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**SENATORS KENNEDY, HATCH, CLINTON, ENZI ANNOUNCE FDA BIOLOGICS
AGREEMENT**

WASHINGTON, D.C.— Today, Senators Kennedy, Hatch, Clinton, and Enzi announced an agreement on legislation authorizing the FDA to approve a follow-on version of biologic therapies. The legislation includes standards for the FDA to approve follow-on biologics, a mechanism to resolve patents in an expedited way, and strong but responsible incentives to encourage innovation and the development of new therapies. A summary of the legislation will follow.

Senator Kennedy said, "This century of the life sciences offers unlimited promise of new hope and new help for millions of patients. Congress has a responsibility to encourage the innovation that leads to these new medical miracles, and to see that they are affordable for the patients who need them. The bipartisan legislation we announce today achieves these two important goals. Just as generic drugs have helped bring down the costs of medicines for millions of Americans, new "follow-on" versions of breakthrough biologics will make these innovative treatments more affordable for the patients who need them. Our bipartisan legislation also includes strong and responsible incentives to encourage dynamic new biotechnology companies to invest in the innovations that will produce the cures of tomorrow. Our legislation also includes strong safeguards to ensure patient safety."

Senator Hatch said, "It's crucial that Congress get this right because biologics are the future of medicine. It's taken a lot of effort, but we've achieved a good balance in this bill. Just as we did with Hatch-Waxman in 1984, we're giving incentives for both pioneer and generic drug firms. We're ensuring that we continue to get the latest medical breakthroughs while creating a clear pathway to get less expensive biologics on the market quickly."

Senator Clinton said, "Allowing generic versions of biologic drugs will help fulfill the promise of these cutting-edge medicines. By breaking the pharmaceutical industry's monopoly on these medications, we will improve healthcare and reduce costs dramatically for seniors, families and employers. We will stretch precious healthcare dollars further in Medicare and Medicaid. And we will enable more Americans access to affordable treatments that could improve or even save their lives. This is truly a win-win for consumers and our country."

Senator Enzi said, "This legislation captures a delicate balance between access and innovation while maintaining the highest standard of safety. I predict that very shortly, Senators Kennedy, Hatch, Clinton, and I will look back at this legislation with great pride, as it will be seen as a vital part of insuring our aging population has access to innovative, reliable, and safe medicines. Biologics already are making it possible for thousands of Americans to live productive lives and changing the way we treat deadly diseases like cancer and infectious diseases. The agreement we've reached today holds new hope that we can further expand access of these remarkable medicines to more patients who need help combating deadly diseases."

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