

Janet Woodcock
Acting Commissioner of Food and Drugs
Center for Drug Evaluation and Research
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

September 1, 2021

Dear Dr. Woodcock,

Hormonal contraceptives have been on the market for over sixty years and, while their formulations and routes of delivery have changed, their basic mechanism of action has remained the same. In the intervening years since hormonal contraceptives were first introduced, numerous studies have documented their myriad side effects. Some of these side effects appear over time, some within weeks, and others may take months or years to materialize, but all can have a serious impact on a woman's health and quality of life.

A team of experts was assembled to perform a series of comprehensive literature surveys to better understand the immediate and long-term side effects of hormonal contraceptives. The results of this literature review uncovered a significant number of side effects that range from likely to definitively related to hormonal contraceptive use, some of which are lethal. Some of these risks and side effects are acknowledged by current prescribing information and package inserts, yet many more are not mentioned at all.

Among the unacknowledged side effects for depot medroxyprogesterone acetate (DMPA) is a significantly increased risk of contracting HIV infection. For combination contraceptives, the unacknowledged side effects include: breast cancer, cervical cancer, venous thromboembolism, Crohn's disease, ulcerative colitis, systemic lupus erythematosus, depression, mood disorders and suicides (especially among women twenty-five years of age and younger, in the first six months of use), multiple sclerosis, interstitial cystitis, female sexual dysfunction, osteoporotic bone fractures (especially for progesterone-only contraceptives), and weight gain. Misleading prescribing information regarding cardiovascular and thrombotic risks is also noted.

In one case—that of DMPA—the increased risk of contracting HIV has been conclusively demonstrated to be both real and unique to this drug. Considering the availability of numerous alternatives, there is no justification for the continued marketing of DMPA to the public.

Through our research and review, we were able to assess that up to 1.2 million American women are currently affected by one or more of these serious medical conditions, as a direct result of their past or current use of hormonal contraceptives. We have also deduced that between 300-400 women die per year from venous thromboembolism directly related to their use of hormonal contraceptives.

It has now been approximately 2 years since we submitted a Citizen's Petition to the FDA reporting this crisis. In that time, the information in the petition has been published, and is available on PubMed in 2 separate peer-reviewed journal articles. Both are referenced below.

These articles confirm the unacknowledged risks and misleading information in the prescribing information and package inserts for hormonal contraceptives. We also note that the marketing of hormonal contraceptives to women has increased with no mention of any of these serious risks.

As you are undoubtedly aware, online providers like NURX now directly market these potent medications to women without a face-to-face interaction with a physician, and without presenting sufficient information regarding their risks. As online retailers of birth control continue to proliferate, more young women will experience side-effects, some with tragic consequences, as a result of this lack of information.

Only the FDA can correct this dire situation and require more transparency from pharmaceutical manufacturers and prescribers.

We appreciate your consideration of this urgent matter. We are counting on your understanding of the needs of physicians and the women they serve--and on your commitment to serve them.

Our concern is solely for women's health. We urge you to take action on their behalf.

Sincerely,



William V. Williams, M.D.

On behalf of the Contraceptive Study Group
620 South Eagle Road
Havertown, PA 19083

Cc: Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

References:

Hormonally Active Contraceptives Part I: Risks Acknowledged and Unacknowledged.

William V. Williams, MD, FACP, Joel Brind, PhD, Laura Haynes, PhD, MA, Michael D. Manhart, PhD, Hanna Klaus, MD, FACOG, Angela Lanfranchi, MD, FACS, Gerard Migeon, ESCP, Michael Gaskins, BA, Elvis I. Šeman, MBBS, FRANZCOG, EUCOGE, FRCOG, NFPMC, PhD, Lester Ruppertsberger, DO, Kathleen M. Raviele, MD

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Hormonally Active Contraceptives, Part II: Sociological, Environmental, and Economic Impact
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Hanna Klaus, MD, FCOG, Angela Lanfranchi, MD, FACS, Gerard Migeon, ESCP, Michael Gaskins, BA, Elvis
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