

FOR IMMEDIATE RELEASE  
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## DELAURO CALLS FOR ACTION TO ENSURE ACCESS TO SAFE, AFFORDABLE MEDICATIONS

*14,900% proposed increase in cost for drug to help prevent premature births*

Washington, DC— Congresswoman Rosa DeLauro (CT-3), Ranking Member on the Labor, Education, Health, and Human Services Appropriations Subcommittee, sent a letter to Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration and Dr. Francis Collins, Director of the National Institutes of Health, today expressing her concern over the cost of KV Pharmaceutical's new drug Makena and the need to ensure balance in public-private research partnerships.

KV Pharmaceutical will be charging \$1,500 for each dose of Makena, which needs to be administered once a week for about 20 weeks, totaling approximately \$30,000 for each at-risk pregnancy. Compounded products similar to the patented Makena have been used for years and available at a fraction of the cost—about \$10 to \$20 per dose.

Congresswoman DeLauro asked both Commissioner Hamburg and Director Collins about each agency's plans regarding federal investments in regulatory science and translational research that may result in private patents. Additionally, the Congresswoman asks for answers about how to ensure access to affordable and effective generic versions of FDA-approved drugs.

“The precedent that may soon be set by KV Pharmaceutical is unconscionable. For years pregnant women and their health care providers have had access to this effective drug at an affordable price. KV Pharmaceutical did not invest in the initial research in the drug, though the American public did support that research through NIH funding. Understandably, there must be market incentives for the FDA approval of treatments. But those same incentives should not come at a cost to the public health, or the welfare of women and children across the country. Nor should they make previously affordable treatments out of reach or no longer cost effective options for health care providers,” Congresswoman DeLauro wrote. “FDA approval of a drug should not make us question the very tenets of federal oversight to ensure patient safety, including oversight of compounded products.”

The text of the letter appears below.

March 30, 2011

Margaret Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
U.S. Department of Health and Human Services  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Dr. Francis Collins, M.D., Ph.D.  
Director  
National Institutes of Health  
10 Center Drive  
Bethesda, MD 20892

Dear Drs. Hamburg and Collins:

I am writing to express concern about the precedent being set by the approval and outrageous marketing scheme surrounding the drug “Makena.” While similar products have been used by health care providers and patients for years, this drug was recently approved by the Food and Drug Administration (FDA) to prevent preterm births. This encouraging news was overshadowed by the announcement of an unreasonable price increase for this replacement for an effective medication that is less expensive.

I am encouraged by recent efforts of both the FDA and the National Institutes of Health (NIH) to ensure that Americans have access to affordable, safe, and efficacious treatments for a range of ailments. This includes the recent emphasis on strengthening regulatory science, encouraging translational research, and finding the appropriate balance for public-private partnerships. It is imperative that such partnerships recognize the investment of federal funds that support the pipeline of research for new and improved therapeutics.

The precedent that may soon be set by KV Pharmaceutical is unconscionable. For years pregnant women and their health care providers have had access to this effective drug at an affordable price. KV Pharmaceutical did not invest in the initial research in the drug, though the American public did support that research through NIH funding.

Understandably, there must be market incentives for the FDA approval of treatments. But those same incentives should not come at a cost to the public health, or the welfare of women and children across the country. Nor should they make previously affordable treatments out of reach or no longer cost effective options for health care providers. FDA approval of a drug should not make us question the very tenets of federal oversight to ensure patient safety, including oversight of compounded products.

In addition to the general concerns outlined above, I am requesting responses to the following questions related to this situation.

- How will both the FDA and the NIH ensure that the results of publicly-funded research are accessible to the public?
- What is the general framework for the partnerships that both the FDA and NIH are entering to support regulatory science and translational research as both agencies consider additional investments in research that may ultimately result in patents or periods of exclusive rights for non-government entities?
- How will both the FDA and the NIH ensure that the appropriate balance of public-private partnerships supported by federally appropriated funds is maintained as research supports the approval of treatments?
- As the NIH considers details of the proposed National Center for Advancing Translational Sciences,
- How can we ensure continued access to affordable and effective drugs, such as 17 Hydroxyprogesterone Caproate, during the exclusivity period if federal funds supported research that was critical to drug approval? Should we consider approval of generic versions of some FDA-approved drugs for off label use in specific situations for drugs that are not novel?

Thank you for your attention to this issue. I look forward to the responses to these questions and to our continued work to ensure that Americans have access to safe and affordable treatment options.

Sincerely,

ROSA L. DeLAURO

Ranking Member

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

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