

2011 FEDERAL POLICY AGENDA

FDA Regulatory Environment

A strong, efficient, effective FDA is equally in the interest of industry, the American public, and patients. Unfortunately, a growing body of survey research, interviews with industry executives and analysis of published data confirm a common view of the FDA: namely, that the agency represents a serious, and growing, barrier to innovation. More specifically, evidence indicates that the FDA regulatory review process is becoming increasingly unpredictable, cumbersome and inefficient with a dramatic slowdown in approval times across drugs and devices. At the same time, overseas regulatory bodies, such as in the EU, have made a concerted effort to improve the efficiency of their regulatory processes in order to invigorate their own domestic biomedical industry. The results are that many new medicines and medical devices are being approved first in Europe -- sometimes up to four years earlier than in the United States.

CHI believes that the FDA and its policies, including some of them enacted by Congress, need to be appropriately evaluated in order to maintain the FDA's gold standard of product safety and efficacy review while also promoting a more efficient, predictable and transparent review process that ensures needed innovations, and resulting jobs, are approved in a timely manner to benefit patients. For example, the 112th Congress will reauthorize the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Modernization Act (MDUFMA). And the FDA itself has already undertaken potentially fundamental changes to the device 510(k) review process and has begun to evaluate how to enact a new pathway for the approval of follow-on biologics, or biosimilars. These will all present an opportunity for the new Congress to reexamine key questions about the agency including:

- How FDA regulation influences private-sector investment;
- How the policies and actions of the FDA influence job creation and U.S. competitiveness;
- How the agency is funded – the mix of industry user fees and government appropriations;
- How FDA performance affects American patients.

In 2011, CHI will:

- Publish a series of reports quantifying the current and trending state of the FDA regulatory process and its implications on patient care, U.S. biomedical investment, innovation, jobs creation and competitiveness.
- Develop and communicate a "Call to Action" outlining how Congress, the Agency, industry and other stakeholders can begin to reinstate regulatory efficiency. Before suggesting further significant increases in user fees or expansive new authorities and requirements, we must first determine what has gone wrong and focus on solutions that will make the process more efficient once again. This includes encouraging a

more informed dialogue on the appropriate balance between benefit and risk as well as potentially evaluating and fine-tuning provisions from prior user-fee laws.

- Support FDA improvements to 510(k) review while defending against proposals that will make the process more costly, inefficient and cumbersome, to the detriment of industry and patients alike.
- Monitor FDA implementation of the new biosimilars pathway to ensure its adherence to the letter and spirit of the law, which was strongly supported by CHI.

Government Coverage and Payment Policies

In the new Congress, the new Republican House majority has made clear its intentions to reign in federal spending. And while it is uncertain to what extent reforms to entitlement programs like Medicare and Social Security will be included in those efforts, coverage and payment policy is likely to remain an important priority of the life sciences sector. Some approaches to cost containment could seriously harm the delicate cycle of medical innovation by reducing incentives for investment in new research and product development, and ultimately limit patient access to needed treatments, therapies and technologies.

For example, CHI generally supports the new comparative effectiveness research (CER) provisions of the new healthcare reform law as an important tool in providing information to improve clinical decision-making. However, there remain real risks to patient access and biomedical innovation if CER is misapplied primarily as a cost-containment mechanism. Similarly, CHI concerns around cost containment also extended to other policy objectives within the new healthcare law, such as with the establishment of the new Independent Payment Advisory Board (IPAB).

In 2011, CHI will:

- Address proposals by the Administration and Congress to ensure that drug, device and diagnostic coverage and reimbursement policies are reasonable, accurate, sensitive to patients' needs, and adequate to encourage future innovation.
- Engage the California delegation and the administration as the new CER-entity established under the healthcare reform law, the Patient-Centered Outcomes Research Institute (PCORI), is instituted, with a focus on transparency of process and stakeholder input, confinement to clinical comparative effectiveness research, and appropriate dissemination and application of research findings.
- Monitor and support efforts to mitigate the impact of the IPAB on biomedical investment, innovation and patient care.
- Oppose policies such as removal of the Medicare Part D non-interference clause, drug importation, and other initiatives that enlarge the federal government's role in price setting.

Patent Reform

Life sciences research is extremely expensive, and attracting investment into companies developing the next generation of innovative treatments, therapies, and technologies

depends on a strong, reliable and fairly administered patent system. For example, the biomedical industry in California consists mainly of smaller, entrepreneurial, and venture capital-backed firms that have yet to bring products to market. For these companies, intellectual property (IP) is typically their most valuable – sometimes only – asset. Thus, enforcement of patent rights has been a top priority across the sector, from California's world-class research universities and biomedical industry leaders, to its many small, emerging life sciences firms and inventors.

While past proposals to reform U.S. patent law over the past number of years have included provisions (apportionment of damages, post grant "second window," U.S. Patent and Trademark Office (PTO) rule-making authority, failure to address inequitable conduct) that would dramatically undermine patent certainty and quality, upon which life sciences investment and innovation depend, recent efforts have progressed to where CHI's past objections have been largely addressed. At the same time, new concerns have arisen. For example, false patent marking suits have increased substantially since December 2009 when the Federal Circuit Court ruled in *Forest Group, Inc. v. Bon Tool Co.* that the offense under current statute applies to each article that has been falsely-marked as opposed to each decision to mark.

In 2011, CHI will:

- Support efforts to promote quality improvements at the PTO.
- Lead efforts emphasizing the importance to biomedical research and innovation across the sector—research universities, small venture capital backed firms, and industry leaders— of patent certainty, quality and enforcement rights.
- Support efforts to address the growing abuse of false marking claims.

Research Funding

Research funding from the National Institutes of Health (NIH) and other agencies has long proven critical to advancing biomedical innovation in California and nationwide. And while recent years have seen a renewed Congressional and Administration commitment to the support of science research funding, it is questionable if those increases will be sustained in the new Congress.

In 2011, CHI will:

- Support consistent, strong, and sustained growth in science funding.
- Illustrate that funding (NIH, NSF, etc.) is a proven and critical investment to promote innovation, save lives, and encourage economic growth and job creation.

Other Issues

- **Science and Math Education:** CHI will support efforts to illustrate the importance of math and science education at all levels to the immediate and long-term workforce development needs of the biomedical industry in California.
- **Tax Policy:** CHI will support efforts to repeal the medical device tax and address the impact of any comprehensive tax reform proposals on life sciences investment, innovation, job creation and competitiveness.

- **Trade Policy:** CHI will work to address trade policies and related issues of importance, such as compulsory licensing, IP protections (or lack thereof), and piracy with key delegation and administration officials.
- **Health disparities:** CHI will conduct outreach and education regarding the California's life sciences community's programs to improve health literacy, screening and prevention, participation in clinical trials, and access to best care, specifically those targeting minority and economically disadvantaged communities.