Remarks

April 25, 2022 meeting with the HHS

1. Introduction: Dr. Malone, USA

- We are an international group of clinicians and researchers committed to promoting evidence-based practices in the field of gender medicine, with a focus on children, adolescents, and young adults.
- I'm joined today by several colleagues who will be making comments about how their particular countries are restructuring gender services for minors:
    - From the UK we have Dr. Byng, a professor of medicine, and Mr. Stephens, both members of the NHS England working group on Gender Dysphoria.
    - From Finland we have Dr. Kaltiala, psychotherapist and the leader of Finland's pediatric gender services.
    - Dr. Hjaltadottir will give an update on recent changes in Sweden.
    - Last to speak will be Ms. Ayad and Ms. Marchiano, US-based therapists who work with gender dysphoric youth.
- Our group is committed to equality and we object to any discrimination against LGB or T individuals. A number of our group members are LGB and others have family members who identify as transgender.
- Our concern is that the proposed rule by HHS may harm the long-term health of gender dysphoric youth, by effectively forcing physicians to provide hormonal and surgical interventions that have not been proven to be effective at providing lasting psychological improvements but carry serious risks of harm.
- Gender-affirmative care is a euphemism for a highly invasive treatment protocol for minors. To illustrate this:
    - A 10-year old feminine boy is teased for being gender-non-conforming, and determines that his interest in dolls and makeup, indicates that he is transgender.
    - Under the affirmative care paradigm, clinicians would have to affirm this child's belief and begin preparing him for transition starting with puberty blockers.
    - Puberty blockers will halt his genital development—his genitalia will stay very small—prepubertal size, only slightly larger than infant sized genitalia. It will also

stop accrual of bone density, and alter his brain development, and impact the development of every part of his body in ways that we do not fully understand.

- In nearly 100% of cases, puberty blocked kids proceed to cross sex hormones.
- At around age 14, estrogen will be given, which results in the destruction of future sperm producing potential, rendering sterility. This young person will be dependent on estrogen life-long which will increase the risks of strokes and blood clots by several fold and may increase the risk of cancer.
- At age 17, a surgeon will remove the pre-pubertal sized and non-functional testes.
- At age 18, a surgeon will create a neovagina from the penile tissue, but because the penis is the same small size they it was at age 10, a section of colon will need to be used.
- This neovagina may carry the odor of colon tissue, and will be susceptible to developing disease of the bowel such as colitis.
- It is not clear whether this young person will ever experience sexual desire or be able to have an orgasm.
- What is clear is that the young person will never be able to reproduce and will face a life time of medical patient-hood.
- Today, kids like the one I described are presenting in record numbers seeking sex reassignment. As many as 10% of youth identify and transgender.
- Affirmative care asks that children make life-changing decisions that carry irreversible consequences at an age when the ability to provide meaningful consent is questionable.

- Interventions of such impact should only be provided when the evidence of benefit outweighs the risk of harm. In our highly politicized environment, it is claimed this is the case. However, HHS may be interested to know that every credible systematic review of evidence conducted to date—from the US to Finland to Sweden and the UK, has failed to demonstrate any lasting or credible benefits of these interventions while noting very significant risks.
- I'd like to be clear, because of the low quality of evidence, no established standard of care for the treatment of youth with gender dysphoria currently exists.
    - The World Professional Association for Transgender Health (WPATH) acknowledges that despite the misleading name, WPATH Standards of Care 7 and upcoming 8 are also practice guidelines, not standards of care.

- Even the Endocrine Society's guidelines admit that they "cannot guarantee any specific outcome, nor do they establish a standard of care".

- In the last 24 months, multiple guidelines have been developed by health authorities worldwide, which are increasingly divergent from US Guidelines regarding who should be treated, how they should be treated, when they should be treated, and whether medical interventions for minors can be ethically initiated outside of clinical trials.
- The HHS proposed rule will strongly signal to physicians that prescriptions of puberty blockers and cross sex hormones and referrals for surgeries will be required of them to maintain secure employment. What will be the fallout of such a decision? We know how this ends, we've been here before
- Two decades ago, Physicians were instructed , against their better judgment, to treat pain as the fifth vital sign and to liberally prescribe opioids.
- The short term relief the patients experienced backfired into the biggest medical scandal of modern times, the current the opioid crisis.
- I, and great many of my physician colleagues are concerned that we are in the midst of a similar or perhaps even greater epidemic of harm directly resulting from physician actions, where there is no consensus as to how to determine medical necessity for treatment within a very large and diverse population of patients. The long term medical harm at a massive scale will be unavoidable.

2. Summary of the UK Evolving Approach -- the "Cass Review" (Dr. Byng, Mr. Stephens)

The UK's National Health Service is reviewing how it helps young people to overcome gender dysphoria. Following the two evidence reviews, and various legal and regulatory concerns, it was judged unsafe to continue with the existing model of care. So an eminent pediatrician, Dr Hilary Cass, was asked to fundamentally redesign the system from first principles, bringing it closer to mainstream pediatric practice.

Recently Dr Cass published her interim report, which sets out difficult questions for the medicalized approach to gender dysphoria that has developed in recent years. Firstly, she observes that gender problems used to mostly impact birth-registered males starting in early childhood, but now it's mostly females starting in puberty, and complex and vulnerable children – for example with autism or mental health problems – are now over-represented. Cass reports a general lack of evidence, both nationally and internationally; and that what little data

we do have doesn't apply to what's become the largest patient group: adolescent birth-registered females.

Secondly, throughout Cass is cautious about puberty blockers. She notes that research has focused on short-term mental health outcomes, but not on longer-term development. Cass notes that adolescence is a time of significant changes in the brain. If adolescent hormone surges are suppressed, there may be irreversible impacts on the patient's maturation and cognition.

Thirdly, the DSM-5 diagnostic criteria tell us that a patient's gender dysphoria has reached a clinically significant level, but they don't help us understand its causes, nor how to respond. Cass says that many factors can contribute to gender dysphoria, including sexual abuse or other childhood trauma, autism, and questioning of sexual orientation. Cass insists that clinicians develop a full picture of a young person's development and wellbeing, and to undertake a differential diagnosis to rule out other causes.

Finally, there is no assessment model to determine who may benefit from a medical transition, and who may be harmed. Approaches vary widely, and Cass found that many clinicians feel pressured to adopt an unquestioningly affirmative approach, that's at odds with how they deal with every other clinical encounter. Cass encourages an exploratory assessment process.

Cass's final report, containing her detailed recommendations, will appear later this year or early next. But it's already clear that she envisages a more developmentally-informed approach that foregrounds talking therapies, and where medical interventions are likely to be reserved for a highly selective sub-group of patients.

3. Summary of Finland's New Policy Change (Dr. Kaltiala, Finland)

For Finland's National Guidelines, a systematic review of evidence in transition care was performed to review evidence related to mental health outcomes in children and adolescents treated for gender dysphoria. The scientific evidence for medical or surgical interventions for child and adolescent gender dysphoria is of very low quality ,if not totally lacking. Particularly it has not been shown that medical gender reassignment during adolescent years would improve mental health, decrease psychiatric morbidity, or improve psychosocial functioning. Actually, Finland's research shows that mental health of a considerable share of patients treated with "gender-affirming" care with hormones worsens.

Evidence for medical treatment of childhood onset gender dysphoria is questionable, but no studies that can advise about the natural course and optimal treatments of adolescent onset gender dysphoria, which is exactly the big issue nowadays. Huge numbers of adolescents have recently started to question their gender, and we have no knowledge of the natural course of such personal crisis, nor the outcomes of any treatment.

In adolescence, identity consolidation, personality development, and decision-making competency are still in the making. Most of the adolescents seeking for gender reassignment

present with severe psychiatric disorders that further delay their identity consolidation, personality development and competence.

Because of this, the national guidelines in Finland are relatively conservative. After the onset of puberty, the first line intervention is psychosocial intervention promoting identity exploration, and if necessary, appropriate treatment of comorbid psychiatric disorders into remission.

If after this, considering medical gender reassignment interventions is warranted, a thorough assessment by the nationally centralized multidisciplinary gender identity teams is carried out. This comprises excluding severe psychiatric disorders and urgent child welfare needs that may complicate identity development; assessment of identity development as a whole; and helping the young person and their family to prepare for the medical transition, if appropriate.

If medical transition appears appropriate, hormonal interventions can be initiated during adolescent years, but we do not allow for surgical treatments for those under the age of 18.

Because of lack of evidence and accumulating negative clinical observations, it is of outmost importance that treatment decisions are based on careful assessment and made case by case. In Finland, we do not consider saying “no” to a teenager who eagerly wishes to receive hormones to be discrimination. We consider it prudent medical care to assess each case individually. For a considerable number of young people, we will recommend delaying hormonal interventions until their identity stabilizes, which for a number of patients does not happen for several years after reaching the legal age.

4. Summary of Sweden’s Recent Policy Change (Dr. Hjaltadottir, Sweden)

Thank you for the opportunity to present the highlights from the newly published Swedish Guidelines on treatment for children and youth <18 with gender dysphoria. The guidelines were put forward by the Swedish National Board of Health and Welfare in February 2022 and are built on a recently completed systematic review of the evidence.

The systematic review found that the evidence base for hormonal interventions for gender-dysphoric youth is of low quality, and that hormonal treatments may carry risks and that at present, the risks of hormonal interventions for gender dysphoric youth outweigh the potential benefits. The review also concluded that the evidence for pediatric transition comes from studies where the population was markedly different from the cases presenting for care today. The studies involve the group that presented with the classic childhood onset of gender dysphoria but the largest group presenting today are teenagers , predominantly females ,with adolescent-onset gender dysphoria. This poorly understood change in demographics warrants extra caution.

It is also recognized that we are seeing increasing reports of detransition and transition-related regret among youth who transitioned in recent years. In light of above limitations in the evidence base, the fact that identity formation is ongoing in youth, and in view of the reality that gender transition has pervasive and lifelong consequences, the Swedish Health Authority has concluded that these interventions cannot be provided in general medical settings. Instead,

they can only be provided in the context of a clinical trial, which will take place at highly specialized medical centers, and can only be offered to adolescents with the "classic" early childhood-onset of gender dysphoria and cross-sex identification.

For those whose transgender identity emerged after puberty, or those with a non-binary identity, psychiatric care and gender-exploratory psychotherapy will be offered instead. Children with Autistic Spectrum Disorders (ASD) will need an additional evaluation as it of concern that their well-known lack of adherence to gender norms could lead them to misattribute their experience to being "transgender" and inappropriately transition.

It is also important to point out that the Treatment eligibility will be based on the criterion of "distress," and not "identity. The DSM diagnosis of "gender dysphoria" will be a prerequisite for eligibility for "gender-affirming" hormonal interventions. The presence of a transgender identity that is not causing distress or functional impairments is not sufficient for medical interventions.

To summarize, as of 2022, following a systematic review of evidence, Sweden found that the risks of gender-affirming care outweighs the benefits, and has sharply limited access to "gender-affirming" hormones and surgeries to a small subset of minors, and these interventions can only be administered in the context of clinical trial settings. No new gender transitions for <18s will be occurring in general medical settings in Sweden. The link to the summary of Sweden's changes in English is here.

5. Importance of Slowing Things Down to Explore: Mrs. Ayad, LPC (USA)

I am a licensed professional counselor. I have been working with gender dysphoric youth for the last 8 years, first encountering this population while counseling in the school setting, and working exclusively with them in private practice for 6 years. To date, I've worked with over 500 families, and personally treated dozens of gender dysphoric teens.

When young people show up at the provider's office, they often present with a powerful conviction that they definitely transgender, and that medical intervention is necessary. The heightened emotions and feelings of urgency in these children can easily lead providers to conclude that gender-affirming care is required immediately. However, in the last 6 years, I've observed that focusing on stabilization, slowing down the process, and explicitly working to establish mental wellbeing first leads to surprising and favorable outcomes for long-term mental health.

As we know, there is currently a mental health crisis among teens, with elevated rates of depression and suicidality, particularly among females. My experience has led me to conclude many of the youth adamantly demanding medical transition are merely a subset of depressed teens, looking for relief. In my experience, many of them change their mind about gender transition once they resolve their other difficulties. If these young people are provided medical transition, they will likely feel quite harmed by 'affirmative care' when they get a bit older.

Let me use an example of one of my clients, a biological female whom I'll call "Bee." Bee's family first approached me when she was 16, in high school, and identifying as a transman. Like

many youths on the autism spectrum, Bee had cycled through several obsessions prior to her fixation on gender. When she discovered, online, the concept of becoming a transman, she became convinced that gender explained many of her other difficulties, especially feeling alienated from the other girls and distress when receiving sexual attention from boys. At 16, Bee was incredibly confident in her identity, and she listed in great detail all the surgeries and medical interventions that she wanted. But now, 5 years later, Bee looks back at that time with mixed feelings. She's very comfortable with her body now, but believes she had become confused in her teen years and that her trans identity was simply validating the shame she felt about her body and identity at the time.

Bee easily met the diagnosis of gender dysphoria when I first met her. My concern is that physicians who suspect that kids like Bee are not going to persist with their trans identity life-long will not be able to slow their teen patients down. Instead, they will feel pressured to facilitate hormones and surgeries, for the fear of being accused of discrimination.

5. Medical Harm, Detransition, Regret: Ms. Marchiano, LCSW, USA

My name is Lisa Marchiano. I am a licensed clinical social worked and a Jungian therapist. Recently, I began to to be approached by youth who underwent gender transition and experienced regret. I have worked with six detransitioners in my private practice and I have helped a few dozen other detransitioners to find therapists who are sensitive to their issues. L is one of the detransitioners with whom I have worked, and I share her story with her permission.

L realized she was same sex attracted when she was 13. She developed a severe eating disorder at 15 and was hospitalized for anorexia at 16 and then again when she was 17. She also developed bulimia and obsessive-compulsive disorder. She began identifying as trans at age 19 and started to transition at 20 after she and her girlfriend were subjected to homophobic bullying by peers. She saw a psychologist who affirmed her as trans and did not explore her OCD, her bulimia, or her same sex attraction. L went on testosterone at 20 and had a double mastectomy six months later. She was distressed by the results and subsequently had two revision surgeries. She binged and purged daily throughout her period of trans identification. She developed an obsessive fear of becoming pregnant even though she wasn't having sex with men. L remembers taking frequent pregnancy tests for reassurance. This obsessive fear of pregnancy in part led her to seek a hysterectomy and an ovariectomy when she was 21.

L detransitioned a year and a half later after she came to understand that her trans identification had been influenced by internalized homophobia and complex mental health issues. She became severely suicidal, believing that she had ruined her life. She now sees herself as a lesbian woman. She regrets her deepened voice and her scarred chest, but most of all she regrets and worries about the significant health consequences of having received a hysterectomy so young and of being dependent for life on exogenous hormones.

Previously, regret was considered to be low. However, in recent years, since gender affirmation became popularized in medicine, we are seeing more and more young people who regret their

transition. Newer research from the UK shows rates of detransition and regret are nearing 10% after just 16 months.

With as many 2-10% of young people now claiming a trans identity, I and many of my colleagues are concerned that we are creating an epidemic of wrongly – treated young people by providing them with permanent body-altering interventions. If clinicians are afraid to exercise their judgement because non-provision of hormones and surgeries is equated with discrimination, tens of thousands of young people will be permanently harmed.