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Testimony of Joe Panetta, President and CEO, BIOCOM

House Committee on Oversight and Reform

"Federal Policies Affecting Innovation and Job Growth in the Biotech and Pharmaceutical Industries," April 21, 2011

Chairman Issa and Members, I am Joe Panetta, President and CEO of BIOCOM.

BIOCOM leads the advocacy efforts of the Southern California life science community with more than 560 members that include biotherapeutics, medical device, diagnostics, industrial biotechnology and biofuels companies, universities and research institutions. Our industry members range in size from emerging growth companies to very small entrepreneurs investing in Research and Development.

The San Diego life science cluster is one of the most robust in the world. There are approximately **40,000 employees** in the life science community in San Diego County at more than 700 companies, including biotherapeutics, medical device, diagnostic and technology companies, research institutes, and the providers associated with those companies.

In 2010, not including Recovery Act funding, CA received over 7000 NIH grants totaling over $3.3 billion. San Diego County alone received over $824 million of those grants. We are rightfully proud of the fact that San Diego is internationally recognized for producing some of the best and most exciting discoveries in the life science research arena.

But the real challenge is taking the next step, and many of BIOCOM's member companies share one thing in common: their fate is completely dependent on a single federal agency, the FDA. Without approval from the FDA in each stage of the commercialization process, nothing else about the company matters. Life science companies must have transparent, predictable regulatory processes to encourage the immense investment it takes to get a concept from discovery to commercialization. Unfortunately, according to many of BIOCOM's members, the current environment at the Food and Drug Administration (FDA) will prevent some of these discoveries from ever being able to reach the patients they are intended to help.

As you may know, the business plans of our members rely heavily on the FDA's regulatory process. We appreciate the relationship that BIOCOM has had with Congress and greatly value the relationship we as an organization have with leadership at the FDA, and I appreciate the opportunity to address you on behalf of BIOCOM's members, to provide some perspective on the agency.

The FDA's mission is clear. The agency's primary mission is to protect and promote the public health as it relates to approval of drugs, devices, diagnostics, and the food supply. FDA Commissioner Dr. Margaret Hamburg states on the agency's web site that she is committed to strengthening programs that "find novel ways to prevent illness and promote health". BIOCOM

industry members share a common goal with the agency and support the desire to improve public health by bringing innovative, high quality products to patients in a timely fashion. Unfortunately, many of our member companies feel increased risk aversion and inconsistent guidance from the agency overshadows the kind of innovation which promises to improve patient outcomes, reduce health care costs and maintain America's leadership in biomedical research.

BIOCOM continues to hear from its industry members that, with each coming year, review times become longer, more unpredictable, and more data seems to be required than in previous submissions. Our members believe this is not a reflection on the quality of the submissions so much as a lack of effective communication between reviewers and the industry, as well as the issue of reviewers' access to training and education on the newest technologies.

New product approval is a prime example of the need for a revitalized FDA. As you probably know, the industry is assessed user fees for both prescription drugs and medical devices. In theory, these fees are supposed to supplement staffing levels and expedite the drug review and approval process by charging the industry user fees for the review of products. In practice, user fees now account for approximately 70 percent of the overall budget for the FDA's Center for Drug Evaluation and Research (CDER). In 1996, the FDA approved 53 new drugs, but by 2010, the number of new drug approvals had shrunk more than 50 percent to only 21. In that time, the FDA's budget, when user fees are included, has more than doubled. Drugs are not more dangerous, it is just many expect a "risk free" drug. There is no such thing. The FDA instead should be weighing the benefit to the patient when evaluating these drugs.

The 2010 edition of a survey conducted by PwC and BIOCOM called "Improving America's Health - V" (I've provided copies for all members of the committee), indicates a growing concern that the FDA is becoming more detached from the industry it regulates. The survey seeks to evaluate the relationship between the FDA and he companies regulated by it. Six in ten survey respondents stated the FDA changed its position during the course of a review, up from 40% just four years ago. Almost half felt products were denied in part because of inadequate resources at the agency. And only a third of respondents felt user fees accelerated the review process.

It is not enough that the federal government invests more than $30 billion per year in basic biomedical research within its National Institutes of Health. The drug and medical device industries invest twice that each year trying to bring new products to market. Unfortunately, in recent years we have seen a significant migration of jobs and investment dollars away from an industry the United States was the unquestioned leader in. Investors are either pressuring companies to pursue approval in Europe or other places where the process is seen to be more transparent and predictable, or they are investing in other industries altogether.

I do want to point out it appears the FDA has recognized there is a problem and is implementing some measures to address specific issues. But BIOCOM is concerned that these changes will not go far enough. We would welcome a constructive dialogue with the agency in which lawmakers, the industry, and the patient population we all seek to help can come together to insure patient safety and advance the cures and treatments that will reduce overall health costs and benefit all Americans.

Joseph D. Panetta
President and CEO
BIOCOM

Since 1999, Joseph Panetta has been President and CEO of BIOCOM, the Southern California association that advocates for more than 550 companies, service firms, universities and research institutes working in the life sciences. A 25-year veteran of the life sciences, in both business and regulatory roles, Mr. Panetta has been responsible for leading BIOCOM's efforts to position the regional life science community to achieve global success. Working with an experienced professional staff and a 60 member Board of Directors, he leads programs in capital formation, public policy, workforce education, and member services. He also oversees several subsidiaries of BIOCOM, including a Purchasing Group, which provides more than $34 million in savings on products and services to members and the BIOCOM Institute. He is also Chairman of the California Biotechnology Foundation, a joint initiative to inform legislators and the media about the life science industry in the state.

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Joseph D. Panetta

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2008. Include the source and amount of each grant or contract.

BIOCOM Institute received a Department of Labor grant for $499,625. BRIDGE Grant

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

BIOCOM - President and CEO

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2008, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

I certify that the above information is true and correct.
Signature: Joseph D. Panetta Date: 4/18/11