

Paul Campanelli

President

Par Pharmaceutical at Endo International PLC

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Chestnut Ridge, NY 10977

John Hendrickson

Chief Executive Officer

Perrigo, Inc.

515 Eastern Avenue

Allegan, MI 49010

September 2016

Dear President Campanelli and CEO Hendrickson:

We the undersigned – physicians, public health professionals, advocates and members of the lesbian, gay, bisexual (LGB), transgender and gender non-conforming (TG/NC) communities – write to share our deep concern about the national shortage of injectable estrogen. We urge that Par Sterile and Perrigo Pharmaceuticals restock and manufacture injectable estradiol in 40 mg/mL dosages. The impact of this shortage is a public health emergency for thousands of transgender women who rely on these hormones to live whole and healthy lives.

Hormone therapy to affirm gender identity is a medically necessary intervention for many transgender individuals.¹ It is often the first, and sometimes only, medical gender affirmation intervention accessed by transgender individuals looking to develop characteristics consistent with their gender identity.² Studies have shown that gender affirmation through hormone therapy can improve psychological adjustment and quality of life.^{3,4} One study found that once estrogen therapy began, transgender women experienced improvement in social functioning and reduced anxiety and depression.⁵ The class of estrogen used for feminizing therapy is 17-beta estradiol and is commonly delivered to transgender women through a patch, oral or sublingual tablet, or injection.⁶

Further, in the last 10 years, many professional associations, including the American Medical Association, American Association of Family Physicians, the Endocrine Society, American Psychiatric Association, American Psychological Association, American College of Obstetricians and Gynecologists, and the American Public Health Association, have issued statements or guidelines supporting effective treatment protocols for Gender Dysphoria, and review articles have been published in major peer-reviewed journals such as *the Journal of the American Medical Association*, *Nature*, *the Journal of Clinical Endocrinology*, and *Archives of Pediatric and Adolescent Medicine*, among others.⁷

¹ Feldman J & Spencer K. (2015). Chapter 18 Medical and surgical management of the transgender patient: What the primary care clinician needs to know. In Makadon HJ, Mayer KH, Potter J, & Goldhammer H (Eds.), *Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health 2nd Edition* (479-511). Philadelphia: American College of Physicians.

² Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, et al. (2012 August) Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *International Journal of Transgenderism*. 13(4):165-232.

³ Feldman J & Spencer K. (2015). Chapter 18 Medical and surgical management of the transgender patient: What the primary care clinician needs to know.

⁴ White Hughto JM & Beisner SL. (2016, January) A systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals. *Transgender Health*. 1(1):31-31.

⁵ Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillamon A, Godás T, Cruz Almaraz M, et al. (2012, May) Hormone-treated transsexuals report less social distress, anxiety and depression. *Psychoneuroendocrinology*. 37(5):662-70.

⁶ Deutsch MB. (2016) "Overview of feminizing hormone therapy." *Center of Excellence for Transgender Health*. Retrieved from: <http://transhealth.ucsf.edu/trans?page=guidelines-feminizing-therapy>

⁷ Transgender Law Center, communication with Truven Health Analytics, August 2015.

As you are aware, there is a current shortage of estradiol valerate Injection.⁸ This shortage is affecting the availability of Delestrogen and its generic counterpart estradiol valerate. The shortage includes Delestrogen injection from Par Sterile Products and estradiol valerate injection from Perrigo, in both the 20 mg/mL and 40 mg/mL formulations. We understand from Par and Perrigo spokespersons that there is a manufacturing delay for Delestrogen as well as manufacturing issues for the generic counterpart. We also understand that both companies have these products on back order, but cannot estimate release dates. While Delestrogen injection is currently available from Par Sterile Products in the 10 mg/mL formulation,⁹ injectable estrogen at the 40 mg/mL dosage is the highest dosage and very often prescribed to transgender women in our experience.¹⁰ The shortage began 18 months ago and has not since returned to the market. In July 2016, a federally-qualified health center based in New York City received none of the 40 mg/mL and 20 mg/mL formulations in their weekly drug shipment and were told that the shortage would last until at least October.¹¹ This shortage impacts 900 transgender women at that clinic alone.

Due to the severity of the effects of this shortage on the wellbeing of transgender women, we urge you – the manufactures – to take immediate action by restocking the 40 mg/mL dosage of injectable estrogen in both brand and generic versions.

Manufacturers need to restore the 40 mg/mL dosage of injectable estrogen because it is the preferred regimen for many transgender women. Many patients started their transition with injectable estrogen years ago and rely on regular injections. Further, many transgender women on hormone therapy for gender affirmation experience injectables as more effective than patches or pills. Some providers are working to educate patients about the efficacy of patches and pills; but this does not negate the immediate need for injectable estrogen.

While the 40 mg/mL dosage has been unavailable, providers have made due by doubling up on the 20 mg/mL dosage. This is a temporary work-around as some patients report discomfort with the injections. Most providers will not prescribe the 10 mg/mL dosage. In order to maintain the estrogen levels that patients were able to achieve with the 40 mg/mL dosage, patients would need to inject four times as much liquid into their muscles every one to two weeks, which can be very painful for patients.

The lack of injectable estrogen is a public health crisis. Patients could likely turn to street injections to replace what they were receiving in clinics, which could put themselves at risk. Black market injectable estrogen is often diluted or laced with other potentially harmful ingredients. This shortage could contribute to further marginalization of the transgender community, putting women at risk of injecting adulterated estrogen.

The shortage of this preferred method of gender affirmation therapy has already created obstacles for clinicians to be able to provide comprehensive care to transgender patients. This injectable estrogen shortage is triggered by a lack of FDA-approval for all estrogen modalities. Therefore, the FDA should also take action by approving estrogen for gender affirmation, affording transgender women the same range of choices as menopausal women are currently given. Advocates are working to this end.

In the meantime, thousands of transgender women across the United States are unable to access injectable estrogen thereby putting their health and lives in danger. **We urge Par Sterile and Perrigo Pharmaceuticals to restock the 40 mg/mL dosage of injectable estrogen immediately.** If helpful, we can arrange a conference call to discuss this further.

⁸American Society of Health-System Pharmacists. (2016, July 20). "Current Shortages: Estradiol Valerate Injection." *ASHP*. Retrieved from: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/bulletin.aspx?id=1186>

⁹ American Society of Health-System Pharmacists. (2016, July 20). "Current Shortages: Estradiol Valerate Injection."

¹⁰ Moore C. (2016, August 4). "Exclusive: There's an injectable estrogen shortage that's leaving trans women in Crisis." *Out*. Retrieved from: <http://www.out.com/out-exclusives/2016/8/04/exclusive-theres-injectable-estrogen-shortage-thats-leaving-trans-women/>

¹¹ Moore C. (2016, August 4). "Exclusive: There's an injectable estrogen shortage that's leaving trans women in Crisis."

Please feel free to contact Kimberleigh J. Smith, Senior Director for Community Health Planning and Policy at the Callen-Lorde Community Health Center in New York City with questions and/or to send a response to this request: ksmith@callen-lorde.org or 212-271-7184.

Sincerely,

(See attached for full list of signatures)

cc Richard Klein, Director, Patient Liaison Program of the Office of Health and Constituent Affairs, U.S. Food and Drug Administration

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Callen-Lorde Community Health Center
New York, NY

Fenway Health
Boston, MA

Treatment Action Group
New York, NY

Centro SInAPSi Naples University federico II (Italy)
Naples, Italy

Access Esperanza Clinics Inc
McAllen, TX

ACT UP New York
New York, NY

Adolescent AIDS Program, Children's Hospital at Montefiore Medical Center
Bronx, NY

African American Office of Gay Concerns
Newark, NY

Ali Forney Center
New York, NY

Ansara Psychotherapy
Sydney, Australia

API Wellness Center
San Francisco, CA

Apicha Community Health Center
New York, NY

Asian and Pacific Islander Wellness Center
San Francisco, CA

Brooklyn Community Pride Center
Brooklyn, NY

Capitol Hill Medical
Seattle, WA

Central Illinois Pride Health Center
Bloomington-Normal, IL

Choices Counseling and Consulting
Albany, NY

Clear Skies Psychological Services
Colorado Springs, CO

Cortland LGBTQ Resource Center
Cortland, NY

CrescentCare
New Orleans, LA

Destination Tomorrow
Bronx, NY

Dr. Toby Meltzer
Scottsdale, AZ

EndAIDSNow
New York - Paris - Copenhagen

Equi Institute
Portland, OR

Equitas Health
Columbus, OH

First Choice Health Centers, Inc.
East Hartford, CT

Gary Howell, PsyD, PC
Tampa, FL

Gay Men's Health Crisis (GMHC)
New York, NY

Gender Justice League
Seattle, WA

Girls United
Baltimore, MD

GLMA: Health Professionals Advancing LGBT Equality
Washington, DC

Greater Milwaukee Center for Health and Wellness
Milwaukee, WI

Harlem United Community AIDS Center, Inc.
New York, NY

HEAT Program/SUNY Downstate Medical Center
Brooklyn, NY

Housing Works, Inc.

ORGANIZATIONS

New York, NY

Howard Brown Health
Chicago, IL

Huntridge Family Clinic
Las Vegas, NV

interACT
National

Keeping Ballroom Community Alive Network
Brooklyn, NY

Lowcountry AIDS Services Consumer Advisory
Board
North Charleston, SC

Lyon-Martin Health Services, a program of
HealthRIGHT 360
San Francisco, CA

Make the Road NY
New York, NY

Mally Speaks
Washington, DC

Mazzoni Center
Philadelphia, PA

Mira Krishnan LLC
Grand Rapids, MI

National Center for Lesbian Rights
Washington, DC

National Coalition for LGBT Health
Washington, DC

National LGBT Cancer Network
New York, NY

National LGBTQ Task Force
Washington, DC

New Alternatives for LGBT Homeless Youth
New York, NY

New York City Anti-Violence Project
New York, NY

NYTAG New York Trans Advocacy Group
Brooklyn, NY

Penn Medicine Program for LGBT Health
Philadelphia, PA

Perceptions for People with Disabilities
New York, NY

PFLAG National
Washington, DC

Planned Parenthood of New York City
New York, NY

Pride Center of Western New York
Buffalo, NY

Pride for Youth/Long Island Crisis Center
Long Island, NY

PrimeCare Community Health
Chicago, IL

Private mental health practitioner
Seattle, WA

Project Inform
San Francisco, CA

PROMO
St. Louis, MO

Rainbow Access Initiative
Albany NY

SAGE
New York, NY

Same Boat Consulting
Boston, MA

The Center for Black Equity-Baltimore
Baltimore, MD

The Lesbian, Gay Bisexual and Transgender
Community Center
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Transcend Legal
New York, NY

Translatina Network
New York, NY

Trillium Health
Rochester, NY

ORGANIZATIONS

University of Pennsylvania Student Health
Service
Philadelphia, PA

Urban Coalition for HIV/AIDS Prevention
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Valley AIDS Council / Westbrook Clinics
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