No. 2017-1460

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, AND THE TRANSGENDER AMERICAN VETERANS ASSOCIATION,

Petitioners,

v.

SECRETARY OF VETERANS AFFAIRS,

Respondent.

On Petition for Review from the United States Department of Veterans Affairs

BRIEF FOR PETITIONERS

ILONA M. TURNER
SHAWN THOMAS MEERKAMPER
TRANSGENDER LAW CENTER
P.O. Box 70976
Oakland, CA 94612
(510) 587-9696

M. DRU LEVASSEUR
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
(212) 809-8585

ALAN SCHOENFELD
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

TARA L. BORELLI
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
730 Peachtree Street NE,
Suite 640
Atlanta, GA 30308-1210
(404) 897-1880

SASHA J. BUCHERT
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
1875 I Street NW
Washington, D.C. 20006
(202) 999-8083

PAUL R.Q. WOLFSON
MICHAEL POSADA
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue
Washington, DC 20006
(202) 663-6390

June 21, 2017

Attorneys for Petitioners

CERTIFICATE OF INTEREST

Counsel for Petitioners, Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association, certifies the following:

1. The full name of every party or amicus represented in this appeal is:

Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association

2. The names of the real parties in interest represented in this appeal are:

Not applicable.

3. The names of all parent corporations and any publicly held companies that own 10 percent of the party represented are:

None.

4. The names of all law firms and the partners or associates that are expected to appear in this appeal for Petitioners are:

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.: Tara L. Borelli, Sasha J. Buchert, M. Dru Levasseur

TRANSGENDER LAW CENTER: Ilona M. Turner, Shawn Thomas Meerkamper

WILMER CUTLER PICKERING HALE AND DORR LLP: Michael Posada, Alan E. Schoenfeld, Paul R.Q. Wolfson

5. The following law firms and counsel formerly appeared in the district court in prior phases of the case:

None.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD

June 21, 2017

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No appeal in this case was previously before this Court or any other court. Petitioners submitted a petition for rulemaking to the U.S. Department of Veterans Affairs ("VA" or "Department") on May 9, 2016.

JURISDICTION

This Court has jurisdiction under 38 U.S.C. §502 to review the denial of a petition for rulemaking. *See Preminger v. Secretary of Veterans Affairs*, 632 F.3d 1345, 1352 (Fed. Cir. 2011). The petition was denied on November 10, 2016, and Petitioners filed a petition for review on January 9, 2017, within 60 days of the denial, as required by Circuit Rule 47.12.

ISSUES PRESENTED

On May 9, 2016, Petitioners filed a petition for rulemaking requesting that the Department amend its regulations excluding "medically necessary sex reassignment surgery for transgender veterans from the[ir] medical benefits package." Appx74. The VA acknowledged receipt but never directly responded to the petition. The VA did respond, however, to inquiries from Members of Congress about its treatment of transgender veterans, stating in a letter that although the VA would "continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available," any rulemaking that would

allow the VA to perform or pay for such treatment is "not imminent." Appx1. The questions presented are:

1. Whether the VA's refusal to initiate rulemaking is subject to judicial review at this time.

2. If so, whether the VA's denial of the petition for rulemaking must be set aside as arbitrary and capricious or because the VA's policy excluding medically necessary sex reassignment surgery from the veterans' benefits package is contrary to constitutional right or otherwise not in accordance with law.

STATEMENT

A. The VA's Medical Benefits Package

Veterans "risk[] both life and liberty in their military service to this country." *Sneed v. Shinseki*, 737 F.3d 719, 728 (Fed. Cir. 2013). In return for their service, the United States provides a comprehensive benefits scheme that is "'imbued with special beneficence from a grateful sovereign.'" *Id.* (quoting *Bailey v. West*, 160 F.3d 1360, 1370 (Fed. Cir. 1998) (en banc) (Michel, J., concurring)). "A veteran, after all, has performed an especially important service for the Nation, often at the risk of his or her own life." *Shinseki v. Sanders*, 556 U.S. 396, 412 (2009).

As part of the benefits scheme, the Secretary of Veterans Affairs is directed to "furnish hospital care and medical services which the Secretary determines to be

needed." 38 U.S.C. §1710. As relevant here, the Secretary has implemented that directive by establishing the veterans' medical benefits package, which "explain[s] what care would and would not be provided to veterans enrolled in the VA healthcare system." Enrollment—Provision of Hospital and Outpatient Care to Veterans, 63 Fed. Reg. 37,299, 37,300 (July 10, 1998). The benchmark for inclusion in the package is generally whether the particular care is "medically needed"—that is, "care that is determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice." *Id.* (codified at 38 C.F.R. §17.38(b)). Applying that definition, the VA regulation establishing the benefits package (the "Regulation") enumerates an array of health care services available to veterans through the VA, including nutrition education, vaccines, surgical care, substance abuse counseling, prescription-drug coverage, bereavement counseling, and prosthetic equipment. 38 C.F.R. §17.38(a); Appx48-50.

B. VA's Exclusion Of Medically Necessary Surgical Procedures For Transgender Veterans

This case involves the VA's decision to exclude specific surgical procedures from its benefits package only when they are used for a specific reason: to relieve a transgender veteran's gender dysphoria by facilitating the veteran's gender transition.

According to recent estimates, there are more than 130,000 transgender veterans of the United States Military, the United States Reserves, and the National Guard. Appx89. Typically, people designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. Appx143. For transgender individuals, the person's gender identity differs from the sex assigned at birth. Appx142-143. The medical diagnosis for the distress that incongruence often causes is gender dysphoria, which major medical associations and diagnostic manuals uniformly recognize as a serious medical condition. Appx143; *see also* Appx305; Appx321. As treatment for gender dysphoria, individuals may undergo a gender transition, which is a "[p]eriod of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role" and "may or may not include feminization or masculinization of the body through hormones or other medical procedures." Appx288. "The nature and duration of transition is variable and individualized." *Id.*

The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People ("Standards of Care"), promulgated by the World Professional Association for Transgender Health, set forth the protocol accepted by medical professionals for the diagnosis and treatment of gender dysphoria. Appx231-298. The Standards of Care—recognized as authoritative by other

professional medical societies, including the American Medical Association, the Endocrine Society, and the American Psychological Association, Appx145—identify the following treatment protocols for individuals with gender dysphoria:

- Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and
- Surgery to change primary and/or secondary sex characteristics (*e.g.*, removal or construction of the breasts, penectomy, vaginoplasty, phalloplasty, and penile and testicular implants), often referred to as sex reassignment surgery.

Appx237.

Major medical associations uniformly recognize sex reassignment surgery as an effective treatment for gender dysphoria—and indeed one that is critical for some transgender individuals. Appx133; Appx147. Although not all individuals

with gender dysphoria require such surgery, the Standards of Care recognize that hormone therapy and psychotherapy may be inadequate to treat severe cases of gender dysphoria. Appx265; Appx146-147. In those cases, failure to provide sex reassignment surgery may cause the patient serious mental and physical health issues—including anxiety, depression, and suicidality. *Id.*

The VA's policies and practices recognize that gender dysphoria is a serious medical condition requiring treatment. *See, e.g.*, Appx1 (November 2016 letter from the VA to members of Congress); Appx305 (VA draft proposed rule regarding "Removing Exclusion of Gender Alterations from the Medical Benefits Package"); Appx321 (impact analysis for proposed rule); Appx330 (memorandum from VHA CFO regarding impact analysis for proposed rule). For that reason, the VA provides mental health counseling and hormone therapy for transgender veterans experiencing gender dysphoria. Appx57-58 (VHA Directive 2013-003). The VA also provides preoperative evaluation for transgender veterans, as well as continuing hormone replacement therapy and postoperative care to veterans who have received sex reassignment surgery outside the VA health care system. *Id*. Indeed, reflecting its commitment to provide medically needed care to transgender veterans, the VA has recently opened clinics in Cleveland and Tucson that specialize in providing medical care to those veterans. Appx89. In addition, the VA Boston Healthcare System has formed the Interdisciplinary Transgender

Treatment Team, which provides medical care tailored to the needs of transgender veterans. *Id*. As the VA also has acknowledged, the agency actually provides "the majority" of the care needed for transgender veterans—without any specific appropriation from Congress. Appx323 (impact analysis for proposed rule).

Nonetheless, the VA categorically refuses to provide sex reassignment surgery, even though it acknowledges that the surgery is now "widely accepted" as "medically necessary" to treat gender dysphoria. *See, e.g.*, Appx1; Appx305; Appx321; Appx330. In particular, the Regulation expressly excludes "[g]ender alterations" from the medical benefits package. 38 C.F.R. §17.38(c)(4). VHA Directive 2013-003 (the "Directive") clarifies that this exclusion constitutes an absolute bar to coverage for "sex reassignment surgery," which the Directive defines to encompass "any of a variety of surgical procedures … done simultaneously or sequentially with the explicit goal of transitioning from one sex to another." Appx57. The excluded procedures include "vaginoplasty and breast augmentation in MtF [male-to-female] transsexuals and mastectomy and phalloplasty in FtM [female-to-male] transsexuals." *Id.* Despite the overwhelming medical consensus that sex reassignment surgery is not cosmetic and is medically necessary for some individuals suffering from gender dysphoria, the Directive puts

such surgery on equal footing with "plastic reconstructive surgery for strictly cosmetic purposes." Appx61.[1]

The VA harbors no medical objection to the *procedures* that constitute sex reassignment surgery. Indeed, it already provides surgeries similar to those that constitute sex reassignment surgery—when done for reasons other than to treat gender dysphoria. Appx53 (VHA Directive 2011-024); Appx324 (impact analysis for proposed rule). For example, the VA offers veterans "[r]econstructive (plastic) surgery required as a result of disease or trauma," Appx49, which under VHA Directive 1091 (Feb. 21, 2014) includes "those surgical procedures performed for the revision of external bodily structures which deviate from normal either from congenital or acquired causes," Appx70. Under 38 C.F.R. §17.38(a)(1)(x) and VHA Directive 1091, the VA offers breast reconstruction to cisgender (*i.e.*, non-transgender) women following a mastectomy, as well as penile and testicular implants to cisgender males whose penises or testes have been damaged.[2]

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[1] As originally promulgated, the Regulation prohibited the surgical implantation of penile prostheses. *See* 63 Fed. Reg. at 37,307. That exclusion was subsequently removed, *see* Enrollment—Provision of Hospital and Outpatient Care to Veterans, 64 Fed. Reg. 54,207, 54,210 (Oct. 6, 1999), and penile prostheses remain available to veterans under the benefits package—so long as the prosthesis is not sought in connection with a veteran's being transgender.

[2] "Cisgender" is a term used to describe a person whose gender identity conforms to the sex assigned at birth—*i.e.*, someone who is not transgender. *See Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1120 n.9 (N.D. Cal. 2015).

Appx87; *see also* Appx49; Appx70. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk. Appx87. The VA also provides orchiectomies, scrotectomies, and penectomies to cisgender males for various medical reasons. Appx87. Yet it denies those same procedures to transgender veterans when needed for purposes of treating gender dysphoria. Finally, VA policy covers surgery for intersex veterans "in need of surgery to correct inborn conditions related to reproductive or sexual anatomy." Appx57; Appx61.[3]

To sum up: The VA recognizes that gender dysphoria is a serious medical condition that requires treatment, and it provides transgender veterans with an array of medically needed care, including preoperative and postoperative care for sex reassignment surgery performed outside the VA system. The VA categorically refuses, however, to provide transgender veterans with health care coverage that includes sex reassignment surgery itself or to pay for it—regardless of the medical

[3] "'Intersex' is an umbrella term used to describe a wide range of natural bodily variations. Intersex people are born with sex characteristics that do not fit conventional binary notions of bodies designated 'male' or 'female.' In some cases, intersex traits are visible at birth, while in others they are not apparent until puberty. Some variations may not be visibly apparent at all." *Zzyym v. Kerry*, 220 F. Supp. 3d 1106, 1110 n.1 (D. Colo. 2016) (quoting plaintiff's complaint); *see also* Ben-Asher, *The Necessity of Sex Change: A Struggle for Intersex and Transsex Liberties*, 29 Harv. J. L. & Gender 51, 51 n.2 (2006) ("The intersex category today covers: (1) chromosomal variations, (2) gonadal variations (atypical ovaries or testes), (3) hormonal variations, and (4) external morphologic variations (genitalia that is neither clearly male nor female).").

need for such surgery in any particular case, and even though it provides substantively identical procedures to intersex veterans and other veterans for various reasons.

C. Treatment Of Sex Reassignment Surgery By Other Agencies, Insurers, And Employers

The VA's position is not only internally incoherent, it also is divorced from an ever-growing consensus among federal and state agencies, insurance carriers, and private businesses regarding coverage for sex reassignment surgery. Perhaps most relevant here, the Defense Department has stated that it would provide sex reassignment surgery (among other transition-related care) to some transgender active-duty servicemembers.[4] Other federal agencies have taken a similar tack. For example, in 2014, the Department of Health and Human Services ("HHS") Departmental Appeals Board overturned a thirty-year-old policy denying Medicare coverage for sex reassignment surgery. *See* Decision No. 2576, HHS Departmental Appeals Board (May 30, 2014); Appx150. The Board deemed the exclusion unreasonable in light of significant and unchallenged contemporary

[4] *See* Kime, *Pentagon to cover sex-reassignment surgery for transgender active-duty troops*, MilitaryTimes, Sept. 19, 2016, http://www.militarytimes.com/articles/defense-department-covers-gender-reassignment-surgery; *see also* U.S. Department of Defense, *Transgender Service in the U.S. Military, An Implementation Handbook* (Sept. 30, 2016); *Interim Guidance for Service of Transgender Navy Personnel*, NAVADMIN 248/16 ("Transition medical treatment differs for each individual and may include any or all of the following: behavioral health counseling, cross-sex hormone therapy, surgery, and real-life experience.").

empirical evidence supporting the safety, effectiveness, and necessity of that treatment for certain individuals with severe gender dysphoria.

More broadly, federal and state agencies have taken a dim view of categorical exclusions for coverage of health services related to gender transition, such as the VA's Regulation. For example, the Office of Personnel Management, recognizing "the evolving professional consensus that treatment may be medically necessary to address … gender dysphoria," stated in a letter to health insurance carriers participating in the Federal Employees Health Benefits Program that no carrier "may have a general exclusion of services, drugs or supplies related to gender transition." Appx92. An increasing number of states, including California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington, as well as the District of Columbia, have adopted similar statutes, rules, and directives prohibiting such categorical exclusions of care. *See* Appx92; Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,189-54,190 (Sept. 8, 2015).[5]

[5] *See also* Delaware Dep't of Ins., Domestic/Foreign Insurers Bulletin No. 86 (Mar. 23, 2016); Haw. Rev. Stat. §§432D, 432:1, 431:10A; Mich. Dep't of Ins. & Fin. Servs., Bulletin 2016-10-INS (Mar. 14, 2016); Mont. Comm'r of Secs. & Ins., Advisory Memorandum: Requirements for Health Plan Form Filings and Qualified Health Plan Certification (Mar. 31, 2016).

Federal courts also have recognized both the seriousness of gender dysphoria, *see Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1*, __ F.3d __, 2017 WL 2331751, at *11 (7th Cir. May 30, 2017); *Evancho v. Pine-Richland Sch. Dist.*, __ F. Supp. 3d __, 2017 WL 770619, at *5 n.12 (W.D. Pa. Feb. 27, 2017); *Board of Educ. of Highland Local Sch. Dist. v. U.S. Dep't of Educ.*, 208 F. Supp. 3d 850, 855 (S.D. Ohio 2016), and the medical need for sex reassignment surgery. The Tax Court, for example, held that expenses associated with the surgery were medically necessary and therefore deductible for federal tax purposes. *O'Donnabhain v. Commissioner*, 134 T.C. 34, 65-70 (2010). Courts have also struck down categorical bans on sex reassignment surgery, deeming them deliberately indifferent to a prisoner's medical needs in violation of the Eighth Amendment. *See, e.g.*, *De'lonta v. Johnson*, 708 F.3d 520, 523, 526 (4th Cir. 2013); *Fields v. Smith*, 712 F. Supp. 2d 830, 863-864 (E.D. Wis. 2010), *aff'd*, 653 F.3d 550 (7th Cir. 2011).

Finally, private businesses and insurance carriers increasingly cover sex reassignment surgery as part of the complement of benefits provided to employees. According to one 2016 study, nearly a third of large employers nationwide include

the surgery as part of their employee health benefits packages.[6] The nation's largest insurers likewise cover surgery.[7]

D. Petitioners' Military Service And Medical Need For Sex Reassignment Surgery

Petitioners Dee Fulcher and Giuliano Silva served with distinction as members of the U.S. Armed Forces. As veterans, they participate in the VA medical benefits package; as transgender veterans, they are deprived by the Regulation of care that their VA health care practitioners have determined is medically necessary as part of their gender transition.

Ms. Fulcher is a veteran of the Marine Corps. Appx116 (affidavit of Dee Fulcher). She received a diagnosis of gender dysphoria from her physician and mental health social worker at the VA, and her clinicians have since recommended that she receive sex reassignment surgery, including a penectomy and a vaginoplasty, as part of her gender transition. Appx118. However, because of the Regulation, Ms. Fulcher cannot receive this prescribed treatment through the VA. *Id.*

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[6] *See* Japsen, *More Employers Cover Transgender Surgery As Politics Shift*, Forbes.com (May 17, 2016).

[7] *See, e.g.*, Aetna Policy No. 0615 (Gender Reassignment Surgery); Anthem Blue Cross Blue Shield Clinical Guideline CG-SURG-27 (Sex Reassignment Surgery); Cigna Medical Coverage Policy No. 0266 (Treatment of Gender Dysphoria); UniCare Clinical Guideline CG-SURG-27 (Sex Reassignment Surgery).

Mr. Silva is a veteran of the U.S. Army. Appx124 (affidavit of Giuliano Silva). He has also received a diagnosis of gender dysphoria from his VA physicians but could not receive necessary sex reassignment surgery as treatment under the Regulation.

Ms. Fulcher and Mr. Silva are members of petitioner Transgender American Veterans Association ("TAVA"), a non-profit organization that advocates for transgender veterans within the VA health care system. Appx111 (affidavit of Evan Young, National President of TAVA); Appx116; Appx124. TAVA works with veterans, active duty servicemembers, Congress, and LGBT organizations to influence VA and military policy, regulations, and procedures regarding the provision of health care to veterans with gender dysphoria. Appx111-112. TAVA members "experience extreme and sometimes life-threatening hardships because they cannot obtain coverage for these health care services that their doctors deem to be medically necessary." Appx114.

E. Agency Proceedings

Pursuant to 5 U.S.C. §553(e), Ms. Fulcher, Mr. Silva, and TAVA submitted a petition for rulemaking on May 9, 2016, requesting that the VA amend or repeal the rules and regulations—including 38 C.F.R. §17.38(c)(4) and any implementing directives—that exclude medically necessary sex reassignment surgery from the medical benefits package. *See* Appx72-109. Petitioners argued that the VA's

policies regarding treatment of transgender veterans were both internally inconsistent and in conflict with the emerging consensus among federal and state agencies concerning coverage for sex reassignment surgery. Appx93-96. Petitioners further argued that the Regulation is arbitrary and capricious and violates the equal protection component of the Fifth Amendment's Due Process Clause because it discriminates against transgender people and is not supported by any rational justification. Appx96-109. The VA acknowledged receipt of the petition but never directly responded to it.

In the spring of 2016—the exact date is unclear from the record—the VA drafted a Notice of Proposed Rulemaking ("NPRM") proposing to amend or repeal the Regulation by removing the exclusion of "gender alterations" from the medical benefits package. Appx305-315. As the draft NPRM explained, that exclusion had been enacted in 1999 on the theory that sex reassignment surgery was "not considered medically needed" for transgender veterans. Appx307. Even if that rationale had been tenable seventeen years earlier, the VA explained, it was no longer consistent with the statute and regulation under which the agency provided the medical benefits package, given intervening medical developments:

> Increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria. Additionally, recent medical research shows that the failure to provide transition

> surgeries to certain patients suffering from gender dysphoria can have severe medical consequences.

Appx305. "In light of these medical advances and the evolving standard of care," the NPRM explained, the VA "propose[d]" to "revise its medical benefits package regulation to remove this exclusion." *Id.* With the exclusion removed, "the treating VA healthcare provider [could] determine, in the exercise of his or her clinical judgment, that such services are medically necessary in a particular clinical case and so offer them to the patient." Appx308.

In the summer of 2016—again, the precise date is not clear from the record—the VA announced that it would include the NPRM in the Fall 2016 Unified Agenda for Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the federal government. *See* Appx1.

In conjunction with the draft NPRM, the VA conducted an economic impact analysis of the proposed removal of the exclusion for sex reassignment surgery. Appx320-330. It concluded that projected costs for 2018-2020 would be approximately $18 million, depending on patient interest in and awareness of the procedures. Appx329. Given that the VA already provided certain aspects of transition-related care, the analysis observed that "[f]ortunately, the addition of medically necessary transition-related procedures is viewed as an event-based expense per unique veteran, rather than ongoing medical expense to the system."

Appx323. That is, the VA would incur no incremental fixed costs, but only the expense associated with each procedure sought and provided.

Moreover, the analysis observed that those costs might be offset by efficiencies introduced by the VA's provision of sex reassignment surgery through its own network of providers. *See* Appx327. For example, the VA explained that "[m]any Veterans" had undergone sex reassignment surgery abroad, with little or no planned post-surgical care. *Id*. That arrangement not only imposed significant hardship on the affected veterans—requiring them, for example, to "sit[] on the surgical site for an extended airline trip" and consequently requiring visits to VHA emergency rooms, *id.*—but also imposed significant cost on the VA: Because the VA provides post-surgical care regardless of where the surgery takes place, it is obligated to address—and bear the financial consequence of—"post-operative complications related to international travel from surgical centers and poor surgical care." *Id.* By removing the exclusion, the analysis explained, "these types of complications can be reduced and continuity of care will be enhanced." *Id.* The agency further explained that "transition-related surgery has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the [VA]." *Id.*

The chief financial officer of the Veterans Health Administration concurred in the financial analysis. Appx330.

During the summer and fall of 2016, Members of Congress sent letters to the VA requesting information about the status of the proposed rulemaking. Some wrote to the VA to express "serious concerns" about the proposal to cover sex reassignment surgery. Appx316-319. Those Members argued that the provision of non-service-connected medical care to veterans was "misguided" given "challenges" the VA was facing "in delivering health care to those veterans whose service directly resulted in their need for medical treatments." Appx316. (Those Members did not take issue, however, with the fact that the VA provides extensive care for non-service-connected conditions to veterans.) Others wrote to urge the VA to move forward on the proposed NPRM. Appx331-336. Those Members emphasized that other federal agencies "recognized [a] de minimis fiscal impact in findings in final regulations prohibiting such exclusions [of sex reassignment surgery] for Marketplace health plans and for employee plans of federal contractors." Appx334.

On November 10, 2016, the VA sent an identical letter to each of the 47 Members of Congress who had written to the agency about the NPRM. Appx1-47. Signed by respondent David J. Shulkin, M.D.—then the Under Secretary for Health and now the Secretary of Veterans Affairs—the letter acknowledged both that the VA "currently provides many services for transgender Veterans to include hormone therapy, mental health care, preoperative evaluation, and long-term care

following sex reassignment surgery," and that "[i]ncreased understanding of both gender dysphoria and surgical techniques in this area has improved significantly and is now widely accepted as medically necessary treatment." Appx1. The letter nonetheless disclosed that the VA was withdrawing the NPRM from the Fall 2016 Unified Agenda. *Id.* Then-Under Secretary Shulkin explained that the "VA has been [exploring] and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package," but only "when appropriated funding is available." *Id.* Any future rulemaking on the subject, moreover, was "not imminent." *Id.*

On January 19, 2017, after the petition for review was filed in this Court, the VA reissued VHA Directive 2013-003, reiterating the Department's categorical position that "[s]ex reassignment surgery cannot be performed or funded by VA." Appx57. According to the reissued Directive, this is the VA's position until at least February 28, 2018. *Id.*

SUMMARY OF ARGUMENT

I. The VA has denied the petition for rulemaking, and that final agency action is ripe for this Court's review. In official correspondence between the agency and Congress, the VA stated unequivocally that it does not intend to engage in rulemaking. That correspondence reflects both the consummation of the agency's decisionmaking process and the agency's definitive decision to deny the

petition. Nothing more is required to present agency action for this Court's review. If this Court determines that the November 10 letter was not a denial, then the Court should nonetheless compel the VA to engage in rulemaking because the agency's one-year delay is unreasonable and unjustified. The agency has no basis for further delay, which will result in grave harm to the transgender veterans affected by the Regulation.

II. This Court should set aside the denial and compel the VA to engage in rulemaking. First, the agency's action is arbitrary and capricious. The VA's proposed rulemaking materials in the record, as well as its own policies, indicate that the VA understands the medical necessity of sex reassignment surgery—yet the VA has refused to engage in rulemaking to address the inconsistency caused by its policy of refusing to provide that surgery. The VA's stance is also directly contrary to the medical community's understanding that sex reassignment surgery is a medically necessary treatment for gender dysphoria, an understanding that an ever-growing number of courts have embraced. In its letter to Members of Congress, the VA claimed that it requires "appropriated funding" to engage in rulemaking, but there is no support for that claim. In fact, the proposed rulemaking materials and other documents considered by the agency in the record undermine the VA's proffered reason for the denial.

III. The VA's denial of the petition should also be set aside on the independent ground that the Regulation discriminates against transgender veterans on the basis of sex and transgender status, in violation of both the equal protection component of the Fifth Amendment's Due Process clause and Section 1557 of the Affordable Care Act. Although the VA provides medically necessary care to non-transgender veterans, it withholds substantially similar medically necessary procedures from transgender veterans on the basis of their sex and transgender status alone. Numerous courts have held that discrimination against transgender individuals is discrimination on the basis of sex or transgender status and that classifications based on transgender status (like those based on sex) are suspect and thus subject to strict or at least heightened scrutiny. Regardless of the level of scrutiny applied, the Regulation cannot survive because the VA cannot present any government interest—including cost considerations—to justify it. Accordingly, the VA's denial should be set aside, the VA should be compelled to engage in rulemaking to protect and preserve the health of transgender veterans.

STANDARD OF REVIEW

This Court will set aside an administrative agency's denial of a petition for rulemaking if the denial was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Preminger v. Secretary of Veterans Affairs*, 632 F.3d 1345, 1353 (Fed. Cir. 2011) (quoting *Massachusetts v. EPA*, 549

U.S. 497, 527-528 (2007)); *see also* 5 U.S.C. §706(2)(A). A reviewing court must ensure that "'the [agency] has adequately explained the facts and policy concerns it relied on and … satisfy [itself] that those facts have some basis in the record.'" *Preminger*, 632 F.3d at 1353 (citation omitted). In addition, this Court must "hold unlawful and set aside" any VA action "contrary to constitutional right." 5 U.S.C. §706(2)(B); *see also Griffin v. Secretary of Veterans Affairs*, 288 F.3d 1309, 1317 (Fed. Cir. 2002).

ARGUMENT

I. THE VA HAS DENIED THE PETITION FOR RULEMAKING

The Secretary's November 10 letter makes clear that the VA has denied the petition for rulemaking. That denial is final agency action susceptible to this Court's review.

A. The November 2016 Letter Demonstrates That The VA Has Denied The Petition For Rulemaking

As the Supreme Court has explained, for agency action to be "final" and therefore fit for judicial review, "the action must mark the 'consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature" and "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177-178 (1997) (citations omitted); *see also Systems*

Application & Techs., Inc. v. United States, 691 F.3d 1374, 1384 (Fed. Cir. 2012). The VA's November 10, 2016 letter satisfies both requirements.

The letter reflects the consummation of the agency's decisionmaking process. By mid-2016, the VA had drafted an NPRM, conducted an extensive internal analysis to gauge the proposed rule's financial impact, and undertaken to include the NPRM in the Fall 2016 Unified Agenda. *See supra* pp. 15-16. The November 2016 letter announced conclusively that the draft NPRM had been withdrawn from the Unified Agenda and that any future rulemaking was "not imminent." Appx1. The subsequently reissued VHA Directive 2013-003 confirmed that the ban on coverage for sex reassignment surgery would remain through at least February 28, 2018. Appx56. In short, all the preliminary steps necessary to engage in rulemaking had been completed, and yet the agency made the decision not to go forward.

Nothing more is required to finalize the agency's determination. The absence of any formal statement that the petition was denied is immaterial. *WildEarth Guardians v. Salazar*, 741 F. Supp. 2d 89, 104 (D.D.C. 2010). Nor does it matter that the VA did not foreclose the possibility of future regulatory action. An agency cannot render its decision non-final by promising to consider the issue again at some future point. *See Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1037-1038 (D.C. Cir. 2002) ("[T]he Commission argues that the *1998*

Report is not final because the agency intends to continue considering the ownership rules. That, however, does not mean the determination is not 'final' as a matter of law."), *opinion modified in part on reh'g on other grounds*, 293 F.3d 537 (D.C. Cir. 2002); c*f. Henley v. FDA*, 873 F. Supp. 776, 783, 786 (E.D.N.Y. 1995) (reviewing FDA denial of a petition for rulemaking that expressly left open the possibility of different agency action in the future), *aff'd*, 77 F.3d 616 (2d Cir. 1996).

A particularly instructive decision on this point is *National Parks Conservation Association v. United States Department of Interior*, 794 F. Supp. 2d 39 (D.D.C. 2011). Citing unreasonable delay, the plaintiffs there moved to compel a response from two federal agencies after receiving letters from the agencies opining that the existing regulations adequately addressed the plaintiffs' concerns and that the agencies reserved the right to revisit their determinations in the future if necessary. *Id.* at 43-44. The court found that it was "clear from the face of the response letters … that [the agencies] have reached a 'definitive decision' to deny Plaintiffs' petitions." *Id.* at 45. The court also rejected the plaintiffs' argument that the possibility of undetermined future action rendered their responses non-final: "Although it is true that [the agencies] left open the possibility that they may initiate the type of rulemaking Plaintiffs want in the future," the court explained,

"they have also made clear that they are denying Plaintiffs' petitions at this time." *Id.* at 46.

Likewise here, the VA has reached a "definitive decision" to deny the petition for rulemaking "at this time," and the agency's suggestion that it might reinitiate rulemaking "when appropriated funding is available" does not somehow make its denial non-final. That conclusion is underscored by the VA's January 2017 decision to reissue VHA Directive 2013-003, reiterating the categorical exclusion of sex reassignment surgery from the medical benefits package and declaring, again, that this would be the agency's policy at least through February 28, 2018. *See supra* p. 19. In other words, having withdrawn its proposed rulemaking in November 2016, the VA elected to reconfirm its policy in January 2017. That is final (indeed, decisive) agency action. Were it otherwise, an agency could perpetually evade judicial review of denials of petitions for rulemaking merely by suggesting that it would revisit issues at an unspecified time in the future.

Any argument that the November 2016 letter was mere correspondence and thus does not reflect a final denial of the petition for review would be meritless. Courts regularly review denials of petitions for rulemaking embodied in correspondence. *See American Horse Prot. Ass'n, Inc. v. Lyng*, 812 F.2d 1, 5 (D.C. Cir. 1987) (reviewing a denial in the form of letters to the plaintiff

association and two litigation affidavits provided by an agency officials); *Henley*, 873 F. Supp. at 780, 783 (reviewing an agency's letters denying the petition and affirming denial on reconsideration). Although in those cases the correspondence was directed to the petitioning party or expressly referred to the petition (or both), that distinction is not meaningful. A letter to Congress by a high-ranking agency official, after all, is not just any correspondence; it is an official act by the agency with respect to another branch of government. The letter here reflects an authoritative statement of the VA's position, sent in response to official inquiries by Members of Congress specifically regarding the NPRM, all of which were sent after Petitioners filed their petition. That the VA chose to state its denial of the petition by writing to Congress rather than responding directly to Petitioners (as it should have) does not render its decision any less final.

B. At A Minimum, The VA's Year-Long Delay In Addressing The Petition Is Unreasonable

Even if the Court concludes that the November 2016 letter did not finally deny the petition, it should nonetheless compel the VA to act. Under the Administrative Procedure Act, an agency is required to proceed on a matter before it "within a reasonable time." 5 U.S.C. §555(b). If the agency fails to do so, a reviewing court "shall … compel agency action." *Id.* §706(1).

1. "[T]here is no per se rule as to whether a given delay is reasonable"; rather, "courts must determine the reasonableness of delay based on the totality of

the circumstances." *Families for Freedom v. Napolitano*, 628 F. Supp. 2d 535, 541 (S.D.N.Y. 2009). Relevant factors in making that determination include not only the length of time elapsed, but also whether the relevant statute provides any justification; the nature and extent of the interests prejudiced by the delay—and in particular whether the delay affects economic interests or health and welfare; and the effect that compelling agency action will have on other agency priorities. *See Telecommunications Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984). A court need not find ill motive behind the delay in order to hold that a delay is unreasonable. *Id*.

Here, all the factors support a finding of unreasonable delay. First, even if the VA has not officially denied the petition, it nonetheless has failed to act for more than a year. That is unreasonable given that the VA was able to draft a proposed rulemaking and conduct an impact analysis within a few months of receiving the petition. The VA has received and prepared all necessary materials to respond to the petition but has nonetheless unjustifiably failed to provide any indication as to when it may respond. *See Khan v. Johnson*, 65 F. Supp. 3d 918, 929 (C.D. Cal. 2014) ("Courts have … been less likely to favor the government … when [it] has 'fail[ed] to provide any indication of when' adjudication of the application might take place.").

Second, there is no basis in either 38 U.S.C. §1710 or the Regulation warranting the VA's prolonged delay in responding to the petition. Indeed, the delay is antithetical to the relevant statute's goal of providing veterans with medically needed care. *Cf. Public Citizen Health Research Grp. v. Commissioner, FDA*, 740 F.2d 21, 34 (D.C. Cir. 1984) ("In response to a request that the court 'compel agency action … unreasonably delayed' pursuant to 5 U.S.C. §706(1), the court should review the pace of the agency decisional process to ensure that it is not lagging unreasonably in light of the nature and extent of public health considerations." (ellipsis in original)).

Third, the delay worsens "grave health and safety problems for the intended beneficiaries of the statutory scheme." *National Customs Brokers & Forwarders Ass'n of America, Inc. v. United States*, 883 F.2d 93, 103 (D.C. Cir. 1989). The VA's own documents reflect the agency's recognition of the severe health concerns implicated by the Regulation. In particular, the VA has concluded based on sound medical authority that failure to provide sex reassignment surgery when it is medically indicated "can lead to serious medical problems, including 'clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death.'" Appx308-309 (draft NPRM); *see also* Appx327 (VA economic impact analysis for draft NPRM stating that "transition-related surgery

has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the [VA].”). While the agency delays, therefore, transgender veterans are denied critical medical care—in contravention of both Congress’s statutory directive, and the agency’s own regulatory goal of providing medical care “to promote, preserve, or restore the health of the individual.” 38 C.F.R. §17.38(b).

Lastly, the VA has no plausible claim that addressing the petition will unduly burden the agency or divert its resources. The Department has already laid the groundwork for the rulemaking by drafting the NPRM and conducting a thorough financial impact analysis. Only minor work remains to be done to formally initiate the rulemaking.

2. The ordinary remedy for an agency’s unreasonable delay in responding to a petition for rulemaking is for the Court to direct a response. *See, e.g.*, *McHugh v. Rubin*, 220 F.3d 53, 61 (2d Cir. 2000); *Families for Freedom*, 628 F. Supp. 2d at 541. Such an order would be futile here, however. As discussed, the VA has unambiguously decided—as announced in public correspondence with Congress—not to initiate a rulemaking. Hence, “[a] remand to the agency for further proceedings would serve no purpose and would only add to the delay already encountered.” *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D.D.C. 1986). This Court should therefore simply direct the VA to initiate rulemaking.

Cf. 5 U.S.C. §555(b) ("With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency *shall proceed to conclude* a matter presented to it." (emphasis added)).

As the court explained in *Heckler*, courts will "overturn an agency judgment not to institute rulemaking … 'if a significant factual predicate of a prior decision on the subject (either to promulgate or not to promulgate specific rules) has been removed.'" 653 F. Supp. at 1241 (quoting *WWHT, Inc. v. FCC*, 656 F.2d 807, 818 (D.C. Cir. 1981)). Those admittedly "rare and compelling circumstances," *id.*, are present here. The draft NPRM explains that the exclusion of sex reassignment surgery from the medical benefits package was based on the VA's 1999 view that surgery was "not considered medically needed." Appx307. That "factual premise" has now been removed; the VA acknowledges that "surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria." Appx305. Because "[t]here is no longer any question of fact as to whether" sex reassignment surgery is medically needed in some cases, *Heckler*, 653 F. Supp. at 1241, this Court should order the VA to initiate rulemaking to reconsider its categorical exclusion of such surgery from the medical benefits package.

II. THE VA'S DENIAL OF THE PETITION FOR RULEMAKING IS ARBITRARY AND CAPRICIOUS

An agency's denial of a petition for rulemaking is reviewed under the familiar Administrative Procedure Act standard to determine "whether the agency's decision was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Preminger v. Secretary of Veterans Affairs*, 632 F.3d 1345, 1353 (Fed. Cir. 2011) (quoting *Massachusetts v. EPA*, 549 U.S. 497, 526-527 (2007)). Although "an agency's refusal to institute rulemaking proceedings is at the high end of the range of levels of deference given to agency action under th[at] standard," the Court must nonetheless ensure that the agency "has adequately explained the facts and policy concerns it relied on and … that those facts have some basis in the record." *Id.* (alteration in original) (citation omitted). "In other words, a court 'look[s] to see whether the agency employed reasoned decisionmaking in rejecting the petition.'" *Id.* (alteration in original) (citation omitted); *see also Service Women's Action Network v. Secretary of Veterans Affairs*, 815 F.3d 1369, 1374 (Fed. Cir. 2016); *Level the Playing Field v. FEC*, __ F. Supp. 3d __, 2017 WL 437400, at *11 (D.D.C. Feb. 1, 2017) (applying quoted standard and remanding to the agency for reconsideration of petition).

The VA's unreasoned denial of Petitioners' rulemaking request is arbitrary and capricious. As the VA recognized when it was poised to open a rulemaking in this matter, the Regulation and its implementing directives are inconsistent with

the statute requiring the agency to provide for veterans' medically necessary care. Appx305. The VA's regulatory exclusion of sex reassignment surgery from the medical benefits package contradicts accepted medical standards as well as the agency's professed goal of promoting, preserving, and restoring veterans' health. The VA's only proffered justification for maintaining the exclusion—that "appropriated funding" is not yet available—is unsupported by the record and in any event insufficient. The VA conducted a comprehensive financial analysis of a proposed rule to remove the exclusion for sex reassignment surgery. That analysis recognized that the projected cost entailed in offering sex reassignment surgery to veterans would be relatively minor and that the VA would realize cost savings from doing so. That analysis also included a proposed three-year cost-allocation pilot designed to better understand the costs (and, presumably, any offsetting financial benefits) associated with providing sex reassignment surgery. Appx326. Having previously proposed a pilot program without any mention of the need for appropriations, the VA cannot now be heard to claim that providing sex reassignment surgery simply cannot be done without specific appropriated funds.

A. The VA's Denial Of The Petition Is Unreasoned

In determining whether an agency's action was arbitrary and capricious, the Court asks "'whether the agency employed reasoned decisionmaking in rejecting the petition.'" *Service Women's Action Network*, 815 F.3d at 1374 (citation

omitted). Here, the answer is no, because the relevant facts, factors, and policy concerns all militate in favor of amending the Regulation to remove the exclusion for sex reassignment surgery—and, at a minimum, in favor of opening a rulemaking to receive comments on such a proposal.

1. The Regulation is contrary to the statutory directive to provide "needed" care to veterans

As the VA acknowledges, 38 U.S.C. §1710 "requires VA to 'furnish hospital care and medical services which the Secretary determines to be needed' for eligible veterans." Appx306-307 (draft NPRM (quoting statute)). The agency has implemented that statutory directive by providing an operative definition of the statutory term "needed"—namely "medically needed," which the agency in turn defines to mean "care that … appropriate healthcare professionals [determine] to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice." Appx307 (alteration in original) (quoting 63 Fed. Reg. 37,299, 37,300 (July 10, 1998)); *see also* 63 Fed. Reg. at 37,300 ("The Secretary has authority to provide healthcare as determined to be medically needed." (citing 38 U.S.C. §1710)).

As the draft NPRM explained, the exclusion of sex reassignment surgery was introduced in 1999 based on the view that the surgery was "not considered medically needed." Appx307. That rationale, the VA recognizes, has now been thoroughly debunked: "[M]ultiple medical professional organizations, including

the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the American Congress of Obstetricians and Gynecologists, and the World Professional Association for Transgender Health have all issued statements affirming that transition surgery is medically necessary care for some patients." Appx309. Yet the VA's categorical exclusion of sex reassignment surgery remains in place, even as "other provisions of this regulation have been modified over the years." Appx307.

The VA's recognition that sex reassignment surgery is sometimes medically necessary is consistent with a wall of medical authority on the point. "Indeed, every psychiatric reference text that has been established as authoritative in this case endorses sex reassignment surgery as a treatment for [gender dysphoria] in appropriate circumstances," and "[n]o psychiatric reference text has been brought to the Court's attention that fails to list, or rejects … sex reassignment surgery as the accepted treatment regimen for [gender dysphoria]." *O'Donnabhain*, 134 T.C. at 65-66; *see supra* pp. 4-6. In recognition of that medical consensus, multiple federal agencies—including the Department of Defense—have either expressed a willingness to provide sex reassignment surgery for covered transgender people or direct participating providers or insurance carriers to do so in appropriate cases. *See supra* p. 10. A growing number of state agencies take the same approach (*see*

supra p. 11), as do an increasing number of private businesses and insurance carriers. Yet the VA clings to its categorical exclusion.

As this Court has explained, even under the "narrow" scope of review applicable to an agency's denial of a petition for rulemaking, the "'agency's decision not to initiate a rulemaking'" will be set aside where there has been "'a fundamental change in the factual premises previously considered by the agency.'" *Service Women's Action Network*, 815 F.3d at 1375 (citation omitted). Those circumstances are clearly met here, as the agency itself has recognized that the factual premise for its current regulation—which it reissued after denying the petition for rulemaking—has been "fundamental[ly] change[d]." *Id.* The VA's decision to deny the petition should be set aside for this reason alone.

2. The VA's illogical approach to transition-related care is arbitrary and capricious

The Regulation and its implementing directives are independently arbitrary and capricious because they result in a regimen for transition-related care that is incoherent and contrary to the VA's professed goal of promoting, preserving, and restoring veterans' health. As explained (*see supra* pp. 6-7), the VA recognizes that gender dysphoria is a serious medical condition that requires treatment—including, in some cases, sex reassignment surgery. The VA accordingly provides transgender veterans with treatments such as "hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-

term care following sex reassignment surgery to the extent that the appropriate health care professional determines that the care is needed to promote, preserve, or restore the health of the individual." Appx53. The VA categorically refuses, however, to provide transgender veterans with sex reassignment surgery—irrespective of the medical need for it in a particular case, and notwithstanding that it provides substantively identical procedures to intersex veterans and to other veterans for various reasons. *Id.* The rulemaking petition expressly challenged that irrational state of affairs, and the VA's denial offered no justification for this irrationality. That failure to adequately explain or defend the agency's regime warrants setting aside the denial.

Moreover, as the VA recognized in the draft NPRM, the Regulation strips VA clinicians of the ability to determine whether sex reassignment surgery is medically necessary on a case-by-case basis. Because that categorical bar is contrary to "the medical literature," the VA proposed that "surgical procedures currently available to aid individuals in gender transitioning may be reasonably determined by a treating VA healthcare provider to be … in accord with generally accepted standards of medical practice." Appx308. "In other words, we would permit the treating VA healthcare provider to determine, in the exercise of his or her clinical judgment, that such services are medically necessary in a particular clinical case and so offer them to the patient." *Id.* The agency's denial of the

rulemaking petition means that notwithstanding the VA's apparent recognition that the categorical exclusion runs contrary to medical judgment, it remains in place.

The VA's decision to maintain that exclusion is not only unreasoned, but also contrary to a line of cases holding that categorical bans on sex reassignment surgery are improper because they refuse medically necessary treatment. Several courts have held these bans invalid because they preclude an "individualized medical evaluation" of the need for sex reassignment surgery, contrary to "prudent professional standards" and the Standards of Care. *Fields*, 712 F. Supp. 2d at 858-862 (internal quotation marks omitted); *see also De'lonta*, 708 F.3d at 523, 526 ("[J]ust because Appellees have provided De'lonta with *some* treatment consistent with the [gender dysphoria] Standards of Care, it does not follow that they have necessarily provided her with *constitutionally adequate* treatment."). The VA's refusal to reconsider its contrary view is arbitrary and capricious.

B. The VA's Proffered Reason For Denying The Petition Is Meritless

The VA denied the petition on the sole ground that it would wait until "appropriated funding is available." Appx1. That is inadequate.

To the extent the VA means to say that it cannot even initiate the rulemaking process absent funding, that is incorrect. The VA does not require any additional funding to issue an already-drafted NPRM, solicit and respond to comments, and issue a final rule. In fact, given that all the groundwork—including the proposed

rule and financial impact analysis—has been laid, lack of funding is a particularly illegitimate reason to refuse even to open the rulemaking process.

If the VA instead means that it cannot or will not undertake a rulemaking because funding is not yet available to cover the expected demand for sex reassignment surgery in the event the categorical exclusion is removed, that justification fails because it has no basis in the record.

First, as explained, the agency recognizes the medical needs of transgender veterans and has provided transition-related care for years—without the need for specific rulemaking or appropriations from Congress. The VA offers no explanation why appropriated funding is uniquely warranted to provide transgender veterans with sex reassignment surgery. That is particularly the case in view of the agency's determination that "the addition of medically necessary transition-related procedures is viewed as an event-based expense per unique veteran, rather than ongoing medical expense to the system." Appx323 (economic impact analysis). The VA has not explained why specific appropriated funds are necessary to cover this incremental event-based expense.

Second, as also discussed, the VA already provides procedures substantially similar to those constituting sex reassignment surgery, so long as the medical need is not related to a veteran's gender transition. *See supra* pp. 8-9. The VA thus will not need to develop new technologies or acquire new equipment to meet the needs

of transgender veterans. This further undermines the agency's apparent position that removing the categorical bar would impose some material cost on the agency that demands specifically appropriated funds.

Third, the VA's own financial analysis of the proposed rule—drafted by agency staff and concurred in by the CFO of the Veterans Health Administration—concluded that projected costs for 2018 through 2020 would be approximately $18 million. Appx329. That figure represents less than 0.01% of the VA's $186.5 annual budget for 2018, far too little to justify withholding medically necessary care.[8] Moreover, as the financial analysis makes clear, that figure would likely be offset substantially by eliminating costs associated with (1) serious health consequences from untreated gender dysphoria and (2) post-operative care needed by veterans who receive sex reassignment surgery from non-VA (and often low-quality) providers. Appx327. Confirming this point, the petition cited a recent analysis demonstrating that the upfront costs of sex reassignment surgery would be far outweighed by these savings. Appx95. Yet the VA denied the petition without

[8] *Annual Budget Submission*, Office of Budget, U.S. Department of Veterans Affairs, https://www.va.gov/budget/products.asp (last visited June 18, 2017) ("The President's 2018 Budget includes $186.5 billion in budget authority for VA in 2018. This includes $82.1 billion in discretionary resources and $104.3 billion in mandatory funding."); Rein, *Veterans Affairs budget is in line to grow by 6 percent*, The Washington Post (Mar. 16, 2017), http://wapo.st/2muumtJ?tid=ss_mail ("[President Trump's] first spending plan would boost VA's budget by $4.4 billion, to $78.9 billion.").

making any effort to reconcile the projected costs and financial benefits of removing the exclusion. *Cf. Heckler*, 653 F. Supp. at 1239 ("No evidence has been presented which shows that to additionally require the regulation of certified raw milk, contrary to the Secretary's bare assertion that resources will be diverted from truly national problems, will impose a significant burden on the agency's budget or personnel."). While an agency has "broad discretion" in its decision to engage in rulemaking, that discretion "should not be construed as providing a blanket exception to APA review in any matter involving the allocation of agency resources." *Compassion Over Killing v. U.S. Food & Drug Administration*, 849 F.3d 849, 857 (9th Cir. 2017). Thus, "[i]n denying a petition for rulemaking, an agency must, at a minimum, clearly indicate that it has considered the potential problem identified in the petition and provide a 'reasonable explanation as to why it cannot or will not exercise its discretion' to initiate rulemaking." *Id.* Here, the VA has failed to provide any reasonable explanation of why the minimal costs involved in providing sex reassignment surgery require denial of the petition, particularly in view of the corresponding efficiencies and offsets.

III. THE VA'S DENIAL OF THE PETITION MUST BE SET ASIDE BECAUSE THE REGULATION DISCRIMINATES AGAINST TRANSGENDER VETERANS

This Court must "hold unlawful and set aside" any VA action that is either "contrary to constitutional right" or otherwise "not in accordance with law." 5 U.S.C. §706(2)(A), (B). That mandate provides an independent basis to invalidate

the VA's denial of the petition, because the Regulation and its implementing directives discriminate against transgender veterans on the basis of sex and transgender status, in violation of both the equal protection component of the Fifth Amendment's Due Process Clause and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116.

A. The Regulation Discriminates On The Basis Of Sex And Transgender Status

The Regulation and its implementing directives deny transgender veterans medically necessary care that is available to non-transgender veterans to meet their medical needs. Under the Regulation, for example, a transgender woman may not receive vaginoplasty through the medical benefits package if it is intended to treat her gender dysphoria. *See supra* p. 7. By contrast, the VA would provide a cisgender woman that same procedure to treat an array of medical needs, including for "genital reconstruction due to blast injuries." Appx324 (economic impact analysis). That differential treatment is plainly discriminatory. *See*, *e.g.*, *Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1120 (N.D. Cal. 2015) (California regulation is "facially discriminatory because it explicitly distinguishes between treatment for transsexual women that is designated as presumptively 'not medically necessary' … and the same treatments for non-transgender women …, which are explicitly exempted from this bar"); *Denegal v. Farrell*, No. 1:15-cv-01251, 2016 WL 3648956, at *7 (E.D. Cal. July 8, 2016) (plaintiff stated equal

protection claim based on allegation that prison "discriminate[d] against transgender women by denying surgery (vaginoplasty) that is available to cisgender women"); *Cruz v. Zucker*, 195 F. Supp. 3d 554, 581 (S.D.N.Y. 2016) (holding that a state's blanket ban on sex reassignment procedures constituted a "categorical exclusion on treatments of gender dysphoria" and discriminated on the basis of "sex"), *modified in part on reconsideration*, 218 F. Supp. 3d 216 (S.D.N.Y. 2016). Excluding from coverage procedures necessary for "gender alteration"—which by definition only transgender veterans would use—imposes a distinct and discriminatory burden on transgender people. *See, e.g., International Union v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991) (company's "use of the words 'capable of bearing children' … as the criterion for exclusion … must be regarded, for Title VII purposes, in the same light as explicit sex discrimination").

1. Discrimination based on a person's transgender status is itself discrimination based on sex. The decision to treat a woman who is transgender differently from a woman who is cisgender is necessarily taken on the basis of whether the woman's gender matches her sex assigned at birth, and is thus based on sex. *See Macy v. Holder*, No. 0120120821, 2012 WL 1435995, at *7 (EEOC Apr. 20, 2012) ("When an employer discriminates against someone because the person is transgender, the employer has engaged in disparate treatment 'related to the sex of the victim.'" (citing *Schwenk v. Hartford*, 204 F.3d 1187, 1202 (9th Cir.

2000))). Thus, as both agencies and courts have recognized, "discrimination based on transgender status" is "cognizable" as a form of "sex discrimination." *Id.* at *4.

Moreover, "discrimination against a transgender individual on the basis of an intended, ongoing, or completed gender transition is literally discrimination because of [that person's] sex." *Macy*, 2012 WL 1435995, at *14 n.10 (internal quotation marks omitted). As the EEOC has explained, analogizing religious conversion to gender transition:

> Imagine that an employee is fired because she converts from Christianity to Judaism. Imagine too that her employer testifies that he harbors no bias toward either Christians or Jews but only "converts." That would be a clear case of discrimination "because of religion." No court would take seriously the notion that "converts" are not covered by the [antidiscrimination] statute. Discrimination "because of religion" easily encompasses discrimination because of a change of religion.

Macy, 2012 WL 1435995, at *11 (citing *Schroer v. Billington*, 577 F. Supp. 2d 293, 306 (D.D.C. 2008)). By the same rationale, discrimination against a person on account of his or her transition from male to female or female to male is definitionally discrimination "because of sex."

Here, the VA provides certain procedures to veterans to treat an array of medical needs—except for needs associated with gender transition. Discriminatory treatment based on gender transition—as on the face of the Regulation's exclusion for "gender alterations"—is direct evidence of sex discrimination. *See Glenn v. Brumby*, 663 F.3d 1312, 1320-1321 (11th Cir. 2011)

("Brumby['s] admitt[ing] that his decision to fire Glenn was based on 'the sheer fact of the transition' … provides ample direct evidence to support the district court's conclusion" that sex discrimination occurred; "If this were a Title VII case, the analysis would end here."); *Schroer*, 577 F. Supp. 2d at 306 ("[T]he Library's refusal to hire Schroer after being advised that she planned to change her anatomical sex by undergoing sex reassignment surgery was *literally* discrimination 'because of … sex.'"); *Macy*, 2012 WL 1435995, at *5 (discrimination claim based on "gender transition/change of sex" was "simply [a] different way[] of stating the same claim of discrimination 'based on … sex,' a claim cognizable under Title VII"); *see also Chavez v. Credit Nation Auto Sales, LLC*, 641 F. App'x 883, 890-892 (11th Cir. 2016) (employer's concerns about employee's "gender transition" sufficient to demonstrate pretext for discrimination on the basis of sex).[9]

[9] As the EEOC's decision in *Macy* explains, while there are several different ways to view discrimination against transgender people as a form of sex discrimination, each constitutes "disparate treatment 'related to the sex of the victim.'" *Macy*, 2012 WL 1435995, at *7 (quoting *Schwenk*, 204 F.3d at 1202). In particular, the same conclusion obtains "regardless of whether an employer discriminates against an employee because the individual has expressed his or her gender in a non-stereotypical fashion, because the employer is uncomfortable with the fact that the person has transitioned or is in the process of transitioning from one gender to another, or because the employer simply does not like that the person is identifying as a transgender person." *Id.*

Finally, under a distinct but related theory, the First, Sixth, Seventh, Ninth, and Eleventh Circuits have recognized that discrimination against transgender individuals is impermissible discrimination because of sex under the Equal Protection Clause of the Constitution and federal civil rights statutes. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1*, __ F.3d __, 2017 WL 2331751, at *9-11 (7th Cir. May 30, 2017); *Glenn*, 663 F.3d at 1316-1320; *Smith v. City of Salem*, 378 F.3d 566, 572-575 (6th Cir. 2004); *Rosa v. Park W. Bank & Trust Co.*, 214 F.3d 213, 215-216 (1st Cir. 2000); *Schwenk*, 204 F.3d at 1200-1203. As these courts have explained, discrimination on the basis of sex encompasses disparate treatment based on an individual's nonconformity with assumptions about how men and women should look and behave. *See, e.g.*, *Price Waterhouse v. Hopkins*, 490 U.S. 228, 250-252 (1989). Because transgender individuals' "outward behavior and inward identity do not meet social definitions" associated with their sex assigned at birth, *Schwenk*, 204 F.3d at 1201, there is inherently "a congruence between discriminating against transgender … individuals and discrimination on the basis of gender-based behavioral norms," *Glenn*, 663 F.3d at 1316. As a result, any discrimination against transgender people because they are transgender—*i.e.*, against "individuals who, by definition, do not conform to gender stereotypes—is … discrimination on the basis of sex." *Finkle v. Howard County, Maryland*, 12 F. Supp. 3d 780, 788 (D. Md. 2014); *see also Evancho v. Pine-Richland Sch. Dist.*, __

F. Supp. 3d __, 2017 WL 770619, at *11 (W.D. Pa. Feb. 27, 2017) ("[D]iscrimination based on transgender status in these circumstances is essentially the epitome of discrimination based on gender nonconformity, making differentiation based on transgender status akin to discrimination based on sex for these purposes."); *accord Fabian v. Hospital of Central Connecticut*, 172 F. Supp. 3d 509, 526-527 (D. Conn. 2016) ("Discrimination on the basis of the 'peculiarities' that 'typically' manifest as maleness and femaleness … would surely include discrimination on the basis of gender stereotypes, and just as surely discrimination on the basis of gender identity."); *Rumble v. Fairview Health Servs.*, No. 14-cv-2037, 2015 WL 1197415, at *2 (D. Minn. Mar. 16, 2015) ("Because the term 'transgender' describes people whose gender expression differs from their assigned sex at birth, discrimination based on an individual's transgender status constitutes discrimination based on gender stereotyping.").

2. Discrimination against transgender people is independently impermissible discrimination on the basis of transgender status. The Supreme Court has recognized that certain classifications are inherently invidious, such as those that single out certain groups through a suspect classification. *Massachusetts Board of Retirees v. Murgia*, 427 U.S. 307, 312-313 (1976). Because transgender people have been "saddled with such disabilities, or subjected to such a history of purposeful unequal treatment, or relegated to such a position of political

powerlessness as to command extraordinary protection from the majoritarian political process," *id.* (citation omitted), several courts have concluded that transgender status is a suspect classification, and accordingly subjected statutes and regulations that discriminate on the basis of that status to heightened scrutiny, *see, e.g.*, *Board of Educ. of Highland Local Sch. Dist. v. U.S. Dep't of Educ.*, 208 F. Supp. 3d 850, 873-874 (S.D. Ohio 2016); *Norsworthy*, 87 F. Supp. 3d at 1119; *Adkins v. City of N.Y.*, 143 F. Supp. 3d 134, 138-140 (S.D.N.Y. 2015).

Those courts' conclusion is correct. The Supreme Court consistently has applied heightened scrutiny where the group subject to the classification at issue has suffered a history of discrimination and the classification has no bearing on a person's ability to perform in society. *See, e.g.*, *Murgia*, 427 U.S. at 313 (heightened scrutiny is warranted where a classified group has "experienced a 'history of purposeful unequal treatment' or been subjected to unique disabilities on the basis of stereotyped characteristics not truly indicative of their abilities"). The Court has also sometimes considered whether the group is a minority or relatively politically powerless, and whether the characteristic is defining or "immutable." *See, e.g.*, *Lyng v. Castillo*, 477 U.S. 635, 638 (1986); *see also Kerrigan v. Commissioner of Public Health*, 957 A.2d 407, 425-429 (Conn. 2008) (analyzing federal equal protection law to conclude that history of discrimination and ability to contribute to society are the two central considerations, and

collecting authorities). While not all considerations need point toward heightened scrutiny, *Golinski v. Office of Personnel Management*, 824 F. Supp. 2d 968, 983 (N.D. Cal. 2012), here all demonstrate that laws that discriminate based on transgender status should be subjected to heightened review.

"There is no denying that transgender individuals face discrimination, harassment, and violence because of their gender identity." *Whitaker*, 2017 WL 2331751, at *12; *see also Adkins*, 143 F. Supp. 3d at 139-140; Scholars Who Study The Transgender Population Amicus Br. Indeed, "[t]he hostility and discrimination that transgender individuals face in our society today is well-documented," *Brocksmith v. United States*, 99 A.3d 690, 698 n.8 (D.C. 2014)," and "this history of persecution and discrimination is not yet history," *Adkins*, 143 F. Supp. 3d at 139. Today, transgender people face staggering rates of harassment, discrimination, or other mistreatment at school and at work, as well as in access to employment, housing, and healthcare. *See Whitaker*, 2017 WL 2331751, at *12; *Adkins*, 143 F. Supp. 3d at 139-140; Scholars Who Study The Transgender Population Amicus Br.

Transgender people have "immutable [and] distinguishing characteristics that define them as a discrete group, or as the Second Circuit put it … 'the characteristic of the class calls down discrimination when it is manifest.'" *Highland*, 208 F. Supp. 3d at 874 (quoting *Windsor v. United States*, 699 F.3d 169,

183 (2d Cir. 2012)); *see also Adkins*, 143 F. Supp. 3d at 139-140 ("mismatch" between sex assigned at birth and gender identity "calls down discrimination"). A person's transgender status is "inherent in who they are as people," *Evancho*, 2017 WL 770619, at *13, and "so fundamental" to their identity that they "should not be required to abandon" it, *Hernandez-Montiel v. INS*, 225 F.3d 1084, 1093 (9th Cir. 2000), *overruled on other grounds*, *Thomas v. Gonzales*, 409 F.3d 1177 (9th Cir. 2005). And, as the service of thousands of transgender soldiers in our Nation's defense makes clear, an individual's transgender status has no relation to that person's ability to contribute to society. *See Highland*, 208 F. Supp. 3d at 874.

Finally, "as a tiny minority of the population, whose members are stigmatized for their gender non-conformity in a variety of settings, transgender people are a politically powerless minority group." *Highland*, 208 F. Supp. 3d at 873-874. Transgender people's lack of "strength to politically protect themselves from wrongful discrimination" is self-evident. *Windsor*, 699 F.3d at 184; *Adkins*, 143 F. Supp. 3d at 140 ("Particularly in comparison to gay people at the time of *Windsor*, transgender people lack the political strength to protect themselves.").

B. The Regulation Cannot Survive Any Level Of Review

Although the Regulation and its implementing directives could not (as discussed below) satisfy even rational-basis review, the fact that they discriminate on the basis of sex and transgender status means they are subject to strict or at least

heightened scrutiny. *See Craig v. Boren*, 429 U.S. 190, 197 (1976) (sex); *Adkins*, 143 F. Supp. 3d at 140 (transgender status). Accordingly, they require a compelling or "exceedingly persuasive justification"—and must be narrowly or "substantially related to the achievement of those objectives." *Berkley v. United States*, 287 F.3d 1076, 1082 n.1 (Fed. Cir. 2002) (quoting *United States v. Virginia*, 518 U.S. 515, 533 (1996)). The burden to satisfy heightened scrutiny "is demanding and … rests entirely on the [government]," *Virginia*, 518 U.S. at 531, and the justifications on which the VA relies "must be genuine, not hypothesized or invented *post hoc* in response to litigation," *id.* at 533. Further, as the Supreme Court recently explained, a classification subject to heightened scrutiny "must serve an important governmental interest *today*, for 'new insights and societal understandings can reveal unjustified inequality … that once passed unnoticed and unchallenged.'" *Sessions v. Morales-Santana*, No. 15-1191, __ S. Ct. __, 2017 WL 2507339, at *2 (June 12, 2017) (quoting *Obergefell v. Hodges*, 135 S. Ct. 2584, 2603 (2015)).

The required showings are absent here. Neither the proposed nor the final Regulation offered any justification for the exclusion of sex reassignment surgery. *See* 63 Fed. Reg. 37,299 (July 10, 1998) (proposed rule); 64 Fed. Reg. 54,207 (Oct. 6, 1999) (final regulation). Nor did implementing directives. *See* Appx52-70. As discussed, however, the VA has explained that the exclusion was based on the

VA's 1999 view that "such services were not considered medically needed." Appx307 (draft NPRM). Given the VA's own subsequent rejection of that view, it obviously cannot satisfy strict or even heightened scrutiny.

Nor is the explanation in the VA's denial letter sufficient. Although the cost associated with regulatory action may in some instances be relevant to the "arbitrary and capricious" inquiry, it has no bearing on the constitutional question presented here. The Supreme Court has long made clear that cost cannot justify discrimination; in the Court's words, the government cannot "protect the public fisc by drawing an invidious distinction between classes of its citizens." *Memorial Hospital v. Maricopa County*, 415 U.S. 250, 263 (1974); *see also Graham v. Richardson*, 403 U.S. 365, 374-375 (1971); *Shapiro v. Thompson*, 394 U.S. 618, 633 (1969), *overruled in part on other grounds*, *Edelman v. Jordan*, 415 U.S. 651 (1974).

More broadly, no legitimate governmental objective is served by withholding medically necessary treatment from transgender veterans while providing the same treatment to other veterans. As discussed, the VA has never offered any explanation for that illogical arrangement. *Cf. Norsworthy*, 87 F. Supp. 3d at 1120 (government was unable to identify any "important governmental interest" in policy barring sex reassignment surgery, "much less describe how their gender classification—which makes it more difficult for a transgender person to

receive vaginoplasty than it is for a cisgender woman—[could be] substantially related to that interest"). That failure confirms that "treat[ing a transgender person] differently from a similarly situated non-transgender [person] in need of [the same] medically necessary surgery" violates equal protection. *Id.*

Indeed, the Regulation cannot survive even rational-basis review. As the Supreme Court has explained, "even in the ordinary equal protection case calling for the most deferential of standards, we insist on knowing the relation between the classification adopted and the object to be attained." *Romer v. Evans*, 517 U.S. 620, 632 (1996); *see also Heller v. Doe by Doe*, 509 U.S. 312, 321 (1993) (under rational basis review, the classification must "find some footing in the realities of the subject addressed by the legislation"). This Court's review, in other words, is not "toothless," *Matthews v. Lucas*, 427 U.S. 495, 510 (1976), particularly given that the policy in question targets a vulnerable group, *see Romer*, 517 U.S. at 634-635 (invalidating law that burdened the "politically unpopular group" of lesbian, gay, and bisexual people).

Applying these standards, the Regulation comes up short. The VA recognizes that the original rationale for the exclusion is now untenable, Appx307-308 (draft NPRM), and the agency has offered no rational reason for providing transgender veterans with some, but not all, medically necessary treatment for gender dysphoria, nor explained why the procedures that constitute sex

reassignment surgery ought to be covered for some medical needs but not others. *Cf. Crawford v. Cushman*, 531 F.2d 1114, 1121-1125 (2d Cir. 1976) (Marine Corps regulation requiring the automatic discharge of pregnant soldiers was unconstitutional on equal protection and due process grounds because Corps had no rational basis for treating pregnant soldiers different from other soldiers with a temporary disability). And the budgetary rationale the agency has put forward is indefensible on its own terms (*see supra* pp. 37-40), and illegitimate as a justification for maintaining a plainly discriminatory rule.

Simply put, there is no rational—much less legitimate or compelling—basis for the rule, and the VA's refusal to revisit it through rulemaking must be set aside.

C. The Regulation Violates The Affordable Care Act

For the same reasons just discussed, the Regulation and directives are also "not in accordance with law" because they violate the statutory prohibition on health care discrimination contained in the Affordable Care Act ("ACA"), 42 U.S.C. §18001 *et seq*. Under Section 1557 of the ACA, no individual may be "excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance … or under any program or activity that is administered by an Executive Agency" on grounds prohibited by various federal antidiscrimination statutes, including Title IX of the Education Amendments of

1972. 42 U.S.C. §18116. Title IX, in turn, prohibits discrimination in certain programs "on the basis of sex." 20 U.S.C. §1681(a). As explained, that prohibition protects transgender people from discrimination. *See supra* pp. 45-46; *see also Rumble*, 2015 WL 1197415, at *7, *10 (transgender status is covered by "sex" under section 1557). And, again for the reasons discussed above, the VA's exclusion constitutes discrimination against transgender veterans. *See supra* pp. 41-42, 52-53; *see also Cruz*, 195 F. Supp. 3d at 581 ("categorical exclusion on treatments of gender dysphoria" violates section 1557).[10]

Where agency action is inconsistent with a statute, it must be set aside as "not in accordance with law." *See, e.g.*, *New York v. Nuclear Regulatory Commission*, 681 F.3d 471, 476, 481-482 (D.C. Cir. 2012) (setting aside agency action under Nuclear Waste Policy Act for failure to comply with National

[10] This interpretation of Section 1557 accords with HHS's implementing regulations. As noted, HHS clarified there that discrimination against an individual on the basis of transgender status constitutes discrimination on the basis of sex. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,387-31,388 (May 18, 2016); *see also* 45 C.F.R. §92.207(b)(3)-(5). Although HHS's rule does not apply to the VA (which is not a "covered entity" under the rule), it implements a statute that does cover the VA, and it reflects the straightforward proposition that the statutory bar on discrimination in health care prohibits the VA's categorical bar on sex reassignment surgery. A district court has enjoined federal agency enforcement of this portion of the HHS rule, *see Franciscan Alliance, Inc. v. Burwell*, No. 7:16-cv-00108, 2016 WL 7638311 (N.D. Tex. Dec. 31, 2016), but the rule has not been rescinded.

Environmental Policy Act). The VA's denial of the rulemaking petition should therefore be set aside as inconsistent with Section 1557.

CONCLUSION

The Court should direct the Department to undertake a rulemaking to amend or repeal the Regulation.

Respectfully submitted,

/s/ Alan E. Schoenfeld

M. DRU LEVASSEUR
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
(212) 809-8585

TARA L. BORELLI
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
730 Peachtree Street NE, Suite 640
Atlanta, GA 30308-1210
(404) 897-1880

ILONA M. TURNER
SHAWN THOMAS MEERKAMPER
TRANSGENDER LAW CENTER
P.O. Box 70976
Oakland, CA 94612
(510) 587-9696

SASHA J. BUCHERT
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
1875 I Street NW
Washington, D.C. 20006
(202) 999-8083

ALAN E. SCHOENFELD
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

PAUL R.Q. WOLFSON
MICHAEL POSADA
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue
Washington, DC 20006
(202) 663-6390

Attorneys for Petitioners

ADDENDUM

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DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

November 10, 2016

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

Dear Senator Warren:

This is in response to your September 22, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

VA regularly reviews regulations across the full spectrum of medical services to provide the highest quality health care to our Nation's Veterans. Where there is new data, research, or changes to health care policies across Federal agencies that suggest a need for review, VA makes every effort to examine the circumstances and openly discuss actions that could improve Veteran health care. We note that VA has not published a NPRM to remove the exclusion of gender alterations from VA's medical benefits package, but rather announced it was considering issuance of such a NPRM in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the Federal Government.

VA currently provides many services for transgender Veterans to include hormone therapy, mental health care, preoperative evaluation, and long-term care following sex reassignment surgery. Increased understanding of both gender dysphoria and surgical techniques in this area has improved significantly and is now widely accepted as medically necessary treatment. VA has been and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available. Therefore, this regulation will be withdrawn from the Fall 2016 Unified Agenda. While VA has begun considering factors impacting this rulemaking process, it is not imminent.

Should you have further questions, please have a member of your staff contact Ms. Angela Prudhomme, Congressional Relations Officer, at (202) 461-6471 or by email at Angela.Prudhomme@va.gov.

Thank you for your continued support of our Nation's Veterans.

Sincerely,

David J. Shulkin, M.D.

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of June, 2017 I filed the foregoing Brief for Petitioners with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Circuit Rule 32(a).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 12,368 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

June 21, 2017