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CALIFORNIA HEALTHCARE INSTITUTE

Written Statement

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U.S. House of Representatives
Committee on Oversight and Government Reform

Field Hearing

"Federal Policies Affecting Innovation and Job Growth
in the Biotech and Pharmaceutical Industries"

April 21, 2011

Good afternoon, my name is David Gollaher and I serve as the President and CEO of CHI, the California Healthcare Institute. I appreciate the opportunity to address with this committee a number of important federal policies affecting innovation and job creation in California's biotechnology and pharmaceutical sectors.

CHI is the statewide public policy organization representing California's innovative biomedical community, including the state's premier research universities and institutes, venture capital firms, and medical device, diagnostics and biotechnology companies. Our mission is to identify and advocate policies that encourage life sciences research, investment and innovation.

California's biomedical industry is responsible for breakthrough treatments, therapies and technologies that are improving and extending the lives of millions in the United States and around the world. It is also a key component of our state and national economy. As reported in our CHI/PricewaterhouseCoopers/BayBio 2011 California Biomedical Industry Report (hereafter referred to as the "California Biomedical Industry Report"), California is home to over 2,200 biomedical companies, employing 268,000 people, making it one of the top high-tech employers in the state. San Diego County accounts for over 24,000 of those jobs.[1] The sector is responsible for over $114 billion in annual revenues, $15.4 billion in exports and $19.4 billion in wages and salaries.[2] Last year, California's biomedical

[1] California Healthcare Institute/PricewatehouseCoopers/BayBio "2011 California Biomedical Industry Report," p. 4. Available at http://www.chi.org/uploadedFiles/2011%20CA%20Biomed%20Industry%20Report_FINAL.pdf.
[2] Id.

innovators also attracted $3.2 billion in National Institutes of Health (NIH) research funding and $2.6 billion in venture capital (VC) investment.[3]

Over the past generation, California has developed a remarkably rich and diverse ecosystem that has fostered the growth of vibrant biopharmaceutical and medical technology industries. This ecosystem is shaped and influenced by many factors that can bolster or weaken it. At the federal level, these factors include policies set by Congress and government agencies in areas such as science funding, intellectual property, tax policy, Medicare coverage and payment policy, and regulation by the U.S. Food and Drug Administration (FDA).

My testimony today serves to briefly highlight recent trends in some of these federal policies and how they have affected biopharmaceutical and device investment, innovation and job creation, especially in light of other external macroeconomic forces. In short, the biomedical innovation ecosystem today is under considerable stress. The reasons are many, and while Congress cannot control all of them, a better recognition and understanding of their significance, such as through today's oversight hearing, will hopefully result in thoughtful and reasoned policies to begin to rejuvenate and bolster the ecosystem, strengthen our economy and improve patient care and public health.

Federal Biomedical Science Funding

As reported in our California Biomedical Industry Report:

> The U.S. government pays for an estimated 36 percent of the country's medical research. Conducted primarily by university and independent research labs, government-supported research often leads to important discoveries that add to basic understanding of the natural world. University-driven discoveries also often are key to identifying promising targets for treating or curing diseases, unraveling mysteries of how diseases or the human body work, or inspiring new approaches to difficult problems.[4]

For California's biopharmaceutical industry, federally-funded biomedical research at our state's leading universities and research institutes has historically served as the fuel priming the pump of biomedical innovation. In fact, the biotechnology industry was born in California with the founding of companies like Amgen and Genentech based upon biomedical research at institutes such as Stanford and the University of California. Today, one-third of our state's biotechnology firms were founded by University of California scientists.

[3] Id.
[4] Id at 67.

California has averaged 15 percent of NIH-awarded funding over the past decade. In 2009, NIH grants, excluding R&D contracts as well as stimulus bill-funded projects, totaled $21.483 billion. That year, 7,082 California applicants were selected for funding that totaled $3.2 billion. This was 38 percent more than Massachusetts, the next highest recipient, which received $2.3 billion. The bulk of that funding (nearly 96 percent -- $3.087 billion and 6,240 grants) went to research funding, with the San Diego region, and institutes such as UC San Diego, The Scripps Research Institute and the Sanford-Burnham Medical Research Institute, being the top recipient.[5]

As NIH funding helped make California and the United States the global leader in biopharmaceutical innovation, the future of the industry will likewise be tied to the commitment of Congress to continue its support for such funding, even in such fiscally challenging times as today. But unfortunately, early decisions by the new Congress, namely H.R. 1, sought to apply a 5.2 percent cut across the NIH, which would have resulted in the loss of approximately $160 million in research funding to California. Moving forward, CHI is hopeful that Congress will better recognize the value of NIH funding as an investment into the innovations, jobs, and medicines of the future and commit to a more thoughtful approach to instead strengthen and sustain support for the nation's biomedical research infrastructure.

Intellectual Property

Biopharmaceutical and medical technology research is extremely expensive, and attracting investment into companies developing the next generation of innovative treatments, therapies, and technologies depends on strong intellectual property (IP) protections and, in particular, a strong, reliable and fairly administered patent system. Further, this industry in California consists mainly of smaller, entrepreneurial, and venture capital-backed firms that have yet to bring products to market. For these companies, IP is typically their most valuable – sometimes only – asset. Thus, certainty and enforcement of patent rights has been a top priority across California's biomedical sector – research universities and biopharmaceutical and medical technology industry leaders, along with the state's small life sciences companies, venture capital investors and inventors.

CHI has consistently supported balanced and reasonable efforts to improve the U.S. patent system, particularly efforts that would improve patent quality up front by modernizing operations at and providing additional resources to the U.S. Patent and Trademark Office (USPTO), promoting patent certainty through an up-front and reasonably limited Post Grant Review process, and limiting the abuse of false marking claims on patented products.

[5] Id at 68.

Two Congresses ago, when the House of Representatives last considered patent reform legislation, CHI strongly opposed the bill because it stood to pick a winner – the large high-tech industry – while leaving all others – biotechnology, medical devices, research universities, VC, traditional manufacturers and even labor unions – on the outside. Since then much progress has been made, through hard work and compromise, to move patent reform from a one-sided measure to one that more fairly considers the input of all sectors of the California and U.S. economy. This year, that more thoughtful, balanced approach resulted in a bill, supported by CHI, that passed with an astoundingly bipartisan 95-5 vote in the U.S. Senate. In the House, we have seen similar efforts and hard work, since the bill's introduction and continuing through last week's markup. And while we believe there is still more work to be done in some important areas, we remain hopeful that we will see the successful conclusion of meaningful patent reform that protects patent rights and promotes patent certainty and value – the lynchpin of biomedical investment, innovation and job creation in our state and across the nation.

FDA Regulatory Environment

History shows that a strong, science-based FDA and well-articulated, predictable and consistent regulatory process are essential to biopharmaceutical and medical technology investment, innovation and patient care. Until recently, FDA policies and organizational structure have served as models for regulators around the globe. Indeed, the technical strength of the Agency and the clarity of its regulatory processes helped the United States become the global leader in medical device and biotechnology innovation.

Unfortunately, in recent years there has been a significant deterioration in the environment for biopharmaceutical and medical technology innovation. This is partly the result of concerns with policies addressed above, along with the financial crisis and ensuing Great Recession, which sharply reduced investment capital. But the most important factor has been the declining performance of the FDA.

Beginning in approximately 2007, evidence clearly confirms that FDA biopharmaceutical and medical device regulation has become increasingly slow and unpredictable.

The evidence here is both anecdotal and quantitative. When asked whether the current FDA regulatory approval process has slowed the growth of their companies, 74 percent of respondents to the 2011 California Biomedical Industry Report CEO survey reported that it had. At the same time, 69 percent of the respondents *disagreed* with the proposition that the U.S. FDA regulatory approval process is the best in the world.[6]

[6] Ibid, page 49.

These executives' views reflect the recent slowdown in product clearances and approvals that are documented by the FDA's own data in our recent CHI report, "Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry."[7] Comparing the latest data with the 2003-2007 period:

- Drug and biologics review times have increased by 28 percent
- 510(k) device clearances have slowed by 43 percent
- PMA device approval times have lengthened by 75 percent

It is difficult to attribute these slowdowns to resource constraints at the Agency. In fact, funding – through congressional appropriations and industry user fees – associated with human drug review has grown from $409 million in FY2003 to $855 million in FY2009. Similarly, the Center for Devices and Radiological Health (CDRH) has seen funding associated with device review grow from $141 million in FY2003 to $271 million in FY2009. During the same period, the number of human drug and device review full-time employees (FTEs) increased from 2,696 to 3,630 and from 1,485 to 1,707, respectively.[8]

No single factor explains this decline. Clearly, part of the problem lies beyond the direct control of the FDA and its leadership. In recent years, for example, Congress has enlarged the Agency's scope into new fields (e.g., tobacco) and added to its responsibilities and authority. Yet federal appropriations have largely failed to keep up with new mandates, forcing greater reliance on industry-funded user fees. Similarly, expanded and tightened responsibilities under the FDA Amendments Act of 2007 (FDAAA), such as intensified conflict of interest rules on advisory committees, have constrained the Agency's capacity.

These increased responsibilities would be hard to manage even if science stood still. But, of course, it has not. The past decade has witnessed an explosion of knowledge, exemplified by the Human Genome Project, that has transformed drug and device innovation. Scientists today routinely employ high-throughput genetic sequencing to indentify targets for small-molecule drugs. And medical device makers are working on ways to integrate nanotechnology and wireless communications in

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[7] California Healthcare Institute and The Boston Consulting Group, "Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry," available at http://www.chi.org/uploadedFiles/Industry_at_a_glance/Competitiveness_and_Regulation_The_Future_of_America's_Biomedical_Industry.pdf

[8] Total FTEs in Human Drug Review Program, Source: 1993-1999 from FDA White Paper: Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications; 2000-2009 from FDA Annual Budget All Purpose Table Human Drug Program Total FTEs; Total Cost of Human Drug Review, Source: FDA PDUFA Annual Financial Reports, Total Cost of the Process for the Review of Human Drug Applications; FDA Annual Budget All Purpose Tables Program Level Total Device FTEs; FDA MDUFMA Annual Financial Reports; Total Cost of the Device Review Process; BCG analysis

leading-edge technologies. The accelerating rate of scientific and technological advances severely challenges the FDA's ability to keep pace — and poses significant limits on the Agency's future responsiveness and performance.

Perhaps the most important factor in the Agency's recent history, though, has been a change in its culture. Faced with accusations from the press, consumer groups, and some in Congress that its reviews were too lax and failed to protect the public from safety problems with drugs and devices, the FDA has shifted emphasis in product reviews from the benefits of new products to an increasing weight on their possible risks. When broken down, industry anecdotes about Agency uncertainty, unpredictability, "moving goalposts" and the like all seemingly revolve around ever increasing demands that are not justified by science or by any increased risk profile of the medicines or devices to which those demands are associated. From the perspective of an FDA device reviewer, this is understandable. After all, an individual reviewer has nothing to gain by approving a product, but much to lose by approving a product that has a problem in the future.

In a larger sense, a serious problem for device and drug innovation alike is that there is no shared understanding of the benefit-risk calculus. Most medical advances carry some risks. And a basic principle of medicine is that the risk of any intervention – a procedure, a drug, a device – should be commensurate with the seriousness of the patient's disorder. Accordingly, for example, patients with advanced coronary artery disease are typically willing to accept risks for new minimally-invasive procedures and technologies that have a chance to not only treat the condition but result in faster recovery times and shorter hospital stays. What has happened within the FDA, though, is that more and more attention has been focused on the potential *direct* risks of new medicines and technologies without sufficient appreciation of potential benefits.
But just as important to consider are *indirect* risks – distortions in the regulatory process, for example. How do we calculate and consider the public health loss to patients if investors and companies avoid entire diseases and conditions because the FDA's demands for clinical data are so extensive and its standards for approving new products so uncertain?

With this in mind, CHI believes that it is critical that Congress, the FDA, industry, patient groups and other stakeholders come together with the will and ideas to restore Agency performance – to rejuvenate, support and sustain a strong, science-based FDA and efficient, consistent and predictable review processes to ensure safe and innovative therapies, treatments and technologies for patients in need.

For example, instead of creating expansive new authorities and responsibilities requiring higher user fee levels, Congress and the FDA should focus on re-centering the Agency to its primary mission and core competencies, addressing the serious inefficiencies and performance breakdowns of recent years. In preparation for 2012

reauthorization of the drug and device user fee acts, the time is also right to evaluate, and where appropriate, correct any measures within those laws that may have detracted from the FDA's performance without any commensurate improvement to patient safety, such as the stricter advisory committee conflict of interest rules instituted under FDAAA.

Similarly, while increased funding might not always be the best solution, in this case, cutting the Agency's budget would be damaging. As mentioned earlier, Congress has underfunded the Agency for many years, and while recent budget increases have helped in terms of staff recruitment and retention, what is needed is a steady and sustained congressional commitment to FDA funding, even in today's difficult budget environment.

We also believe that the Agency and industry stakeholders should be encouraged to collaborate, interact and work together more now than at any time in the past. For example, dialogue between a reviewer and a company on a new submission can help identify important questions and provide clarity around Agency expectations early in the process – leading to fewer delays and improved certainty.

Finally, consideration must be given, including through constructive congressional oversight such as today, to the costs of regulation, both direct and indirect. As this Committee and the Congress seek paths to create new jobs and a more business friendly environment, the costs of the regulatory system should be carefully weighed. As the global economy grows ever more connected, American leadership in the biopharmaceutical and medical device sectors faces intense competition: for capital, for markets, for talent and for jobs. As these competitive forces gather momentum, investors, managers and policymakers ignore them at their peril. If FDA regulation is just one factor among several, it nonetheless can be pivotal.

<u>External, Macroeconomic Factors</u>

In addition to these federal policies, another factor has worsened the environment for the biopharmaceutical and medical device industries. Beginning in 2008, the Great Recession devastated investment portfolios, including the pension funds and institutional endowments that historically have been the main source of life sciences venture capital. Meanwhile, VC firms themselves also sought to reduce risk, trending away from early-stage investments – ones that combine the greatest innovation with the greatest risk. To make matters worse, the initial public offering (IPO) market for biotechnology and medical device companies all but vanished. After the collapse of iconic firms such as Lehman Brothers, Wall Street had little interest in offerings from young companies with no operating revenues that would need continuing infusions of capital over many years.

Smaller companies were forced to adapt by redesigning the biomedical business model – receive regulatory approval, demonstrate adoption by physicians and patients, and present to potential acquirers as a lower-risk investment. From the perspective of company and investor alike, winning approval sooner in any market became far more valuable than gaining FDA approval later.

Levels of regulatory uncertainty – delays, missed timelines, doubts about eventual approval – that had been uncomfortable in good economic times became intolerable after the economic downturn. Especially, as investors and executives came to realize, there are practical, more efficient routes to market outside the U.S.

Overseas regulators have recognized that regulatory efficiency can bolster biomedical innovation, investment and job creation without undermining patient safety. The European Medicines Agency (EMA) has been especially forthcoming about its ambitions to encourage and facilitate biomedical investment and innovation in the EU. For example, in its strategic document, "Road Map to 2010: Preparing the Ground for the Future," the EMA stated that "its role in enabling the pharmaceutical industry to achieve the objective of industrial competitiveness is crucial."[9] They have begun to succeed. Today, complex medical devices approved via the PMA process in the United States are approved in Europe on average nearly four years ahead of the United States, up from just over a year earlier this decade.[10] And where new medicines were approved first in the U.S. by an average on nearly seven months between 2004 and 2006, recent years show products approved on average two-and-a-half months earlier in the EU, a shift of nine months.[11] Of course, in either case, the result is that European patients benefit from U.S. innovations before Americans do. And no evidence exists to suggest that these faster approval times in Europe have led to systemic patient safety-related problems.

Conclusion

The California biopharmaceutical and medical technology sectors are important elements of our state and nation's continued vitality in the increasingly competitive 21st century global economy. They are also, just as important, critical to improving patient care and public health here in the United States and around the world.

As I hope my testimony has illustrated, policy decisions made in the halls of Congress and by the Administration, over 3,000 miles away, have a tremendous impact on California's biomedical industry. The biomedical innovation ecosystem here and nationwide is under tremendous stress. And in today's still uncertain

[9] The European Medicines Agency "Road Map to 2010: Preparing the Ground for the Future" available at http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/10/WC500004903.pdf
[10] "Competitiveness and Regulation", pg 14
[11] Id.

economic environment, it is especially important that policymakers thoughtfully weigh the full consequence of decisions and trends in the areas noted above – and others, such as the new healthcare law's medical device tax and Medicare coverage and payment policy – in order to relieve that stress and, instead, foster and stimulate the environment to encourage job creation, attract investment and promote continued biomedical innovation.

Thank you, and I would be happy to answer any questions you might have.

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Professional Experience

1993 - present
La Jolla, CA

President & CEO – California Healthcare Institute

- Organized and built leading U.S. state biomedical industry/university organization to 276 members
- Effective federal and state policy advocacy
- Close working relationships with California legislators, members of Congress, federal agencies (FDA, CMS, NIH)
- Extensive contact with pharmaceutical, biotech and medical device CEOs and academic research leaders

1991 – 1994
San Diego, CA

Professor of Public Health – SDSU

- Director of joint university Health Policy Center
- Graduate medical school teaching and research in healthcare finance, health policy, and management

1985 –1991
La Jolla, CA

Vice President – Scripps Clinic and Research Foundation

- Responsible for managed care, strategic planning, business development and corporate communications
- Increasing revenue responsibility from $16MM to $127MM
- Member clinical board of governors

1982 – 1985
San Diego, CA

Vice President – Phillips Ramsey (McCann Erikson)

- Account management group director
- Clients: American Medical International, Ticor, WD-40

1980 – 1982
New York City

Account Executive – Young & Rubicam

- New business concepts strategy group
- Clients: General Foods, Merrill Lynch, Johnson & Johnson

1975 – 1980
Cambridge, MA

Lecturer and Senior Tutor – Harvard University
History of Science, History and Literature

1977 – 1979

Lecturer – Overseas School of Rome

Education

	Harvard University - Cambridge, MA
1992	Ph.D. History of American Civilization (science and medicine)
1991	Houghton Fellow
1978 - 79	Harvard Business School
1974	M.T.S. History of Religion
1971	University of California – Santa Barbara, CA
	B.A. (*cum laude*) Religious Studies

Fellowships, Awards, Boards

1995 – present	Director – California Healthcare Institute
1997 - present	Director – Vision Robotics Corporation
1999 – present	Health Policy Advisory Board – Gilead Sciences
2006 - present	Member – Massachusetts Historical Society
2002 - present	Advisory Board – California Council on Science and Technology
2007 - 2009	Advisory Board – Congressional Homeland Security Committee
2002 - 2006	California State Legislature Stem Cell Advisory Panel
1999 - 2002	Director – Medical Technology Leadership Forum
1997 – 2002	Director – California Medical Association Foundation
1996 - 1999	California State Legislature Commission on Cloning
1997	Avery O. Craven Award – Organization of American Historians
1996	California Governor's Council on Biotechnology
1994 – 1996	Fellow – National Endowment for the Humanities

Publications and References

Available upon request

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

Name: David Gollaher, PhD, CHI President & CEO

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.

N/A

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

California Healthcare Institute (CHI) represents 250 leading biotechnology, medical device, diagnostic, and pharmaceutical companies, and public and private academic biomedical research organizations. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery. I am the president and chief executive officer of CHI.

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.

N/A

I certify that the above information is true and correct

Signature: 

Date: April 11th, 2011

David Gollaher, PhD
President & CEO