ATTACHMENT G

Florida Medicaid Project: Treatment for Transgender Children

Medical Experimentation without Informed Consent:

An Ethicist's View of Transgender Treatment for Children

G. Kevin Donovan, MD, MA
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I. The Issue

Growing controversy attends the diagnosis and treatment of individuals identifying as transgender, particularly those who are still children or adolescents. As was recently pointed out, leading medical, mental health, and public health organizations support understanding gender-diverse youth and providing gender-affirming medical (hormonal) and other(surgical) care as the standard of care, including the American Academy of Pediatrics, American Psychological Association, Centers for Disease Control and Prevention, Society for Adolescent Health and Medicine, and the American Medical Association. Major nursing organizations—the American Nurses Association and the American Academy of Nursing— have made statements that young people's access to inclusive, safe, and competent health care is a human rights issue. (Wolfe, I., & Goepferd, A. "Child Abuse in Texas." *The Hastings Center*. 14 Mar. 2022) However, this widespread support is not going unchallenged, even by those who have been providing medical interventions for these children and adolescents.

Recently, questions have arisen about the appropriateness of both the diagnosis, and the safety and efficacy of these interventions that have been strongly encouraged up until now. Currently, less than half of state Medicaid programs provide gender affirming care. (Mallory, C., & Tentindo,W. "Medicaid coverage of gender-affirming care." Williams Institute, UCLA School of Law. Oct 2019). The Florida Surgeon General has said that minors should not undergo gender transition procedures, puberty blockers and hormone treatments. "Florida Department of Health Releases Guidance on Treatment of Gender Dysphoria for Children and Adolescents." 20220420-Gender-Dysphoria-Press-Release | Florida Department of Health.) In Texas, the state attorney general issued a decision that gender-affirming medical treatments such as puberty-suppressing hormones fall under the definition of child abuse in Texas state law. In fact, 34 states have introduced legislation to limit hormonal and surgical interventions for such transgender patients. This aligns with similar reassessments and limitations in the United Kingdom, Sweden, Finland, and France. A new position statement from the Royal Australian and New Zealand College of Psychiatrists (RANZCP) stresses the importance of a mental health evaluation for people with gender dysphoria — in particular for children and adolescents — before any firm decisions are made on whether to prescribe hormonal treatments to transition or to perform surgeries, often referred to as "gender-affirming care." "There is a paucity of quality evidence on the outcomes of those presenting with gender dysphoria. In particular, there is a need for better evidence in relation to outcomes for children and young people," the guidance states.

Given the legitimate concerns about the diagnosis, treatment, and the paucity of supportive, scientific studies in regard to the interventions being offered to minors who identify as transgender, I will offer a view of these from the perspective of an ethicist and pediatrician. This will be done in the face of strong and sometimes heated opposition to any variance from the currently prevailing recommendations. Each category of currently recommended or potential treatments will be briefly considered within this framework. The evidence base for these will be reviewed, and an overall argument made that such interventions must be considered as medical experimentation, subject to the requirements of research in childhood with informed consent. Finally, I will conclude with an examination of the fundamental flaw of the transgender project in childhood, and how it is leading to inevitable and controversial challenges.

In order to do this, we must review the ethical requirements for medical research in childhood and the elements of **informed consent**. Because of numerous abuses in the past, a strong system of regulations and oversight has been developed for the protection of human subjects in the United States. This began with the Belmont Report: (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) The report not only described the ethical principles listed below, but led to guidelines for research protections that are now codified in Federal regulations (Code of Federal Regulations, or 'CFR') and monitored by the U.S. Department of Health and Human Services (DHHS). These led to the establishment of IRBs (Institutional Review Boards) which are responsible for the protection of human subjects in federally funded research—IRBs are the Federally mandated committees that review research activities for the protection of human subjects. The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the DHHS. The OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research. These measures have laid the ground rules for human research, in adults and children including the need for informed consent.

Although adults may be included in research, this should only be done with *fully informed consent*, and the requirements will differ for children and other vulnerable subjects. The bedrock of these protections lies in obtaining the informed consent from the participant. Informed consent to medical treatment and research involvement is fundamental to both ethics and law. The process requires that a *fully autonomous patient* have the ability to *understand relevant medical information* about the proposed interventions, including the *risks, benefits if any, and alternatives* (including doing nothing/non-participation). and consent *voluntarily* without *coercion*. This is rooted in respect for the **ethical principles** of **autonomy**, **beneficence**, and **justice**.

Autonomy is derived from respect for persons, which requires that we not only respect those who are fully autonomous but protect those individuals that are not fully autonomous. Vulnerable subjects such as children cannot legally or ethically participate in the consent process due to their age and maturity level. The rules for their involvement are set out by the Code of Federal Regulations (46 CFR 401-409). While consent cannot be given for another person, parents or guardians can give "permission" and children can give assent to the extent that they are able. The process of obtaining assent should be appropriate to the age, maturity, and psychological development of the child. The consent process must contain three ethically required components: *information*, *comprehension*, and *voluntariness*. Deficiencies in any of these categories would invalidate the process. The main contention here is that deficiencies in *all* these categories can be found in the current approach to minors who identify as transgender, and current attempts at treatment should not proceed as they are now practiced.

Beneficence is reflected in the complementary expressions of (1) do no harm and (2) maximize possible benefits and minimize possible harms. An assessment of risks and benefits will depend heavily on the delivery of accurate and complete information as described above. An assessment of risk will include both the probability and the severity of envisioned harms, both physical and psychological.

Finally, ***justice*** requires fairness in distribution of risks and benefits. It suggests that not only should like cases be treated alike, but different approaches are appropriate for different circumstances. This is highly relevant in the selection process for those being subjected to the various interventions while still minors.

Thus the process of informed consent must proceed with a correct diagnosis, the nature and purpose of recommended interventions, the known burdens and benefits of all options, including doing nothing or forgoing the intervention. While not able to do an exhaustive review of these elements as they apply to the main treatment approaches recommended for transgender minors, we can briefly examine each category to assess for obvious deficiencies. The issue of deficient information will be significant in each category, and questions of comprehension and voluntariness will be addressed at the end.

II. The Interventions

Surgery

A variety of surgeries have been performed on transgender adults. These range from removal of both breasts (bilateral mastectomy) and associated chest reconstruction, nipple repositioning, dermal implant and tattooing, to gender surgery for trans men which includes construction of a penis (phalloplasty or metoidioplasty), construction of a scrotum (scrotoplasty) and testicular implants, or a penile implant. Removal of the womb (hysterectomy) and the ovaries and fallopian tubes (salpingo-oophorectomy) may also be considered. Surgery for trans women includes removal of the testes (orchidectomy), removal of the penis (penectomy), construction of a vagina (vaginoplasty), construction of a vulva (vulvoplasty), construction of a clitoris (clitoroplasty), as well as breast implants for trans women, facial feminisation surgery and hair transplants. Certainly there are multiple known risks to this long list of surgeries. These used to be described as "sex-change" operations: they are now termed "gender affirming surgeries." The semantic shift is important, as we will see.

Most, but not all, practitioners would delay undertaking these permanent alterations in minor children and adolescents. This may be as much for legal reasons as for medical considerations. However, the lack of sexual maturity in younger patients, especially if previously delayed by puberty blocking agents, makes the sparse tissue more difficult to work with and outcomes less favorable, with problems such as wound rupture more likely. These are not challenges that are routinely described to minors at the beginning of their treatment progression with puberty blocking agents or hormones. This deficit of information would be a major failing.

Hormonal Treatment

Treatment with cross-sex hormones is a mainstay of gender affirming care. These result in the changes in body habitus, facies, voice tone, and hair development that transgender patients seek. They are described as "gender affirming", "life-saving" and "a human right" by their proponents. They have been prescribed by Planned Parenthood clinics and others after a first visit for gender dysphoria (https://www.plannedparenthood.org/planned-parenthood-greater-texas/patient-resources/transgender-healthcare). Surely no one would argue that such a precipitous practice has been accompanied by a full psychological evaluation, or disclosure of medical risks. Chief among these is the fact that the resulting bodily changes will not disappear, even if the initial desire for them changes. And this change is no unlikely development – upwards of 80% of minors who identify as transgender will reverse this identity by the time they reach their mid-20's if left untreated, and revert to their previous identification, albeit possibly with a same-sex attraction. It is more than simply changes in one's body that are at risk; sex hormones have an important and lasting effect on brain development and adolescent psychology. To not fully appreciate this fact, or to not have it delineated in the first place, is an egregious failure of informed consent.

Puberty Blockers

Perhaps the greatest failure of informed consent, and non-disclosure of human experimentation outcomes, is found in the supposedly benign use of puberty blocking agents in minors. They are routinely and widely prescribed with the thought that this will "buy time" for those questioning their gender as minors. Children and their supportive parents are assured that they are a benign intervention whose effects are easily reversible, just in case the child decides not to transition. Some potential effect on the development of bone density may be mentioned. The extent of this danger is just now being appreciated, with severe and disabling osteoporosis described in at least one child in Sweden. This led to new guidelines for gender-affirming care issued in February by the National Board of Health and Welfare. It stated that, based on current knowledge: "the risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits, and that the treatments should be offered only in exceptional cases." However, the effect of puberty blocking agents (started in early adolescent development) on long-term sexual function seems to be largely unstudied. Current guidelines recommend starting puberty blockers at the earliest stage of sexual maturation in children (Tanner two). These will not only prevent the enlargement of penile tissue, it will desensitize the orgasmic potential for tissues later exposed to cross-sex hormones. Simply put, transgender adults treated in early adolescence with puberty blockers may never experience orgasm. When children with gender dysphoria are given these powerful hormones (around age 11) they are too young to appreciate the implications of what will happen.

It is not simply a matter of chronology. As children mature into adolescents and adults, their brains are also being formed and reformed under the influence of sex hormones. There is evidence for structural changes, and these are likely to be demonstrated in cognitive and behavioral changes. In fact, the development of the adolescent brain and the maturation of its rational and executive functions does not typically complete until one's early 20s. Although the deleterious effects on sexual development and function in adulthood from puberty blockers may be predicted, no one is entirely certain of the effects on other critical areas such as brain development and bone density. Carefully constructed and monitored studies have not been done. *Until they are, these off-label treatments with puberty blockers and cross sex hormones can only be considered experimental.* Experimental interventions should be done as carefully as any other research, and fully informed consent is the only ethical way to enter into such studies. Clearly, this is not the current practice.

III. The Fundamental Flaw

There appears to have been a headlong rush in the past decade towards the process of gender affirming care described above. After close scrutiny, it can only be seen as off label experimentation, despite the fact that informed consent practices do not conform to this reality. Given this, we must ask ourselves: how can experienced and ethical physicians so mislead others or be so misled themselves? In 2013, the American Psychiatric Association published their update of the Diagnostic and Statistical Manual of Mental Disorders, the DSM-5. In it the diagnosis of "gender identity disorder" was replaced with "gender dysphoria." This was done to "avoid stigma and ensure clinical care for individuals who see and feel themselves to be a different gender" other than the one to which they were born. The APA stated that "it is important to note the gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition." Dysphoria is a state of uneasiness, unhappiness, or dissatisfaction. With this change in terminology there was also a shift from seeking or correcting the underlying cause of the dysphoria, and a focus on transitioning to the preferred gender.

This revision has probably done more harm than good by accepting a self-diagnosis characterized by the belief that the patient (or their essence) is "trapped in the wrong body." This concept relies on the Cartesian duality, a body-self dichotomy. It reverts to the fallacious "ghost in the machine" concept. In reality, we cannot be trapped in the wrong body; we **are** our bodies, which are an integral and inseparable part of ourselves. To assert that there is a female self inside a male body (or the reverse), is to fail to achieve a full understanding that we are embodied persons, unified body and mind, if you will. A generation ago, sex and gender were taken to be synonyms for the same phenomena. Even now, a transgender female, no matter how much or how long of a hormonal therapeutic regimen they undergo, is still genetically male. Ignoring this fact has led to a contradiction, where sympathetic practitioners recommend "holistic care" while insisting on a fragmented concept of the self. This approach has been warmly embraced, even insisted upon, by many practitioners while viewed as nonsensical and even ludicrous by many laypersons.

Inevitably this has led to added difficulties. Even young patients are encouraged to begin puberty blockers and then hormones based on a self-diagnosis. Self-diagnosing psychiatric conditions is always fraught with the possibility of error. In this case, there can be no confirmatory lab tests, radiologic exams, or genetic findings. Moreover, the dysphoria can only be diagnosed and opened to treatment if it is causing significant trauma to the individual. The clinically significant distress manifests itself in underlying psychiatric diagnoses such as depression and suicidality. It is argued that embarking on affirmative treatment as early as possible is urgently needed to prevent further psychiatric complications, a contested assertion. Studies have shown that adult transgender persons continue to have evidence of depression and suicidality following treatment. The rate of suicide among post-operative transgender adults in a study from Sweden found an incidence 20 times greater than that of the general population. Such treatment may not be urgently needed to protect adolescents; it may not even be effective protection for their adult counterparts.

The claim of urgency coupled with an impulse toward nonjudgmental empathy for the disturbed patients has led to a frantic insistence on a single approach that may seem almost cult like in its insularity and opposition to outside challenges. Both parents (Trinko, K.(Nov. 19, 2018 "What It's Like to Lose Your Children to the 'Transgender Cult,' From a Mom Who Knows." *The Daily Signal*, 30 Oct. 2019) and teachers (Manning, M. for The Mail on Sunday. "Whistleblower Teacher Makes Shocking Claim That 'Most Are Autistic'." *Daily Mail Online*, Associated Newspapers, 19 Nov. 2018, https://www.dailymail.co.uk/news/article-6401593/Whistleblower-teacher-makes-shocking-claim-autistic.html.) report that their children or students are being wrongly encouraged at school to think of themselves as transgender. Sometimes this is the result of overenthusiastic acceptance or "love bombing". Sometimes it appears to influence the susceptible, as in autistic children. Sometimes transgender counseling is taking place even without the parents' knowledge, and this troubling approach has been supported in the literature with statements that adolescents should be legally empowered to obtain puberty-blocking without parental consent (Priest, M. Transgender Children and the Right to Transition: Medical Ethics When Parents Mean Well but Cause Harm. Am J Bioeth. 2019 Feb;19(2):45-59).

Inevitably, this has resulted in complications and conflicts. The media have been replete with reports of such things as contested accessibility of transgender females to such things as domestic abuse shelters, female prisons, and female sports competitions. Similar issues regarding bathroom accessibility in schools recently came to a boil in Virginia, when it came to light that a sexual assault by a self-described trans- female (with a penis) was repeated in another school after the perpetrator was transferred. (Poff, J. "Loudoun superintendent failed to inform state of school sexual assault." Washington Examiner, 4 May 2022.) These issues are far from any resolution by debate, discussion, or legislation. In fact, both sides of the debate have doubled down with insistence that the opposing viewpoint must not only be rejected but considered unethical and made illegal.

Some disturbing trends have developed resulting not only from this dichotomy of opinion about the proper treatment approach, but ultimately based in the acceptance of the mind-body dichotomy. There has been a change in the diagnosed population. As Abigail Schrier pointed out:

> For the nearly 100-year diagnostic history of gender dysphoria, it overwhelmingly afflicted boys and men, and it began in early childhood (ages two to four). According to the DSM-V, the latest edition of the historical rate of incidence was 0.01 percent of males (roughly one in 10,000).
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> For decades, psychologists treated it with "watchful waiting" — that is, a method of psychotherapy that seeks to understand the source of a child's gender dysphoria, lessen its intensity, and ultimately help a child grow more comfortable in her own body. Now such an approach is disdained by the term "conversion therapy", and labelled as unethical, and even made illegal.

She continues:

> Since nearly seven in 10 children initially diagnosed with gender dysphoria eventually outgrew it, the conventional wisdom held that, with a little patience, most kids would come to accept their bodies. The underlying assumption was children didn't always know best. But in the last decade, watchful waiting has been supplanted by "affirmative care," which assumes children do know what's best. Affirmative care proponents urge doctors to corroborate their patients' belief that they are trapped in the wrong body. The family is pressured to help the child transition to a new gender identity — sometimes having been told by doctors or activists that, if they don't, their child may eventually commit suicide. From there, pressures build on parents to begin concrete medical steps to help children on their path to transitioning to the "right" body. That includes puberty blockers as a preliminary step. Typically, cross-sex hormones follow and then, if desired, gender surgery. (Shrier, A. "Top Trans Doctors Blow the Whistle on 'Sloppy' Care." Emmaus Road Ministries, 5 Oct. 2021)

These pressures apply not only to parents, but to the children themselves because of the strong emphasis on affirmative support for anyone declaring themselves transgender. As one mother described: "A lot of these kids have concurrent mental health issues, and they find a place to fit in because as soon as you say that you're trans, you get love-bombed," she reflects. "You get love-bombed online, you get love-bombed on at school … As soon as you say you're trans, you turn into a star. And kids are thirsty for that kind of affirmation." (Trinko, 2019)

Two phenomena may be associated with this. Strong affirmation for the diagnosis and hormonal treatment may be altering the natural course of the phenomenon in childhood. It may not only be easier to identify as transgender in today's environment; it may be more difficult to turn ones back on the diagnosis. This may help explain a recent report that found that an average of 5 years after their initial social transition, 7.3% of youth had retransitioned (changed gender identity) at least once. At the end of this period, most youth identified as binary transgender youth (94%), including 1.3% who retransitioned to another identity before returning to their binary transgender identity. 2.5% of youth identified as cisgender and 3.5% as nonbinary. Later cisgender identities were more common amongst youth whose initial social transition occurred before age 6 years; the retransition often occurred before age 10. Unlike previous studies of transgender youth, males were not predominant, but were outnumbered by 2 to 1. Moreover, this is a direct contradiction of previous data showing a high rate of reversion towards a sex/gender coherence in children as they mature. (Olson, Kristina R., Durwood, Lily, Horton, Rachel, Gallagher, Natalie M., & Devor, Aaron; Gender Identity 5 Years

After Social Transition. Pediatrics 2022; 10.1542/peds.2021-056082) We must ask if this represents a shift towards being trapped in a wrong diagnosis, rather than a child being trapped in a wrong body.

In fact, there has been another shift. Unlike in the past, we now see increased numbers of females identifying as transgender, and later in their adolescence. Sometimes this occurs in large cohorts within a single school or peer group, a phenomenon labelled "rapid onset gender dysphoria." Both these phenomena call into question the underlying cause for the concept of gender dysphoria. Rather than approaching it as an accurate self-diagnosis that must be affirmed and treated to change the outward sexual appearance, isn't there a better model? We may be making a fundamental mistake in approaching transgender phenomena, not as a disease or disorder, but at most a dysphoria that is a cause for affirmation. This contrasts with our approach to similar conditions claiming a mind- body divergence, such as anorexia nervosa or body integrity identity disorder. The former is familiar to most Americans. The latter is a rare mental disorder characterized by a desire to have a physical disability, claiming discomfort with being able-bodied and often resulting in a request for amputation of the body part that makes them uncomfortable. People with this condition may refer to themselves as "trans abled."

In all three of these conditions there is a claim for a mismatch between one's mental bodily image and physical body. All tend to find an onset in prepubescence and are frequently associated with other mental disturbances. "Affirmative care" is the only recommended standard for transgender patients. It is horribly disturbing to contemplate amputation of a healthy limb because of a mental disorder (although this has been done). No one would seriously consider surgery to limit caloric intake or weight gain for a patient with anorexia nervosa, in order to support and affirm her distorted body image. Nevertheless, sex change operations have been recast as "gender affirming surgeries". The change in language reflects the change in attitude that distorts the approach to treatment for a psychiatric, not medical/surgical, disorder.

Finally, what are we to make of this situation, as a medical profession, and as a society? This question cannot be answered until both the affected people and profession can overcome our collective hubris. It is not enough to admit we don't know all the answers. We must see that we are not yet certain of all the questions that must be answered. In such a situation, competing interests must not pretend to take the moral high ground when no one can be certain where it will be located. First and foremost, we must back off from our current approaches until questions can be answered with proper studies, done with sufficient patients, and sufficient controls, over a sufficient period of time. Any insistence on a single course of therapy without this information could prove to be the same type of morally unacceptable interventions that caused formal research protections to be created in the first place.

In the meantime, we must adopt a more respectful tone with those whom we disagree. As John Milton said, "Where there is much desire to learn, there of necessity will be much arguing, much writing, many opinions; for opinion in good men is but knowledge in the making." Most important of all, in order to protect the current and future well-being of these affected children, we must rely on the ancient principal of medical ethics "In the first place, do no harm." Until we can demonstrate the efficacy and safety of any proposed treatment or intervention, its usage must properly be considered a medical experimentation and require fully informed consent. Anything less is a betrayal of both our principles and our progeny.

About the author: *Dr. Donovan's observations flow from his professional experience. He has been a Board-certified pediatrician for over 40 years, as an academic physician who rose to Vice-chair of the Department of Pediatrics and ultimately interim Chair at the University of Oklahoma in Tulsa. His professional role and interests expanded in the 1990's after he took a sabbatical in medical ethics at*

Georgetown University under the world-famous Dr. Edmund Pellegrino, a founding father of modern bioethics. He subsequently went on to earn a master's degree in Bioethics and founded the first bioethics center in his home university, where he was responsible for ethics training and education for students and physicians. He also served as clinical ethics consultant for three teaching hospitals. He was chair of the Section on Bioethics for the American Academy of Pediatrics (AAP) for three years and then their first liaison member of the AAP Committee on Bioethics. He has also served as the chair for a hospital Intuitional Review Board for 17 years. Finally, he was asked to become Director for the Center for Clinical Bioethics at Georgetown University School of Medicine, where he served from 2012-2020. His duties included teaching, consultation, publishing papers and speaking on bioethics extensively at the local, national, and international level on four continents. He has been interviewed and quoted on National Broadcasting Company (NBC), National Public Radio (NPR), Eternal Word Television Network (EWTN), and Al Jazeera, as well as the New York Times and the Washington Post, among others. He was awarded the Humanism in Medicine award from the Gold Foundation, which recognizes physicians to have successfully integrated humanism into the delivery of care to their patients and families. He has also offered formal testimony on bioethical issues before state legislatures and the U.S. Congress.