

**Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852**

**Re: FDA Public Hearing on “Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products can be Considered Nonprescription”
[Docket No. FDA-2012-N-0171]**

May 7, 2012

To Whom it May Concern,

The Asian & Pacific Islander American Health Forum and the National Asian Pacific American Women’s Forum thank you for the opportunity to comment on expanding access to drug products that can be considered nonprescription. The Asian & Pacific Islander American Health Forum (APIAHF) influences policy, mobilizes communities, and strengthens programs and organizations to improve the health of the Asian American, Native Hawaiian and Pacific Islander community. The National Asian Pacific American Women’s Forum (NAPAWF) is the only national, multi-issue Asian and Pacific Islander women's organization in the country, and works to achieve social justice and human rights for Asian and Pacific Islander women and girls, including their ability to access health services.

As organizations devoted to improving the health of Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) women and communities, we are pleased that the FDA is considering a new paradigm to use innovative tools and technologies to increase the availability of certain drug products, and encourage the Administration to make oral contraceptives available to consumers without a prescription, or “over the counter” (OTC). We encourage the FDA to explore OTC availability for OC because: (1) Oral contraceptives are necessary medical care and OTC access will reduce some of the barriers that prevent many women—especially those who are immigrant, low-income, and of color—from obtaining OC; (2) Over the counter access would result in more Asian American, Native Hawaiian and Pacific Islander women being able to obtain oral contraceptives; (3) Practitioner oversight is not necessary for proper usage; and (4) Expanding access to oral contraceptives would reduce the burden of providing health care on individual healthcare providers, on an increasingly stretched healthcare system, and on emergency rooms.

A. Types of Technology and Conditions of Safe Use

We applaud the FDA’s interest in introducing minimally burdensome dispensing methods. Electronic kiosks, retail clinics, and self-dispensing machines have been shown to be acceptable and appropriate for clients willing to forego in-person consultation with a health care professional.ⁱ For women who want to consult with a health care professional, expanded use of

telephone or provider-to-patient video interface have similarly been met with patient satisfaction, demonstrated acceptable outcomes, and helped to lower health care costs.

As the FDA continues to explore these options, we urge the Administration to ensure that the impact of OTC status on safety, efficacy, and access for individuals with limited English proficiency as well as limited health literacy is seriously considered and evaluated.

B. Pharmacy, Consumer, and Health Care Provider Issues

I. Over the counter (OTC) availability of oral contraceptives would increase access to this necessary medical care.

Oral contraceptives (OCs) are necessary part of women's medical care. Millions of American women rely on it to prevent unwanted pregnancies and other medical conditions. Seventeen percent of women ages 15-44 in the U.S. use OCs each year, making OCs the most popular method of contraception.ⁱⁱ Moreover, hormonal contraception is often prescribed to treat or prevent medical conditions such as endometriosis, iron-deficiency anemia, uterine fibroid tumors, abnormal bleeding, pain associated with ovulation, pelvic inflammatory disease, and ovarian cysts. It also reduces a woman's risk of developing ovarian and endometrial cancers.ⁱⁱⁱ Therefore, contraception is basic, necessary health care that benefits women and their families.

Over the counter (OTC) availability would create a much needed expansion of access to oral contraceptives. We therefore encourage the FDA to explore this paradigm change to OTC availability. This would eliminate visits to doctors' offices which can cost up to \$250 per year,^{iv} take more time than OTC access, may be geographically inconvenient for many women, and can take a long time to schedule. Appointment delay is a major obstacle even for women who have access to care: a national survey found that a new patient waits for more than 2 weeks for an obstetrics-gynecology appointment.^v Many clinics and physician's offices also do not provide hours that accommodate women's varied work schedules. Additionally, visits for preventive care such as oral contraception are often dependent on a woman's access to health insurance, which for many women may not be consistent. If a woman experiences a lapse or change in coverage, she may need to become a new patient with a different provider, which can result in a delay in getting a prescription and obtaining the medication. OTC access would eliminate this obstacle and the associated delays to access.

II. Asian American, Native Hawaiian, and Pacific Islander women would use oral contraceptives more frequently if the prescription barrier were removed.

AA and NHPI women have disproportionately high rates of unintended pregnancies and abortion.^{vi} Research suggests this may be related to barriers they face to contraceptive access. One study documenting the reproductive health practices of Chinese and Filipina American college-age women found that Chinese American women were four times less likely to use hormonal methods of birth control than white women.^{vii} The study further indicated that both Chinese and Filipina American women were more likely to use the withdrawal method compared to their white counterparts, increasing their likelihood of becoming pregnant unintentionally.^{viii} Moreover, national data reveals that Asian American women choose to terminate 35% of their

pregnancies, the second highest percentage for all racial/ethnic groups, compared to 18% for white women.^{ix} These data indicate that Asian American and Pacific Islander women experience more unintended pregnancies than others, in part because they are using contraceptives at a disproportionately low rate. Evidencing that OTC access would help remedy this, a 2004 study shows that 70% of Asian American women would use hormonal contraceptives if they were available in a pharmacy without a prescription.^x

For many AA and NHPI women, especially those who are immigrants, there are several barriers to using oral contraceptives. Among them are language barriers, being uninsured, lack of financial resources, lack of awareness of contraceptive options, and not being able to navigate our medical system. Furthermore, for undocumented immigrant women, there is often a deterrent to seeking medical care due to “public charge” fears and possible interactions with public officials that could lead to immigration enforcement actions, particularly in states such as Arizona and Alabama. Being able to conveniently obtain this medication at a local pharmacy, without visiting a doctor, would remove one of the many obstacles to healthcare that AA and NHPI women face.

III. Women will be able to use oral contraceptives safely and effectively without the oversight of a clinician.

Studies conducted in metropolitan areas across the United States show that clinician or pharmacist presence is not required for consumers to understand product necessity, appropriateness, contraindications, and product utilization.^{xi xii xiii} There is evidence that women can safely and effectively use daily hormonal contraceptive pills without clinical supervision.^{xiv} Proper oral contraceptive use is not difficult; women simply take one pill a day.^{xv} In addition, research indicates that self-screening for medical contraindications can be safe and effective,^{xvi} as can pharmacist-led screening and prescribing.^{xvii}

Additionally, consistent use of oral contraceptives is an important factor in maximizing its effectiveness, and OTC access would contribute to its consistent use. If women miss a day or more of OC use because they are unable to obtain a prescription in time, the method may fail and women are put at risk of unwanted pregnancy. At least one study found that travel away from home and running out of pill packs were frequent reasons women missed pills.^{xviii} Moreover, over the counter availability of OCs will not affect consumers’ access to clinicians if they wish to consult with a clinician prior to use.

IV. Expanding access to oral contraceptives would reduce the burden of providing health care services on the healthcare system, individual healthcare providers, and emergency rooms.

Increasing access to cost effective medical care, including oral contraception, is an urgent concern for the health of women and families. As a result of the advances under the Affordable Care Act (ACA), it is projected that 32 million new patients will have health care coverage and will be entering into our already burdened system.^{xix} In 2016, it is projected that 2 million Asian

Americans who would otherwise be uninsured will gain or be eligible for coverage.^{xx} This large influx of users will bring new stressors on the health care system and will require forward looking approaches to ensure that all consumers maintain appropriate access to care, including oral contraception. Moreover, individual health care providers, particularly providers in free clinics, Community Health Centers, and Title X clinics, would be able to redirect their limited time and resources to other patients if there was less of a need to schedule office visits for routine contraception prescriptions.

Expanded access to OCs could also relieve some of the burden on emergency rooms by leading to a lower incidence of unintended pregnancy and childbirth.

C. Other Related Issues

Language access for persons with limited English proficiency and limited health literacy should be considered and evaluated.

It is important to note the implications of language access on the safe and effective use of contraception if it is to become available OTC. According to the U.S. Census, roughly one out of every three AA and NHPIs is limited English proficient and one in five AA and NHPI households is linguistically isolated.

Under Title VI of the Civil Rights Act of 1964 and its associated federal regulations, federal funds may not be used in an intentionally discriminatory manner, or in a way that creates a disparate impact on the basis of race, color or national origin. Title VI's prohibition against national origin discrimination includes preventing meaningful access to federally funded services for patients who are LEP.

Therefore, women who are LEP are entitled to access programs that receive federal financial assistance and must receive interpretation and translation services if necessary to access these programs on equal terms with English speakers. These requirements apply to pharmacies because they are considered a "program or activity" under Title VI, and receive federal financial assistance through Medicaid and Medicare. We urge the FDA to consider the impact of non-prescription status for medications such as oral contraception and ensure that individuals will maintain access to language services under the paradigm change. For example, the FDA should consider whether standards such as the Department of Health and Human Services' (DHHS) Guidance and Standards on Language Access Services, and the DHHS Language Access Policy are in place in pharmacies where safety and efficacy evaluations are conducted, and whether they will remain in effect for medications available over the counter. A resource guide for improving language access at pharmacies is available at:

http://www.healthlaw.org/images/stories/Language_Services_Pharmacy_Resource_Guide_2010.pdf

Conclusion

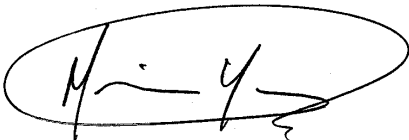
For the reasons described above, we believe that removing the prescription barrier to oral contraceptives could improve access to contraception for Asian American, Native Hawaiian, and Pacific Islander women. Preliminary research indicates that removing this barrier will increase contraceptive uptake, improve patient adherence and continued use of this highly effective method, and reduce unintended pregnancy among AA and NHPI women. Exploring a nonprescription paradigm for oral contraceptive access, with attention to the unique barriers faced by immigrant women of color and women with limited English proficiency, will empower many AA and NHPI women to care for their health and families.

Thank you very much for the opportunity to comment on this topic. We welcome any opportunities to work with the FDA to expand access to this medically necessary, safe, and effective medication. Please contact Priscilla Huang, Policy Director of APIAHF or Miriam Yeung at NAPAWF with any questions. They can be reached, respectively, at phuang@apiahf.org and myeung@napawf.org.

Sincerely,



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Miriam Yeung, Executive Director
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ⁱ Grossman D, et al. *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*. *Obstetrics & Gynecology*. 118(2):296-303

ⁱⁱ Mosher, WD, and Jones, J, *Use of Contraception in the United States: 1982–2008*, Centers for Disease Control Data from the National Survey of Family Growth. Available at: http://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf

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- ⁱⁱⁱ Johannes C Huber, Eva-Katrin Bentz, Johannes Ott & Clemens B Tempfer *Non-contraceptive benefits of oral contraceptives*, University of Vienna School of Medicine, Department of Gynaecologic Endocrinology and Reproductive Medicine, Vienna, Austria
- ^{iv} Center for American Progress, *The High Cost of Contraception*. Available at: http://www.americanprogress.org/issues/2012/02/BC_costs.html
- ^v Sharon Cohen Landau, Molly Parker Tapias, Belle Taylor McGhee, *Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception*. Pharmacy Access Partnership, Oakland, CA 94610, USA, 14 July 2006, 463.
- ^{vi} Amy G. Lam, Thida C. Tan, Sareen J. Leong, and Amy K. Mak, *Unmasking the Reproductive Health Behaviors of Asian American Young Women: A Comparison of Heterosexual Chinese, Filipina, and White American College Students* (notes on file with NAPAWF staff). Provide more on this cite- date and place of publication.
- ^{vii} Id.
- ^{viii} Id.
- ^{ix} Id.
- ^x Id., 466.
- ^{xi} Raymond EG, et al. *Comprehension of a prototype emergency contraception package label by female adolescents*. *Contraception*. 79(3): 199-205
- ^{xii} *Birth Control Within Reach – A national survey on women's attitudes and interest in pharmacy access to hormonal contraception*, June 2004, Pharmacy Access Partnership.
- ^{xiii} Raine TR, et al. *An over-the-counter simulation study of single-tablet emergency contraceptive in young females*. *Obstetrics and Gynecology*. 119(4):772-79.
- ^{xiv} *Should the contraceptive pill be available without prescription?* January 24, 2009, http://pcsotc.org/wp-content/uploads/2010/12/Grossman_Jarvis_should-OCs-be-avail-without-a-prescription.pdf
- ^{xv} Planned Parenthood, Health and Info Services: Birth Control Pills. Available at: <http://www.plannedparenthood.org/health-topics/birth-control/birth-control-pill-4228.htm>
- ^{xvi} Grossman, D., et al., *Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use*, *Obstet Gynecol*. 2008 September ; 112(3): 572–578
- ^{xvii} Gardner, JS., et al., *Pharmacist prescribing of hormonal contraceptives: results of the Direct Access study*, *J Am Pharm Assoc* (2003). 2008 Mar-Apr;48(2):212-21.
- ^{xviii} Smith JD, Oakley D. *Why do women miss oral contraceptive pills? An analysis of women's self-described reasons for missed pills*. *J Midwifery Womens Health* 2005;50(5):380-5.
- ^{xix} White House, *The Affordable Care Act Implementation Timeline*. Available at: <http://www.whitehouse.gov/healthreform/timeline>
- ^{xx} Rose Chu, Daniel Wong, Wilma Robinson, and Kenneth Finegold, ASPE HHS ASPE Research Brief, *The Affordable Care Act and Asian Americans and Pacific Islanders*. Available at: <http://aspe.hhs.gov/health/reports/2012/ACA&AsianAmericans&PacificIslanders/rb.shtml>