Congress of the United States
Washington, DC 20515

October 30, 2013

Dr. Margaret Hamburg
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Commissioner Hamburg:

We write today with significant concerns regarding Merck & Co.'s birth control device, NuvaRing, and the health risks it may pose to women. We urge the Food and Drug Administration (FDA) to change the label on the NuvaRing so that it properly includes a "VTE Warning Statement" similar to the one on the label of Johnson & Johnson's Ortho Evra. Such a label change would provide women and their doctors with critical information – that a side effect of the drug is potentially life-threatening blood clots – and better enable them to make informed healthcare decisions.

The contraceptive methods currently available in the United States, including NuvaRing, are very safe for most women; however, studies show that women using NuvaRing are more likely to develop a blood clot than women taking most currently available birth control pills. NuvaRing carries a higher risk for thromboembolism and blood clots than previous generations of oral combined hormonal contraceptives. Several studies have been done on this, including one published by the British Medical Journal in 2012 which found that users of NuvaRing have nearly double the risk of suffering a venous thrombotic event (VTE) than users of second-generation hormonal birth control pills. The current label does not provide adequate information to support women in making an informed decision, leaving a troubling information gap that affects many young, healthy women.

In 2010, over 5.5 million prescriptions were written for NuvaRing. By 2011, over 1,000 cases of blood clots were reported to the FDA after use. These cases included a healthy 32-year old woman who suffered a seizure and died en route to the hospital from a blood clot that migrated from her pelvic area to her lungs. Merck was aware that NuvaRing users could develop blood clots from its own pre-approval clinical trials in which an otherwise healthy woman developed deep vein thrombosis after only eight days of using the device. In additional clinical trials performed by Merck post-NuvaRing's approval, three other cases of VTEs were found. Despite these findings, NuvaRing's label remains unchanged.

Around the same time that NuvaRing was approved by the FDA, Ortho-Evra, the third-generation hormonal contraceptive patch, also was approved. Unlike NuvaRing, the "VTE Warning Statement" was included in Ortho-Evra's label as a result of a pulmonary embolism that occurred during one of its clinical trials.

Women and health care providers rely on the FDA to ensure that they have clear, comprehensive, and accurate drug information when making health care decisions. Failure to provide this information is irresponsible and potentially dangerous. Therefore, we urge the FDA to act in the best interest of women's health and amend NuvaRing's label to include the "VTE Warning Statement." Thank you, and we look forward to your response to this letter.

Sincerely,

Louise M. Slaughter
Member of Congress

Gwen Moore
Member of Congress

John Conyers
Member of Congress

Mark Takano
Member of Congress

Michelle Lujan Grisham
Member of Congress

Jan Schakowsky
Member of Congress

cc: The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services
Dr. Francis Collins, Director, National Institutes of Health