Dear Secretary Becerra, Acting Secretary Su, and Secretary Yellen,

On behalf of Robin Corelli, PharmD, UCSF School of Pharmacy; Lisa Kroon, PharmD, UCSF School of Pharmacy; Cynthia Harper, PhD, UCSF; Claire Brindis, DrPH, UCSF; Eleanor Schwarz, MD, MS, UCSF; Kathryn Phillips, PhD, UCSF; Mark Fendrick, MD, University of Michigan; And Erin Isenberg, MD, University of Michigan, we submit the following comments in response to the RFI released on coverage of over-the-counter (OTC) preventative services. These comments address cost and coverage data related to OTC contraceptive products. Our bottom line is this: **The Administration must ensure that insurance plans cover a 12-month supply of OTC contraception, without requiring a prescription or cost-sharing.**

How should pharmacy and pharmacist concerns and barriers be managed with regard to coverage for OTC contraception?

Multiple options will be needed to provide the most flexibility for pharmacies and patients at the time of purchase as one approach will not work for all patients. Ideally, pharmacies/ pharmacists should be able to bill insurance directly, rather than asking members to pay out of pocket and submit receipts for reimbursement (which may not be feasible for those with limited cash flow). A requirement to submit receipts for reimbursement would also limit use by young people on their parent's insurance who would not be familiar with the process or would lack direct access to insurance reimbursements. This policy to include a recommendation to dispense 12 months of pills to any woman who wanted them given the strong evidence supporting this as a cost-effective strategy.[1] Since 2017, CA SB999 has required health plans to cover 12-months of self-administered hormonal contraception. As less than a 12-month supply of OC triples rates of unintended pregnancy. The VA policy of dispensing 12-month OC is projected to annually save over $2 million.

For providers, what kinds of medical management limitations are unnecessary and create other barriers to OTC contraceptive access?

Hormonal contraception has multiple non-contraceptive health benefits, including reducing anemia and pelvic pain/dysmenorrhea in ways that increase school attendance and decrease days off of work) and decreasing risk of ovarian and uterine cancer.[2] Other OTC contraceptives include levonorgestrel

[1] Judge-Golden CP JAMA Intern Med 2019 Foster DG, et al Obstet Gynecol. 2011

[2] https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception#:~:text=Additionally%2C%20noncontraceptive%20benefits%20may%20include,of%20endometrial%20and%20ovarian%20cancer ; https://pubmed.ncbi.nlm.nih.gov/34587539/; Fu Z, Brooks MM, Irvin S, Jordan S, Aben KKH, Anton-Culver H, Bandera EV, Beckmann MW, Berchuck A, Brooks-Wilson A, Chang-Claude J, Cook LS, Cramer DW, Cushing-Haugen KL, Doherty JA, Ekici AB, Fasching PA, Fortner RT, Gayther SA, Gentry-Maharaj A, Giles GG, Goode EL, Goodman MT, Harris HR, Hein A, Kaaks R, Kiemeney LA, Köbel M, Kotsopoulos J, Le ND, Lee AW, Matsuo K, McGuire V, McLaughlin JR, Menon U, Milne RL, Moysich KB, Pearce CL, Pike MC, Qin B, Ramus SJ, Riggan MJ, Rothstein JH, Schildkraut JM, Sieh W, Sutphen R, Terry KL, Thompson PJ, Titus L, van Altena AM, White E, Whittemore AS, Wu AH, Zheng W, Ziogas A, Taylor SE, Tang L, Songer T, Wentzensen N, Webb PM; AOCS Group; Risch HA, Modugno F. Lifetime ovulatory years and risk of epithelial ovarian cancer: a multinational pooled analysis. J Natl Cancer Inst. 2023 May 8;115(5):539-551. doi: 10.1093/jnci/djad011. PMID: 36688720; PMCID: PMC10165492; Iversen L, Sivasubramaniam S, Lee AJ, Fielding S, Hannaford PC. Lifetime cancer risk and combined oral contraceptives: The Royal College of General Practitioners' Oral Contraception Study. *American Journal of Obstetrics and Gynecology* 2017; 216(6):580.e1–580.e9.

emergency contraceptive pills and condoms which prevent sexually transmitted infections, including HIV and syphilis, and infertility.

What strategies can be implemented to either prevent states from limiting access to OTC contraception or to increase utilization of OTC contraception? How should this change and coverage be communicated to consumers and impacted businesses?

Although there are concerns regarding the impact of OTC OCP coverage on medical expenditures, available data indicate that providing contraceptive coverage as part of a health insurance benefit does not add to the cost of providing insurance coverage. OTC oral contraception pills are an extremely rare example of medical services that improve health, increase member satisfaction, enhance equity, and lower health care spending. They also allow rural and underserved communities living far from medical care to access needed contraception, especially important in our current context of state restrictions on reproductive rights.[3] It is estimated that nearly 90% of Americans live within 5 miles of a community pharmacy, providing an important access point for OTC OCP, and during hours when medical offices are closed.[4] Unlike most clinical services, requiring insurers to cover OTC contraception is not expected to increase aggregate expenditures for insurers or lead to higher premiums for enrollees. When considering the direct and indirect costs of unintended pregnancy, evidence from well-documented prior expansions of contraceptive coverage indicates that there is a net savings (approximately $100 per employee annually) to issuers.[5] It was this body of cost-benefit and other research evidence that supported the recommendations made by the then Institute of Medicine (now National Academy of Medicine) to propose the elimination of no-out of pocket expenses for the provision of contraceptive care and counseling in 2011 as part of a portfolio of eight preventive health services for women, which was initially adopted as part of the Affordable Care Act, and then more widely implemented by private and public insurance plans.[6] Policies that increase access to contraception and prevent undesired pregnancy offer considerable savings to States and the Federal budgets; in 2021 Medicaid covered 41% of U.S. births. It is estimated that every dollar invested in contraceptive services produces 6-fold savings.[7] In addition, hormonal contraceptives offer savings by reducing school and workplace absenteeism and preventing multiple forms of cancer. Lastly, insurers are very willing to cover costs of other medications, e.g., phosphodiesterace-5 enzyme inhibitors (e.g., Viagra).

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[3] https://powertodecide.org/what-we-do/contraceptive-deserts#:~:text=Lack%20of%20Access%20%3D%20Lack%20of%20Power%20to%20Decide&text=Living%20in%20a%20contraceptive%20desert,full%20range%20of%20contraceptive%20methods

[4] Berenbrok, LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. J Am Pharm Assoc. 2022;62: 1816-1822.

[5] https://aspe.hhs.gov/reports/cost-covering-contraceptives-through-health-insurance

[6] https://www.nationalacademies.org/news/2011/07/iom-report-recommends-eight-additional-preventive-health-services-to-promote-womens-health

[7] https://www.cdc.gov/nchs/products/databriefs/db468.htm#:~:text=Data%20from%20the%20National%20Vital,3.9%25%20as%20self%2Dpay .; Frost JJ, Zolna MR, Frohwirth L. Contraceptive needs and services, 2010 . New York (NY): Guttmacher Institute; 2013. Available at:http://www.guttmacher.org/pubs/win/contraceptive-needs-2010.pdf.