

# REPORT OF THE BOARD OF TRUSTEES

B of T Report 10-A-18

Subject: Over-the-Counter Contraceptive Drug Access (Resolution 110-A-17)

Presented by: Gerald E. Harmon, MD, Chair

Referred to: Reference Committee E  
(Douglas Martin, MD, Chair)

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## 1 INTRODUCTION

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3 At the 2017 Annual Meeting, Resolution 110-A-17, “Over-the-Counter Contraceptive Drug  
4 Access,” introduced by the Illinois Delegation and referred by the House of Delegates (HOD),  
5 asked:

6  
7 That our American Medical Association (AMA) condemn age-based, cost-based, and other  
8 non-medical barriers to contraceptive drug access;

9  
10 That our AMA adopt policy supporting equitable access to over-the-counter (OTC)  
11 contraception, including those forms of contraception recommended for OTC sale, patient risk  
12 assessment screening tools, and prescribing by non-physicians;

13  
14 That our AMA support policy solutions that prohibit cost-sharing obstacles to OTC  
15 contraceptive drug access, and full coverage of all contraception without regard to prescription  
16 or OTC utilization, since all contraception is essential preventive health care; and

17  
18 That our AMA advocate for the legislative and/or regulatory mechanisms needed to achieve  
19 improvements for OTC contraceptive drug access and quality.

20  
21 This report outlines the issues associated with OTC contraceptive drug access and provides a  
22 recommendation based on current evidence. Access to emergency contraception is not a focus of  
23 this report.

## 24 25 BACKGROUND

26  
27 Unintended pregnancy is a major public health issue in the United States accounting for  
28 approximately 45% of all pregnancies and is associated with increased risks for negative outcomes  
29 for mothers and infants and increased health care costs.<sup>1</sup> Currently, OTC oral contraception is  
30 available in more than 100 countries. Although no OTC oral contraceptives are available in the  
31 United States, interest in their availability is high, with surveys finding that 62% of U.S. women  
32 support such access.<sup>2</sup>

33  
34 Oral contraceptive pills consist of the hormones estrogen and/or progestin and are taken orally once  
35 per day. Three types are available in the United States: the combination pill with estrogen and  
36 progestin, the progestin-only pill, and the continuous use pill. The three types of oral contraceptives  
37 vary in their hormonal composition and the regimen for their use.<sup>3</sup> Emergency contraceptive pills,

1 which consist of the progestin levonorgestrel, are also considered a type of oral contraceptive not  
2 intended for daily use, but that can be used to prevent pregnancy after unprotected sex.<sup>3</sup> Oral  
3 contraceptives are primarily used for pregnancy prevention, but they are also used to treat other  
4 health conditions such as menstrual pain, irregular menstruation, fibroids, endometriosis-related  
5 pain, menstrual-related migraines, and acne.<sup>3</sup>

6  
7 Policy statements from the American Academy of Family Physicians (AAFP), the American  
8 College of Obstetricians and Gynecologists (ACOG), and American Public Health Association  
9 (APHA) support OTC oral contraceptive access.<sup>4-6</sup> An Oral Contraceptives Over-the-Counter  
10 Working Group was formed in 2004 with the aims “to improve access to contraception and reduce  
11 disparities in reproductive health outcomes by making a low-cost oral contraceptive product  
12 available OTC in the United States.” Over 80 organizations have signed onto the Working Group’s  
13 statement of purpose, including the American Academy of Pediatrics and ACOG.<sup>7</sup>

14  
15 A variety of concerns have been raised in discussions of OTC oral contraceptives, including  
16 barriers to access, cost of a potential OTC oral contraceptive, and safety, which are briefly  
17 discussed below.

#### 18 19 BARRIERS TO CONTRACEPTIVE USE

20  
21 One third of women at risk for unintended pregnancy who attempted to obtain a prescription for  
22 contraception reported having trouble doing so.<sup>8</sup> Access and cost issues are the most commonly  
23 cited reasons why women do not use oral contraceptives, use them inconsistently, or discontinue  
24 use early. Women may experience difficulty obtaining oral contraceptives for a variety of reasons  
25 including the prescription requirement, lack of insurance, and inaccessibility when travelling.  
26 Research suggests that OTC access would increase the use of contraception and facilitate  
27 continuity of use.<sup>9</sup> Additional time and cost benefits include less travel, fewer physician office  
28 visits, and less time off work.

#### 29 30 INSURANCE COVERAGE AND ACCESS

31  
32 Under the Patient Protection and Affordable Care Act (ACA), most private health insurance plans  
33 are required to provide coverage for at least one product in each of the 18 contraceptive methods  
34 approved by the U.S. Food and Drug Administration (FDA) for women with no cost-sharing.<sup>10</sup>  
35 This coverage also applies to OTC contraceptives used by women, such as emergency  
36 contraception, barrier methods, and spermicide, but a prescription is required.<sup>11</sup> Plans are not  
37 required to cover male contraception methods such as vasectomy and male condoms. Federal law  
38 requires Medicaid programs to cover family planning services and supplies without cost-sharing.  
39 States that expanded Medicaid under the ACA must follow the ACA requirements for oral  
40 contraceptives. Coverage for oral contraceptives is required in the Indian Health Service and in the  
41 TRICARE program, but is not a requirement for Medicare. Regulations exist to exclude some or all  
42 contraceptive methods and services from health plans provided by employers who morally object  
43 to oral contraceptive use or have religious exemptions. However, enforcement of these regulations  
44 has been blocked by the courts.

45  
46 Cost is an important consideration. A survey of U.S. women indicated that the maximum they are  
47 willing to pay for an OTC oral contraceptive is \$20.<sup>2</sup> A cost modeling analysis determined that full  
48 insurance coverage of an OTC oral contraceptive without any out-of-pocket expenses would result  
49 in the largest reduction of unintended pregnancies.<sup>12</sup> The analysis also found that use would be  
50 highest, and the estimated reduction in unintended pregnancy greatest, among low-income women,  
51 if an OTC oral contraceptive was fully covered by insurance with no cost-sharing. Full coverage

1 would also be cost effective for insurers because of the savings associated with averting unintended  
2 pregnancies.<sup>12</sup> AAFP, ACOG, and APHA policy statements include support for insurance coverage  
3 of OTC contraceptive products without the need for a prescription. Federal or state legislative or  
4 administrative changes to ACA policy would be needed to include non-prescribed contraceptives in  
5 coverage and pharmacies would need billing mechanisms for processing claims without a  
6 prescription. Billing mechanisms that do not rely on a prescription are used by Medicaid programs  
7 in several states to cover OTC emergency contraception. These billing mechanisms have been  
8 incorporated into existing software, and it may be feasible for additional insurers to incorporate the  
9 ability to process claims without a prescription. Computerized kiosks providing a prescription for  
10 contraception after the completion of a self-screening tool are currently being piloted, and the  
11 potential exists for women to be able to generate a prescription in a pharmacy or at home using  
12 web-based tools from insurers.<sup>13</sup> Congress has introduced legislation addressing this issue, and a  
13 few states have passed laws requiring insurers to cover OTC contraceptives without a prescription.<sup>3</sup>

14  
15 Concerns have been raised that overall access to oral contraceptives may be hindered if an OTC  
16 product becomes available and the switch negatively affects insurance coverage for other  
17 prescription oral contraceptives or creates new barriers to obtaining these products.<sup>13</sup> Insurers may  
18 employ formulary management strategies such as preferred drug lists, prior authorization, and step-  
19 therapy programs.<sup>13</sup>

20  
21 Some states allow pharmacists to provide oral contraceptives without physician oversight. Policies  
22 in such states vary including age requirements, type of contraceptive allowed, and length of supply.  
23 Some discussion has centered around the issue of increasing the dispensing period of oral  
24 contraceptives to a 12-month supply to facilitate access. Dispensing requirements vary by insurer  
25 and laws requiring coverage for a 12-month supply have been passed in several states.<sup>3</sup>  
26 Additionally, online services and smartphone applications have emerged for women to speak with  
27 providers via video, obtain prescriptions, and order oral contraceptives from mail delivery services.  
28 Requirements and cost vary based on the application.<sup>3</sup>

## 29 30 SELF-SCREENING

31  
32 In 2016, the U.S. Centers for Disease Control and Prevention (CDC) published an updated Medical  
33 Eligibility Criteria for Contraceptive Use (U.S. MEC), an evidence-based list of conditions and  
34 medications considered contraindications to contraceptive methods. The U.S. MEC states that all  
35 contraindications for combined oral contraceptives, other than hypertension, can be identified by  
36 reviewing a woman's medical history; progestin-only oral contraceptives have a shorter list of  
37 contraindications that does not include hypertension.<sup>1,14</sup>

38  
39 Concern has been raised from physicians that women might not be able to self-diagnose  
40 contraindications associated with oral contraceptives or may ignore label warnings. Studies have  
41 shown that women can accurately use checklists to determine if they have contraindications to  
42 hormonal contraception; in one study, 96% of cases evaluated demonstrated agreement between a  
43 women's assessment of her contraindications using a checklist and a clinician's independent  
44 evaluation, and women often take a more conservative approach compared with clinicians.<sup>15,16</sup>

45  
46 Another concern that has been voiced about OTC oral contraceptives is that women would not  
47 obtain recommended preventive screenings for cervical and breast cancer and for sexually  
48 transmitted infections that often accompany physician visits for contraceptives. The World Health  
49 Organization, FDA, and ACOG state that oral contraceptives can be safely and effectively  
50 prescribed without a pelvic examination. Although experts have stated that that preventive  
51 screening is not medically necessary or required for the provision of hormonal contraception,<sup>17</sup>

1 many clinicians continue to link the services.<sup>18</sup> A recent study found that a high proportion of  
2 women in Texas who acquired oral contraceptives from Mexico without a prescription obtained  
3 screening tests at a rate higher than the U.S. national average.<sup>19</sup>

#### 4 5 AGE RESTRICTIONS

6  
7 Adolescents face age-related barriers to contraception access, which could be reduced with OTC  
8 access, including concerns about disclosing their confidential information and their ability to access  
9 services without the consent of a parent or guardian. An age restriction for an OTC product is  
10 uncommon, but is a relevant topic related to OTC oral contraceptives. Some states that allow  
11 pharmacists to provide oral contraceptives include age restrictions in their policy. When  
12 levonorgestrel emergency contraception became available OTC, there was an age restriction that  
13 was later removed. The consensus is that oral contraceptives are safe and the prevalence of  
14 contraindications is greater in women 35 years and older compared to younger users and is low  
15 among women of all ages for a progestin-only product.<sup>5,15</sup>

16  
17 A 2011 survey revealed that most women do not support an age restriction for oral contraceptives  
18 and a survey of teenagers found that approximately three-quarters supported oral contraceptive  
19 OTC access.<sup>8,20</sup> Additionally, studies showed that sexual risk-taking behaviors did not increase in  
20 teenagers when their access to emergency contraception increased, and the increased access may  
21 aid in improving their use of more effective contraception methods.<sup>21</sup>

#### 22 23 FDA APPROVAL PATHWAY

24  
25 The FDA has pathways in place for the development and regulation of OTC products, the  
26 monograph process or the New Drug Application (NDA) process. Products for which an OTC  
27 monograph does not exist or that do not conform to an existing final monograph, as is the case for  
28 oral contraceptives, primarily use the NDA process. A sponsor seeking to market a product OTC,  
29 either as a new NDA or a switch from a prescription product, applies to the Division of  
30 Nonprescription Drug Products in the Office of Drug Evaluation IV.<sup>22</sup>

31  
32 Once a sponsor submits an NDA to change one oral contraceptive product that is already registered  
33 as a prescription product to an OTC product, there are consumer studies, safety data evaluations,  
34 and regulatory reviews required by the FDA. The required information includes the following:

- 35 • Post-market safety data review: Toxicity data, addictive properties, and interactions with  
36 other drugs are evaluated to establish the safety of the medication as a prescription product.
- 37 • Label comprehension study: Ability of potential users to understand OTC labeling of  
38 medication and take the medication as indicated without a physician's explanation are  
39 evaluated.
- 40 • Self-selection study: Ability of potential users to determine whether the product is  
41 appropriate for them is evaluated.
- 42 • Actual use study: Correct use of the product by potential users in a simulated OTC  
43 environment is evaluated.
- 44 • Human factors study: Interacting with the product by potential users is evaluated.

45  
46 Following collection and submission of data, FDA staff reviews and evaluates the findings in  
47 consultation with an advisory committee. Many of the required studies can occur simultaneously;  
48 however, this process can take three to four years from NDA initiation until an application is  
49 approved. Evidence published in peer-reviewed literatures suggests that oral contraceptives  
50 generally meet FDA requirements for an OTC switch.<sup>23</sup>

1 Over fifty formulations, accounting for hundreds of different branded products of oral  
2 contraceptives, exist as prescription medications. Only the specific product for which an NDA was  
3 submitted will be evaluated for OTC sale. All others would remain as prescription medications  
4 unless an NDA or Abbreviated New Drug Application (ANDA), in the case of a generic with the  
5 same drug formulation, is submitted and required studies are individually performed for each one.  
6

7 Progestin-only oral contraceptives have fewer and more rare contraindications than combined oral  
8 contraceptives, which may make them a better candidate for FDA approval for OTC sale. A  
9 progestin-only product has been put forward as a potential first candidate for an OTC oral  
10 contraceptive. In December 2016, Ibis Reproductive Health announced a partnership with HRA  
11 Pharma to conduct the research needed and submit an application to the FDA to bring a progestin-  
12 only oral contraceptive pill to the United States OTC market.<sup>24</sup> The 2006 FDA approval of OTC  
13 sale for progestin-only levonorgestrel emergency contraception, which contains a higher dose of  
14 progestin than is found in oral contraceptives, may make it easier to obtain approval for an OTC  
15 progestin-only product than for a combined oral contraceptive product.<sup>13</sup>  
16

#### 17 CURRENT AMA POLICY

18

19 Several current AMA policies address contraceptives. Policy D-75.995, "Over-the-Counter Access  
20 to Oral Contraceptives," directs our AMA to recommend to the FDA that manufacturers of oral  
21 contraceptives be encouraged to submit the required application and supporting evidence for the  
22 Agency to consider approving a switch in status from prescription to OTC for such products and  
23 encourages the continued study of issues relevant to over-the-counter access for oral  
24 contraceptives. Policy H-75.990, "Development and Approval of New Contraceptives," encourages  
25 manufacturers to conduct post-marketing surveillance studies of contraceptive products. Policy  
26 H-75.998, "Opposition to HHS Regulations on Contraceptive Services for Minors," opposes  
27 regulations that require parental notification when prescription contraceptives are provided to  
28 minors through federally funded programs, since they create a breach of confidentiality in the  
29 physician-patient relationship. Policy H-180.958, "Coverage of Prescription Contraceptives by  
30 Insurance," supports federal and state efforts to require that every prescription drug benefit plan  
31 include coverage of prescription contraceptives. Policy H-75.987, "Reducing Unintended  
32 Pregnancy," urges health care professionals to provide care, assistance, and education for women  
33 of reproductive age, supports reducing unintended pregnancies as a national goal, and supports the  
34 training of all primary care physicians and relevant allied health professionals in the area of  
35 preconception counseling. Policies H-75.985, "Access to Emergency Contraception," and  
36 D-75.997, "Access to Emergency Contraception," support the access to emergency contraception.  
37

#### 38 CONCLUSION

39

40 An FDA pathway exists for the conversion of prescription products, such as oral contraceptives, to  
41 OTC products if manufacturers submit the required application and data. A potential first candidate  
42 for an OTC progestin-only oral contraceptive product was recently announced by a manufacturer  
43 because progestin-only products have fewer contraindications than other types of oral  
44 contraceptives.  
45

46 Research has shown that women support the idea of OTC oral contraceptives and can effectively  
47 self-screen for their use. Additionally, removing the prescription access barrier to oral  
48 contraceptives would increase and facilitate continuity of use. Full insurance coverage, without  
49 cost sharing, of an OTC oral contraceptive would likely result in the largest reduction of  
50 unintended pregnancies as well as cost effectiveness for insurers. However, concerns regarding

1 hindrance of overall access to oral contraceptives because of insurance formulary management  
2 strategies exist.

3  
4 RECOMMENDATIONS

5  
6 The Board of Trustees recommends the following be adopted in lieu of Resolution 508-A-17, and  
7 the remainder of the report be filed:

- 8  
9 1. That our AMA amend Policy D-75.995, "Over-the-Counter Access to Oral Contraceptives;"  
10 D-75.995, Over-the-Counter Access to Oral Contraceptives

11 Our AMA:

- 12 1. ~~Our AMA Encourages~~ will recommend to the US Food and Drug Administration that  
13 manufacturers of oral contraceptives ~~be encouraged~~ to submit the required application  
14 and supporting evidence to the US Food and Drug Administration for the Agency to  
15 consider approving a switch in status from prescription to over-the-counter for such  
16 products.  
17 2. ~~Our AMA Encourages~~ the continued study of issues relevant to over-the-counter  
18 access for oral contraceptives. (Modify Current HOD Policy)  
19  
20 2. That our AMA amend Policy H-180.958, "Coverage of Prescription Contraceptives by  
21 Insurance;"  
22 H-180.958, Coverage of ~~Prescription~~ Contraceptives by Insurance  
23 1. Our AMA supports federal and state efforts to require that every prescription drug  
24 benefit plan include coverage of prescription contraceptives.  
25 2. Our AMA supports full coverage, without patient cost-sharing, of all contraception  
26 without regard to prescription or over-the-counter utilization because all contraception  
27 is essential preventive health care. (Modify Current HOD Policy)

Fiscal Note: Less than \$500

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