

# Congress of the United States

Washington, DC 20515

January 30, 2004

Commissioner Mark McClellan  
FDA Commissioner  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Commissioner McClellan:

We respectfully write to express our support for the recommendation of the expert panel convened by the Food and Drug Administration (FDA) to grant over-the-counter (OTC) status for Plan B, an emergency contraceptive pill (ECP). As you know, scientific research has shown ECPs to be extremely safe and effective at reducing unintended pregnancy and therefore appropriate for over-the-counter use. We urge you to ensure that the FDA bases its decision upon the clear scientific evidence supporting the expert panel's recommendation.

ECPs contain the same hormones and work the same way as ordinary birth control pills. They do not cause abortion and do not work if a woman is already pregnant. Instead, ECPs prevent pregnancy by inhibiting ovulation, fertilization, or implantation.

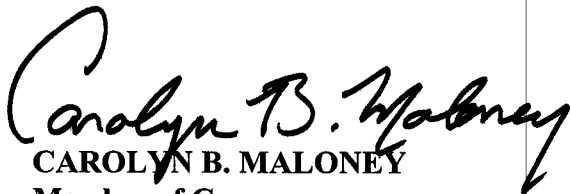
If taken within 24 hours of unprotected sex, ECPs can prevent 95 percent of pregnancies, or 89 percent of pregnancies if taken within 72 hours. Almost half the pregnancies in the U.S. are unintended. Allowing women to purchase ECPs over-the-counter - including during hours when doctor's offices and pharmacies are not open - could cut this rate in half. Granting over-the-counter status for ECPs would also result in significant reductions in health care costs. According to a report recently issued by the New York State Comptroller, the state of New York could trim nearly half a billion dollars from its health care expenditures if ECPs are made widely available.


Moreover, the American Medical Association and the American College of Obstetricians and Gynecologists, along with more than 70 medical and public health groups, endorse making ECPs available over-the-counter because they are proven to be safe to use without medical supervision.

Finally, the scientific evidence is clear that ECPs are safe, simple to use, and are not associated with any serious or harmful side effects which would require medical supervision. As such, they meet the FDA's criteria for over-the-counter drug status. We hope you will make your final decision based on this factual evidence.

We strongly urge you to support the recommendation of the expert panel and grant over-the-counter status to Emergency Contraceptive Pills which has the potential to cut in half the nearly three million unintended pregnancies in the U.S. each year.


Sincerely,

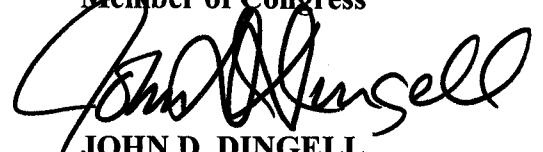
  
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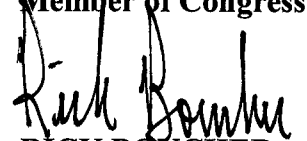
  
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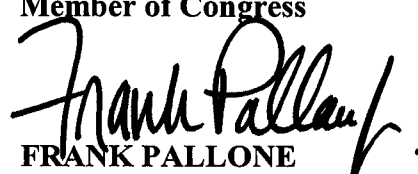
  
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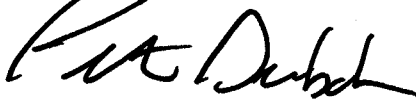
  
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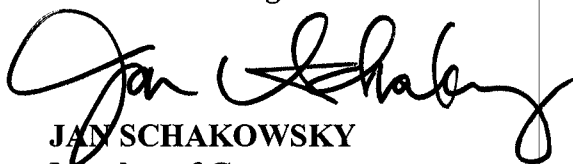
  
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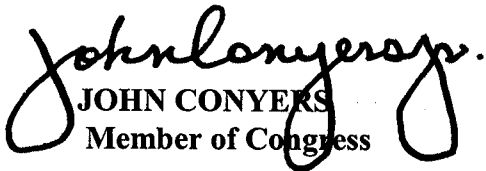
  
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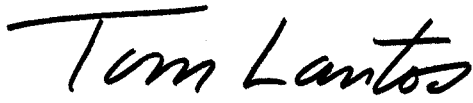
  
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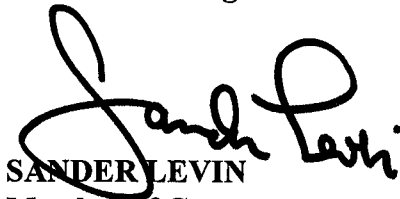
  
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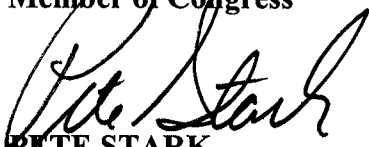
  
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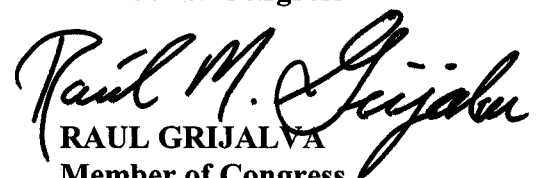
  
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