

Bennet Urges FDA to Work to Foster Innovation, Drive Global Economy

August 18, 2011

Denver, CO – Colorado U.S. Senator Michael Bennet today urged the Food and Drug Administration's (FDA) Commissioner Margaret Hamburg to reform FDA regulations to foster innovation and competitiveness and serve as a driver of the global economy.

“At a time when our nation's drug, biotechnology, and medical device startup companies are struggling to access capital, we must strive to provide them with regulatory clarity and predictability in a way that is safe for patients but also meets their expectations regarding innovation,” **Bennet wrote in the letter.** “I believe we have an opportunity to do good things for patients and a critical sector of the U.S. economy. I look forward to partnering with you to ensure the FDA fosters innovation and promotes economic growth.”

In his letter to Commissioner Hamburg, Bennet asked how the agency plans to address the following areas as it strives to modernize its regulatory system to adapt to the 21st century:

- Regulatory reform and transparency that will simplify manufacturing processes, rather than add complexity to business operations
- Incorporation of modern scientific tools, standards, and approaches to advance innovation
- Recognition of innovative approaches taken by other global regulatory systems to enhance certainty and predictability
- Incorporation of private-public approaches to ease investment in innovation

Earlier this week, the FDA announced a “Strategic Plan for Regulatory Science,” which aims to foster innovation through better science. While Bennet applauds those efforts, he is urging the FDA to do more to promote economic growth, American competitiveness and innovation.

Full text of the letter is included below.

Dear Dr. Hamburg:

I write to request that the Food and Drug Administration (hereinafter, “FDA” or the “Agency”) address the challenges and opportunities that the Agency faces in competing in our global economy. I applaud the FDA's efforts to advance regulatory science through the recent release of the Agency's “Strategic Plan for Regulatory Science” but believe there is much more to be done.

At a recent Senate Health, Education, Labor, and Pensions hearing, you and I had a thoughtful and constructive exchange. You testified that you share a number of my concerns, most importantly how the FDA can better serve as a driver of the global economy. Your testimony about the agency's role in fostering innovation demonstrates a real commitment and leadership on your part and I want to commend you.

Fostering innovation is a goal I share and have been actively working towards through a variety of legislative efforts, from securing the global supply chain to encouraging smart regulation that benefits patients and critical industries. I agree with you that we must work with both government and outside stakeholders on ways to reform how the FDA regulates if we want to continue leading

the world in science and medical innovation. It is time to take the next big step in that direction by mapping a clear path forward.

I believe the FDA should prepare a sound framework to address how the Agency plans to compete in the global economy. As the FDA strives to modernize and update its regulatory system to adapt to the twenty-first century, it would be helpful to understand how the FDA plans to address the following areas:

- Regulatory reform and transparency that will simplify manufacturing processes, rather than add complexity to business operations
- Incorporation of modern scientific tools, standards, and approaches to advance innovation
- Recognition of innovative approaches taken by other global regulatory systems to enhance certainty and predictability
- Incorporation of private-public approaches to ease investment in innovation

Patients in this country are demanding that we lead in innovation and timely access to breakthrough therapies and cures. At a time when our nation's drug, biotechnology, and medical device startup companies are struggling to access capital, we must strive to provide them with regulatory clarity and predictability in a way that is safe for patients but also meets their expectations regarding innovation. I believe we have an opportunity to do good things for patients and a critical sector of the U.S. economy. I look forward to partnering with you to ensure the FDA fosters innovation and promotes economic growth.

Thank you in advance for your consideration.

If you have any questions regarding the foregoing, please do not hesitate to contact me or my staff, Rohini Kosoglu, at 202-224-5852.