The National Catholic Bioethics Center

November 14, 2022

Non-prescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee
U.S. Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: FDA-2022-N-1959-0001. "Joint Meeting of the Non-prescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments."

Dear Advisory Committees:

The U.S. Food and Drug Administration has announced that your committees will discuss a supplemental new drug application 017031/S-041 for OPILL (norgestrel) Tablet, 0.075 mg, submitted by Laboratoire HRA Pharma. OPILL is proposed for non-prescription use as a once-daily oral contraceptive to prevent pregnancy.

We represent thousands of health care providers and medical ethicists[1] committed to delivering, as well as advocating for policies that promote, health care that meets the Hippocratic imperative "to do no harm." We strenuously oppose the non-prescription availability of OPILL because such access to OPILL violates this inviolable standard of care.

Any patient having access to a medication that has the documented and potentially life-threatening side effects that can be present with OPILL, at a minimum, should be medically

[1] The USCCB itself does not represent providers or ethicists but otherwise joins these comments in full.

evaluated for contraindications to the drug. The manufacturer provides the following information concerning OPILL contraindications:[2]

- Known or suspected pregnancy;
- Known or suspected carcinoma of the breast, or other progestin-sensitive cancer, now or in the past;
- Undiagnosed abnormal uterine bleeding;
- Hypersensitivity to any component of this product;
- Benign or malignant liver tumors;
- Acute liver disease.

OPILL is a synthetic progestin-only contraceptive, also called the "minipill," which potentially can induce the following side effects that clearly include indicators of organ failure, e.g., liver, cardiovascular, hemopoietic, or neurological systems: difficulty breathing, swelling of the ankles or feet, severe stomach or pelvic pain, unusual tiredness, dark urine, yellowing of the eyes or skin (jaundice), sudden shortness of breath, chest, jaw, and left arm pain, confusion, coughing up blood, sudden dizziness, fainting, pain, swelling, or warmth in the groin or calf, tingling, weakness, or numbness in the arms or legs, headaches with or without vision changes, lack of coordination, existing migraines becoming worse, sudden or very severe headache, trouble speaking, weakness on one side of the body, and vision problems.[3] Any of these symptoms could indicate serious and irreversible damage to a vital organ system.

This hormonal contraceptive may cause abnormal bleeding, ovarian cysts and, most importantly, depression, which has already been a significant problem since Covid-19 in young people. Even for those who do not share these very important concerns, which we think are dispositive, questions would presumably remain as to the drug's effectiveness that call into question its proposed over-the-counter availability. The failure rate of the minipill is higher than that of other hormonal contraceptive methods and will result in many unintended pregnancies, leading to potentially more abortions. In addition, the minipill will not protect the patient from sexually transmitted infections.[4] Thus, without regular care with a physician, pelvic inflammatory disease or sterility may result.

Consumers not only need to be screened for these potential vulnerabilities, but regularly monitored by health care providers for these side effects of progestin-only contraceptives. Furthermore, pelvic and breast examinations, including mammograms, may be needed to monitor for these unwanted effects. Without on-going physician monitoring, as we have seen during COVID-19, these preventive assessments often are not done.

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[2] Laboratoire HRA Pharma, Opill® Tablets (ND). Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017031s035s036lbl.pdf.

[3] William V. Williams, Joel Brind, Laura Haynes, Michael D. Manhart, Hanna Klaus, Angela Lanfranchi, Gerard Migeon, Mike Gaskins, Elvis I. Seman, Lester Ruppersberger, Kathleen M. Raviele, "Hormonally Active Contraceptives Part I: Risks Acknowledged and Unacknowledged" *Linacre Quarterly* 88:2 (2021), 126-148. Available at https://doi.org/10.1177/0024363920982709.

[4] Mayo Clinic, "Minipill (progestin-only birth control pill)," *Mayo Clinic* (ND). Available at Minipill (progestin-only birth control pill) - Mayo Clinic.

Making such a potentially harmful medication available without a prescription can only cause avoidable harm, violating the Hippocratic tradition embraced by the Food and Drug Administration, which has been protecting the people of the United States for over a century. We rely on the Administration to continue to do so. Some of our most vulnerable residents, teenagers who will have access without parental notification, can be seriously harmed. Even if they read the package insert, evidence documents that teenagers take risks disproportionate to their own safety needs. When this is compounded by the lack of parental notification or health provider supervision, the results could be catastrophic.

We, representing thousands of health care providers and medical ethicists, committed to "doing no harm," and, in fact "doing good" consistent with the Hippocratic tradition, strongly advise that OPILL not be made available over-the-counter.

Sincerely yours,

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