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**Re: Over-the-Counter (OTC) Status for Oral Contraceptives**

Dear Ms. Dupont, Ms. Dickinson and Ms. Bhatt:

We at the New York City Bar Association (“City Bar”), through our Science & Law and Sex & Law Committees (the “Committees”), respectfully urge you to take action to give oral contraceptives over-the-counter (OTC) status.

Since its founding in 1870, the City Bar has grown to over 24,000 members who work for the public good through consideration of and advocacy for legal reform. The City Bar’s Science &

Law Committee, whose membership includes lawyers with backgrounds in engineering and the physical and social sciences, is committed to forward-thinking solutions to complex legal and ethical problems influenced by rapidly changing developments in the fields of science and technology. And the Sex & Law Committee focuses on issues pertaining to gender and the law in a variety of areas, including reproductive rights, gender discrimination, poverty, matrimonial and family law, employment law, and same-sex marriage. Together, our membership includes lawyers with extensive experience in many aspects of litigation and regulation.

In recent months the Committees<sup>1</sup> have taken note of widespread<sup>2</sup> bipartisan support for initiatives to move oral contraceptives to over-the-counter status. Beyond the critical role that contraception plays in women's lives and ability to participate equally in the social, political and economic life of our nation, there are solid scientific and medical bases for making oral contraceptives available without a prescription. We urge you to support this policy – which strengthens both gender equality and women's healthcare -- through legislation and policy initiatives to make oral contraception more readily accessible in New York State and across the country.

## **BACKGROUND**

Tens of millions of healthy American women have used oral contraception without undue risk or harm for decades. As described below, efforts to increase access to oral contraception by allowing over-the-counter (OTC) access are supported by compelling scientific and medical evidence and are in line with smart public health policy. First, professional supervision of oral contraceptive use does not change health outcomes or screening; thus, while it is important for women to discuss their reproductive and sexual health with health care providers, monitoring and limiting oral contraceptive use is not necessary to achieve these ends. Second, oral contraceptives already meet the FDA's criteria for OTC status.<sup>3</sup> Third, the current prescription status for oral contraception bars access to these medications for many women, putting those women at greater risk of unintended pregnancies and poor health outcomes. Fourth, some states have already taken steps to improve access to oral contraception through OTC initiatives, demonstrating the political momentum and clear science behind better and easier access to oral contraception for women throughout the country.

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<sup>1</sup> The City Bar Patents Committee assisted in the preparation of this letter.

<sup>2</sup> Sara Libby, The Weird Bipartisan Consensus on Over-the-Counter Birth Control, THE ATLANTIC (Sep. 24, 2014), <http://www.theatlantic.com/politics/archive/2014/09/birth-control-consensus/380584>. The article notes support from Senate and House of Representatives members in Colorado, North Carolina, Minnesota, Louisiana, and California.

<sup>3</sup> Prescription pharmaceuticals may be subject to one or more patents or other exclusivity periods, insulating them from generic competition. If the OTC product is the same as the prescription version, the OTC product will have the same patent protection. Once the patent on the drug expires or is invalidated and approved generics enter the market, consumers have the benefit of the generally far lower cost of the generic substitute. One strategy the branded companies have used to deal with imminent patent expiration is to request the switch from prescription to OTC when the patent term is ending, and thus have access to a different market.

Moreover, depending on the FDA's requirements, the move from prescription to OTC may delay generic competition and its cost savings. If the FDA requires additional clinical trials as a condition for the switch, the company may be able to obtain a further three year period of exclusivity.

## 1. There is no evidence that medical supervision of oral contraception improves outcomes for otherwise healthy women

There is no established medical need for a woman to undergo a pelvic exam in order to obtain a prescription for oral contraceptives; however, such exams are routinely performed before a doctor is willing to write the prescription. Indeed, in 2012, the U.S. Preventative Services Task Force released guidelines stating that healthy women do not need an annual gynecological screening.<sup>4</sup> Furthermore, both the World Health Organization and the American College of Obstetricians and Gynecologists have long held that a yearly exam is unrelated to and unnecessary for the prescription of oral contraception.<sup>5</sup>

In addition to the lack of a scientific justification for requiring a yearly exam for oral contraception, there is sociological evidence that the prescription requirement does not change whatever risk may be associated with the use of oral contraception, and may actually increase it. First, the guidelines for use are already sufficiently clear for OTC use.<sup>6</sup> Second, studies have shown that self-monitored women taking oral contraception are more attentive to its risks than their physicians are and are more likely to report contraindications.<sup>7,8</sup> Third, women are less likely to discontinue use of their oral contraception if it is available over-the-counter, thereby significantly decreasing the incidence of unwanted pregnancies<sup>9</sup> and exposure to more invasive medical interventions.<sup>10</sup>

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<sup>4</sup> Cervical Cancer: Screening, U.S. PREVENTIVE SERVICES (Mar. 2012), <http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/cervical-cancer-screening>. Traditionally, this yearly exam was required for reproductive health screenings, particularly related to ovarian and cervical cancer.

<sup>5</sup> Amy Norton, Women Seeking Birth Control Get Unneeded Pelvic Exams, REUTERS (Nov. 22., 2010), <http://www.reuters.com/article/2010/11/22/us-birth-control-idUSTRE6AL67X20101122>.

<sup>6</sup> S Shotorbani et al., *Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors*, 73 *Contraception* 501-6 (2006);73:501-6.; D Grossman et al., *Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use*, 112 *OBSTETRICS & GYNECOLOGY* 572-8 (2008).

<sup>7</sup> JS Doshi et al., *Feasibility of a Self-Completed History Questionnaire in Women Requesting Repeat Combined Hormonal Contraception*, 34 *JOURNAL OF FAMILY PLANNING AND REPROD. HEALTH CARE* 51-4 (2008).

<sup>8</sup> It is worth noting that in addition to self-monitored women being sufficiently attentive to contraindications, the risks of modern oral-contraception have been recognized to be quite low. The American College of Obstetricians and Gynecologists (ACOG) noted in a recent committee report No. 544 (Dec. 2012, reaffirmed 2014) that safety concerns about blood clots are unfounded because the incidence of venous thromboembolism in oral contraceptive users is very low, especially in comparison to the risk of blood clots associated with pregnancy and postpartum. In the same report, ACOG noted that the concern that women will forego preventive services and screening if they can get oral contraceptives OTC is also unfounded based on available studies comparing women who were able to receive oral contraceptives with or without a mandatory physical exam.

<sup>9</sup> In 1965, the year the Supreme Court of the United States legalized use of birth control by married couples in *Griswold v. Connecticut*, 381 U.S. 479 (1965), there were 31.6 maternal deaths per 100,000 live births whereas in 2007 there were only 12.7 maternal deaths per 100,000 live births. Similarly, in 1965, 24.7 infants under one year of age died per 1,000 live birth, while in 2011 there were only approximately 6 infant deaths per 1,000 live births. The increasing availability of reliable ways to avoid undesired pregnancies has coincided with a dramatic increase in maternal and infant health. "Taking Control: The Ongoing Battle to Preserve the Birth Control Benefit in the Affordable Care Act," report published in 2013, available at [https://www.plannedparenthood.org/files/4913/9611/7011/BC\\_Report\\_062713\\_vF.PDF](https://www.plannedparenthood.org/files/4913/9611/7011/BC_Report_062713_vF.PDF), last accessed Dec 7 2015.

<sup>10</sup> JE Potter et al., *Continuation of Prescribed Compared with Over-the-Counter Oral Contraceptives*, 117 *OBSTETRICS & GYNECOLOGY* 551-557 (Mar. 2011).

## 2. Oral contraception meets the FDA's criteria OTC status

Modern oral contraception is a safe and effective medication that is used, with minimal side effects, by millions of women around the world. Indeed, the FDA has already effectively recognized that OTC treatment for oral contraceptives is appropriate by approving Plan B Emergency Contraception, a progestin-only contraceptive already available in OTC form and that includes a larger dose of the same active ingredient used in standard oral contraception.<sup>11</sup>

Given the growing body of scientific evidence supporting the safety and efficacy of oral contraceptives, making these medications available over the counter simply makes sense.<sup>12</sup> The case is so strong that many professional associations of doctors and other health professionals have endorsed the idea, including the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Public Health Association, and the Women's Health Practice and Research Network of the American College of Clinical Pharmacy.<sup>13</sup>

## 3. The prescription requirement serves as a barrier to oral contraceptive access

Simply put, the prescription requirement serves as an unnecessary and, at times, prohibitive barrier to access to oral contraceptives. This barrier, in turn, can lead to detrimental health outcomes for many women that could be avoided by providing OTC access. For example, removing the prescription requirement for oral contraceptives would result in up to a 25% reduction in unwanted pregnancies for the most at-risk women.<sup>14</sup> Moreover, surveys show that significant numbers of women would rely on oral contraception for their birth control needs if the prescription requirement were removed, thus providing access to safer and more reliable birth control than is currently available over-the-counter.<sup>15</sup>

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<sup>11</sup> Plan B: Questions and Answers, FDA (Aug. 24, 2006), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm109783.htm>

<sup>12</sup> AM Kaunitz, *Hormonal Contraception in Women of Older Reproductive Age*, 358 NEW ENGLAND JOURNAL MED. 1262-70 (2008); TM Farley et al., *Cardiovascular Disease and Combined Oral Contraceptives: Reviewing the Evidence and Balancing the Risks*, 5 HUMAN REPROD. UPDATE 721-35 (1999); DA Grimes, *Over-the-Counter Oral Contraceptives—An Immodest Proposal?* 83 Am. Journal of Pub. Health 1092-4 (1993).

<sup>13</sup> Over-the-Counter Oral Contraceptives, AAFP (Mar. 8, 2015), <http://www.aafp.org/about/policies/all/otc-oral-contraceptives.html>; Committee Opinion Number 615, THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (Jan. 2015), <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception>; American Medical Association Committee Resolution No 507: Support of Over-the-Counter Sales of Oral Contraceptives, AMERICAN MEDICAL ASSOCIATION (2013), <http://ocsotc.org/wp-content/uploads/2013/07/AMAResolution5071.pdf>; Improving Access to Over the Counter Contraception by Expanding Insurance Coverage, Policy Number: 20111, AMERICAN PUBLIC HEALTH ASSOCIATION (Nov. 1 2011), <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/24/10/31/improving-access-to-over-the-counter-contraception-by-expanding-insurance-coverage>; An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy, 31 PHARMACOTHERAPY 424-37 (Apr. 2011).

<sup>14</sup> D Foster et al., *Potential Public Sector Cost-Savings from Over-the-Counter Access to Oral Contraceptives*, CONTRACEPTIONJOURNAL.ORG (Feb. 27, 2015) (in proof for journal publication), available at [http://www.contraceptionjournal.org/article/S0010-7824\(15\)00011-6](http://www.contraceptionjournal.org/article/S0010-7824(15)00011-6).

<sup>15</sup> SC Landau et al., *Birth Control Within Reach: A National Survey on Women's Attitudes toward and Interest in Pharmacy Access to Hormonal Contraception*, 74 CONTRACEPTION (Dec. 2006) 463-470; Prepregnancy

The prescription requirement is also accompanied by additional related barriers that further impede access. At present, in order to receive a prescription for oral contraceptives, women are usually obliged to visit a health care provider's office for the de facto requirement of an annual gynecological exam, thereby creating an additional barrier to oral contraception. Such de facto requirements act as deterrents for many women seeking out contraception they would otherwise use.<sup>16</sup> Removing the prescription requirement for oral contraceptives would enable women to get these medications without the process of visiting a health care provider which, as discussed above, is unnecessary and often burdensome.<sup>17</sup>

#### **4. State policies moving towards an OTC regime show feasibility and practicality**

In July 2015, a bill allowing for the purchase of oral contraceptives at a pharmacy without a doctor's prescription passed with overwhelming approval in the Oregon state House and Senate.<sup>18</sup> Oregon also ensured easier availability of oral contraception through rules allowing women to obtain a yearlong supply of medication, thereby sparing them unnecessary trips to the pharmacy as well as to a physician.<sup>19</sup> Similarly, California is finishing the regulations associated with a 2013 law enacted to allow women to receive oral contraception directly from a pharmacist without the need for a visit to a healthcare provider's office.<sup>20</sup> The California and Oregon laws were both passed in response to the fact that requiring women to see a physician for an oral contraception prescription increases discontinuance of its use.<sup>21</sup> Representatives in these states also expressed concern about growing physician shortages.<sup>22</sup>

#### **Other concerns**

One controversy surrounding the move of oral contraceptives to OTC status is grounded in concerns over who will bear the cost of these drugs. The switch to OTC would likely lower the

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Contraceptive Use Among Teens with Unintended Pregnancies Resulting in Live Births—Pregnancy Risk Assessment Monitoring System (PRAMS), 2004–2008, CENTERS FOR DISEASE CONTROL AND PREVENTION (Jan. 20, 2012), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6102a1.htm>; SC Landau SC, Tapias MP, McGhee BT.

<sup>16</sup> Meredith Melnick, Are Doctors' Exams a Barrier to Birth Control?, TIME (Dec. 6, 2010), <http://healthland.time.com/2010/12/06/why-annual-exams-shouldnt-be-required-to-get-birth-control-pills>.

<sup>17</sup> The burdensome nature of a physician's visit can be understood intuitively by anyone who has had to take time away from work to see a physician. The cost and associated stress of arranging the time for such a visit, which can involve the loss of working hours or the cost of childcare arrangements made to accommodate the visit, or both, can be quite high. There is also often a financial burden associated with a physician's visit. With respect to oral contraception, which must be taken at a regular time each day to preserve its effectiveness, the burden is increased by the friction imposed particularly on women knowing they must not even miss even a day's dose of their oral contraception if they want the medication to be effective.

<sup>18</sup> Natalie Schachar, Birth Control Will Be Available to Women Over the Counter in Oregon, THE L.A. TIMES (Jul. 18, 2015).

<sup>19</sup> *Id.*

<sup>20</sup> April Dembosky, California Women Can Soon Go Right To The Pharmacist For Birth Control, NPR (Jun. 5, 2015).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

cost of oral contraception for health insurance companies if they were to continue covering the cost of oral contraception in an OTC form. Most drugs that are moved to OTC status experience substantial price decline.<sup>23</sup> On average, \$1 spent on OTC medicines is equal to at least \$6 in savings for the U.S. health system because patients avoid unnecessary physician appointments and more expensive care associated with these appointments, including unintended pregnancy and childbirth.<sup>24</sup> Moreover, the Affordable Care Act mandates coverage for other forms of birth control, thereby allowing women the choice of an alternative, prescription-based form of contraception.

## CONCLUSION

This urgent matter affects the daily lives of over 50% of your constituents. The United States has always been a leader in science and medicine, and making oral contraceptives available OTC would continue this tradition as well as set an example for other countries seeking to ensure ready access to cost-effective healthcare. It has been fifty-five years since the FDA approved the first oral contraception.<sup>25</sup> It is time for a new scientific and social advance in this domain.

Respectfully,



Henry P. Behnen  
Chair, Science & Law Committee



Katharine Bodde  
Chair, Sex & Law Committee

Cc:     Hon. Charles E. Schumer     Hon. Steve Israel     Hon. Kathleen Rice  
          Hon. Kirsten Gillibrand     Hon. Hakeem Jeffries     Hon. Charles Rangel  
          Hon. Yvette Clarke     Hon. John Katko     Hon. Tom Reed II  
          Hon. Chris Collins     Hon. Peter King     Hon. Jose Serrano  
          Hon. Joseph Crowley     Hon. Nita Lowey     Hon. Louise Slaughter  
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          Hon. Richard Hanna     Hon. Grace Meng     Hon. Lee Zeldin  
          Hon. Brian Higgins     Hon. Jerrold Nadler

<sup>23</sup> Herrick Devon and Paul Kittinger, Patient Power: Over-the-Counter Drugs, NATIONAL CENTER FOR POLICY ANALYSIS (Aug. 22 2005), <http://www.ncpa.org/pub/ba524>.

<sup>24</sup> Pfizer, The Value of OTC Medicines, Pfizer Value of Medicines (Mar. 2014), [http://www.pfizer.com/files/health/VOM\\_OTC.pdf?linkId=7921337](http://www.pfizer.com/files/health/VOM_OTC.pdf?linkId=7921337).

<sup>25</sup> A Nikolchev, A Brief History of the Birth Control Pill, PBS (May 7, 2010), <http://www.pbs.org/wnet/need-to-know/health/a-brief-history-of-the-birth-control-pill/480>.