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Prepared Statement

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# Pathway To FDA Medical Device Approval: Is There A Better Way?

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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 several important issues concerning the review and approval of medical devices by the U.S. Food and Drug Administration (FDA). The FDA exerts critical influence on medical technology innovation and investment, which, in turn, affects job creation, U.S. competitiveness and, most important of all, the tests and treatments available to patients. My testimony is based on a recent report CHI produced with The Boston Consulting Group (BCG) entitled "Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry."

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 medical device industry is responsible for breakthrough treatments 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. There are more than 8,000 medical device firms in the United States employing over 400,000 people. California is home to some 1,200 of these medical device firms, far more than any other state in the nation. In addition, the 107,000 medical device jobs in California represent roughly one-quarter of our country's total medical technology workforce.

Over the past generation, California has developed a remarkably rich and diverse biomedical ecosystem that has fostered the growth of medical technology companies. This ecosystem is shaped and influenced by many external 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, tax policy, intellectual property law, as well as Medicare coverage and payment policy, and regulation by the FDA.

History shows that a strong, science-based FDA and well-articulated, predictable and consistent regulatory processes are essential to medical device 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 medical technology innovation. This is partly the result of 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 regulation of medical devices has become increasingly slow and unpredictable for both 510(k) as well as more complex premarket approval (PMA) products.

The evidence here is both anecdotal and quantitative. When asked to rate the influence of federal policies on their industry's ability to advance biomedical research, innovation and investment in California, over 80 percent of respondents to the CHI/PricewaterhouseCoopers/BayBio 2011 CEO survey described the FDA as "extremely important." They rated the FDA as more critical than coverage and reimbursement policy, intellectual property, and tax and finance issues.[1] And when asked whether the current FDA regulatory approval process has slowed the growth of their companies, 74 percent 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.[2]

These executives' views reflect the recent slowdown in product clearances and approvals that are documented by the FDA's own data in our "Competitiveness and Regulation" report. Comparing 2010 with the 2003-2007 period of the first medical device user fee law (the Medical Device User Fee and Modernization Act of 2002):

- 510(k) clearances have slowed by 43 percent
- PMA approval times have increased by 75 percent

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[1] California Healthcare Institute/PricewaterhouseCoopers/BayBio "California Biomedical Industry 2011 Report," page 17, http://www.chi.org/uploadedFiles/2011%20CA%20Biomed%20Industry%20Report_FINAL.pdf.
[2] Ibid, page 49.

No single factor explains this decline. But it is difficult to attribute the slowdowns to resource constraints at the Agency's Center for Devices and Radiological Health (CDRH). In fact, 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 device full-time employees (FTEs) increased from 1,485 to 1,707.[3]

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 that has transformed drug and device innovation. Today, for example, medical device makers are working on ways to integrate nanotechnology and wireless communications in 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 devices and drugs, the FDA has shifted emphasis in product reviews from the benefits of new devices 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 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 device that has a problem in the future.

In a larger sense, a serious problem for device and for 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

[3] 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

focused on the potential risks of technologies without sufficient appreciation of potential benefits.

Concurrent with these trends within the Agency, another form of risk has darkened the prospects for medical device investment and innovation. 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 (VC). 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 medical device and biotechnology 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 especially 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, especially in Europe, have recognized that regulatory efficiency can bolster biomedical innovation, investment and job creation without undermining patient safety. 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.[4] And even for 510(k) products there is a clear trend that the more complex a product is, the more likely it is to be approved in Europe before the United States.[5] 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.

The FDA and its regulatory policies profoundly influence the current state and future strength of the U.S. biomedical industry. It is, indeed, part and partner in the dynamic ecosystem of biomedical research and innovation. But its regulatory processes have become unpredictable and slow, which, when combined with the impact of the Great Recession, the capital markets crisis, and more efficient regulatory processes in Europe, have had enormous and far-reaching effects on the American medical technology industry.

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[4] Ibid, pg 14
[5] Ibid, pg 14

Today, Congress, the FDA, industry, patient groups and other stakeholders can 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 technologies and devices for patients in need.

## Six Recommendations on How to Improve the Overall Environment for Medical Device Innovation

First, focus on core principles: safety and efficacy. Instead of creating expansive new authorities and responsibilities requiring ever increasing 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 device user fee act, the time is also right to evaluate, and where appropriate, correct any measures within that law that may have detracted from the FDA's performance without any commensurate improvement to patient safety. One example, for both devices and drugs, is the stricter advisory committee conflict of interest rules instituted under the Food and Drug Agency Amendments Act of 2007 (FDAAA), which have made it increasingly difficult for the most experienced medical experts to serve on advisory committees.

Second, 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, we are concerned with the recent House proposal that would cut $285 million from the FDA for FY2012, an 11.5 percent reduction from FY 2011. What is needed – to support medical technology innovation, job creation and patient and public health -- is a steady and sustained congressional commitment to FDA funding, even in today's difficult budget environment.

Third, more must be done to train Agency reviewers and managers. This is an area of widespread agreement across all stakeholders, and we applaud CDRH Director Dr. Jeffrey Shuren for making this a top Center priority, along with the publication of guidance documents important for both review staff and industry, for example, what is expected in a 510(k) submission and how it should be presented.

Fourth, while the European model of device review and approval differs significantly from that of the FDA, there still may be lessons in terms of process and managerial improvements to address the numerous consistency, predictability and efficiency concerns industry has experienced. To that end, CHI is undertaking a follow-up to our "Competitiveness and Regulation" report to explore and examine device approval processes in Europe. We plan to complete this project this summer and we hope it will provide this and other Committees, the FDA and others with the needed information to make the best decisions on possible Agency process improvements.

For example, the study may lead to ideas for improvements and enhancements to the Center's third-party review process.

Fifth, we 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 sponsor 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.

More generally, and as noted earlier, the rate of scientific and technological advancements is something the Agency is largely unable to keep up with. We applaud Dr. Shuren and the Center for its Innovation Initiative announced earlier this year. While the details of the various elements of the Initiative are still in the works, we hope that one important theme will include Agency, industry and other stakeholder partnerships and collaborations.

We believe this is an especially important element given the recent and disheartening decision by regulatory bodies, including the FDA, unilaterally to disband the Global Harmonization Task Force (GHTF), thus ending the co-equal partnership between international regulators and industry at the GHTF that, since its inception in 1992, has served "to achieve greater uniformity between national medical device regulatory systems" with two key aims in mind being "enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world."

Finally, and perhaps critical, is the need to address, including through constructive congressional oversight such as today, an improved, more appropriate balance between benefit and risk. Today, the FDA, the press, Congress, consumer groups and others overwhelmingly focus on "direct" risks: product side effects, adverse events and technical product failures. 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?

Similarly, consideration must be given 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 medical device sector 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.

That concludes my formal statement. That you again for the opportunity to testify on this important issue, and I would be pleased to answer any questions you may have.