

[ORAL ARGUMENT REQUESTED]

No. 18-1453

**IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT**

DANA ALIX ZZYVM,

Plaintiff-Appellee,

v.

MICHAEL R. POMPEO,
in his official capacity as Secretary of State, and

STEVEN J. MULLEN,
in his official capacity as Director of the Colorado Passport Agency
of the United States Department of State,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Colorado
District Court Case No. 15-cv-2362 (Judge R. Brooke Jackson)

CORRECTED APPENDIX FOR APPELLANTS v.3

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XV

Applicability of the Standards of Care to People With Disorders of Sex Development

Terminology

The term *disorder of sex development* (DSD) refers to a somatic condition of atypical development of the reproductive tract (Hughes, Houk, Ahmed, Lee, & LWPE51/ESPE2 Consensus Group, 2006). DSDs include the condition that used to be called *intersexuality*. Although the terminology was changed to *DSD* during an international consensus conference in 2005 (Hughes et al., 2006), disagreement about language use remains. Some people object strongly to the “disorder” label, preferring instead to view these congenital conditions as a matter of diversity (Diamond, 2009) and to continue using the terms *intersex* or *intersexuality*. In the *SOC*, WPATH uses the term *DSD* in an objective and value-free manner, with the goal of ensuring that health professionals recognize this medical term and use it to access relevant literature as the field progresses. WPATH remains open to new terminology that will further illuminate the experience of members of this diverse population and lead to improvements in health care access and delivery.

Rationale for Addition to the SOC

Previously, individuals with a DSD who also met the *DSM-IV-TR*'s behavioral criteria for Gender Identity Disorder (American Psychiatric Association, 2000) were excluded from that general diagnosis. Instead, they were categorized as having a “Gender Identity Disorder - Not Otherwise Specified.” They were also excluded from the WPATH *Standards of Care*.

The current proposal for *DSM-5* (www.dsm5.org) is to replace the term *gender identity disorder* with *gender dysphoria*. Moreover, the proposed changes to the *DSM* consider gender dysphoric people with a DSD to have a subtype of gender dysphoria. This proposed categorization – which explicitly differentiates between gender dysphoric individuals with and without a DSD – is justified: In people with a DSD, gender dysphoria differs in its phenomenological presentation, epidemiology, life trajectories, and etiology (Meyer-Bahlburg, 2009).

Adults with a DSD and gender dysphoria have increasingly come to the attention of health professionals. Accordingly, a brief discussion of their care is included in this version of the SOC.

Health History Considerations

Health professionals assisting patients with both a DSD and gender dysphoria need to be aware that the medical context in which such patients have grown up is typically very different from that of people without a DSD.

Some people are recognized as having a DSD through the observation of gender-atypical genitals at birth. (Increasingly this observation is made during the prenatal period by way of imaging procedures such as ultrasound.) These infants then undergo extensive medical diagnostic procedures. After consultation among the family and health professionals – during which the specific diagnosis, physical and hormonal findings, and feedback from long-term outcome studies (Cohen-Kettenis, 2005; Dessens, Slijper, & Drop, 2005; Jurgensen, Hiort, Holterhus, & Thyen, 2007; Mazur, 2005; Meyer-Bahlburg, 2005; Stikkelbroeck et al., 2003; Wisniewski, Migeon, Malouf, & Gearhart, 2004) are considered – the newborn is assigned a sex, either male or female.

Other individuals with a DSD come to the attention of health professionals around the age of puberty through the observation of atypical development of secondary sex characteristics. This observation also leads to a specific medical evaluation.

The type of DSD and severity of the condition has significant implications for decisions about a patient's initial sex assignment, subsequent genital surgery, and other medical and psychosocial care (Meyer-Bahlburg, 2009). For instance, the degree of prenatal androgen exposure in individuals with a DSD has been correlated with the degree of masculinization of gender-related *behavior* (that is, *gender role and expression*); however, the correlation is only moderate, and considerable behavioral variability remains unaccounted for by prenatal androgen exposure (Jurgensen et al., 2007; Meyer-Bahlburg, Dolezal, Baker, Ehrhardt, & New, 2006). Notably, a similar correlation of prenatal hormone exposure with gender *identity* has not been demonstrated (e.g., Meyer-Bahlburg et al., 2004). This is underlined by the fact that people with the same (core) gender identity can vary widely in the degree of masculinization of their gender-related behavior.

Assessment and Treatment of Gender Dysphoria in People with Disorders of Sex Development

Very rarely are individuals with a DSD identified as having gender dysphoria *before* a DSD diagnosis has been made. Even so, a DSD diagnosis is typically apparent with an appropriate history and basic physical exam – both of which are part of a medical evaluation for the appropriateness of hormone therapy or surgical interventions for gender dysphoria. Mental health professionals should ask their clients presenting with gender dysphoria to have a physical exam, particularly if they are not currently seeing a primary care (or other health care) provider.

Most people with a DSD who are born with genital ambiguity do not develop gender dysphoria (e.g., Meyer-Bahlburg et al., 2004; Wisniewski et al., 2004). However, some people with a DSD will develop chronic gender dysphoria and even undergo a change in their birth-assigned sex and/or their gender role (Meyer-Bahlburg, 2005; Wilson, 1999; Zucker, 1999). If there are persistent and strong indications that gender dysphoria is present, a comprehensive evaluation by clinicians skilled in the assessment and treatment of gender dysphoria is essential, irrespective of the patient's age. Detailed recommendations have been published for conducting such an assessment and for making treatment decisions to address gender dysphoria in the context of a DSD (Meyer-Bahlburg, in press). Only after thorough assessment should steps be taken in the direction of changing a patient's birth-assigned sex or gender role.

Clinicians assisting these patients with treatment options to alleviate gender dysphoria may profit from the insights gained from providing care to patients without a DSD (Cohen-Kettenis, 2010). However, certain criteria for treatment (e.g., age, duration of experience with living in the desired gender role) are usually not routinely applied to people with a DSD; rather, the criteria are interpreted in light of a patient's specific situation (Meyer-Bahlburg, in press). In the context of a DSD, changes in birth-assigned sex and gender role have been made at any age between early elementary-school age and middle adulthood. Even genital surgery may be performed much earlier in these patients than in gender dysphoric individuals without a DSD if the surgery is well justified by the diagnosis, by the evidence-based gender-identity prognosis for the given syndrome and syndrome severity, and by the patient's wishes.

One reason for these treatment differences is that genital surgery in individuals with a DSD is quite common in infancy and adolescence. Infertility may already be present due to either early gonadal failure or to gonadectomy because of a malignancy risk. Even so, it is advisable for patients with a DSD to undergo a full social transition to another gender role only if there is a long-standing history of gender-atypical behavior, and if gender dysphoria and/or the desire to change one's gender role has been strong and persistent for a considerable period of time. Six months is the time period of full symptom expression required for the application of the gender dysphoria diagnosis proposed for DSM-5 (Meyer-Bahlburg, in press).

Additional Resources

The gender-relevant medical histories of people with a DSD are often complex. Their histories may include a great variety of inborn genetic, endocrine, and somatic atypicalities, as well as various hormonal, surgical, and other medical treatments. For this reason, many additional issues need to be considered in the psychosocial and medical care of such patients, regardless of the presence of gender dysphoria. Consideration of these issues is beyond what can be covered in the SOC. The interested reader is referred to existing publications (e.g., Cohen-Kettenis & Pfäfflin, 2003; Meyer-Bahlburg, 2002, 2008). Some families and patients also find it useful to consult or work with community support groups.

There is a very substantial medical literature on the medical management of patients with a DSD. Much of this literature has been produced by high-level specialists in pediatric endocrinology and urology, with input from specialized mental health professionals, especially in the area of gender. Recent international consensus conferences have addressed evidence-based care guidelines (including issues of gender and of genital surgery) for DSD in general (Hughes et al., 2006) and specifically for Congenital Adrenal Hyperplasia (Joint LWPES/ESPE CAH Working Group et al., 2002; Speiser et al., 2010). Others have addressed the research needs for DSD in general (Meyer-Bahlburg & Blizzard, 2004) and for selected syndromes such as 46,XXY (Simpson et al., 2003).



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APPENDIX A

GLOSSARY

Terminology in the area of health care for transsexual, transgender, and gender nonconforming people is rapidly evolving; new terms are being introduced, and the definitions of existing terms are changing. Thus, there is often misunderstanding, debate, or disagreement about language in this field. Terms that may be unfamiliar or that have specific meanings in the *SOC* are defined below for the purpose of this document only. Others may adopt these definitions, but WPATH acknowledges that these terms may be defined differently in different cultures, communities, and contexts.

WPATH also acknowledges that many terms used in relation to this population are not ideal. For example, the terms *transsexual* and *transvestite* – and, some would argue, the more recent term *transgender* – have been applied to people in an objectifying fashion. Yet such terms have been more or less adopted by many people who are making their best effort to make themselves understood. By continuing to use these terms, WPATH intends only to ensure that concepts and processes are comprehensible, in order to facilitate the delivery of quality health care to transsexual, transgender, and gender nonconforming people. WPATH remains open to new terminology that will further illuminate the experience of members of this diverse population and lead to improvements in health care access and delivery.

Bioidentical hormones: Hormones that are *structurally* identical to those found in the human body (ACOG Committee of Gynecologic Practice, 2005). The hormones used in bioidentical hormone therapy (BHT) are generally derived from plant sources and are structurally similar to endogenous human hormones, but they need to be commercially processed to become bioidentical.

Bioidentical compounded hormone therapy (BCHT): Use of hormones that are prepared, mixed, assembled, packaged, or labeled as a drug by a pharmacist and custom-made for a patient according to a physician's specifications. Government drug agency approval is not possible for each compounded product made for an individual consumer.

Crossdressing (transvestism): Wearing clothing and adopting a gender role presentation that, in a given culture, is more typical of the other sex.

Disorders of sex development (DSD): Congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical. Some people strongly object to the "disorder" label and instead view these conditions as a matter of diversity (Diamond, 2009), preferring the terms *intersex* and *intersexuality*.

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Female-to-Male (FtM): Adjective to describe individuals assigned female at birth who are changing or who have changed their body and/or gender role from birth-assigned female to a more masculine body or role.

Gender dysphoria: Distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b).

Gender identity: A person's intrinsic sense of being male (a boy or a man), female (a girl or woman), or an alternative gender (e.g., boygirl, girlboy, transgender, genderqueer, eunuch) (Bockting, 1999; Stoller, 1964).

Gender identity disorder: Formal diagnosis set forth by the *Diagnostic Statistical Manual of Mental Disorders, 4th Edition, Text Rev (DSM IV-TR)* (American Psychiatric Association, 2000). Gender identity disorder is characterized by a strong and persistent cross-gender identification and a persistent discomfort with one's sex or sense of inappropriateness in the gender role of that sex, causing clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender nonconforming: Adjective to describe individuals whose gender identity, role, or expression differs from what is normative for their assigned sex in a given culture and historical period.

Gender role or expression: Characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine (that is, more typical of the male or female social role) (Ruble, Martin, & Berenbaum, 2006). While most individuals present socially in clearly male or female gender roles, some people present in an alternative gender role such as genderqueer or specifically transgender. All people tend to incorporate both masculine and feminine characteristics in their gender expression in varying ways and to varying degrees (Bockting, 2008).

Genderqueer: Identity label that may be used by individuals whose gender identity and/or role does not conform to a binary understanding of gender as limited to the categories of man or woman, male or female (Bockting, 2008).

Male-to-Female (MtF): Adjective to describe individuals assigned male at birth who are changing or who have changed their body and/or gender role from birth-assigned male to a more feminine body or role.

Natural hormones: Hormones that are derived from natural *sources* such as plants or animals. Natural hormones may or may not be bioidentical.

Sex: Sex is assigned at birth as male or female, usually based on the appearance of the external genitalia. When the external genitalia are ambiguous, other components of sex (internal genitalia, chromosomal and hormonal sex) are considered in order to assign sex (Grumbach, Hughes, & Conte,

2003; MacLaughlin & Donahoe, 2004; Money & Ehrhardt, 1972; Vilain, 2000). For most people, gender identity and expression are consistent with their sex assigned at birth; for transsexual, transgender, and gender nonconforming individuals, gender identity or expression differ from their sex assigned at birth.

Sex reassignment surgery (gender affirmation surgery): Surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity. Sex reassignment surgery can be an important part of medically necessary treatment to alleviate gender dysphoria.

Transgender: Adjective to describe a diverse group of individuals who cross or transcend culturally-defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth (Bockting, 1999).

Transition: Period of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in "the other" gender role; for others this means finding a gender role and expression that is most comfortable for them. Transition may or may not include feminization or masculinization of the body through hormones or other medical procedures. The nature and duration of transition is variable and individualized.

Transphobia, internalized: Discomfort with one's own transgender feelings or identity as a result of internalizing society's normative gender expectations.

Transsexual: Adjective (often applied by the medical profession) to describe individuals who seek to change or who have changed their primary and/or secondary sex characteristics through feminizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role.

APPENDIX B

OVERVIEW OF MEDICAL RISKS OF HORMONE THERAPY

The risks outlined below are based on two comprehensive, evidence-based literature reviews of masculinizing/feminizing hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009), along with a large cohort study (Asscheman et al., 2011). These reviews can serve as detailed references for providers, along with other widely recognized, published clinical materials (e.g., Dahl et al., 2006; Ettner et al., 2007).

Risks of Feminizing Hormone Therapy (MtF)

Likely increased risk:

Venous thromboembolic disease

- Estrogen use increases the risk of venous thromboembolic events (VTE), particularly in patients who are over age 40, smokers, highly sedentary, obese, and who have underlying thrombophilic disorders.
- This risk is increased with the additional use of third generation progestins.
- This risk is decreased with use of the transdermal route of estradiol administration, which is recommended for patients at higher risk of VTE.

Cardiovascular, cerebrovascular disease

- Estrogen use increases the risk of cardiovascular events in patients over age 50 with underlying cardiovascular risk factors. Additional progestin use may increase this risk.

Lipids

- Oral estrogen use may markedly increase triglycerides in patients, increasing the risk of pancreatitis and cardiovascular events.
- Different routes of administration will have different metabolic effects on levels of HDL cholesterol, LDL cholesterol and lipoprotein(a).
- In general, clinical evidence suggests that MtF patients with pre-existing lipid disorders may benefit from the use of transdermal rather than oral estrogen.

Liver/gallbladder

- Estrogen and cyproterone acetate use may be associated with transient liver enzyme elevations and, rarely, clinical hepatotoxicity.
- Estrogen use increases the risk of cholelithiasis (gall stones) and subsequent cholecystectomy.

Possible increased risk:Type 2 diabetes mellitus

- Feminizing hormone therapy, particularly estrogen, may increase the risk of type 2 diabetes, particularly among patients with a family history of diabetes or other risk factors for this disease.

Hypertension

- Estrogen use may increase blood pressure, but the effect on incidence of overt hypertension is unknown.
- Spironolactone reduces blood pressure and is recommended for at-risk or hypertensive patients desiring feminization.

Prolactinoma

- Estrogen use increases the risk of hyperprolactinemia among MtF patients in the first year of treatment, but this risk unlikely thereafter.
- High-dose estrogen use may promote the clinical appearance of preexisting but clinically unapparent prolactinoma.

Inconclusive or no increased risk: Items in this category include those that may present risk, but for which the evidence is so minimal that no clear conclusion can be reached.

Breast cancer

- MtF persons who have taken feminizing hormones do experience breast cancer, but it is unknown how their degree of risk compares to that of persons born with female genitalia.
- Longer duration of feminizing hormone exposure (i.e., number of years taking estrogen preparations), family history of breast cancer, obesity (BMI >35), and the use of progestins likely influence the level of risk.

Other side effects of feminizing therapy:

The following effects may be considered minor or even desired, depending on the patient, but are clearly associated with feminizing hormone therapy.

Fertility and sexual function

- Feminizing hormone therapy may impair fertility.
- Feminizing hormone therapy may decrease libido.
- Feminizing hormone therapy reduces nocturnal erections, with variable impact on sexually stimulated erections.

Risks of anti-androgen medications:

Feminizing hormone regimens often include a variety of agents that affect testosterone production or action. These include GnRH agonists, progestins (including cyproterone acetate), spironolactone, and 5-alpha reductase inhibitors. An extensive discussion of the specific risks of these agents is beyond the scope of the SOC. However, both spironolactone and cyproterone acetate are widely used and deserve some comment.

Cyproterone acetate is a progestational compound with anti-androgenic properties (Gooren, 2005; Levy et al., 2003). Although widely used in Europe, it is not approved for use in the United States because of concerns about hepatotoxicity (Thole, Manso, Salgueiro, Revuelta, & Hidalgo, 2004). Spironolactone is commonly used as an anti-androgen in feminizing hormone therapy, particularly in regions where cyproterone is not approved for use (Dahl et al., 2006; Moore et al., 2003; Tangpricha et al., 2003). Spironolactone has a long history of use in treating hypertension and congestive heart failure. Its common side effects include hyperkalemia, dizziness, and gastrointestinal symptoms (*Physicians' Desk Reference*, 2007).

Risks of Masculinizing Hormone Therapy (FtM)

Likely increased risk:

Polycythemia

- Masculinizing hormone therapy involving testosterone or other androgenic steroids increases the risk of polycythemia (hematocrit > 50%), particularly in patients with other risk factors.
- Transdermal administration and adaptation of dosage may reduce this risk

Weight gain/visceral fat

- Masculinizing hormone therapy can result in modest weight gain, with an increase in visceral fat.

Possible increased risk:

Lipids

- Testosterone therapy decreases HDL, but variably affects LDL and triglycerides.
- Supraphysiologic (beyond normal male range) serum levels of testosterone, often found with extended intramuscular dosing, may worsen lipid profiles, whereas transdermal administration appears to be more lipid neutral.
- Patients with underlying polycystic ovarian syndrome or dyslipidemia may be at increased risk of worsening dyslipidemia with testosterone therapy.

Liver

- Transient elevations in liver enzymes may occur with testosterone therapy.
- Hepatic dysfunction and malignancies have been noted with oral methyltestosterone. However, methyltestosterone is no longer available in most countries and should no longer be used.

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Psychiatric

Masculinizing therapy involving testosterone or other androgenic steroids may increase the risk of hypomanic, manic, or psychotic symptoms in patients with underlying psychiatric disorders that include such symptoms. This adverse event appears to be associated with higher doses or supraphysiologic blood levels of testosterone

Inconclusive or no increased risk: Items in this category include those that may present risk, but for which the evidence is so minimal that no clear conclusion can be reached.

Osteoporosis

- Testosterone therapy maintains or increases bone mineral density among FtM patients prior to oophorectomy, at least in the first three years of treatment.
- There is an increased risk of bone density loss after oophorectomy, particularly if testosterone therapy is interrupted or insufficient. This includes patients utilizing solely oral testosterone.

Cardiovascular

- Masculinizing hormone therapy at normal physiologic doses does not appear to increase the risk of cardiovascular events among healthy patients.
- Masculinizing hormone therapy may increase the risk of cardiovascular disease in patients with underlying risks factors.

Hypertension

- Masculinizing hormone therapy at normal physiologic doses may increase blood pressure but does not appear to increase the risk of hypertension.
- Patients with risk factors for hypertension, such as weight gain, family history, or polycystic ovarian syndrome, may be at increased risk.

Type 2 diabetes mellitus

- Testosterone therapy does not appear to increase the risk of type 2 diabetes among FtM patients overall.

- Testosterone therapy may further increase the risk of type 2 diabetes in patients with other risk factors, such as significant weight gain, family history, and polycystic ovarian syndrome. There are no data that suggest or show an increase in risk in those with risk factors for dyslipidemia.

Breast cancer

- Testosterone therapy in FtM patients does not increase the risk of breast cancer.

Cervical cancer

- Testosterone therapy in FtM patients does not increase the risk of cervical cancer, although it may increase the risk of minimally abnormal Pap smears due to atrophic changes.

Ovarian cancer

- Analogous to persons born with female genitalia with elevated androgen levels, testosterone therapy in FtM patients may increase the risk of ovarian cancer, although evidence is limited.

Endometrial (uterine) cancer

- Testosterone therapy in FtM patients may increase the risk of endometrial cancer, although evidence is limited.

Other side effects of masculinizing therapy:

The following effects may be considered minor or even desired, depending on the patient, but are clearly associated with masculinization.

Fertility and sexual function

- Testosterone therapy in FtM patients reduces fertility, although the degree and reversibility are unknown.
- Testosterone therapy can induce permanent anatomic changes in the developing embryo or fetus.
- Testosterone therapy induces clitoral enlargement and increases libido.

Acne, androgenic alopecia

Acne and varying degrees of male pattern hair loss (androgenic alopecia) are common side effects of masculinizing hormone therapy.

APPENDIX C

SUMMARY OF CRITERIA FOR HORMONE THERAPY AND SURGERIES

As for all previous versions of the SOC, the criteria put forth in the SOC for hormone therapy and surgical treatments for gender dysphoria are clinical guidelines; individual health professionals and programs may modify them. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm reduction strategies. These departures should be recognized as such, explained to the patient, and documented through informed consent for quality patient care and legal protection. This documentation is also valuable to accumulate new data, which can be retrospectively examined to allow for health care – and the SOC – to evolve.

Criteria for Feminizing/Masculinizing Hormone Therapy (one referral or chart documentation of psychosocial assessment)

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the SOC for children and adolescents);
4. If significant medical or mental concerns are present, they must be reasonably well-controlled.

Criteria for Breast/Chest Surgery (one referral)

Mastectomy and creation of a male chest in FtM patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the SOC for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a pre-requisite.

Breast augmentation (implants/lipofilling) in MtF patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the SOC for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Although not an explicit criterion, it is recommended that MtF patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

Criteria for genital surgery (two referrals)

Hysterectomy and ovariectomy in FtM patients and orchiectomy in MtF patients:

1. Persistent, well documented gender dysphoria;

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2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be well controlled;
5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).

The aim of hormone therapy prior to gonadectomy is primarily to introduce a period of reversible estrogen or testosterone suppression, before a patient undergoes irreversible surgical intervention.

These criteria do not apply to patients who are having these surgical procedures for medical indications other than gender dysphoria.

Metoidioplasty or phalloplasty in FtM patients and vaginoplasty in MtF patients:

1. Persistent, well documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be well controlled;
5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones);
6. 12 continuous months of living in a gender role that is congruent with their gender identity.

Although not an explicit criterion, it is recommended that these patients also have regular visits with a mental health or other medical professional.

The criterion noted above for some types of genital surgeries – i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity – is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery.

APPENDIX D

EVIDENCE FOR CLINICAL OUTCOMES OF THERAPEUTIC APPROACHES

One of the real supports for any new therapy is an outcome analysis. Because of the controversial nature of sex reassignment surgery, this type of analysis has been very important. Almost all of the outcome studies in this area have been retrospective.

One of the first studies to examine the post-treatment psychosocial outcomes of transsexual patients was done in 1979 at Johns Hopkins University School of Medicine and Hospital (USA) (J. K. Meyer & Reter, 1979). This study focused on patients' occupational, educational, marital, and domiciliary stability. The results revealed several significant changes with treatment. These changes were not seen as positive; rather, they showed that many individuals who had entered the treatment program were no better off or were worse off in many measures after participation in the program. These findings resulted in closure of the treatment program at that hospital/medical school (Abramowitz, 1986).

Subsequently, a significant number of health professionals called for a standard for eligibility for sex reassignment surgery. This led to the formulation of the original *Standards of Care* of the Harry Benjamin International Gender Dysphoria Association (now WPATH) in 1979.

In 1981, Pauly published results from a large retrospective study of people who underwent sex reassignment surgery. Participants in that study had much better outcomes: Among 83 FtM patients, 80.7% had a satisfactory outcome (i.e., patient self report of "improved social and emotional adjustment"), 6.0% unsatisfactory. Among 283 MtF patients, 71.4% had a satisfactory outcome, 8.1% unsatisfactory. This study included patients who were treated before the publication and use of the *Standards of Care*.

Since the *Standards of Care* have been in place, there has been a steady increase in patient satisfaction and decrease in dissatisfaction with the outcome of sex reassignment surgery. Studies conducted after 1996 focused on patients who were treated according to the *Standards of Care*. The findings of Rehman and colleagues (1999) and Krege and colleagues (2001) are typical of this body of work; none of the patients in these studies regretted having had surgery, and most reported being satisfied with the cosmetic and functional results of the surgery. Even patients who develop severe surgical complications seldom regret having undergone surgery. Quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2003). The vast majority of follow-up studies have shown an undeniable beneficial effect of sex reassignment surgery on postoperative outcomes such as subjective well being, cosmesis, and sexual function (De Cuypere et al., 2005; Garaffa, Christopher, & Ralph, 2010; Klein & Gorzalka, 2009), although the specific magnitude of benefit is uncertain from

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the currently available evidence. One study (Emory, Cole, Avery, Meyer, & Meyer III, 2003) even showed improvement in patient income.

One troubling report (Newfield et al., 2006) documented lower scores on quality of life (measured with the SF-36) for FtM patients than for the general population. A weakness of that study is that it recruited its 384 participants by a general email rather than a systematic approach, and the degree and type of treatment was not recorded. Study participants who were taking testosterone had typically been doing so for less than 5 years. Reported quality of life was higher for patients who had undergone breast/chest surgery than for those who had not ($p < .001$). (A similar analysis was not done for genital surgery). In other work, Kuhn and colleagues (2009) used the King's Health Questionnaire to assess the quality of life of 55 transsexual patients at 15 years after surgery. Scores were compared to those of 20 healthy female control patients who had undergone abdominal/pelvic surgery in the past. Quality of life scores for transsexual patients were the same or better than those of control patients for some subscales (emotions, sleep, incontinence, symptom severity, and role limitation), but worse in other domains (general health, physical limitation, and personal limitation).

It is difficult to determine the effectiveness of hormones alone in the relief of gender dysphoria. Most studies evaluating the effectiveness of masculinizing/feminizing hormone therapy on gender dysphoria have been conducted with patients who have also undergone sex reassignment surgery. Favorable effects of therapies that included both hormones and surgery were reported in a comprehensive review of over 2000 patients in 79 studies (mostly observational) conducted between 1961 and 1991 (Eldh, Berg, & Gustafsson, 1997; Gijs & Brewaeys, 2007; Murad et al., 2010; Pfäfflin & Junge, 1998). Patients operated on after 1986 did better than those before 1986; this reflects significant improvement in surgical complications (Eldh et al., 1997). Most patients have reported improved psychosocial outcomes, ranging between 87% for MtF patients and 97% for FtM patients (Green & Fleming, 1990). Similar improvements were found in a Swedish study in which "almost all patients were satisfied with sex reassignment at 5 years, and 86% were assessed by clinicians at follow-up as stable or improved in global functioning" (Johansson, Sundbom, Höjerback, & Bodlund, 2010). Weaknesses of these earlier studies are their retrospective design and use of different criteria to evaluate outcomes.

A prospective study conducted in the Netherlands evaluated 325 consecutive adult and adolescent subjects seeking sex reassignment (Smith, Van Goozen, Kuiper, & Cohen-Kettenis, 2005). Patients who underwent sex reassignment therapy (both hormonal and surgical intervention) showed improvements in their mean gender dysphoria scores, measured by the Utrecht Gender Dysphoria Scale. Scores for body dissatisfaction and psychological function also improved in most categories. Fewer than 2% of patients expressed regret after therapy. This is the largest prospective study to affirm the results from retrospective studies that a combination of hormone therapy and surgery improves gender dysphoria and other areas of psychosocial functioning. There is a need for further research on the effects of hormone therapy without surgery, and without the goal of maximum physical feminization or masculinization.

Overall, studies have been reporting a steady improvement in outcomes as the field becomes more advanced. Outcome research has mainly focused on the outcome of sex reassignment surgery. In current practice there is a range of identity, role, and physical adaptations that could use additional follow-up or outcome research (Institute of Medicine, 2011).

APPENDIX E

DEVELOPMENT PROCESS FOR THE STANDARDS OF CARE, VERSION 7

The process of developing *Standards of Care, Version 7* began when an initial SOC “work group” was established in 2006. Members were invited to examine specific sections of SOC, *Version 6*. For each section, they were asked to review the relevant literature, identify where research was lacking and needed, and recommend potential revisions to the SOC as warranted by new evidence. Invited papers were submitted by the following authors: Aaron Devor, Walter Bockting, George Brown, Michael Brownstein, Peggy Cohen-Kettenis, Griet DeCuypere, Petra DeSutter, Jamie Feldman, Lin Fraser, Arlene Istar Lev, Stephen Levine, Walter Meyer, Heino Meyer-Bahlburg, Stan Monstrey, Loren Schechter, Mick van Trotsenburg, Sam Winter, and Ken Zucker. Some of these authors chose to add co-authors to assist them in their task.

Initial drafts of these papers were due June 1, 2007. Most were completed by September 2007, with the rest completed by the end of 2007. These manuscripts were then submitted to the *International Journal of Transgenderism (IJT)*. Each underwent the regular *IJT* peer review process. The final papers were published in Volume 11 (1-4) in 2009, making them available for discussion and debate.

After these articles were published, a *Standards of Care* Revision Committee was established by the WPATH Board of Directors in 2010. The Revision Committee was first charged with debating and discussing the *IJT* background papers through a Google website. A subgroup of the Revision Committee was appointed by the Board of Directors to serve as the Writing Group. This group was charged with preparing the first draft of SOC, *Version 7* and continuing to work on revisions for consideration by the broader Revision Committee. The Board also appointed an International Advisory Group of transsexual, transgender, and gender nonconforming individuals to give input on the revision.

A technical writer was hired to (1) review all of the recommendations for revision – both the original recommendations as outlined in the *IJT* articles and additional recommendations that emanated from the online discussion – and (2) create a survey to solicit further input on these potential revisions. From the survey results, the Writing Group was able to discern where these experts stood in terms of areas of agreement and areas in need of more discussion and debate. The technical writer then (3) created a very rough first draft of SOC, *Version 7* for the Writing Group to consider and build on.

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The Writing Group met on March 4 and 5, 2011 in a face-to-face expert consultation meeting. They reviewed all recommended changes and debated and came to consensus on various controversial areas. Decisions were made based on the best available science and expert consensus. These decisions were incorporated into the draft, and additional sections were written by the Writing Group with the assistance of the technical writer.

The draft that emerged from the consultation meeting was then circulated among the Writing Group and finalized with the help of the technical writer. Once this initial draft was finalized it was circulated among the broader SOC Revision Committee and the International Advisory Group. Discussion was opened up on the Google website and a conference call was held to resolve issues. Feedback from these groups was considered by the Writing Group, who then made further revision. Two additional drafts were created and posted on the Google website for consideration by the broader SOC Revision Committee and the International Advisory Group. Upon completion of these three iterations of review and revision, the final document was presented to the WPATH Board of Directors for approval. The Board of Directors approved this version on September 14, 2011.

The plans are to disseminate this version of the SOC and invite feedback for further revisions. The WPATH Board of Directors decides the timing of any revision of the SOC.

Funding

The *Standards of Care* revision process was made possible through a generous grant from the Tawani Foundation and a gift from an anonymous donor. These funds supported the following:

1. Costs of a professional technical writer;
2. Process of soliciting international input on proposed changes from gender identity professionals and the transgender community;
3. Working meeting of the Writing Group;
4. Process of gathering additional feedback and arriving at final expert consensus from the professional and transgender communities, the *Standards of Care, Version 7* Revision Committee, and WPATH Board of Directors;
5. Costs of printing and distributing *Standards of Care, Version 7* and posting a free downloadable copy on the WPATH website;

6. Plenary session to launch the *Standards of Care, Version 7* at the 2011 WPATH Biennial Symposium in Atlanta, Georgia, USA.

Members of the Standards of Care Revision Committee¹

Eli Coleman, PhD (USA)* - Committee chair	Arlene Istar Lev, LCSW (USA)
Richard Adler, PhD (USA)	Gal Mayer, MD (USA)
Walter Bockting, PhD (USA)*	Walter Meyer, MD (USA)*
Marsha Botzer, MA (USA)*	Heino Meyer-Bahlburg, Dr. rer.nat. (USA)
George Brown, MD (USA)	Stan Monstrey, MD, PhD (Belgium)*
Peggy Cohen-Kettenis, PhD (Netherlands)*	Blaine Paxton Hall, MHS-CL, PA-C (USA)
Griet DeCuypere, MD (Belgium)*	Friedmann Pfaefflin, MD, PhD (Germany)
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Randall Ehrbar, PsyD (USA)	Bean Robinson, PhD (USA)
Randi Ettner, PhD (USA)	Loren Schechter, MD (USA)
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¹ * Writing Group member

All members of the *Standards of Care, Version 7 Revision Committee* donated their time to work on this revision.

International Advisory Group

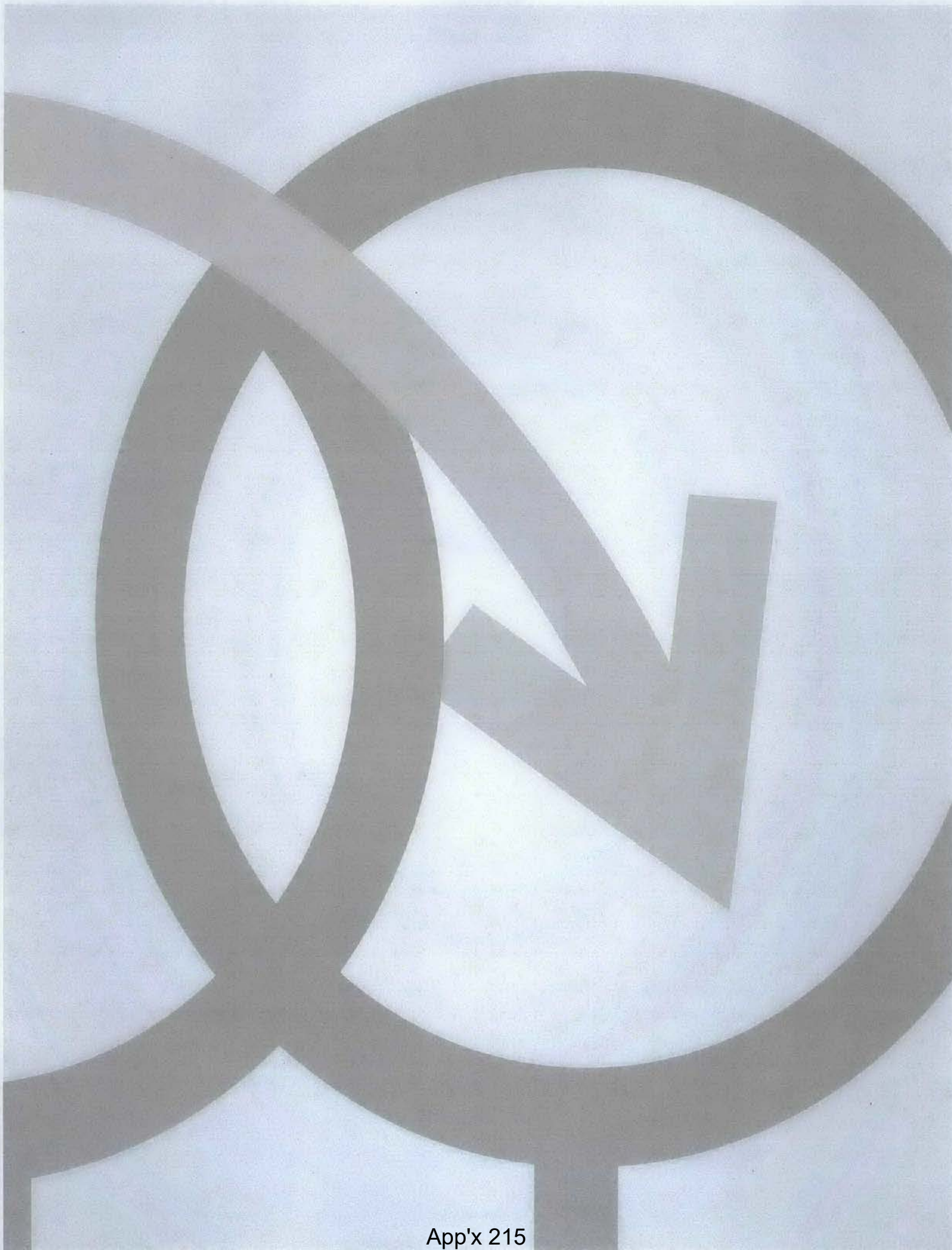
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Craig Andrews, FTM Australia (Australia)
Christine Burns, MBE, Plain Sense Ltd (UK)
Naomi Fontanos, Society for Transsexual Women's Rights in the Phillipines (Phillipines)
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No. 15-cv-02362-RBJ

DANA ALIX ZZYYM,

Plaintiff,

v.

MICHAEL R. POMPEO, *in his official capacity as Secretary of State*, and
STEVEN J. MULLEN, *in his official capacity as the Director of the Colorado Passport Agency
for the U.S. Department of State*,

Defendants.

NOTICE OF APPEAL

Notice is hereby given that Defendants Michael R. Pompeo, in his official capacity as Secretary of State, and Steven J. Mullen, in his official capacity as the Director of the Colorado Passport Agency for the U.S. Department of State, appeal to the United States Court of Appeals for the Tenth Circuit from this Court's Final Judgment of September 19, 2018, ECF No. 89, entered pursuant to the Court's order of the same day, ECF No. 88.

Dated: November 19, 2018

Respectfully submitted,

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Assistant Attorney General

JASON R. DUNN
United States Attorney

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Deputy Director

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UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Civil Action No. 15-cv-02362-WYD

DANA ALIX ZZYYM,

Plaintiff,

v.

MICHAEL POMPEO, ET AL.,

Defendants.

DECLARATION OF CARL C. RISCH

I, Carl C. Risch, do hereby state and declare as follows, pursuant to 28 U.S.C. § 1746:

1. I am the Assistant Secretary of State for Consular Affairs of the U.S. Department of State (the “Department”). Under the direction of the Secretary of State, I am responsible for the formulation and implementation of policy relating to immigration, provision of consular services, and determination of U.S. citizenship. Specifically, I direct policies, procedures, and regulations relating to functions of the Bureau, including the adjudication and issuance of passports, visas, and related services; protection and welfare of U.S. citizens and interests abroad, provision of third-country representation, and the determination of U.S. citizenship/nationality. I provide guidance and recommendations on related foreign policy issues to Department of State principals and to U.S. embassies and consulates. The statements made herein are based on information gathered through the execution of my official duties with the Department. I have served in my current position since August 11, 2017, and previously served in several senior leadership positions with U.S. Citizenship and Immigration Services (“USCIS”).

2. This declaration is submitted in support of Defendants’ Motion for a Stay of the Court’s Injunction Pending Appeal. This declaration is based on my

personal knowledge and on information conveyed to me by others within the Department's Bureau of Consular Affairs ("CA").

The Executive Branch Has Strong Foreign Policy Interests in the U.S. Passport and its Content

3. A U.S. passport is both a travel document permitting a U.S. citizen to transit between the United States and other countries, and a diplomatic communication between sovereign nations. In the text of the document, the United States identifies the bearer as a U.S. national, and requests that any foreign sovereign to which the document is presented provide the bearer entry and safe passage. Indeed, on the very first page, there is a diplomatic entreaty: "The Secretary of State of the United States of America hereby requests all whom it may concern to permit the citizen/national of the United States named herein to pass without delay or hindrance and in case of need to give all lawful aid and protection." The passport remains the property of the U.S. Government and must be surrendered upon demand. The Executive Branch has a strong foreign policy interest in controlling the content of its diplomatic communications with foreign states, including the diplomatic communication represented by a U.S. Passport.

4. The Department determines what information a passport may contain and regulates the manner in which a passport may be altered by its bearer (*e.g.*, by adding a signature or emergency contact information where space is provided for such purposes). In so doing, the Department is guided by the need for uniformity in design and presentation in order to ensure consistency and security as to the document. To facilitate the acceptance of U.S. passports by foreign border officials, the Department designs passports to be compliant with the international standards and specifications for machine-readable travel documents promulgated by the International Civil Aviation Organization (ICAO).

5. Like the United States, the vast majority of countries use the binary sex designations of "F" and "M" in their passports. Since 1999, ICAO standards have allowed, but do not require, countries to permit a third option: "unspecified." Although several countries have begun to offer a third option in their passports, most countries have not.

6. The United States has a sovereign interest in ensuring that U.S. citizens are freely able to traverse international borders without undue hindrance. To that end, the United States has expended a great deal of effort and resources in establishing the U.S. passport as a “gold standard” of international travel documents, and has a sovereign interest in preserving that hard-won status. The Department takes great care to ensure that the U.S. passport is secure, reliable, and recognized around the world as the gold standard of identity and travel documents. For this reason, whenever the Department implements a change, however minor, to the U.S. passport, it undertakes substantial effort to notify all countries about the impending change and send exemplars of the document so that foreign authorities can recognize the valid document. This process ensures that the U.S. passport is recognized as a valid travel document wherever it is presented, and helps to minimize the risk that a foreign border or customs official might fail to recognize the passport’s validity and disrupt the travel of a U.S. traveler.

**Issuance of one U.S. Passport with an “X” Sex Marker
Would Impair the United States’ Interest in Ensuring
that U.S. Passports are Universally Accepted as Reliable.**

7. The issuance of one valid U.S. passport that does not conform to publicized U.S. standards and exemplars would undermine its “gold standard” status, to the detriment of the U.S. government and all U.S. travelers. To the best of my knowledge, since the United States began issuing machine-readable passports in 1981, the Department has never issued a unique passport inconsistent with our published standards and exemplars. Furthermore, I am not aware of any other country that has issued a unique passport inconsistent with its published standards and exemplars. Rather, countries worldwide are aware that U.S. passports use only “F” or “M” as sex markers, and the Department has not announced any intention to depart from that policy. As a result, foreign border and customs officials are likely to identify a U.S. passport containing an “X” designation as an anomaly and may question its authenticity. It is likely that such a passport would be subjected to additional scrutiny, and the bearer would be subject to additional vetting, inconvenience, and delay, and possibly even denial of entry, as a consequence.

8. This would be the case even when traveling to countries that themselves issue passports with an “X” sex marker, simply because it is inconsistent with the

publicized U.S. standards and exemplars. The risk is greater in the majority of countries, which do not recognize a third sex marker in their own identification system, and could be even greater in countries whose laws do not recognize the existence of intersex, non-binary, or transgender individuals, where individuals could be denied entry, or could be subjected to local laws in an arbitrary or inconsistent manner. Indeed, countries that issue “X” passports often provide warnings to their citizens who request an “X” sex marker, advising them that they may face possible complications in using such passports to enter other countries.

9. While it is true that an individual traveler may be willing to accept the risk of using a passport with an “X” sex marker, the United States has a sovereign interest in not creating problems for its own citizens through a document of its own issuance and manufacture. The Department issues passports to U.S. citizens to facilitate the international travel of U.S. citizens, and has designed the U.S. passport to advance that purpose, including by using physical and electronic security features that ensure the credibility of the U.S. passport worldwide. By contrast, issuing a U.S. passport that could cause delays and obstacles for the bearer, rather than removing them, is contrary to U.S. policy and the strongly held interests of the U.S. government.

10. Beyond the possible inconvenience to a U.S. citizen traveling with such a unique passport, the system of international travel depends on countries issuing passports that conform to their published standards and policies. Issuance of one unique passport, not in conformity with the United States’ published standards, could undermine the confidence that other countries rightfully have in our process for ensuring the validity of our passports, and thus give rise to doubts about the credibility of all U.S. passports. This in turn could lead foreign officials in some countries to give increased scrutiny to U.S. passports and U.S. travelers generally, and cause disruption, inconvenience, and delay for U.S. travelers.

**Issuance of one U.S. Passport that Is Inconsistent with
Published Exemplars Would Create a National Security
Risk.**

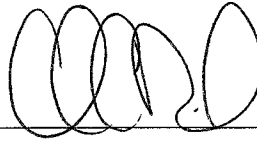
11. The issuance of a U.S. passport that does not conform to the United States’ published standards could harm U.S. interests in additional ways. First, the United

States relies on information and exemplars provided by other countries to protect against the use of fraudulent and altered passports by persons who seek to travel to the United States unlawfully or for a malicious purpose. In this context, leadership by example bolsters the United States' ability to secure commitments from other countries to be similarly transparent about their own passport standards and abide by those standards. Having reliable standards and exemplars from foreign countries provides the U.S. government with an important tool to protect the United States against fraud, illegal entry, and terrorism. By deviating from our own standards for passport issuance, we undermine our ability to insist that other countries abide by theirs, and thus diminish this important tool. Providing a unique passport with an "X" marker, even temporarily in response to litigation, would undercut significant policy interests.

12. In addition, to the extent that foreign officials were to accept a unique U.S. passport, even after additional scrutiny, they could be more inclined to accept, or less able to refuse, similarly nonconforming passports issued by other countries in the future. This would further undermine the reliability of the system of international travel. Moreover, persons who wish to enter foreign countries unlawfully or maliciously could exploit such relaxed scrutiny by using forged nonconforming passports, thereby creating a security vulnerability for those countries. Not only is it contrary to the United States' interests to take steps that could impair the national security of other countries, it may also directly harm the United States' own national security, as bad actors who are able to enter a foreign country may be able to exploit that access as the first step in an effort to travel to, or otherwise harm, the United States.

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge and understanding.

Dated: November 29, 2018

A handwritten signature in black ink, consisting of several overlapping loops and a final vertical stroke, positioned above a horizontal line.

Carl C. Risch
Assistant Secretary of State for Consular Affairs

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Civil Action No. 15-cv-02362-WYD

DANA ALIX ZZYYM,

Plaintiff,

v.

MICHAEL POMPEO, ET AL.,

Defendants.

DECLARATION OF KENNETH J. REYNOLDS

I, Kenneth J. Reynolds, do hereby state and declare as follows, pursuant to 28 U.S.C. § 1746:

1. I am the Director of the Office of Consular Systems and Technology (CST) in the Bureau of Consular Affairs (CA) of the U.S. Department of State (the Department). In this position I oversee the design, development, testing, deployment, and operations and maintenance of the information technology (IT) mission systems in support of the Consular Affairs passport, overseas citizens' services, and visa operations. The statements made herein are based on information gathered through the execution of my official duties with the Department. I have served in CST for around five years, and have been in my current position for approximately two years and six months.

2. This declaration is submitted in support of Defendants' Motion to Stay the Court's Injunction Pending Appeal. As set forth below, the Department is not able to produce a standard, fully integrated U.S. ePassport with an "X" sex marker at this time, and the modifications necessary to do so would require an estimated 24 months and \$11 million.

3. The standard U.S. Passport is an electronic passport, or ePassport. This means that it contains an electronic chip that may be read by border agencies

worldwide and which houses secure digitized image and biographic data about the bearer. It also has public key infrastructure technology that is used to substantiate the authenticity of the data stored on the chip. An ePassport contains identifying information about the bearer, including the bearer's sex, in three places: printed in the Visual Inspection Zone (VIZ) of the passport's biographic data (or biodata) page; printed in the Machine-Readable Zone (MRZ) of the biodata page; and encoded digitally on the chip. To enhance security, the biodata recorded in each of these places must match, including the appropriately documented sex marker. The Department's ePassport issuance process has quality control checks in place to prevent an ePassport from being issued with inconsistent biodata.

4. CA is currently not able to produce an ePassport with a sex marker other than "M" or "F" that would be fully integrated and recognized by our systems. To produce a single ePassport that would be supported through CA's systems would require changes to several of CA's systems, as well as possible corresponding changes to our interagency partners' systems. As explained below, I estimate it would take approximately 24 months and \$11 million to fully integrate the sex marker addition and produce an ePassport, depending on resource availability.

The Process of Producing a Valid U.S. ePassport

5. U.S. ePassports can only be produced using CA systems implemented to support the adjudication, issuance, and printing of U.S. Passports. At this time, a U.S. ePassport can only be printed with an "M" or an "F" using these systems, as these are the only options offered or recognized by the systems for the sex field. An operator or user entry to use a different character for the sex marker is not allowed by CA systems.

6. There are approximately 20 information technology systems containing a significant amount of custom software built and integrated over time that provide the necessary capabilities to support the life-cycle of an ePassport. These include the systems that handle application ingest, identity proofing, application adjudication, passport printing and issuance, and data reporting, all steps that must be completed as part of the process of producing an ePassport. Each of these systems have to be evaluated and modified appropriately to ensure an additional sex marker would be recognized and supported. CST has already identified over

250 procedures (sets of software instructions) and/or data fields, within various systems, that incorporate the sex marker. Many of these procedures and/or fields do not accept “X” as a permissible input or output. Some procedures and/or fields would have to be modified in order to support an “X” option, and others still require analysis to determine whether changes would be required.

7. CA has considered the possibility of printing a single ePassport with an “X” sex marker as a “one-off,” outside of the normal processes. It appears that it is possible to override and incorporate “one-time” modifications to certain systems to change the sex marker in the issuance system’s database, to an “X.” This would allow the passport to be printed with an “X” in the VIZ, a “<” in the MRZ, and a fully functioning chip. Based upon results in a test environment, it would take approximately four weeks to produce such a “one off” passport, including time to test the necessary changes for operational systems. If problems are encountered during testing, that time estimate may change.

8. Issuing such a passport, however, would result in a mismatch with the sex field information in the Department’s internal records system. That system currently supports only “M”, “F”, and “U” sex markers, not “X”. Thus, without the long-term system modifications mentioned previously, including modifications to the Department’s system of record for Passport services, issuing a “one off” passport with an “X” marker would fail to create a matching record in the Department’s records system.

9. This records system is the source from which automated data transfers are executed to supply other Federal agencies, including the Department of Homeland Security (DHS), with information about issued U.S. Passports. I am not aware whether the Department has ever tried to send a record with a “U” to DHS via data transfer. As a result, it is unknown whether the DHS system(s) would accept such a transfer. In either case, unless both the Department’s records system and any corresponding DHS systems were modified to accept an “X” sex marker, there would be a mismatch between the data on the “one off” ePassport and the system(s) DHS uses to process individuals at a port of entry. It is likely that this mismatch would lead DHS officials at ports of entry to require additional screening.

10. A “one off” passport also would take longer to replace if lost or stolen overseas than a standard passport. When a U.S. citizen’s standard ePassport is lost or stolen overseas, he or she can go to any embassy or consulate and, if he or she has urgent travel needs, obtain an Emergency Photo-Digitized Passport (EPDP) by the next business day. Because producing an EPDP with an “X” sex marker requires the use of modified software, as described in paragraph 18 below, it would be highly unlikely, if not impossible, to produce an EPDP with an “X” sex marker on this timeline.

Systems Changes Necessary to Produce a Fully-Integrated ePassport.

11. To create a fully-integrated ePassport, CA would have to implement significant changes to existing software systems. I estimate that such changes would take approximately 24 months and \$11 million, depending on resource availability.

12. These estimates are based on several considerations. CA currently operates and supports over 60 distinct information technology systems used for consular services. Approximately 30% of these systems specifically support U.S. Passport application processing and adjudication, both domestically and overseas and contain a significant amount of custom applications. Most of these systems are over a decade old, and as a result, they are not designed in a way that enables significant technology changes to be made routinely or quickly. This includes approximately 500 distinct databases that are used, at least in part, to support adjudication and issuance of U.S. passports.

13. Each of CA’s various systems was initially built to perform a specific function or purpose, and was not necessarily designed with other systems in mind. In other words, at the time these systems were built, they did not take into account CA’s larger “ecosystem” of now-established systems and processes. Over time, these systems were modified and updated, but changes took place independently, without a consistent set of design principles or common approach to integration across systems. As technology advanced and the Department developed a need to centralize its data and processes, and to share more data with other agencies, CA developed centralized systems, which then had to be grafted to the existing systems

supporting CA's field offices. This process required CA's existing systems to be individually modified in order to communicate with the new centralized systems. Consequently, some of CA's systems communicate in such a way that changes to one system can result in unintended consequences, or "ripple effects," for another system. Additionally, prior system adjustments have sometimes created unintended defects which forced CA to come up with workarounds unique to particular systems.

14. Due to the large number of legacy systems in field offices around the world, the complicated and varied ways in which CA's systems have been modified to communicate with one another, and existing, ad hoc workarounds, there are significant practical challenges to implementing changes across CA's systems. Even for minor changes, a lengthy amount of time is typically needed to implement necessary modifications.

15. I estimate that to make all the modifications necessary to allow CA to issue ePassports with a third sex marker option would take approximately 24 months, at a cost of roughly \$11 million. The time estimate assumes that already-planned CST system development efforts continue as currently planned, and that system modifications would not begin until necessary resources are in place, including additional hiring and funding increases for existing contracts. I estimate that this hiring and increase in funding may require 6-8 months before CST could initiate sex marker system changes. Both the time and resource estimates do not include changes that may be required to other agency systems, such as the Department of Treasury's systems, which are used to perform data entry and automated transmission of passport applications to the Department of State, or to the systems of federal agencies that currently accept automated transmission of ePassport issuance data, including sex marker data, from the Department. Moreover, neither estimate accounts for related policy or regulatory changes that may be required, such as approval of form changes by the Office of Management and Budget, nor do they take into account workflow or resource requirements unrelated to technology.

Alternative Options for Facilitating Plaintiff's International Travel.

16. Without making any modifications to its systems, CA could issue Plaintiff a standard ePassport and address Plaintiff's request to have Plaintiff's sex

identified as “X” through a customized endorsement. An endorsement is an official indication of the circumstances under which a passport was issued or can be used, and can be used to provide relevant information about the passport or its bearer. Such an ePassport would have an “M” or an “F” in the sex field in the VIZ, MRZ, and the chip. This ePassport would be issued through CA’s regular process.

17. CST has also investigated producing for Plaintiff a type of passport known as an Emergency Photo-Digitized Passport (EPDP). An EPDP differs from an ePassport in several ways. For example, it has a shorter validity period, typically one year; fewer visa pages; and can only be printed at overseas posts. An EPDP contains a photograph of the bearer and the bearer’s biographic data within the VIZ and the MRZ. The EPDP lacks an electronic chip containing digitized image and biographic data.

18. As with the ePassport, we have determined in a test environment that it appears to be possible for CA systems administration personnel to override and incorporate “one-time” modifications to change the sex marker in the issuance system’s database to an “X”. This would allow CA to print an EPDP at an overseas post, using modified software, with an “X” in the VIZ and a “<” in the MRZ. Like all EPDPs, this passport would not have an electronic chip, and would require the bearer to renew it more frequently than a standard ePassport. It would take approximately four weeks to produce a one-off EPDP using this technique, including time to test the necessary changes for operational systems. If problems are encountered during testing, the time to produce the EPDP may change.

19. This process would have to be repeated if a replacement EPDP had to be issued for any reason. For example, if the first EPDP was lost or stolen, issuing a replacement EPDP with an “X” sex marker could require as much as four weeks, rather than the next business day standard for issuing an ordinary EPDP. This same process would be used to replace a lost or stolen ePassport issued as described in paragraph 10.

20. As with the ePassport, an “X” sex marker printed on the EPDP would not match the issuance data in CA’s authoritative record systems, which at this time are not capable of accepting an “X” sex marker.

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge and understanding.

Dated: December 3, 2018

A handwritten signature in black ink, appearing to read 'K. Reynolds', is written over a solid horizontal line.

Kenneth J. Reynolds

CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that (1) all required privacy redactions have been made; (2) any paper copies of this document submitted to the Court are exact copies of the version filed electronically; and (3) the electronic submission was scanned for viruses and found to be virus-free.

s/ Lewis S. Yelin
Counsel for Appellants-Defendants

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2019, I electronically filed the foregoing corrected appendix with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Lewis S. Yelin
Counsel for Appellants-Defendants