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Review of "The Need for a Legal Regulatory Framework on Pre-implantation Genetic Testing in the United States to Safeguard the Protection of Savior Siblings in Assisted Reproduction Technology"

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The Need for a Legal Regulatory Framework on Pre-implantation Genetic Testing in the United States to Safeguard the Protection of Savior Siblings in Assisted Reproductive Technology
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Introduction
The author identifies a gap in US policy dealing with reproductive technology that they suggest should be filled with regulation of Preimplantation Genetic Testing (PGT).
PGT has been used for over forty years as part of assisted reproductive technology (ART) to produce what is termed "Savior Siblings". A Savior Sibling is a sibling who is genetically identified or modified to be a genetic match for on older sibling so that the Savior Sibling could provide cord blood, and compatible bone marrow, blood, or other organs. Even though there is a popular novel and movie on the topic, My Sister's Keeper, there is not widespread public debate on the issue.
As the author acknowledges, there are some individuals who advocate prohibition of the practice as morally and ethically wrong. The author recognizes that creation of savior siblings is an example of technology advancing faster than policy or law. Like many advancements, there is a potential for abuse.
The principal arguments against Savior Siblings identified by the author are: a) commodification of the child; b) welfare of the child; and c) slippery slopes, designer babies and discrimination.
Commodification deals with assessing that the creation of the child was created as a

remedy rather than for their own value. The author references Emanuel Kant's statement that society should "never use people as a means but always treat them as an end." The author argues that creation of the child is acceptable as long the child is treated and acknowledged as a human and not a source of "spare parts". The author also argues that there are numerous other motivations for having another child such as for "family balancing" or to "carry on lineage". The creation of a child for the purpose of saving a sibling's life can be a noble purpose, but the point must be made that the Savior Sibling is an independent person.

The Savior Sibling in My Sister's Keeper, Anna, is depicted as feeling as if she is only a source for spare parts. The author acknowledges that there can be instances where utilizing a Savior Sibling fails the test. For example, if a Savior Sibling could be used and then given up for adoption.

To prevent commodification, the author suggests regulation that confirms parents will treat the savior sibling as an individual and not a commodity.

The second issue concerns the physical and emotional wellbeing of the savior sibling . As an analog to the Savior Sibling, studies are available where siblings were involved in organ or bone marrow transplants. These studies show that there are psychosocial and physiological risks for donors and recipients.

The UK considers the risk of harm when evaluating a situation where the donor child is not legally or actually able to give consent. The author concludes that regulation can avoid or minimize damage to the Savior Sibling. The suggestion is quite specific. Creation of savior siblings would only be allowed when "only genetic material required is cord blood, or some other material which can be obtained through minimally or non-invasive procedures, as well as stipulating that the child will not be required to donate an organ until she comes to an age where she can sufficiently understand the implications of the procedure." These limitations certainly mitigate risk.

The slippery slope argument is grounded in the potential use of genetics to produce particular types of children or "designer babies." There are other fears raised about the use of PGT to produce certain characteristics: sex , hair, or eye color . Or could children be genetically created as a source of tissue or organs to save the lives of unrelated sick persons? The author suggests that such threats exist only where ART is not regulated, such as in the US. Therefore, the author suggests approval be limited to medical purposes for related persons.

The author recognizes that there is considerable bioethical debate but suggests that savior siblings are ethically permissible because of the possibility of saving a life or even two.

Regulation of Assisted Reproductive Technology

The author recognizes the difference between the ethical issues and the issue of legally regulating reproductive conduct. There is no question that decisions on reproduction are personal and sensitive. Privacy rights to contraception and to parenting are constitutionally based rights in the US. (Griswold v. Connecticut, 381 U.S. 479 (1965). So are the rights of any individual, including a minor child.

The author endorses the UK mode of regulation and its principles. The principles are sensible and can be described as an attempt to balance the rights of the Savior Sibling, the parents and society as a whole.

The principles are:

1. Define the limits of the use of Savior Siblings prior to performing the procedures.
2. Savior Siblings can only be created to save the life of an existing sibling.
3. The only uses of the Savior Sibling is for donation of tissue which includes only core blood, bone marrow and excludes the continuous donation of biological materials including organs.
4. The parents are counseled.
5. The application is limited to where there is one sick sibling and not multiple sick siblings.

   These principles preclude genetic modification for any purpose other than saving the life of a sibling. So called designer children would be outside the ambit and not allowed. There is a visceral distaste for eugenics and a quest for a "master race" as a dangerous path. But an individual parent or family that rejects eugenics might support creating a Savior Sibling to save the life of their child.

   There are existing procedures that modify genetic structure to try to prevent health problems for a child. It does not appear the author intends to affect that type of procedure.

   These principles combined with the principle of "best interest" of the child model from the US provide a rational basis for establishing US policy.

Potential US Model

The author recognizes the issues that the US Constitutional structure raises in implementing these policies. The federal structure provides that state governments have the general police power. Therefore, direct regulation of clinics and providers would seem to fall to the states as opposed the model in the UK where there is central authority to deal with the health care system.

Of course, the US Federal Government can provide guidance and research to support state models. Moreover, the federal constitutional structure recognizes the rights at issue here. The author noted the case of Curran v. Bosze that developed a test for determining the "best interest" of a minor child in an organ transplant case. The basic principle of recognizing the welfare of the child can be a guiding principle in policy making.

This issue requires balancing the constitutional rights of parents in making procreation decisions, rights for parents to make health care decisions for a minor child, and the individual rights of a minor child. Interestingly, the fictional situation in My Sisters Keeper involved a legal action by guardian ad litem to assert the argument that continuous donations were not in the interest of the savior sibling. In that fictional case the savior sibling prevailed. An actual case might meet the same result under the best interest standard. However, as the author recognizes a case-by-case approach is insufficient.

The ultimate proposal by the author makes sense: there must be a combination of state and federal action consistent with constitutional principles.

Conclusion and Suggestions

The article does a fine job of analyzing a critical current issue. Genetic engineering is a fact of modern science. CRSPR technology allows the changing of detailed genetic characteristics. Early in-utero genetic testing allows parents a wider range of options. The moral, ethical, and legal debate is complex and controversial. This article is a needed analysis, and the concept of Savior Siblings is an excellent context to begin the larger

debate. The Savior Sibling issue is completely relatable: it is easy to empathize with parents who are looking for a means to save a sick child. However, one can also sympathize with an individual whose existence was precipitated in order to save a sibling and still recognize them as a distinct individual with their own rights.
A recent article raises several of the broader issues related to genetic modification for designer babies or
the health of a child and provides additional background and support for the author. The article specifically suggests the need for regulation to deal with the gap between ethics and law and suggests the need for input from science and society. (Barbara Pfeffier-Billaeuer, GENETICALLY-ENGINEERED BEGOTS, HAVE-NOTS, AND TINKERED TOTS: (HIGH SCORING POLYGENIC KIDS AS A HEREDITY-CAMELOT)-AN INTRODUCTION TO THE LEGALITIES AND BIO-ETHICS OF ADVANCED IVF AND GENETIC TESTING, 96 Chi.-Kent L. Rev. 3 (2022). Available at: https://scholarship.kentlaw.iit.edu/cklawreview/vol96/iss1/2
The author recognizes the current limits of federal agencies such as the FDE, CDC and CMS. Also, the author recognizes the American Society for Reproductive Medicine (ASRM) maintains guidelines and the CDC functions as a licensing body for ART clinics. The author suggests that practitioners be required to join ASRM and that ASRM be authorized to issue binding guidelines. There are issues with assigning such a significant policy function to a private entity. In US law, there are limits on the delegation of legislative type policies even to government agencies. Acknowledging Congressional reticence to deal with this complex and sensitive issue, it would be best to get Congress to legislate specific nationwide policies under constitutional authority.

There are several regulatory pathways that the author might wish to consider. Overall, the proposed principles for US policy are logical; however, there could be further discussions of federal options.
A significant issue is finding a constitutional source of authority to enact nationwide policy. Below are three options to evaluate.

The Spending Power
The federal spending power may provide a path to enact laws regulating Savior Sibling practices. The federal spending power has been interpreted broadly. A classic example was conditioning receipt of a portion of highway funds upon implementing a policy requiring a 21-year-old drinking age. South Dakota v. Dole. 483 US 203 (1987). However, there are limits, as outlined in the six-factor test of Dole and the the Court's statements in NFIB v. Seblius—that a complete loss of Medicaid funding was too severe a condition under the Affordable Care Act. The Supreme Court's focus has been whether the legislation is focused on a reasonable financial incentive or is so draconian that it becomes unlawful coercion. An interesting case of implementing health policy using a connection to federal funds was the Livings v. Becerra case. There, the Sixth Circuit upheld a requirement dealing with testing and masking based on statutory authority for Head Start conferred to the Secretary of HHS. The court said:
"…HHS likely has the statutory authority to issue a vaccine requirement for Head Start program staff, contractors, and volunteers. The statute creating the Head Start program gives the Secretary of HHS the power to promulgate regulations to promote the health and well-being of the children in the program."

This administrative law analysis of the HHS rule was focused on the reasonable relation between the congressionally conferred authority to the Department of Health and Human Services and to participants directly enrolled in their Head Start program. Similarly, a federal statute that defined federal regulations on Savior Siblings could be focused on entities receiving federal funding including Medicaid, Medicare, etc. Many of the hospitals and medical providers in the US would likely "accept" such regulations as a conditional "incentive" for their receipt of federal medical reimbursement.

The Commerce Power

The Commerce Power is a traditional source of federal authority. Savior Sibling policy, or lack of policy, has an impact on medical procedures and medical costs that transcend state boundaries. The treatments of the ill sibling, with or without a Savior Sibling, could involve prescription drugs, implantable devices, organ procurement and insurance payments. While Congress is accorded discretion in exercise of the Commerce Clause powers, the legislation would have to show substantial effects on interstate commerce.

Recent Supreme Court holdings demonstrate the limits of the Commerce Clause. In a Supreme Court case, a broad requirement for mandatory vaccination, or testing, that applied to employers with over one-hundred employees was rejected as beyond the power of the Commerce Clause. (NFIB v. OSHA , 142 S.Ct 661). However, it is important to note the circumstances of the case: it was a unilateral requirement that was initiated as self-proclaimed "work-around" by the Executive Branch/OSHA. Specifically, Congress refused to agree on any legislative actions and the Executive Branch took matters into their own hands. The Supreme Court found it strained to assume Congress had intentionally anticipated and conferred upon OSHA the ability to "legislate" the risk mitigation of everyday life to OSHA.

The case represents a limit on administrative action without legislative authority. If there was direct legislative authorization for regulation, the issue is different. At that point, the analysis is the long-standing test that the issue regulated must have a substantial effect on interstate commerce. The question is whether the impact of Savior Sibling health care has a substantial impact on interstate commerce. That conclusion would depend upon the developing facts surrounding the issue of Savior Siblings and the implications for various health care activities.

Section 5 of 14th Amendment- Due Process for the Savior Sibling

A Savior Sibling is likely a citizen of the US. To make sure these citizens' rights are protected, Congress could find that unregulated harvesting of tissue and organs would violate, and individual's due process rights and that Congressional action was justified.

A person should not be deprived of life, liberty, and property—without due process. The Constitution has authorized Congress to enforce these protections by appropriate legislation pursuant to 14th Amendment, Section 5. Here, there is a void in policy protecting Savior Siblings. There are potentially devastating consequences of a risky and unwanted medical harvesting of body parts, combined with a child's inherent inability to advocate effectively for their own interests. That argument could support a need for federal regulatory measures to provide appropriate safeguards. When Congress uses Section 5 as a preventive, rather than remedial tool, those policy regulations must consider the logic in

City of Boerne v. Flores and the Supreme Court's "congruence and proportionality" standard.

This article is timely and deals with a critical issue. The author does a fine job of addressing the complexity of critical and controversial issues. It is certainly worthy of publication.