Bioethics Outlook

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Anticipate and Communicate

Presidential Commission's advice on the ethical management of incidental and secondary findings in clinical, research, and direct-to-consumer contexts

Discovering an incidental finding can be life saving. Discovering an incidental finding can lead to uncertainty and distress without any corresponding improvement in health or wellbeing. Consider the following two scenarios set out at the beginning of this new Report from the Presidential Commission for the Study of Bioethics:

A healthy young medical student participated in research using functional magnetic resonance imaging to look at brain activity while doing a memory test. During this brain scan, the researcher noticed a concerning mass. The student rushed to the hospital for further examination, which was followed by successful treatment of the incidental finding that she credits with saving her life. Two years later, a different woman collapsed from overhydration while running a marathon. During an evaluation, her emergency care team discovered a small brain tumour. She opted, in consultation with her doctors, for a watch-and-wait approach, monitoring the tumour for changes before making any treatment decisions. She has been watching anxiously or almost 10 years, even though the tumour might never affect her health.

In this issue:

Nicholas Tonti-Filippini on Baby Gammy.

With these two cases, America's Presidential Commission for the Study of Bioethical Issues published a report entitled Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts.¹, ²

Its authors, the cream of American Bioethicists including Daniel Sulmasy, mentor and friend to many Australian Catholic bioethicists, recommend that doctors and researchers, and indeed 'direct to consumer' providers, should anticipate and plan for incidental and secondary findings to the best of their ability in order to provide as much information as possible to guide decision making of recipients of those findings. Potential recipients, they say, should be well informed about the possibility of incidental and secondary findings before tests are conducted. To aid this process, professional organizations and other experts should identify the currently-anticipatable findings and provide guidance to doctors, researchers and others about their ethical management.

Anticipatable and unanticipatable incidental findings

We are currently witnessing a movement from discrete tests undertaken for a specific purpose towards large scale genetic sequencing. An *incidental* finding is a result

¹ Hilgenberg, S., Recipient of a finding incidental to research. (2013). Incidental Findings in Research. Presentation to the Presidential Commission for the Study of Bioethical Issues (PCSBI), April 30. Retrieved from http://bioethics.gov/node/1617. Quoted in Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts, Presidential Commission for the Study of Bioethical Issues, December 2013

that arises in a test or a procedure that lies outside the original purpose for which the test or procedure was conducted. Incidental findings can be either 'anticipatable' or 'unanticipatable'. An anticipatable incidental finding is one that is known to be associated with a test or procedure. An unanticipatable incidental finding is one that could not have been anticipated given the current state of scientific findings. And a secondary finding is a finding that is actively sought by the practitioners but is not the primary target.

Foundations of the ethical context: principles, duties, virtues

The Commission sets out the grounds for its recommendations to anticipate and communicate. They say that their recommendations are grounded in four ethical principles, several duties, and the desirability of several virtues of mind and character.

The four principles particularly applicable to the ethical assessment of incidental and secondary findings are respect for person, beneficence, justice and fairness, intellectual freedom and responsibility. They say: 'The principle of respect for persons recognizes the fundamental human capacity rational *self-determination—the* for autonomous ability to identify personal preferences, act on these desires, and direct the course of one's life. The principle of beneficence calls on professionals to take actions to ensure the wellbeing of others, while its corollary non-maleficence requires not imposing harms on others. The principle of justice and fairness requires fair and equitable treatment of all. Finally, the principle of intellectual freedom and responsibility protects sustained and dedicated creative intellectual exploration that furthers scientific progress, while requiring that practitioners

² Krucoff, C., Recipient of a finding incidental to clinical care. (2013). Incidental Findings in the Clinic. Presentation to PCSBI, April 30. Retrieved from http://bioethics.gov/node/1619. Op cit.

take responsibility for their actions.'3 relevant duties result from promises and commitments made by professionals, from the relationships between practitioners and recipients, and from the contexts in which the professionals operate. And, if doctors and researchers and providers are to respond well to the ethical challenges which arise in the context of clinical, research and direct-toconsumer contexts, their communication and collaboration with patients, research participants and consumers will need to be characterized by honesty, courage, humility as well as with (in the former two contexts: business is not a profession!) professional excellence.

Recommendations

- Clinicians, researchers, and direct-toconsumer providers should describe to potential recipients incidental and secondary findings that are likely to arise or be sought from the tests and procedures conducted. Practitioners should inform potential recipients about their plan for disclosing and managing incidental and secondary findings, including what findings will and will not be returned.
- 2 Professional representative groups should develop guidelines that categorize the findings likely to arise from each diagnostic modality; develop best practices for managing incidental and secondary findings; and share these guidelines among practitioners in the clinical, research, and direct-to-consumer contexts.
- 3 Federal agencies and other interested parties should continue to fund research regarding incidental and secondary findings. This research should consider the types and frequency of findings that can arise from various modalities; the potential costs, benefits, and harms of identifying, disclosing,

and managing these findings; and recipient and practitioner preferences about the discovery, disclosure, and management of incidental and secondary findings.

- 4 Public and private entities should prepare educational materials to inform all stakeholders—including practitioners, institutional review boards, and potential recipients—about the ethical, practical, and legal considerations raised by incidental and secondary findings.
- The principle of justice and fairness requires that all individuals have access to adequate information, guidance, and support in making informed choices about what medical tests to undergo, what kind of information to seek, and what to do with information once received. The principle of justice and fairness also requires affordable access to quality information about incidental and secondary findings, before and after testing, which when coupled with access to care can be potentially lifesaving or life enhancing.
- Clinicians should make patients aware that incidental and secondary findings are a possible, or likely, result of the tests or procedures being conducted. Clinicians should engage in shared decision making with patients about the scope of findings that will be communicated and the steps to be taken upon discovery of incidental findings. Clinicians should respect patient's preference not to know about incidental or secondary findings to the extent consistent with the clinician's fiduciary duty.
- 7 In communicating difficult to understand information about incidental and secondary findings, clinicians should consider providing patients with decision aids and graphical representations, using population-based evidence, and describing a patient's absolute risk (the chance of any person getting a disease) rather than or in addition to relative risk (whether a person's chance is higher or lower than another's).

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³ Anticipate and Communicate, op cit, p 4

- 8 Federal agencies and other interested parties should study the comparative benefits to patients and the cost effectiveness of using bundled tests or a battery of tests versus conducting sequential, discrete diagnostic tests.
- 9 Medical educators, both in the classroom and clinic, should continue to cultivate "diagnostic elegance" and "therapeutic parsimony" amongst practitioners—ordering and conducting only tests and interventions necessary for addressing health concerns related to their patient.
- 10 Professional and public health organizations should produce evidence-based standards for proposed screening programs that take into account the likelihood that incidental findings will arise. Professional organizations should provide guidance to clinicians on how to manage these incidental findings.
- During the informed consent process, researchers should convey to participants the scope of potential incidental or secondary findings, whether such findings will be disclosed, the process for disclosing these findings, and whether and how participants might opt out of receiving certain types of findings.
- Researchers should develop a plan to manage anticipatable incidental findings, including but not limited to those findings known to be significant and clinically actionable (and, when relevant, analytically valid and clinically valid). The plan should be reviewed and approved by an institutional review board.
- Researchers should develop a process for evaluating and managing unanticipatable findings. The plan should be reviewed and approved by an institutional review board. During the informed consent process, researchers should notify participants about the possibility of unanticipatable incidental findings, including lifesaving incidental

- findings, and the plan for their management. Researchers who discover an unanticipatable incidental finding of concern should assess its significance, consulting with experts as appropriate.
- 14 Researchers should consider carefully the decision to actively look for secondary findings. In certain circumstances, with approval from an institutional review board, researchers can justifiably adopt a plan that includes looking for selected clinically significant and actionable secondary findings. Approved plans should be disclosed to prospective participants during the informed consent process.
- Direct-to-consumer companies should provide consumers with sufficient information about their services to enable consumers to make informed decisions regarding purchasing their product. Companies should clearly communicate the scope of procedures and the types of findings that the companies could or will discover and disclose, as well as any findings that they know in advance will not be disclosed.
- 16 Federal agencies should continue to evaluate regulatory oversight of direct-to-consumer health services to ensure safety and reliability. State governments should also adopt regulations that ensure a consistent floor of protections for consumers who purchase direct-to-consumer testing.
- 17 Direct-to-consumer companies should aid in the creation of industry-wide best practices concerning the management of incidental and secondary findings. These best practices should include when and how such findings will be disclosed and standards for referral to necessary clinical services. Direct-to-consumer companies should make these "best practices" publicly available to encourage broader adoption.

Virtues of the Report

There is much to admire in this Report. I shall mention just two virtues of its virtues: moral as well as linguistic clarity and a proper recognition of the role of conscientious judgment (as well as respect for it!) in the conduct of good medicine and research.

I admire the Report's clarity with respect to the relevant ethical principles, duties and character traits relevant to the ethical management of incidental and secondary findings in clinical, research, and direct-to-consumer contexts. I admire its clarity with respect to the application of these principles, duties and character traits in three different contexts: medical practice, research, and the 'direct to consumer' selling and buying of genetic information. And I admire its clarity with respect to the *moral distinctiveness* of each of these three contexts.

The writers resist the current tendency to confuse and to conflate the relationship between doctor and patient with the commercial relationship between 'direct consumer' provider and buver ('consumer'). The writers see clearly that, though there are overlaps between these two kinds of human interaction, they are essentially different and thus generate distinct ethical obligations. They do not make mistake of treating medicine asa consumer product which doctors provide and patients consume. And associated with this is clarity of expression: doctors (or, as they are called in the US 'physicians') are said to communicate and collaborate with 'patients', researchers with 'research participants', sellers of commercial products with 'consumers'.

In addition, the writers acknowledge the fact that doctors and researchers have to make conscientious judgments in their relationships with patients and research participants. For instance, doctors and researchers have to decide (in advance) whether and how to respect the wishes of those who choose to opt out of receiving incidental findings.

For instance, the writers argue that, if doctors and researchers have ethical objections to allowing participants to opt out of receiving clinical significant, actionable and lifesaving findings, they need not enrol such individuals in their research. This will minimize one current type of ethically challenging situation once a research project is underway. On the other hand, if researchers do not object to allowing participants to opt out of receiving incidental findings (and remember that research participants may opt out of a research project at any time), and if participants are well informed regarding what opting out could mean for their health and wellbeing, then (the writers argue) researchers may enrol such participants in their study. In offering this kind of advice, the writers implicitly acknowledge that no principle or set of principles dictates its own application, that clinicians and researchers have to make their own judgments about how best to act in each context and on each particular occasion, and that making those judgments calls for attributes such as honesty, courage, professional excellence, humility and compassion.

And in offering this kind of advice, the writers reveal just how shallow a view of medicine and research is implicit in a contemporary view that only the big 'life' questions (of termination of pregnancy and euthanasia) raise issues of conscientious judgment! Medicine and research (and no doubt provider to consumer business!) are shot through with questions about which their practitioners have to make judgments of conscience.

Bernadette Tobin

The Contradictions of Baby Gammy:

Disability, Discrimination and the True Cost of Surrogacy

Nicholas Tonti-Filippini

There has been extensive recent discussion of the circumstances of baby Gammy, suffering from Down's syndrome and heart problems, and apparently left behind with the birth mother in Thailand by the Australian commissioning couple, though they took his well sister home. Australians have responded generously with support for this photogenic little boy so that he can receive appropriate medical treatment.⁴

The Thai government has responded by proposing restrictions on this form of trafficking in human persons and there has been much criticism of the commissioning couple, culminating in the discovery of an apparent history of child abuse by the commissioning male partner.

The public and media reaction to these circumstances has been interesting. The shared premise would seem to be a negative reaction to a couple abandoning their biological child because he has a disability. There is also the plight of the

birth mother who has not apparently received what was due to her under the commercial arrangement. Disquiet has also been expressed about the fact that the arrangement was commercial and exploitative of the poverty of the Thai birth mother.

A matter that seems to be relatively hidden in this discussion is that it would have been normal Western medical practice (around 90% of cases) to have aborted Gammy when it was discovered that he had Down's syndrome, but his birth mother reportedly refused on religious and conscientious grounds. The fact is that whatever a commissioning couple might want, a birth mother has the final say on such matters under the criminal law in most jurisdictions, though of course she may be placed under contractual and financial pressure to do as the agency or the commissioning couple want.

That decision about eugenic abortion generally favoured by the medical profession, and warranting expensive early detection by screening and invasive testing to detect abnormality, raises curious anomalies about attitudes to disability. Disability discovered before birth is seen differently from disability after birth.

http://www.abc.net.au/religion/articles/20 14/08/07/4062429.htm

⁴ This article first appeared on the *ABC*'s *Religion and Ethics website on 7 Aug* 2014:

Before birth, it is accepted practice to inject the heart of the unborn child with potassium chloride to cause death before inducing a stillbirth, or late term there may be a partial birth abortion in which during delivery an instrument is inserted into the child's brain through the back of the neck so it also is born dead. After birth, even the birth of a baby of the same or even less maturity or gestational age, to end the life would be regarded as a criminal offence in most jurisdictions.

Anecdotally, mothers who opt not to have their child given the fatal injection before birth are placed under great pressure to use the technique to prevent the birth of a child with a disability. It is a cognitive dissonance that seems irresolvable that birth, not maturity or gestational age, is what makes the difference in status of the infant.

Cultural attitudes to disability are obviously conflictual. Public reaction appears to condemn the commissioning couple for reportedly deserting a child on the basis of disability and the inherently discriminatory attitude involved, but would presumably have accepted the killing of baby Gammy before birth at the request of the commissioning couple or the agency, if the birth mother had acquiesced.

The moral problems of surrogacy

There are many other conflicts underlying this case. In reality, surrogate motherhood represents a failure to meet the obligations of maternal love, marital fidelity and responsible motherhood. That is to say, carrying a pregnancy involves a unique relationship to the child in which the woman becomes the child's mother. As the mother of the child, she has natural obligations to nurture the child. These

obligations are felt by many mothers despite having decided on abortion. A woman who is about to abort will often express protective views, such as about not taking antibiotics that might harm the child, even though she has decided to abort.

Furthermore, if the woman is married she has entered into a convenantal agreement in which her capacity to become a mother is given exclusively to her husband as he gives himself exclusively to her including his capacity to be a father. That means an inherent conflict between her married status and her allowing her body to be used for commercial gain to become pregnant from outside her relationship to her husband and her family.

One wonders about the impact on Gammy's two siblings in this case, as they see their mother give or in effect sell her birth child to others. What would it mean for Gammy's birth siblings now if, having loved Gammy as a family addition, the commissioning couple were to move to take Gammy away with them? What effects would that have on the confidence they would have had in the bond they have with their mother, and their father, if there is a father in the picture?

Surrogacy and the rights of the child

Commercial or even so-called "altruistic" surrogacy contracts offend the dignity and the right of the child to be conceived, carried in the womb, brought into the world and brought up by their own parents. This right is recognized by the United Nations in the Convention on the Rights of the Child, which upholds the child's right:

 to preserve his or her identity, including nationality, name and family

- relations as recognized by law without unlawful interference;
- not to be separated from his or her parents against their will, except when competent authorities subject to judicial review determine, in accordance with applicable law and procedures, that such separation is necessary for the best interests of the child;
- not to be separated from one or both parents to maintain personal relations and direct contact with both parents on a regular basis, except if it is contrary to the child's best interests;
- to rely on the common responsibilities of both parents for the upbringing and development of the child, and their primary responsibility for the upbringing and development of the child on the basis of the best interests of the child; and
- that in adoption decisions, the authorities shall ensure that the best interests of the child shall be the paramount consideration.

Surrogacy sets up, to the detriment of families, a division between the physical, psychological, emotional and spiritual elements that constitute those families. The woman's capacity to bear a child is implicitly separated from her role as mother to that child and any other children she may have. She must plan to deny any affection she has for the commissioned child she carries. As I have already mentioned, one wonders how her other children may regard the fact that she gives a child away and what that security means for the of their relationship to her.

In that respect, the treatment of the surrogate is problematic because it does not recognize the motherhood that exists in becoming pregnant and nurturing the child until birth. The surrogate is implicitly treated as an object, and her body is used as a mere incubator rather than as the child's mother. As the child's mother, she is linked to the child physically, emotionally, cognitively and spiritually, and that reality ought not to be denied.

To enter into a contract to the contrary by which her connectedness is to be rejected is essentially false. This is borne out by the number of occasions on which birth mothers opt not to give up the child for adoption by the commissioning couple, even when their own gametes are used and the birth mother is not genetically related.

Altruistic surrogacy

So-called "altruistic" surrogacy removes the commercial or trafficking element, but given that it normally happens between relatives, the project is more likely to be fraught with exploitative tension between the commissioning couple and the female relative and her family. I was consulted by a woman who felt pressured in this way by both her infertile sister and her own parents and other family members. They felt she had an obligation. She felt she had no choice. It was not really a matter of consent.

In fact, commercial surrogacy may be a cleaner break and less exploitative, The payment of a sum of money is usually far less complicated than the complex emotional relationships by which a sister may be induced under emotional pressure to perform this service so intimately involving her body, and not without effect on her family relationships, her health and the ongoing significance of actually being the child's birth mother. She would endure all that pregnancy and child birth involves, and then the suffering involved

in relinquishing the bonds formed by carrying the child in her womb for nine months, and then the severance of the bonds formed - especially bonds formed through the hardship and self-investment in the sufferings of childbirth for the sake of the child.

Anyone attending or experiencing labour and birth, cannot help but see how the joy of having the baby in the mother's arms normally seems to override significance of her suffering, however extreme and prolonged. There is such an outpouring of love and delight in the achievement. But for the commissioned birth mother, that is all overshadowed by the removal of the baby, that enormous loss, and coping with the biological reality of no baby to assist her with the milk in her breasts and the many other changes to her body normally induced by the transition from pregnancy to suckling a new babe, aiding the healing of any damage and recovering her normal body.

Biologically and psychologically, the loss of a baby at or soon after birth is an enormous burden to bear - well attested by those who suffer a stillbirth. If the child remains within the extended family, then the conflicted nature of the situation will always be there, particularly if the commissioning couple make decisions with which the birth mother might not have agreed. Medical treatment decisions for the child, and even decisions about schooling have been shown to be a source of tension, because, in reality, pregnancy and childbirth forge a unique connection between the mother and the child she carried. She has invested hugely of herself in the child.

In one case with which I am familiar, the major divisive issue was that the commissioning sister sent the child to the

school that the sisters had both attended, but which had been a miserable experience for the sister who gave birth to the child. She petitioned strongly for a different choice, and clearly saw herself as much more than just the little girl's aunt.

On the periphery are the birth mother's other children and her husband, if she has one. Most agencies will not accept a surrogate who has not completed her own family, because the complication of non-compliance with the agreed relinguishment is more likely to be a problem. What does it mean for a man who has entered into an exclusive relationship, implied by marriage in almost all cultures, to see his partner exploited in this way? Especially, as is usually the case, if they are driven to it by poverty and the financial advantage of her participation? Might he feel that he has failed her?

Meeting the needs of poverty

I chaired an Australian government public enquiry into the selling of human organs and tissues and tissue products. There are several levels of problems that were explained in the submissions. A key concept for us was the extent to which the organ or tissue had been attenuated from the donor. Loss of genetic or other connectedness was significant in reducing likelihood of difficulty. But in surrogacy, motherhood is so significant, even if there is no genetic connection to the child. So much is invested by the birth mother in pregnancy and birth. His mother will never forget Gammy, and his every milestone will affect her.

Other aspects involve commercial exploitation. The amount that is usually paid to the surrogate or to the organ donor is usually too little to make any long

term difference to her family's underlying poverty. Studies by the Philippines government, by whom I was engaged as a consultant, showed no significant difference to poverty for living kidney donors who had received between \$1500 and \$3000 Australian dollars for their effort. They might have bought an old car or some other luxury, but soon after it had broken down and their means of livelihood remained the same.

Also, because they had been paid, they were not offered the medical care and support normally given to living donors, and were clearly worse off for their experience. Greater risks were taken with them, leaving them without the benefits of advanced Western medical care. In surrogacy arrangements, the Western care lavished on a relinquished child is likely to be very different from the care provided for the birth mother and the child's siblings who remain with her, as is obvious for abandoned Gammy, who could not even be provided with an adequate milk supply when he needed it, nor the medical and surgical treatment needed.

Reproductive discrimination

One further complication that has been raised is commissioning couples wanting invasive tests done to determine the gender of the child, with the aim of not transferring a child of the "wrong sex." This is often advocated for "family balancing" reasons in the Australian context, but may also be discriminatory against girls in male-preferring societies often for economic reasons - such as the need to have a son to work the land or to avoid having to pay for an expensive dowry for a girl who later marries.

Obviously sex selection, and in fact invasive testing and selection in relation to avoiding the transfer of unwanted embryos, may be in the contract. However, it remains very expensive and has very poor success rates. The data in the latest report by the Victorian Assisted Reproductive Treatment Agency showed that there were only 17 births in the whole state following over preimplantation genetic diagnosis (PGD) attempts. There are high rates of miscarriage and stillbirth after PGD has been done and much lower pregnancy rates using a reduced number of embryos, given the exclusion of those not wanted, though thev mav have abnormality or disease - just a nonpreferred feature such as female gender. PGD also causes damage resulting in fewer embryos surviving transferred.

PGD presumes to measure the value of a human life only within the parameters of "normality" and physical well-being. By treating the human embryo as mere "laboratory material," the dignity of the developing child embryo is also subjected to discrimination by the practice. Dignity belongs equally to every single human being, irrespective of the parents' desires, or the person's social condition, educational formation or level of physical development.

If at other times in history, while the concept and requirements of human dignity were accepted in general, discrimination was practised on the basis of race, religion or social condition, today there is a no less serious and unjust form of discrimination which leads to the non-recognition of the ethical and legal status of human beings suffering from serious diseases or disabilities. Sick and disabled people are not some separate category of

humanity; rather, sickness and disability are part of the human condition and affect most individuals at some stage. Reproductive discrimination through PGD or prenatal diagnosis and abortion reflects a very sad attitude towards people with disabilities. What would it mean for a child with a disability, to see a sibling excluded by PGD and the unwillingness of the parents to allow a pregnancy of a child with a similar disability?

A child is not a cure for infertility

One of the things to bear in mind in all this is that most couples (77%) who undergo an IVF procedure do not succeed in giving birth to a child from that procedure. The much higher rates of success quoted by the teams involve extrapolating what *might* happen if the woman were to have the procedures numerous times, despite the physical and medical hardship and the costs of earlier failures. In fact, very few women would be prepared to have the multiple surgical procedures and general anaesthetics, even if they could afford the many thousands of dollars involved. For most, the procedure fails them. That is hugely complicated by a surrogacy arrangement and having to deal with for-profit foreign agencies and immigration laws.

In addition, the pain of infertility is not just a matter of being childless. Even if IVF or surrogacy manages to produce a child using someone else's fertility, the couple still remains infertile and that pain will stay with them. Counselling is an important step to assist a couple to come to terms with the tragedy of infertility, whether or not they subsequently seek to have a child by means of the technology.

The evidence also suggests that if surrogacy or donor gametes are used, the

child may become a symbol of that infertility, particularly if the relationship between the child and the commissioning man or woman is strained, as often happens when a child becomes a teenager. It is important not to infantilize children when discussing the consequences of obtaining a child through assisted reproduction. A baby or even a primary school age child may do just as well on average as other children.

The real issues raised by the manner of conception are much more likely to occur later, when the child better understands what happened, and in the case of a donor or donors, that there has been a fragmentation of parenthood and there are others who have a parenting relationship to the child. If the matter has been hidden that may cause resentment. If the young person has identity concerns they may be exacerbated and there may be a need to find the hidden donor and other family members.

Finally, one of the problems with surrogacy contracts is that they are in effect a decision to adopt a child, and adoption by the commissioning parents might not be in the best interests of the child because details of the arrangement may deny the child contact with the birth mother, and with the man who is the child's gestational father through his relationship to her. Essentially surrogacy contracts may involve treating both the birth mother and the child as objects to be used for the benefit of the commissioning couple.

Professor Nicholas Tonti-Filippini is Associate Dean and Head of Bioethics at the John Paul II Institute for Marriage and Family in Melbourne. His most recent book is About Bioethics - Volume IV: Motherhood, Embodied Love and Culture. He has been a member of the Australian Health Ethics Committee of the National Health and Medical Research Council and chair of the sub-committees on the Unresponsive State and Commercialization of Human Tissue.

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