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## **Harkin Calls on Drug Manufacturer to Lower Price of Makena**

WASHINGTON – Today, Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Tom Harkin (D-IA) called on KV Pharmaceuticals to lower the price of Makena, a drug recently approved by the Food and Drug Administration (FDA) to prevent premature birth for women who have had at least one prior preterm birth. He also applauded Health and Human Services Secretary Kathleen Sebelius and the FDA for their decision to exercise enforcement discretion to allow pharmacists to compound affordable versions of Makena. Sebelius made this announcement today during her testimony before the Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, of which Harkin is the Chairman.

“I applaud Secretary Sebelius and the FDA for this judicious exercise of discretion. KV Pharmaceuticals is taking advantage of the law to achieve a monopoly and outrageous price hike at the expense of American families, American taxpayers, and our healthcare system. They are charging \$1,500 per dose for a drug that cost only \$10 last month for a drug that taxpayer dollars helped develop via a 2003 clinical trial at the National Institute of Health,” said Harkin.

“KV even attempted to safeguard its price hike by sending a cease-and-desist letter to compounding pharmacists, advising them that it would be a violation of law to continue to compound Makena-like products. KV’s behavior has been outrageous, and I credit the Secretary and FDA with taking timely action to address this important public health issue. This sort of conduct simply cannot be tolerated. KV must lower the price of Makena immediately. I also intend to explore how this happened, and what can be done to prevent this sort of abuse in the future as we move forward with the user fee reauthorization process.”

The FDA approved Makena as an Orphan Drug earlier this year under provisions of the Federal, Food, Drug, and Cosmetic Act intended to encourage the development of treatments for conditions that afflict fewer than 200,000 Americans by granting drug manufacturers seven years of market exclusivity from the time of approval. Chairman Harkin has long supported efforts to boost development of treatments for these so-called rare diseases, and he believes firmly in the need to ensure that prescription pharmaceuticals are safe and effective for their intended uses via the FDA review process. But, in this instance, he explained that KV Pharmaceuticals has taken advantage of the law.

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