to access or are not offered by the local health system. The purpose of the doctrine of informed consent is to provide the patient with all the necessary means to make an informed choice, namely one supported by all relevant and necessary information to qualify as a voluntary and informed choice. The fact that some alternatives may not be accessible de facto does not, in itself, exclude them from serving as a basis for decision-making. Accessibility per se is only one factor to which the patient (and doctor) should be attentive. While this may create some burden on the healthcare provider including spending more time per patient's visit and providing additional information resources, it nonetheless fosters and secures, in a substantial way, patient-autonomy, thereby strengthening trust in healthcare providers

and the health system generally.

For Further Discussion:

1. Balanced against the risks of the procedure itself, should the court have considered that the delay that would ensue from waiting for an MRI's availability would also engender risks?
2. Given that the duty of informed consent only applies to significant risks – at what point is the risk reduced from significant to insignificant? (It is important to note that in some jurisdictions this has been quantified by case law).

UNIT 6: Persons without Capacity to Consent

Article 7

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“In accordance to domestic law, special protection should be given to persons who do not have capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.”

Introductory Discussion:

Consent for Research from the Vulnerable or Incapacitated

Article 7 deals with the type and manner of consent that should be obtained for decisions about health care or research involving patients without the capacity to consent. Sometimes there is a difference between legal capacity and the de facto capacity to consent in the bioethical sense. The bioethical approach demands respect for the dignity of the patient, no matter what deficiencies s/he may have and requires taking the maximum advantage of the patient's potential contribution to the decision to

be made.

Incapacity can be defined as lacking the freedom to make authentic decisions because of an inability or incapacity. Various groups of people have been traditionally labelled in this way: the mentally ill, children, the elderly and unconscious patients. The criteria for capacity to consent requires the ability to understand given information, to appreciate the nature of the situation, to assess the relevant facts, to exercise choice, to use the information for realistic and reasonable decisions, to appreciate the consequences of giving or refusing consent and to be able to communicate one's decision.

FACT PATTERN 16:

Research on the Incapacitated:

Based on: Prof. John Walker-Smith v. General Medical Council (United Kingdom 2012).

Prof. Wiss (not his real name) was an experienced pediatric gastroenterologist and medical researcher. For one of his research projects, he received his hospital's ethics committee's permission to take two extra mucosal biopsies for research purposes in addition to the four to six biopsies taken for diagnostic purposes during colonoscopies. He then began a research project examining the association between measles vaccination and persistent enteric infection, enteritis and malabsorption of vitamin B12. Under this research project, Prof. Wiss performed a series of tests on children referred to him for treatment by their general practitioner or a unit in the hospital, which included performance of ileo-colonoscopies and upper gastrointestinal endoscopies (during the course of which he took some additional biopsies not strictly necessary for treatment or diagnosis.) The procedures in question involved sedation or general anesthesia. Prof. Wiss was accused by the General Medical Council of undertaking these investigations without receiving permission from the hospital's ethics committee and carrying out medical procedures that were not clinically indicated. In response, he argued that the procedures were clinically appropriate diagnostic techniques or were performed for alleviation of the children's symptoms and did not require ethical approval from the hospital's ethics committee. A disciplinary panel found the physician guilty of professional misconduct. Prof. Wiss sued to have the finding reversed.

Issue: Should the doctor have sought consent for this research from the patients (via their parents)?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: *Yes.*

This research plan was separate from his professional care and not aimed at providing clinical response for these children.

2: *Yes.*

Regardless whether Prof. Wiss's procedures consisted of research or treatment, they disturbed his patients' bodies and thus should be subject to disclosure and consent.

3: *No.*

Prof. Wiss's interventions were medically indicated.

4: *No.*

His authority to carry out these procedures was implied by the consent originally given by these children and their guardians at the time they retained him as their children's treating physician.

Court Decision:

After analyzing the facts pertaining to each of the relevant children involved, the court concluded that the disciplinary panel erred when it found him guilty of professional misconduct. The court held that the panel failed to decide whether the physician-researcher was undertaking research under the guise of providing medical care, in which case unless his actions fell outside the spectrum of reasonable medical practice and in fact, he could be considered guilty.

Bioethical Considerations:

This case involves the situation where medical procedures may be presented as treatment - rather than research - and thus protected by the informed consent obtained at the beginning of the relationship.

However, we should address whether the process of informed consent should be an

ongoing one and not related to a discrete point in time, namely the initial contact between patients and doctors. Even if these medical procedures could be regarded as treatment with a clear clinical benefit, it might be well-argued that all uses should be fully and reasonably disclosed to the patients or their guardians, and informed consent should be obtained for each specific use.

The case also raises the questions 1) whether ethical principles of medical research (as opposed to medical treatment) should be dependent on a subjective test referring to what the researcher believed were the purposes of the medical procedures (whether to benefit the individual or gain knowledge that could be generalized), and 2) what the standard should be when a research team consists of people who have both an intention to heal and to gain generalized knowledge. As this case presents, it may be difficult to distinguish between these two extreme positions, especially when relying on a subjective test of intent, as was the case here. While this test may be appropriate for legal discussion, (regarding drawing the line between a doctor and researcher for evaluation of disciplinary actions), the test may not protect the patient from violation of ethical rights related to autonomy and informed consent.

The issue becomes even more complicated when different members of a research team have different objectives or intentions (as appears to be the case here), some to heal and others to gain general knowledge. Finally, the issue of the invasiveness of the additional procedures (increasing the level of risk to which the children were subjected) should warrant concern.

For Further Discussion:

1. The UNESCO provisions in Article 7 very clearly enunciate a disaffection for research not used for the benefit of the individual patient in question. Only in rare circumstances is research on one patient allowed that might be of beneficial use to others. "Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden". Should this factor govern?
2. Should the dispositive factor in this case be the invasiveness of the procedures?

References

- World Medical Association 1964 Declaration of Helsinki www.wma.org

- Council for International Organizations of Medical Sciences Ethics Guidelines www.cioms.org.
- See also Fact Pattern # 19: *Bearder v. Minnesota*, (Supreme Court of Minnesota, 2011), available at: www.lawlibrary.State.mn.us/archive/supct/1111/OPA100101-1116.pdf

UNIT 7: Human Vulnerability

Article 8

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.”

Introductory Discussion: Protection of the Vulnerable

The principle of respect to human vulnerability reflects a concern for the fragility of human beings whose functioning can easily be disturbed, threatening their health and even their very lives. The principle is related to the principle of personal integrity. Several aspects of vulnerability must be distinguished: Biological or corporeal vulnerability (e.g., sick patients), social vulnerability (e.g., racial minorities) and cultural vulnerability. Vulnerability demands extra care by others, the assumption of this responsibility, and the recognition and non-exploitation of that condition.

Integrity concerns the wholeness of an individual. It refers to fundamental aspects of human life that should be respected. Personal integrity refers to respect for a patient's understanding of his or her own life and illness, and for his or her interests and free will. Each person's life has a coherence, a narrative based on important events in his or her life and by his or her interpretations and values. It is this personal integrity of human beings that must be protected. Principle 8 gives priority to individuals and groups classified as vulnerable, for whom it demands not only protection against being hurt but also respect for their integrity. (Reference: Bioethics Core Curriculum, UNESCO 2008),18.

FACT PATTERN 17:

Suicide of an Involuntarily Detained Mental Patient:

Based on: Savage v. South Essex Partnership NHS Foundation Trust (United Kingdom, 2007, 2008, 2010).

A woman suffering paranoid schizophrenia ran away* ('eloped') from the hospital where she was a detained patient in an open acute psychiatric ward, and shortly thereafter committed suicide by throwing herself in front of a train. Her daughter argued that the medical institution violated her mother's right to life by allowing her to escape and kill herself, and brought suit.

Issue: Should the doctors and the medical institution have taken more aggressive means to prevent the patient from committing suicide?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The patient was already detained and her liberties were already waived either by the patient or her guardian's acceptance of detention.

2: Yes.

The patient's liberties and autonomy are subordinate to fulfillment of her right to life.

3: No.

The patient's right to autonomy empowers her to choose death over life (and commit suicide, if she so chooses).

Court Decision:

The House of Lords ruled that the State has no general obligation, either at common law or under the European Convention on Human Rights, to place obstacles in the way of persons desirous of taking their own life. Different rules, however, may apply in the case of persons at known suicide risk who are detained because of their vulnerable mental state and placed under control of hospital authorities.

Nevertheless, if there is a real and immediate risk of suicide, the High Court held that Art. 2 of the Convention (which protects the right to life), imposes an operational obligation on the medical authorities to do all that could reasonably be expected to prevent the

suicide, especially in vulnerable populations, including imposing restrictions on the patient's freedom and personal autonomy. The facts are to be determined on a case by case basis. The House of Lords, allowing the appeal of the daughter for damages, noted that the operational obligation arose only if members of staff knew or ought to have known that a particular patient presented a “real and immediate” risk of suicide. In those circumstances Art. 2 required them to do all that could reasonably be expected to prevent the patient from committing suicide. If they failed to do that, not only would they and the health authorities be liable in negligence, but there would be a violation of the operational obligation to protect the patient’s life. The House of Lords agreed that under appropriate circumstances this operational obligation (previously confined to prisoners and administrative detainees) should be extended to Mental Health Trusts to prevent patients from committing suicide.

On appeal the court found that the Trust had breached Article 2 as (a) they had the requisite knowledge, actual or constructive, of a real and immediate risk to the patient's life from self-harm, and (b) failed to do all that could reasonably have been expected of it to avoid or prevent that risk. They held that the patient's daughter was eligible to bring the claim as a victim under 7 HRA 1998 and the daughter was awarded compensation of £10,000. See *Savage v South Essex Partnership NHS Foundation Trust* (2010) EWHC 865 (QB).

Bioethical Considerations:

The court accepted the concept of the vulnerable mentally ill patient, whose autonomy may be altered for a non-defined time period. The use of a non-defined time period is problematic, and begs for limitation or objective means for imposing limits.

Further, on one hand, vulnerable patients or those unable to competently protect their own lives are at the greatest risk of ‘unintended’ (to the extent they are capable of rational thought) suicide and the duty of the medical establishment may be greater to someone with diminished mental capacity. Under this view, the relinquishment of the right to autonomy caused by illness creates an obligation of protection by doctors and the state. From this point of view the doctor and the hospital committed negligence as well as violated deontological requirements. On the other hand, often the autonomy and liberty of these patients are already restricted by being institutionalized and courts might consider why the State and doctors should take even more stringent measures to prevent intended suicide.

It could well be argued that by placing himself under the care of the medical institution, the patient is seeking to be protected from these very urges. Alternatively, one can also argue that from their own perspective, the wish of these patients not to continue living should receive greater, rather than less, weight. However, one can also argue that this right to choose was suspended once they entered the Institution's door—that is assuming they had the mental competence to choose to do so, and that the decision was voluntary. Clearly if this is not the case, other considerations must apply.

On a broader level, perhaps respect for autonomy should not necessarily be dependent on patient vulnerability but should receive independent consideration deriving from the content and weight we ascribe to the value of autonomy in society.

Legal Considerations:

'Running away' from the hospital is called "psychiatric elopement" in American medicine and has spawned a host of malpractice litigation.

There are reasonable limits to the duty of care imposed on physicians and hospitals, however. The question is, how far does an institution have to go to prevent suicide by a mentally ill patient? One can argue that the assumption of a duty to treat a patient with diminished mental capacity requires greater care than to persons with full mental capacity with the ability to make rational decisions.

For Further Discussion:

1. Is the right to life the same as the requirement to live – or is it a right to choose life - the former would impinge on a patient's right of autonomy. The patient's right to choose life was not infringed, here.
2. Do incarcerated mental patients have the right to change their mind? After the patient agreed to be detained, apparently, she decided to leave. Isn't that the basic freedom of autonomy?
3. Does the hospital have a duty of due care – (i.e., on a negligence basis) which supersedes any ethical consideration? Does the hospital or mental institution have contractual obligations that supersede ethical interests?
4. What if the patient is involuntarily in an institution – and runs away? Does mental competence influence the amount of autonomy the patient should be granted?

5. Is the issue that the doctors and hospital should have taken better steps to prevent the woman from running away – or from committing suicide? Would it have made a difference in terms of hospital and physician liability if the patient committed suicide in the hospital?

FACT PATTERN 18:

A Person's Right to Bodily Integrity:

Based on: Yearworth v. North Bristol (United Kingdom 2009)

Six men underwent chemotherapy at the defendant's hospital. Each was warned that chemotherapy regimen might damage his fertility and was invited to supply sperm which the defendant would store for them, and which could be used should the chemotherapy damage their ability to have children normally. Each of the men took advantage of the option. The sperm was preserved by freezing – which was done inside tanks of liquid nitrogen. Thereafter, the level of liquid nitrogen in the tanks fell below the required levels, thawing and permanently damaging the sperm. This event rendered some of the men unable to bear natural children – as several sustained permanent loss of fertility due to the chemotherapy.

The men brought suit, alleging that the clinic had failed to take reasonable care in the storage of the sperm and thus caused mental distress and psychiatric injury. The clinic disputed the claims of psychological damage and denied liability, claiming that even if the men suffered harm they were not entitled to compensation on the grounds of negligence. Subsequently the claims were amended and bailment of the plaintiffs' property, i.e., their sperm, was alleged. The claim was rejected by the trial judge and it was appealed.

Issue: Should the clinic be responsible for the management and preservation of the men's semen?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The clinic holds general responsibility for caring for the plaintiff's semen as it belongs to them, whether it was contained inside their bodies or ejaculated out of it. And management of the sperm was the sole responsibility of defendant hospital.

2: No.

Once extracted from the men's bodies, the semen has been abandoned and does not belong to anyone.

Court Decision:

The Court of Appeal held that damage to a substance generated by a person's body which was inflicted after its removal from the body did not constitute a bodily or "personal injury" and that for the purposes of negligence, the claims failed. However, the court held that the claimants owned their sperm, and that the Human Fertilization and Embryology Act preserved their absolute control over its use, continued storage and the right to order its destruction, which are fundamental features of ownership. Hence the court ruled the claimants had sufficient rights to render them as bailors of their sperm. Since the sperm were the men's property, they were not precluded from recovering damages for the defendant's admitted breach of due care as a gratuitous bailee.

Bioethical Considerations:

The court made its decision on technical legal grounds, (rejecting claims for negligence, but accepting the same claims under bailment law). However, the bioethical considerations beg for analysis.

Bodily parts, cells and human fluids extracted from one's body are, in a sense, one's extended property, and the level of one's control depends, inter alia, on the symbolic and functional meaning that they carry for that person. A person's gametes, which are a potential for new human life, especially at times of a serious health threat to a person, should be managed with proper care, while decisions regarding their fate, e.g., storage, destruction, donation, etc., should be left to the person from which they were extracted. In this sense it is the shared responsibility of both the person and the clinic to manage them. While the person from which they were taken should have full control on their destination, the clinic should be regarded as their agent in assisting the person in carrying

out his/her wishes and should be responsible for all damage that ensued from their failure.

References:

<https://mcbridesguides.files.wordpress.com/2013/09/yearworth-v-north-bristol-nhs-trust.pdf>

UNIT 8: The Right to Privacy and Confidentiality

Article 9

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.”

Introductory Discussion: Privacy and Confidentiality

Privacy is the right of an individual or a group to be free from intrusion from others and includes the right to determine which information about themselves should be disclosed to others. It must be recognized that individuals own their personal information, and that respect for this ownership is an essential element of their dignity and personal integrity.

Protection of this right of privacy is achieved by the doctrine of confidentiality, which mandates that personal information should not be disclosed to others without sufficient reason. Thus, there may be cases of justified breaches of confidentiality, for example: mandatory reporting, serious danger to others, sharing information with the patient’s guardian, using interpreters, or teaching medical students. These cases require sensitive balancing of interests of all parties involved, as well as weighing conflicting rights that may be violated in the process.

FACT PATTERN 19:

Use of Retained Blood Samples Taken from Children:

Based on: Bearder v. Minnesota, (Minnesota, USA 2011).

Nine families filed a complaint against the State of Minnesota, alleging that the Minnesota Department of Health retains, uses, stores and disseminates newborn blood samples ostensibly to be used as an initial screening of newborns for certain heritable and congenital metabolic disorders to protect the infants’ health but without explicit

consent. Only one test, for cystic fibrosis, entailed genetic analysis and about 70% of the blood was used for this purpose. The families alleged that the Department allowed outside research organizations to use the remainder of samples to conduct other research and the parent's claim this practice violates the newborns' privacy and proprietary interests and is a violation of their right of informed consent. "They argue that the Genetic Privacy Act requires the Department of Health to obtain informed consent before it may collect, use or disseminate the blood samples that remain after the newborn health screening is complete. The State argues that the Genetic Privacy Act does not limit the Department's handling of the samples because those samples are treated as biological specimens under the Act, not genetic information and moved to dismiss the families' claim." The District Court granted the State's motion to dismiss the case. The Court of Appeals affirmed and the case went to the Supreme Court of Minnesota.

Issue: Should the Department of Health be required to seek consent of parents for retaining, using, storing, disseminating and conducting research on newborn blood samples?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Parents have a right to be informed about the use of their newborn's blood samples, a derivative right from their newborn's right to autonomy.

2: Yes.

Blood samples belong to the newborns (and their parents as guardians), and the Department of Health should protect their privacy and proprietary interests by fully informing of their purpose and obtaining their consent for future use.

3: No.

Blood samples are not considered property of the newborn nor do they carry any significant or symbolic meaning. Hence, neither the infants nor their parents (in

either individual or derivative capacity) have any rights pertaining to them.

Court Decision:

The issue presented to the court was: are blood samples considered ‘genetic information?’ The court ruled that it was, and reversed the lower court decisions noting that:

“Under subdivision (b), genetic information “also means medical or biological information collected from an individual.” Unlike definition (a), definition (b) does not limit its protection to information “obtained” from an analysis of a “biological specimen.” Rather, the definition is broader in scope because it encompasses “medical or biological information” about an individual. As noted under the analysis of subdivision 1(a), biological information includes blood samples. Therefore, an individual's blood samples are biological information subject to protection under definition (b). ...In conclusion, the newborn screening statutes provide an express exception to the Genetic Privacy Act only to the extent that it authorizes the Department to perform newborn screening by testing the samples for heritable and congenital disorders, recording and reporting those test results, maintaining a registry of positive cases for the purpose of follow-up services, and storing those test results as required by federal law. The newborn screening statutes do not expressly authorize the Department to conduct any other use, storage, or dissemination of the blood samples.”

Reversed.

Bioethical Considerations:

The opinion may derive from the specific legislation, but other questions may be asked. What is the purpose of the testing? Is it conducted for determining genetic conditions or for other reasons? Who may benefit from the proposed testing? Is it the individual who provided the material or family members with a genetic connection or someone who is not genetically or otherwise related to that individual - or all of them? The answers may help to clarify whether the newborn and their parents maintain privacy, proprietary and autonomy interests pertaining to these samples under these as well as other circumstances.

For Further Discussion:

1. If the samples are used in such a way that someone obtains a financial benefit for them (such as by patenting a gene sequence obtained from a sample) – would that change the opinion?

2. Should the reasoning hold for biobanks? What kinds of safeguards might be implemented to prevent abuse? Would opt-in, opt out clauses work?
3. In the event the samples will have multiple uses, some to benefit the infant, some to benefit the public at large, and some for financial gain of a proprietary or private organization – would varying levels of required consent address any concerns, e.g., broad consent and specific consents.
4. Is consent required for every one of multiple uses, if it is clear the patient would have consented to the procedure for at least one of the uses?
5. From a legal perspective can the doctrine of informed consent, if violated, be used to support a claim for invasion of privacy and violation of bodily integrity?

References

UNESCO 1997 Declaration on the Human Genome and Human Rights

UNESCO, IBC, NDNS report

<http://caselaw.findlaw.com/mn-supreme-court/1585739.html>

<http://www.casebriefs.com/blog/law/health-law/health-law-keyed-to-furrow/legal-issues-in-human-genetics/bearder-v-minnesota/>

FACT PATTERN 20:

Protection of Confidentiality.

Based on: The Queen on the application of Sue Axon v. Secretary of State for Health and the Family Planning Association (United Kingdom, 2006)

The parents of an adolescent sought judicial review of Department of Health guidelines holding that advice on sexual matters rendered to individuals under 16 who are capable of understanding it and appreciating its implications remain confidential where the adolescent refuses to notify her parents or allow medical professional to do so.

The parents argued that people under 16 are not owed the same duty of confidentiality as those over 16, and that the guidelines violate Article 8 of the European Convention on Human Rights that protects private life.

Issue: Should doctors have an obligation to protect the right to confidentiality of

adolescents?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The best interest(s) of the adolescent patient should be respected.

2: Yes.

An adolescent with sufficient maturity to understand the implications of these matters should be regarded as an adult, with the same protection of his or her rights including confidentiality.

3: No.

The protection of the right to confidentiality entails understanding of the relevant information and adolescents under the age of sixteen are incapable of fully understanding such information.

Court Decision:

The court held that there is no exception to the duty of confidentiality owed to a person under the age of 16, provided that certain safeguards are met, i.e., a showing that the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed. While parents may be the most appropriate to guide, advise and protect their children and that secrecy was destructive of family life, these considerations do not override the duty of confidentiality owed to the minor. The court also ruled that the guidelines do not breach Article 8 of The Convention, noting that: “European case law has established that where the rights under article 8 of the parents and those of the child are at stake the child's rights are the paramount consideration.”

Bioethical Considerations

This ruling is not in line with the way other rights or limitations granting authority to parents are addressed. For ordinary health care matters, guardians of young patients (usually his or her parents) usually have the full authorization to decide treatment.

However, in the present case addressing sexual advice and treatment for adolescents, the best interests of the adolescent – as expressed by the adolescent - overrides the rights and authority of the legal guardian.

References

United Nations 1995 Beijing Declaration

<http://www.familylawweek.co.uk/site.aspx?i=ed1957>

FACT PATTERN 21

The Right to Know Family History and Personal Background:

Based on: Sarah P. v. Prof. Thomas Katzorke (Germany, 2013).

A 21 year old woman conceived with sperm donated at a clinic in Essen, Germany submitted a petition to the court seeking disclosure of her biological father. The physician-operator of the sperm bank opposed her request and claimed that the donor records and applicable data, which were more than ten years old, had been destroyed, as allowed by law. He also claimed the woman did not have a right to this information even if such information was available. The woman sued, claiming that the physician-operator had - at the very least –the obligation to make a thorough search and a good faith effort to try to obtain the information.

Issue: Should a person who was conceived with gamete donation have a protected right to access information concerning her genitor?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Part of the right of autonomy includes the ability to forge a personal identity. Accessing birth record information promotes forming an identity and hence the woman should be entitled to the information.

2: No.

The gamete donor did not give his consent to accessing such information.

3: No.

Acknowledging such a right may create serious burdens on donors and deter gamete donations.

Court Decision:

In 1989, Germany's Constitutional Court decided that individuals should have the right to know their genetic identity. Because physicians would be obliged to share the information, the court decided they could not be held culpable for breaking doctor-patient confidentiality by doing so.

The court in this case decided that the right of a child to know her genetic origin is a fundamental right and the basis of principles of human dignity and individual rights. The court noted that "the interest of the plaintiff in ascertaining her parentage is assessed to be higher than the interests of the defense and the right to nondisclosure of donor information," a right that supersedes the duty of the physician to assure the anonymity of the sperm donor. After finding that the physician had, under questioning, contradicted his argument that all of the data had been destroyed and admitting that some information had been retained, the court held that the responsible physician should make an effort to find the identifying records.

Bioethical Considerations:

On one hand, public policy allowing non-anonymous donations may deter adults from donating their gametes, thereby resulting in unmet donation requests, extending waiting lists for gametes and possibly exacerbating the ethically-disturbing phenomenon of commercial gamete-traffic and associated exploitation. On the other hand, studies show that knowing one's genetic relations significantly contributes to identity and character and is highly important to psychological and possibly physical well-being. This case addressed these competing interests by ruling in favor of the individual's right to know her genetic identity.

In this case, the right to know one's ancestral origins had been recognized repeatedly by Germany's Constitutional Court. The conflict between the legislative recognition and a claimed right of a gamete donor to confidentiality posed a conundrum which was

resolved by the court in favor of the child. Nevertheless, in such cases it is preferable that the legislature, representing the views and wishes of the general public and not the judiciary, be the ones who decide which system better corresponds to prevalent societal mores and values.

It is interesting to note that in Germany, the record-keeping requirement has been extended from ten years (the law at the time the child was born) to thirty years.

For Further Discussion:

1. Should those who once had custody of such information but no longer have it accessible be required to use due diligence and make their best efforts to try and retrieve such data?
2. Would indefinite record-keeping be an unfeasible burden discouraging these types of operations?

References: “Court rules sperm donors' children have right to know.” June, 2, 2013, <http://www.dw.com/en/court-rules-sperm-donors-children-have-right-to-know/a-16580116>

“No anonymity for sperm donors, court rules.” July, 2, 2013 <http://www.dw.com/en/no-anonymity-for-sperm-donors-court-rules/a-16582786>

UNIT 9: Equality of all Human Beings

Article 10

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.”

Introductory Discussion:

Equality and Justice for All

The principle states that people should be treated justly and equitably. All people are considered equals in terms of dignity, rights, opportunities, freedom, benefits and obligations.

There are different types of Justice. These include:

Distributive justice (which ensures that each person receives a fair share of public resources), procedural justice (which ensures a fair process for making decisions), retributive justice (which ensures punishment of wrongdoers), restorative justice (which attempts to repair harm done in the past), social justice (which is a combination of the previous types of justice as applied to society such that individuals and groups receive fair treatment and a just share of the benefits). Justice also contemplates the inclusion of principles of equity.

(Reference: Bioethics Core Curriculum, UNESCO 2008).

FACT PATTERN 22:

Equal Access to Health Care:

Based on: Fok Chun Wa v. Hospital Authority (Hong Kong, 2012).

A pregnant woman who was a resident of the Chinese Mainland, married a Hong Kong resident, and was in the process of becoming a Hong Kong resident herself. She gave birth to a child in a public hospital in Hong Kong where she was not eligible to receive subsidized obstetric services, and was charged at a higher rate than Hong Kong residents for the same package of services. The woman argued that she and women in

her status were unlawfully discriminated against and that their right to equal treatment was breached in that they were not afforded equal care at equivalent cost.

Issue: Should the medical center have treated the woman like Hong Kong residents and subsidized the obstetric services she received?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The woman was married to a Hong Kong resident, resided in Hong Kong for a while, contributed to the society and deserved equal treatment.

2: Yes.

Obstetric care is a basic medical treatment constituting a core right to health. Every person is entitled to free access to such care regardless of his or her citizenship.

3: No.

Limited resources for medical care must be rationed. One acceptable way to ration health care is to predicate decisions on the citizenship of the patient.

Court Decision:

The court ruled that in the area of healthcare, where resources are limited and competing demand from many different interest groups is high, courts are not equipped, nor is it their role, to make difficult judgments pertaining to allocations of funds or type of care. The court held that drawing the line at residency or citizenship status was within the spectrum of reasonableness and justified differential treatment. Due regard for the long-term sustainability of Hong Kong's social services in the context of limited public resources, both financial and manpower, was reasonable and warranted.

Bioethical Considerations:

This case raises the question of whether the right to health care is and should be classified as a human right, such that access should not be dependent upon residency or

citizenship. Alternatively, health care could be conceptualized as a social right which makes demands upon the State that could, in principle, apply to only part of the people residing within it. Nevertheless, even if one regards the right to health as a social right, there still may be some basic minimum core services such that the State has the duty to supply these to every person at the same cost, e.g., emergency obstetric care. The court did not discuss these theoretical questions. Instead, they relied on the concept of rationing based on residency status as a criterion that policy-makers may legitimately use in making their health care allocation decisions.

FACT PATTERN 23

Public and Private Health Insurance:

Based on: Chaoulli v. Quebec (Canada, 2005).

A patient and doctor from the Province of Quebec sought a declaration that Quebec Health Insurance Act and the Hospital Insurance Act's prohibition of private insurance for services provided by the public health system is unconstitutional, as it impedes access to health services and subjects participants to forced waiting lists, thereby violating their right to life and security. The trial judge found that such provisions violate section of the Canadian Charter of Rights and Freedoms, although such infringement is justifiable. A further appeal was brought to the Supreme Court.

Issue: Should the State allow private insurance for services also provided by the social health system?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Every person should have the freedom to improve their well-being in any way they are able, inter alia, by accessing the best healthcare services in as fast and easy way as possible and feasible for them. If people can afford to pay privately for healthcare services, thereby affording them quicker access to health care than members of the public system, they should be free to access them.

2: Yes.

To claim otherwise may jeopardize the health, mental and physical, of people who are able to use private health resources.

3: No.

Services included in the social health system reflect the societal consensus of providing basic health services on an equal basis and without preference to individuals who can afford greater and quicker access to these services.

Court Decision:

Affirmed.

The court held that the Quebec Health Insurance Act and the Hospital Insurance Act violated the Quebec Charter of Human Rights and Freedoms and violated Quebecers' right to life and security of person. The Supreme Court ruled that waiting lists affect the constitutional right to life, as some patients may die before the scheduled surgery. Waiting also causes psychological and emotional tension as well as constitutes a violation of the right of autonomy. Further, no evidence was produced to show that banning private insurance protects the public health care system. While a State may have a legitimate and primary interest in regulating its Health Care System, less drastic or prejudicial measures were available than those that used here. Hence, the court ruled that the aforementioned prohibitions were not justified under the Quebec Charter.

Bioethical Considerations:

Understood as a social right imposing positive duties on the State, the right to health is subject to the principles of justice and equality. One expression of these principles involves the ethical duty to provide health services on an equal basis and avoid distinguishing individuals by arbitrary criteria that differentiates them. The way healthcare services are organized and provided in each country is a public policy issue, reflecting pertinent values and beliefs within that society e.g., individualism, free choice, social justice, solidarity, etc. While systems differ in the way they are structured, some basic and universal principles apply to all. One relates to the duty to provide affordable access to elementary or critical services and not discriminate on the basis of financial affordability. Nevertheless, policy-makers should be free to decide how to implement these imperatives, as long as these principles are met.

UNIT 10: Freedom from Discrimination and Stigmatization

Article 11

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.”

Introductory Discussion:

Social Discrimination and Stigmatization

To discriminate socially is to make a distinction between people based on class or category without regard to individual merit. Discrimination on the basis of race, social class or caste, nationality, religion, sex, sexual orientation, disability, ethnicity, height or age, are examples. Such distinctions constitute an infringement of the ethical theory of egalitarianism and the principle of social equality. (Reference: Bioethics Core Curriculum, UNESCO 2008).

Stigmatization is a discrediting process which strikes an individual considered abnormal or deviant. He or she is reduced to this single abnormal or deviant characteristic, and the label then serves as an (illusory) justification for a range of anti-social conduct including discrimination and exclusion (Encyclopedia Britannica).

FACT PATTERN 24:

Rights and Entitlements of the Deaf:

Based on: Eldridge v. British Columbia (Canada, 1997).

Bea (not her real name) was born deaf. Her preferred means of communication is sign language. In her view, the absence of interpreters within medical institutions impairs her ability to communicate with her health care providers, increasing the risk of misdiagnosis and ineffective treatment. She contends that the failure to provide sign language interpreters as a covered benefit violates her right to equality, and sought to compel a declaration that she and others similarly situated are entitled to this service.

Issue: Should the medical institution be obliged to offer sign language interpreters to help E and other similar patients?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

Without sign language interpreters these patients are unable to make informed choices, depriving them of their right to autonomy, thereby rendering them unequal compared with hearing patients who are afforded this right.

2: Yes.

Such an obligation facilitates equal treatment for people with disabilities.

3: No.

A patient does not have a right to an interpreter under public funding. Such a right is not derivative from the right to health.

Court Decision:

The court held that effective communication is an integral part of delivery of medical services and the failure to provide interpretation services to the hearing-impaired was unconstitutional.

Sign language interpretation is a means by which deaf patients may receive the same quality of medical care as the hearing population. Moreover, in addition to risks involved in the absence of sign language interpreters, it may be impossible for doctors to treat deaf patients properly without them. In this case, the government failed to demonstrate that denial of these services for the hearing-impaired constituted merely a minimum impairment of their rights. While the government argued that providing sign language interpreters would also obligate them to provide interpreters for foreign language speakers, the court ruled there was no evidence to support this claim.

Bioethical Considerations:

This case raises the question whether a right to sign language interpreters should be part of the right to access health services a deprivation of which violates the principles of autonomy and equality. If one answers this question in the affirmative, further inquiry

should be made as to its implications.

Does such a broadened right to health services also include other ancillary or non-medical service such as transportation to a doctor's office? If so, should entitlement to free (or otherwise publicly funded) non-medical services in a universal public scheme receive the same weight as the entitlement to the medical service itself? In times of austerity, one must consider these questions to enable provision of health and health-related services in a responsible, accountable and equitable manner. Such decisions also involve balancing considerations, discussed earlier.

Another approach to determining the issue is based on protecting the rights of the vulnerable population. Those with hearing impairments and other unavoidable communication difficulties are at a greater risk of vulnerability. To address their needs and protect their rights, interpreters must be part of a multidisciplinary health staff.

The question, however, raises concern over how far the State's obligation goes in protecting those with communication difficulties. It is recognized that communications and language are essential in human society, particularly in clinical and health-care related situations but the extent of redress warrants discussion.

For Further Discussion:

1. Would the State be obligated to provide translators in health-care settings to new immigrants whose language skills of their new country are sub-par?
2. Is there a difference in communication difficulties that cannot be remedied (i.e., deafness) with those that are within the patients' control, such as learning the language of their new country?
3. Is there a time limit under which the new immigrant would be provided such services before being expected to become minimally proficient in the language of the new home country?

4. Would the State be obligated to provide translators to emergency refugees who do not speak the language of the host country?
5. Would a failure to provide translators to those with communication difficulties which are remediable (i.e., by attending language classes) be a violation of the dignity of these new immigrants and migrants?

UNIT 11: Respect for Cultural and Religious Diversity

Article 12

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.”

Introductory Discussion:

Respect for Cultural Diversity and Pluralism

Culture is often viewed as the common heritage of humanity. It is regarded as a set of distinctive spiritual, material, intellectual and emotional features of a society or a social group. In addition to art, literature and lifestyle, it encompasses communal living practices, differing value systems, traditions and beliefs. Culture takes diverse forms across time and place. This diversity is embodied in both the uniqueness of individual groups and the plurality of the groups which comprise the society of humankind. Pluralism is, in a general sense, the affirmation and acceptance of diversity. The distinctiveness of individual cultures is an important, integral and even perhaps a necessary component of human evolution and human society and therefore should be safeguarded and preserved for the benefit of present and future generations. Nevertheless, respect for cultural diversity should not be invoked when it infringes upon human dignity, human rights and fundamental freedoms. (Reference: Bioethics Core Curriculum, UNESCO 2008).

FACT PATTERN 25:***End of life Treatment:***

Based on: Cuthbertson v. Rasouli, (Canada, 2013).

The patient is in a persistent vegetative state. He is unconscious and has been on life support for three years. The treating physicians believed that all appropriate treatments had been exhausted and that the patient had no realistic hope for recovery. In the physicians' view, continuing life support would not provide any medical benefit and might cause harm. They sought to remove life support and to provide palliative care until the patient's expected death.

The patient's wife and substitute decision-maker, however, opposed their decision. She refused to accept the doctors' contention that her husband was in a state of permanent and irreversible unconsciousness. Moreover, she believed that, as a devout Shia Muslim, her husband would wish to be kept alive. The wife applied for an order restraining her husband's physicians from withdrawing his life support without her consent. The physicians cross-filed for a declaration that consent is not required when the treatment is futile. The Superior Court of Justice granted the wife a restraining order and the Ontario Court of Appeal upheld the order. The physicians appealed to the Supreme Court of Canada.

Issue: Should doctors be allowed to withdraw life support from a patient without his wife's consent and when the patient's religious culture does not condone such actions?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

A patient's right to autonomy (expressed by his surrogate) does not include a right to prevent withdrawal of treatment that is no longer medically effective or that may be harmful to the patient.

2: Yes.

While the prospect of imminent death elevates the significance of other interests, such as religious beliefs and personal values, these considerations cannot prevail if a doctor considers the treatment to be outside the standard of care due to its futility or harmful effects.

3: No.

A doctors' permission to touch the body of a patient, especially withdrawing life-saving treatment, is subject to the patient's right of autonomy.

Court Decision:

The Canadian Supreme Court opined that while a clinician cannot “veto” a surrogate, neither can a surrogate unconditionally “veto” a clinician and that the choice of treatment and decisions remains patient-focused. A clinician who feels that the surrogate’s refusal to consent is contrary to the patient’s best interests has the option of seeking consent from the Consent and Capacity Board. The court also held that “the law is now clear that treatment cannot be administered [or withdrawn] without consent, irrespective of the ethical imperatives that the physicians may feel.” At Para. 73.

The court also discussed whether the term "treatment" in the Health Care Consent Act is confined to medically beneficial procedures, or should be interpreted as anything done for therapeutic, preventative, palliative, diagnostic and cosmetic or other health-related purpose. In keeping the patient alive and forestalling death, life-support falls within "therapeutic" and "preventative" purposes. While the end-of-life context

creates difficult ethical dilemmas for physicians, this does not alter the conclusion that withdrawal of life-support constitutes treatment requiring consent. In case of a clash between the patient's substitute decision-maker (his wife) and his physicians, the Consent Board is the authorized body to determine whether withdrawal of life-support is in the patient's best interests.

Bioethical Considerations:

This case raises the question of whether cultural, religious and personal values of the patient elevate the rights of the patient. Since religious and cultural mores form a basis of a person's identity which serves as the underpinning of his or her autonomy, one must ask whether these considerations outweigh any others.

The case also raises the question whether the patient's rights are subject to the opinion of the treating physician in cases of futility or harmful treatment. One can argue that if a patient has a right to refuse medical treatment (including life-saving treatment) based on personal values, s/he also should be allowed to insist on continuation of treatment if her values lead her to that decision. While the latter decision may have financial and social implications especially when continuing treatment is funded by public resources, it may result in important social goods, namely respecting cultural diversity and moral pluralism. Every society must decide for itself to what extent it wishes to protect these social goods, and the price it is willing to pay for this protection.

For Further Discussion:

1. If the patient (through his surrogate) has the vested interest (i.e., autonomy) to consent to termination of life-support, does this trump the right of consideration of 'his best interests'? If so, is not the wife (his surrogate decision-maker), the person legally empowered to make that decision?
2. At what point do the patient's rights of consent and autonomy, (including designation of a surrogate decision-maker) get trumped by the institution's right to decide what is in the patient's best interest?

3. Does reversion to the Consent (Medical Ethics) Board of the Hospital present its own problems? The Board may have a conflict of interest in deciding to terminate life-support, as in the case where they need the bed for another patient or where the care is too expensive for them to bear and there is no vehicle for compensating the hospital for this care.
4. Does it matter how old the patient is?
5. If religion were an accepted consideration – how would this promote equity and equal justice? Thus, there may be patients who want to be kept alive but don't have the 'backing' of their religion? Why should these patients be deprived of their wishes to be kept alive, just because they don't belong to a particular religion that espouses that doctrine?

References:

<http://scc.lexum.org/decisia-scc-csc/scc-csc/scc-csc/en/item/13290/index.do>

<http://www.bioethics.net/2013/11/cuthbertson-v-rasouli-limited-guidance-from-supreme-court-of-canada/>

FACT PATTERN 26:

Abortion Rights:

Based on: A, B and C v Ireland (Ireland, 2010).

Three women living in Ireland submitted applications to the Irish authorities for an abortion. These requests were refused, as Ireland's laws allow abortion only where continuation of pregnancy places a woman's life (not merely health or other interests) at risk. (The individual facts precipitating their request are heart-rendering. The reader is referred to the case for further information. Alternatively, Wikipedia contains an excellent synopsis https://en.wikipedia.org/wiki/A,_B_and_C_v_Ireland). The Irish

Constitution section 40.3.3 provides that "the State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right." Violation of these laws (and performance of illegal abortions) are considered a criminal offense in Ireland. The women argued that the restrictions violated their right to not be subject to degrading and humiliating treatment under Article 3, their right to respect for their private lives under article, a right to an effective national remedy for these rights under Article 13, and equal treatment in relation to Convention rights under Article 14. All three women then travelled to England for their abortions which were performed within the first trimester of pregnancy. The women maintained that no legal domestic remedy was available to facilitate access to abortion in a timely manner and that they had no other option. They sought legal redress to compensate them for the damages they sustained.

Issue: Should a State be permitted to prohibit abortions where there is a risk to the life or health of the pregnant woman?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

It is a State's prerogative to decide matters which are morally controversial.

2: Yes

Pregnant women can still travel abroad to perform abortions so as to avoid criminal penalties in their country of domicile, and their health is not adversely affected by such travel.

3: No.

Criminalization of abortion is discriminatory, affronts a women's dignity and stigmatizes women.

4: No.

Criminalization interferes with the most intimate of women's family and private lives, including physical integrity.

Court Decision:

The court found that the impugned restrictions were based on profound moral values concerning the nature of life, as reflected by the beliefs of the majority of the Irish population. The question 'when life begins' falls within the State's aegis. The Court held that "Article 8 [of the European Convention on Human Rights] cannot... be interpreted as conferring a right to abortion." With respect to the individual third applicant, however, the court ruled that Ireland had violated Article 8 of the European Convention on Human Rights because it was uncertain and unclear whether she could have access to abortion in a situation where she believed that her pregnancy was life-threatening. Rather than information being unavailable, the court noted the "significant chilling" effect of Irish legislation and held that she had no place to go in Ireland to secure a legally authoritative determination of her rights.

Bioethical Considerations:

Every State has the prerogative to regulate moral issues and manage ethical dilemmas using tools such as the legal system. One example is a State's decision to criminalize abortions. While every State is autonomous regarding whether, when and to what extent, to prohibit abortions, this case makes an interesting connection between supporting criminalization of abortion and the ability of women to go elsewhere (in this case, across the border) for a legal abortion.

But should the fact that a person can travel to another country to perform an action

which otherwise would be unlawful or unethical in the home country justify the home country's legal decisions and abortion's ethical status? The court does not fully address the financial, emotional and health-related burdens associated with 'abortion tourism', including the effects on inter-personal relationships and intimate interactions. It is suggested that a fuller and a more critical examination of 'abortion tourism' was warranted.

References:

UNESCO Universal Declaration on Cultural Diversity, 2001

UNIT 12: Solidarity among Human Beings

Article 13

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“Solidarity among human beings and international cooperation towards that end are to be encouraged.”

Introductory Discussion:

The Morality of Solidarity

Solidarity is a moral value. Human beings share an identity as members of the same collective. Therefore, they should feel a mutual sense of belonging and responsibility. Solidarity, then, is an ethics of commitment. It implies that care for others should be taken even if it is not in our individual interests. Solidarity reflects group-oriented responsibility to care of all members of the collective society, including (perhaps especially) the weaker and more vulnerable members of the community. On its face, the concept of solidarity may conflict with individual rights. The challenge we face is to address and respect and balance the importance of both.

FACT PATTERN 27:

Organ Donation:

Based on: Kupat Cholim Meuhedet v. Heyman et al., (Israel, 2011).

Thirteen families brought suit against the State for damages they sustained when donating their kidneys to family members who suffered chronic renal failure. They argue that the State and healthcare providers harmed their loved ones by failing to provide kidney transplantation, thus sentencing them to a life-time of dialysis. The families claim they mitigated this harm by donating their own kidneys, bringing substantial

public saving by obviating the need for continuing dialysis. In their view they should receive compensation for the damages they sustained in reducing society's burden.

Although the lower court dismissed most of the appellants' arguments, the court ruled that donors should be compensated for their personal expenses and provided an estimation of such expenses. The case was appealed to the Supreme Court.

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

Issue # 1: Should a donor have the right to elect the recipient of his or her organ(s)?

1: Yes.

It is an autonomous right.

2: Yes.

It represents a family duty.

3: No.

Donation must be an act of solidarity, meaning an individual's actions should be for the benefit of society as a whole, rather than based on partisan or family interests.

Issue # 2: Should the donors be financially compensated?

1: Yes.

The donors should receive benefit for their effort and have their expenses reimbursed under an implied doctrine of corrective justice.

2: Yes.

By donating their kidneys, the donors make a contribution for the public good, and should receive financial compensation for this loss.

3: No.

The donors acted out of solidarity and did not have any expectation, nor right of receiving monetary compensation.

Court Decision:

The Supreme Court ruled that health services provided under the law focuses on medical treatment and that the law does not impose a duty on the State or HMOs (Health Maintenance Organizations or self-insured medical cooperatives) to pay patients who are entitled to services, as opposed to providing actual treatment. The kidney donations were initiated by the appellants and derived from altruistic motives: they wished to improve the quality of life of their loved ones. Creating financial benefit to the donors was only an incidental by-product of their action and could not generate a legally protected expectation to receive monetary compensation for such a benefit.

Bioethical Considerations:

This exceptional case not only raises question of whether organ donors should receive financial compensation but also emphasizes the social benefit created by cost-saving organ donations which benefit society. This affect, intended or otherwise, raises the issue whether donors should be compensated for bringing about this outcome.

It seems fair to argue that the State should compensate individuals who facilitate its duty to provide services or treatment (transplantable organs). Even if one holds that a person's organs are not his or her property and s/he cannot conduct commerce with it, one might claim s/he may still be entitled to receive financial compensation deriving from the social implications of her or his action.

Another question concerns the means through which the State should promote solidarity between its citizens. From this perspective, acknowledging an entitlement to receive financial compensation for organ donation may jeopardize this goal, making people motivated more by financial incentives and less by compassion and sense of help.

Finally, questions concerns the legitimacy of claiming that a person's organs are their property in light of patent cases involving ownership of DNA arise. It would seem strange to deny ownership of one's kidneys when it would be inconceivable to deny ownership to someone's limbs should they be injured by another and seek compensation for the harm.

For Further Discussion:

1. Where and when does ownership of one's bodily parts stop?
2. The slippery slope argument: If it is held that one does not own one's kidneys - can the State compel someone to give one up? What about donations of bodily parts after death?

UNIT 13: Social Responsibility and Health

Article 14

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

1. *“The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.*

2. *Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:*
 - (a) *access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;*
 - (b) *access to adequate nutrition and water;*
 - (c) *improvement of living conditions and the environment;*
 - (d) *elimination of the marginalization and the exclusion of persons on the basis of any grounds;*
 - (e) *reduction of poverty and illiteracy.”*

Introductory Discussion:

Social Responsibility and Health Policy

Health is recognized as both a means to other development goals and as an end in

itself. The principle highlights the ethical significance of public and population health initiatives, as they constitute a dynamic instrument for achieving social and economic development, justice and security.

Health policy is considered to be more than the provision and funding of medical care. The social and economic conditions that make people ill and in need of care are of utmost importance to the health of the population as a whole. The recognition of the highest attainable standard of health as a fundamental human right establishes a heavy burden on health care and related sectors. This is especially so because of the broad definition of 'health' as a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity (WHO Constitution, 1946).

Global health conditions are marked by growing inequities related mostly to poverty and lack of access to health care services. The wide disparities in the global provision of health care raises questions of equality and global justice: These inequities can be found inter alia in the protection of vulnerable populations, differences in level and quality of health care services across national boundaries, differing access to essential drugs es, poverty, the differing responses to HIV/AIDS and other pandemics, differing research prioritizations and standards of care in health research, organ transplantation and views on medical tourism. (Reference: Bioethics Core Curriculum, UNESCO 2008).

FACT PATTERN 28:

Access to Quality Healthcare and Essential Medicines:

Based on: Cruz Bermudez v. Ministerio de Sanidad y Asistencia et al. (Venezuela, 1999).

The petitioner is HIV+. She argues that the Venezuelan government violates her right to life, health and access scientific advances by failing to provide her with antiretroviral (ARV) therapies that would allow her to live longer, perhaps thereby prolonging her life to enjoy the benefits a cure should one be discovered in her lifetime. She seeks to

compel the Ministry of Health to provide such therapies, cover the expenses for blood tests needed to monitor the disease and the effects of medications, and develop and fund policies and programs for people living with HIV in Venezuela.

Issue: Should the government be compelled to provide anti-HIV therapies to CB and other similar patients?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

These are life-saving therapies and constitute part of the core ‘right to health,’ such that access to them cannot be limited or otherwise constrained.

2: No.

At times of austerity and limited resources the government must ration and decide which of its health services are publicly funded.

3: No.

These are not considered life-saving therapies. They only improve the quality of life of people with HIV, and their overall therapeutic effect has not been established.

Court Decision:

The petitioner’s request was granted.

Ruling that the Ministry must provide ARV therapies and associated medicines to all people with HIV in Venezuela starting from that fiscal year, the court held that people with HIV in Venezuela are protected by international law and the constitutional right

to health. The court held that the Ministry of Health was not complying with its duty under the right to health, and as a result placed the lives of the plaintiffs at risk. It observed that the Ministry had available mechanisms through which it could seek additional funds for the medical requirements of people with HIV. Its failure to utilize these mechanisms constituted a violation of the right to health.

Bioethical Considerations:

This case deals with the role of the judiciary in policy decisions such as allocation of funds to promote ‘the right to health’. Specifically, it addresses the question whether governments should be compelled to utilize specific criteria in rationing health services (e.g., protecting life, improving quality of life, assisting some minimum segment of society), or is the State free to decide which services to finance by whatever idiosyncratic mechanism it chooses, including referring to local societal values as discerned these through public polls. Thus, more fundamentally, the case raises the issue of what types of criteria should guide policy-makers in making health-related decisions.

In this case, it was not clear why the court found that the Ministry has a duty to provide and specifically fund ARV therapies. HIV has become a chronic disease and is no longer regarded life-threatening. Although the decision promotes and strengthens the right to health, the court did not clarify what distinguishes HIV from other chronic diseases deserving special treatment, nor upon what basis the court reached its decision.

UNIT 14: Sharing the Benefits of Scientific Research

Article 15

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

- (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
- (b) access to quality health care;
- (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
- (d) support for health services;
- (e) access to scientific and technological knowledge;
- (f) capacity-building facilities for research purposes;
- (g) other forms of benefit consistent with the principles set out in this Declaration.

Benefits should not constitute improper inducements to participate in research.”

Introductory Discussion:

Sharing Scientific Research Benefits

Many benefits of science are unevenly distributed as a result of structural asymmetries

among countries, regions and social groups. As scientific knowledge has become a crucial factor in the production of wealth, so its distribution has become more inequitable. Article 15 is meant to diminish existing inequalities, to prevent a broadening of the gap and to build a basis for international collaboration. It is also meant to protect people who are insufficiently informed or unduly influenced by improper participation in research projects. Thus, it can be said that principles of global justice should take central place in scientific endeavors. This can be actualized through the long term commitment of all stakeholders, public and private, through greater investment, the appropriate review of investment priorities, and the sharing of scientific knowledge.

(Reference: Bioethics Core Curriculum, UNESCO 2008).

FACT PATTERN 29

Should Doctors and Researchers share their profits?

Based on: Moore v. Regents of Univ. of California (California, USA, 1990).

The complainant was a hairy cell leukemia patient at the University of California. He was convinced by doctors and researchers to attend post-surgery follow-up visits during which they withdrew blood, skin, bone marrow, sperm and other cells from his body. While the team told the claimant that these visits were necessary and required for his health and well-being, they were using his T-lymphocytes to develop a new cell-line. When the patient learned about this and that the team eventually obtained a patent on his cell line, he demanded that the profits gained by the development of his cell-line be shared with him.

Issue: Should the doctors and researchers share their profits from the patient's cell-line with him?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The patient's bodily fluids and cells are his property and he deserves a share of profits obtained from these materials.

2: Yes.

The patient was misled by his doctors and the researchers when he gave consent to the medical treatment, believing that the extraction of bodily fluids and cells was solely for his medical treatment and required for his continued well-being. The patient was not informed of any financial interest on the part of those removing bodily tissues, which is a breach of the team's medical duty to him.

3: No.

The patient freely consented to the treatment and he does not own his bodily fluids and cells once he has abandoned them.

Court Decision:

While the court did not accept the claim that the patient had a proprietary interest in the cell line as it was legally distinct from materials removed from his body, it ruled that the case can be based on the theories of breach of fiduciary duty and lack of informed consent. The court held that the patient's physician had an obligation to reveal his financial interests in materials harvested from his body. Furthermore, it was ruled that the claimant's interest in his bodily integrity and privacy are protected by the requirement of informed consent, an obligation which also includes the duty to disclose the team's economic interests.

One consideration that makes the claim of ownership problematic is California statutory law, which drastically limits a patient's control over excised cells. "Pursuant to Health and Safety Code section 7054.4, '[n]otwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of by interment, incineration, or any other method determined by the state department [of health services] to protect the public health and safety.' A primary object of the statute is to ensure the safe handling of potentially hazardous biological waste materials. Yet one cannot escape the conclusion that the statute's practical effect is to limit, drastically, a patient's control over excised cells...[thus] the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to "property" or "ownership" for purposes of conversion law. (51 Cal. 3d 141).

However, the court did hold that a claim lies under the principles of informed consent which "lead[s] to the following conclusions: (1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty."

Justice Arabian's concurring opinion is noteworthy: "I join in the views cogently expounded by the majority. I write separately to give voice to a concern that I believe informs much of that opinion but finds little or no expression therein. I speak of the moral issue. "Plaintiff has asked us to recognize and enforce a right to sell one's own body tissue for profit. He entreats us to regard the human vessel - the single most venerated and protected subject in any civilized society - as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much.... My learned colleague, Justice Mosk, in an impressive if ultimately unpersuasive dissent, recognizes the moral dimension of the matter. "[O]ur society," he writes, "acknowledges a profound ethical imperative to respect the human body

as the physical and temporal expression of the unique human persona. He concludes, however, that morality militates in favor of recognizing plaintiff's claim for conversion of his body tissue. Why? Essentially, he answers, because of these defendants' moral shortcomings, duplicity and greed. Let them be compelled, he argues, to disgorge a portion of their ill-gotten gains to the uninformed individual whose body was invaded and exploited and without whom such profits would not have been possible. I share Justice Mosk's sense of outrage, but I cannot follow its path. His eloquent paean to the human spirit illuminates the problem, but not the solution. Does it uplift or degrade the "unique human persona" to treat human tissue as a fungible article of commerce? Would it advance or impede the human condition, spiritually or scientifically, by delivering the majestic force of the law behind plaintiff's claim? I do not know the answers to these troubling questions, nor am I willing - like Justice Mosk - to treat them simply as issues of "tort" law, susceptible of judicial resolution.... conflicting moral, philosophical and even religious values [are] at stake..... The ramifications of recognizing and enforcing a property interest in body tissues are not known, but are greatly feared - the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the exposure of researchers to potentially limitless and uncharted tort liability." [51 Cal. 3d 149].

Bioethical Considerations:

Other than discussing the question whether bodily fluids and other cells extracted from one's body could be regarded as property for financial reasons, this case raises an important question concerning the doctrine of informed consent. Specifically, and especially when doctors have goals other than therapeutic which solely and directly benefit the patient, should the principle of informed consent also include the duty to disclose financial, reputational or other interests of the treating physicians? The case broadens the duty of disclosure thereby better promoting patient autonomy and trust in physicians which is central to the therapeutic relationship.

For Further Discussion:

What about balancing risks and benefits? If financial inducements will motivate researchers to take on research which will benefit countless of others, should we allow it?

FACT PATTERN 30:***Reaping Profits from Scientific Research:***

Based on: Association for Molecular Pathology v. Myriad Genetics, Inc.. (Supreme Ct USA, 2013).

The Association for Molecular Pathology along with several other medical associations, doctors and patients sued the United States Patent and Trademark Office (USPTO) and Myriad Genetics Inc. to challenge several patents related to human genes. The patents in question related to two human genes associated with breast and ovarian cancer, BRCA1 and BRCA2. The plaintiffs claim these patents are unconstitutional and invalid because human genes are naturally occurring things. The defendant, who obtained these patents, opposed the claim and argued that they invested intensive work (and money) in discovering the precise location and sequence of these genes, mutations of which significantly increase the risk of cancer. This knowledge has enabled the development of medical tests to detect mutations and assess people's risks of cancer.

The District (trial) Court granted summary judgment to petitioners, concluding that the defendant's claims were invalid because they covered products of nature. The Circuit Court reversed and found both isolated DNA and cDNA (complimentary DNA- which is a DNA-copy synthesized from mRNA (messenger RNA) patent-eligible. The case was appealed to the Supreme Court.

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

Issue #1: Should the results of human gene sequencing be regarded as a natural phenomenon and not be considered proprietary or property?

1: Yes.

Naturally occurring matter is not the result of human discovery or invention and should not be allowed to serve as the basis of proprietary interests or property ascribed to human beings.

2: No.

The sequence of human genes is only a natural phenomenon until the point they are discovered by humans and subjected to further research and development from which additional information is gleaned. At that point, human intervention has transformed their status.

3: No.

Researchers deserve proprietary interest following their discovery and contribution of significant knowledge, regardless of classification of the material upon which their labor has been exercised.

Issue #2: Should the intensive work of researchers justify their claim of property-rights regarding this specific genetic knowledge?

1: Yes.

Researchers deserve a proprietary interest following their discovery and contribution

of significant knowledge, regardless of the classification of the material upon which their labor has been exercised.

2: No.

The researchers' primary role is to serve the public and social interest in curing life-treating diseases and producing a better quality of life, regardless of their intensive work.

Issue #3: Can economic rights supersede another human being's rights to health and life?

1: Yes.

Health research is an accepted aspect of economic activities, through which people earn a living, enabling them to better their position and enhance their dignity.

2: No.

Health rights are an intrinsic part of human rights and research is part of activities for human health, independent of the market considerations.

Court Decision:

In a unanimous decision, the U.S. Supreme Court held that naturally occurring gene sequences and their derivative products are not patent eligible under Section 101 of the Patent Act which provides: "Whoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U. S. C. §101. The court explained that "We have long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable. (cites omitted). [Rather,] they are the basic tools of scientific and technological work that lie beyond the domain of patent protection... without this exception, there would be considerable danger that the grant of patents would "tie up"

the use of such tools and thereby inhibit future innovation premised upon them... . This would be at odds with the very point of patents, which exist to promote creation (cites omitted). Products of nature are not created, and manifestations of nature [are] free to all men and reserved exclusively to none.”

However, the Court also held that creation of a new product in the laboratory exempts the product from being considered ‘natural’ and these are patent eligible. Thus, specifically, gene sequences reconfigured and refined in the laboratory – with human intervention - creating molecules which are not naturally occurring, can be patented.

The Supreme Court held that a naturally occurring DNA segment was not patent-eligible merely because it has been isolated, and found that researchers' principal contribution was uncovering the precise location and genetic sequence of the naturally found BRCA1 and BRCA2 genes. Although a labor intensive process, the court ruled that “Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.” As the researchers did not create or alter either the genetic information encoded in the genes, or change the genetic structure of the DNA, this activity was not patent-eligible. However, the court ruled that cDNA (a complementary DNA containing only the axons that occur in the DNA, omitting the intervening introns) is patent- eligible because it is not naturally occurring.

Bioethical Considerations:

In this case the court focused on the distinction between a researcher’s creation of a new product (cDNA) and its labor intensive investigation which discovered a naturally occurring one (BRCA1 and BRCA2). This distinction led the court to accept part of the defendants' claim and acknowledge their proprietary right on cDNA.

However, one should query whether the scientific distinction between cDNA and sequencing human genes should have ethical implications –leading to the conclusion that each of the phenomena should be regarded differently.

Attention should be also drawn to Article 15 of the UDBHR with regard to the sharing of benefits resulting from scientific research.

Another aspect that should not escape consideration is the concern that genetic information, being an integral part of a human being, warrants the same concern for human dignity that its manifested expression, i.e., the intact human, deserves.

For Further Discussion:

Discovering something that pre-existed the human species is reminiscent of discovery of an archaeological relic– is that patentable? (Of course if you took an archaeological relic and transformed it into a face-mask or a wearable amulet, perhaps that might be patentable but that involves both creativity and some change to the form of the relic.)

References

UNESCO 1997 Declaration on the Responsibility of the Present Generations towards Future Generations

UNIT 15: Protection of the Environment, Biosphere and Biodiversity

Article 17

UNESCO Universal Declaration on Bioethics and Human Rights (2005)

“Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.”

Introductory Discussion:

Fostering the Prosperity of Nature for the Purpose of Fostering the Prosperity of the Human

The prosperity of human beings depends on the prosperity of nature. Human beings are part of nature. They have therefore the duty to conserve and protect the integrity of the ecosystem and its biodiversity. A basic principle of environmental ethics is that every generation should leave the following generation an equal (or better) opportunity to live a happy life, and should therefore bequeath a healthy Earth. This may be achieved by adherence to the doctrine of ‘sustainable development. While evaluating the ethical implications of any bioethical research or biotechnology, it is imperative to take into account not only its utility for human welfare, but also its overall impact on our ecosystem. No valid socio-economic or technological paradigm can be built unless man's relationship with the ecosystem and the universe is properly cared for.

FACT PATTERN 31

On Governmental Involvement:

Based on: Massachusetts v. EPA, (Supreme Court USA, 2007)

Twelve states and several cities of the United States brought suit against the Environmental Protection Agency (EPA) to force that federal agency to regulate carbon dioxide and other greenhouse gases (GHGs) as pollutants. The plaintiffs claim that

the Environmental Protection Agency's (EPA) failure to regulate greenhouse gas emissions from motor vehicles results in the greenhouse effect, increases temperatures on the earth, raises ocean levels and increases flooding of low lying areas. They argue that Section 202(a)(1) of the Clean Air Act (CAA), 42 U.S.C. § 7521(a)(1), requires the Administrator of the Environmental Protection Agency to set emission standards for "any air pollutant" from motor vehicles or motor vehicle engines "which in his judgment cause[s], or contribute[s] to, air pollution which may reasonably be anticipated to endanger public health or welfare," provides sufficient basis for the EPA to regulate.

Issue: Should the governments regulate and interfere with gas emissions to minimize 'the greenhouse effect' under a rubric of bioethical constraints?

Instructions for Preliminary Discussion Questions:

Here are a few, but not all, possible answers. Consider them, as well as other possible answers, identifying as many ethical issues as possible; then decide which best applies, giving your reasons.

1: Yes.

The State is part of a global community that has a duty to protect the environment, including minimizing the 'greenhouse effect'.

2: Yes.

By regulating gas emissions, the State encourages individuals and groups within it to take responsibility over their actions and to act in solidarity.

3: Yes.

By regulating gas emissions, the State sets the stage for production of future resources which can be used to benefit humankind.

4: No.

The State should be free to invest its resources on any public goods which it finds appropriate, especially medical science.

5: No.

The primacy of the right of human life and health trumps that of environmental health and should influence all governmental decisions, especially when there is a scarcity of resources.

6: No.

Since the implications of gas emissions and the greenhouse gases on the increase in global surface air temperature are yet unknown, this should not become a priority.

Court Decision:

The Supreme Court noted that EPA did not contest either that anthropogenic (environmental pollution and pollutants originating in human activity) emissions were exacerbating the greenhouse effect, or that, over time, major ramifications would occur as a result. Although the Congress did not necessarily foresee global warming when it enacted the Clean Air Act, [the CAA- see below] the drafters intended the statute to apply to a broad range of air pollutants. The court also held that while scientific uncertainty is a factor that an agency like the EPA may consider, the uncertainty must be so great as to make regulation unlawful, not just imprudent, in order to justify the decision not to regulate, and held “that the CAA gives the EPA the authority to regulate tailpipe emissions of greenhouse gases. Finally, the Court remanded the case to the EPA, requiring the agency to review its position. The Court found their current rationale for not regulating to be inadequate and required the agency to articulate a reasonable basis in order to avoid regulation.”

The Clean Air Act provides:

1. "The Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emission of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare."
2. The CAA defines "air pollutant" as "any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive . . . substance or matter which is emitted into or otherwise enters the ambient air". The majority opinion commented that "greenhouse gases fit well within the CAA's capacious definition of air pollutant."

In 2003, the EPA made two determinations:

1. The EPA lacked authority under the CAA to regulate carbon dioxide and other GHGs for climate change purposes.
2. Even if the EPA did have such authority, it would decline to set GHG emissions standards for vehicles.

The Court here held those resolutions were not binding.

Bioethical Considerations:

There may be many reasons to require governments to regulate environmental conditions, including multi-national treaties, international commerce and encouraging parity of developing nations. However, the issue here is whether principles of bioethics can/should be utilized to compel government attention to the environment and environmental regulation.

The case highlights the State's responsibility to protect the environment, especially in an era where scientific knowledge is evolving. While recent studies refer to significant links between environmental factors and health status, maintaining and protecting the environment has other societal benefits which should receive attention.

In this area, it might be argued that the precautionary principle should apply, according to which scientific uncertainty should not serve as a conclusive justification for not regulating and interfering with individual freedoms, especially when such regulation has important collective outcomes. Policy decision making as well as the processes by which such decisions are being made should be more transparent and subject to review, *inter alia*, in light of the precautionary principle. This case represents a good example for such a review.

Alternatively, it might be argued that proposed environmental regulations without an objective, valid and reliable scientific basis can do more harm than good. In this regard, most people think of increased costs with minimal benefits to sustain their opposition to regulation. However, under the doctrines of non-maleficence and balancing, one might ask whether courts should consider the negative impact of unsubstantiated regulation? If it is proven that some other cause is responsible for global warming (such as sun-spots, or slight shift in the Earth's rotational pattern as a consequence of past underground nuclear testing, or the build-up of internal Earth pressure resulting in the increase in violent tsunamis, earthquakes, and hurricanes) – then not only will the regulation be costly, it will have no impact on the environment and cause a distinct disturbance in other important activities and be detrimental to humans (such as impacting driving costs).

For Further Discussion:

1. There is a far cry between regulating the environment, and claim that the greenhouse effect can be ameliorated by the proposed regulations. Thus, the premise enumerated in this case/discussion may sound worthy, but is there sufficient data to back up the threats to biodiversity and the biosphere as contemplated by the UNESCO directive, such that the UNESCO directive can serve as a basis for regulation?
2. Do the considerations raised in support of environmental regulation (see response #2 above) bear a real relation to the UNESCO Declaration it ostensibly is based on?

3. Should one consider the least minimally invasive intervention to humans to resolve the issue (e.g., minimizing methane gas emissions) similar to the injunction to consider the least minimally invasive method on human research when competing values are at stake?
4. Would the impact of El Niño (with its known effect on global warming) affect the answer? Is it important to take into account and reject other credible non-human-made effects on the environment before regulating human conduct that might deprive people of jobs and a livelihood?
5. Should alternative causes for the claims attributed to green-house gas emissions be evaluated before regulations are enacted?
6. Before regulations are enacted, how much resources should be allocated into evaluating other causes and comparative cost/benefits of other responses (such as reduction in methane gas production)?

(Reference: Rong-Gong Lin H and Rosanna Xia, “El Niño could be the most powerful on record, scientists say,” JERUSALEM POST, Nov. 24, 2015, p. 19).

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The Casebook on Bioethics for Judges offers a much needed and comprehensive tool to help judges address a variety of medical-legal questions. The fact patterns that are presented are based on real cases that perplexed real judges. The discussion and questions following each vignette are based on the wealth of experiences and deep insights of the contributors and the Editor-in-Chief, Professor Amnon Carmi. The natural link between UNESCO and the IOJT will, no doubt, promote the spread of knowledge presented in this book among judges and judicial educators world-wide.

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International Organization for Judicial Training (IOJT)**