

Milken Institute

Global Competitiveness Report Roundtable

with Senator Bennet

April 5, 2012 | Denver, Colorado

Key issues from the Milken Institute report and industry specific issues were discussed during the roundtable discussion — following Ross DeVol's presentation. Holli Riebel requested that Senator Bennet be thoughtful of cuts to the Medicare Program, specifically stating that cuts to Part D and Part B could cut access to new therapies and eventually hinder investments to start-up companies.

Holli also stated that the industry has made a lot of concessions with health reform — like closing the donut hole and accepting additional tax burdens. She explained the issues the industry sees with IPAB and requested the Senator be thoughtful as that process unfolds.

Ed Fitzgerald reiterated the length of time and costs for drug development, and emphasized that shortening the timeline of data exclusivity will hinder the ability of companies to invest in innovation.

Dr. Kristina Lybecker and Dr. Kiki Traylor thanked Senator Bennet for his work on the Trans-Pacific Partnership and requested that he maintain his leadership in this area — requesting for the 12 year data exclusivity to remain intact.



Ross DeVol, Chief Research Officer, Milken Institute



Holli Riebel, Rohini Kosoglu, Senator Michael Bennet



David Kenney, Senator Michael Bennet, Rohini Kosoglu, Dr. Kiki Traylor, Richard C. Duke

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WisBusiness: Expert sees need for reforms to keep U.S. leadership in biotech

By Brian E. Clark
WisBusiness.com
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The United States is in danger of losing its leadership position in the global biomedical industry, the chief research officer of the Milken Institute told a gathering of BioForward members in Madison, home to numerous life science companies and a thriving research centers at UW-Madison.

Ross DeVol, an economist by training, said Europe's biomedical industry – which once led the world – is resurgent and India, China, Korea and other countries in Asia are pumping billions of dollars into universities, research parks and other developments to help companies turn scientific breakthroughs into new products and therapies.

The Milken Institute is an independent economic think tank based in Santa Monica, Calif. that publishes research and hosts conferences that apply market-based principles and financial innovations to a variety of societal issues in the U.S. and internationally.

DeVol called the creation of the U.S. biomedical industry one of the “most dramatic success stories of any American industry over the past 100 years.” But he said federal policy makers seem to be unaware that the U.S. position in that area is eroding and will continue to slip without reforms.

DeVol said many “inside the Beltway” don't understand that the United States didn't always dominate the bioscience industry and assume that American leadership

will go forward unabated.

However, he said he and biotech leaders are working to inform congressional leaders. He said he recently met in Washington D.C. with Senate Majority Leader Harry Reid, House Majority Leader Eric Cantor, the head of the Food and Drug Administration and others to express his concerns.

“We've been working the hallways inside the Beltway and in state capitals, which aren't the problem and where they usually understand it,” he said.

As recently as 1980, he said European firms dominated the bioscience industry, both in terms of market presence and their ability to create new products.

In the '80s, however, the U.S. surged, he said.

“This was no accident,” he explained. “It was the direct result of smart federal policies, including the absence of price controls, the clarity of regulatory approvals, a thoughtful intellectual property system and the ability to attract top foreign talent to this industry in the U.S.”

DeVol said the United States can still keep its position at the top of biotech field. Currently, this country holds a commanding position in the number of patents produced, revenue, jobs, international market share, publications and R&D expenditures.

Private sector employment was 1.2 million in the U.S., while wages and output directly accounted for \$96 billion and \$213 billion respectively. Even more importantly, the average biotech job pays \$78,000, 70 percent above the average wage in the U.S. In Wisconsin, he said, the industry employs 24,000 in the private sector, with another

4,500 at academic institutions and an average wage of \$69,000.

“It is remarkable, however, what other countries are doing,” said DeVol, who recently visited Singapore's “Biopolis” and many other places in Asia.

DeVol said it takes nearly 18 months and somewhere between \$1 billion and \$2 billion in the United States to bring a new drug to market because of the lengthy review process. However, before 2003 and regulatory reform, it took almost 30 months to get drugs approved.

To keep its position at the head of the bioscience and medical device pack, DeVol said this country needs to:

- Increase R&D tax incentives and make them permanent;
- Cut corporate tax rates to match the average levels among countries in the 34-member Organization for Economic Development Cooperation group;
- Extend support for emerging biomedical research fields;
- Provide adequate resources for the FDA and the National Institutes of Health to expedite regulatory reviews and clinical trials;
- Leverage existing strengths in medical devices;
- Build human capital for biomedical innovation by increasing the number of students studying science and math, and working to keep top foreign scholars in the U.S. after they finish their advance degrees; and
- Promote and expand role of universities by adopting best practices in tech transfer and commercialization.

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Tech and Biotech: Federal changes needed to boost biotech, speaker says

By Judy Newman
Wisconsin State Journal
5/11/12

The U.S. risks losing its life science dominance to emerging nations unless Congress takes steps to speed drug approval and to reduce corporate taxes. That's what Ross DeVol, chief research officer for the Milken Institute, said in Madison on Wednesday.

DeVol also said Madison still has a strong future in the biotech industry but local biotechs should focus on niche areas and try to partner with large pharmaceutical companies to boost their chances to succeed.

DeVol was one of the featured speakers at BioForward's monthly breakfast meeting on Wednesday: about 70 people were there.

In an interview afterward, DeVol said Europe dominated the scientific community until the 1970s, with Britain, France, Switzerland and Germany introducing 55 percent of new drugs and the U.S., 31 percent.

Since then, the tables have turned.

Now, 56 percent of new drugs are discovered in the U.S. and 33 percent in Europe.

But DeVol said several factors threaten to disrupt America's edge:

- Countries such as China, India and Singapore are trying to lure prominent scientists.

- Clinical trials of promising drugs are much easier to initiate in China than in the U.S.

- Medical devices can be approved in Europe in half the time of the U.S. process.

- The U.S. has the highest corporate tax in the world.

The Food and Drug Administration is "an ocean liner that needs to change direction," DeVol said. He cited a recent Milken Institute study that recommends speeding the time and cost of an FDA review; making a research and development tax credit permanent; and reducing the corporate tax rate.

Bryan Renk, BioForward executive director, said representatives of the organization have been to Washington, D.C. twice in the last two months to support reauthorization of user fees that companies pay to get their products reviewed. He said the funding

helps the FDA hire enough people to assess new products in a timely manner.

"It's time to look at our industry and say, 'what can we do, going forward?'" Renk said.

DeVol also said, in the interview, Madison has a stronger biotech base than many other communities. "So many places have biotech dreams. Madison has a lot more resources at its disposal than many of these other communities ... You have outstanding university-based research," he said. "But it hasn't gelled sufficiently to develop a true ecosystem."

DeVol suggested that local biotechs develop a "core scientific competency" and then target large pharmaceutical companies to form partnerships with the locals or to set up a research and development center here. Collaboration with early-stage biotechs is the recent industry trend, he said, and "is likely to be the evolution of the industry."

The Milken Institute is an independent economic think tank based in Santa Monica, Calif.