

## **2010 FEDERAL POLICY AGENDA**

### **Government Coverage and Payment Policies**

Whether or not comprehensive healthcare reform legislation is enacted, the federal budget deficit and rapidly increasing costs in Medicare and Medicaid will continue to be the focus of policymakers as they seek to limit spending on medical technologies. 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 supports comparative effectiveness research (CER) as an important tool in providing information to improve clinical decision-making. However, there are real risks to patient access and biomedical innovation if CER is misapplied primarily as a cost-containment mechanism. In 2009, CER was a top priority for CHI as we saw several CER measures introduced and then later subsumed into the overall healthcare reform packages in Congress. CER continues to be a critical issue across CHI's membership. If a healthcare reform package is signed into law, there will be as many issues incumbent to the enactment of the CER provisions within the healthcare reform bill as we faced during the legislative debate. Additionally, CHI concerns around the application of CER has also extended to other policy objectives within Congress, especially in the arena of Medicare coverage and payment and the development of an Independent Medicare Payment Advisory Board.

In 2010, 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 any CER entity and framework is enacted and 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 implementation of any independent Medicare payment entity and its framework and processes in order to engage the delegation and administration on issues of concern or opportunity.
- 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.

### **FDA Regulatory Environment**

Recently the U.S. Food and Drug Administration (FDA) has been viewed with greater public scrutiny as questions arise about the adequacy and effectiveness of the agency. However, there are concerns that the regulatory environment is growing increasingly unpredictable and risk averse to the point where industry has begun to seek product approval overseas before doing so in the United States – meaning patients in Europe and elsewhere might have access to treatments and technologies years ahead of those here. CHI believes that policies need to be appropriately evaluated in order to maintain the FDA's gold standard of product safety and efficacy review while also ensuring that needed innovations, and resulting jobs, are approved in a timely manner to benefit patients in need.

For example, 2010 is likely to see Congress and the Administration turn to issues addressing regulatory oversight of medical device and technologies, including both 510(k) review and medical device preemption. CHI is concerned that there is the potential for serious consequences to biomedical investment, innovation and access if such issues are addressed inappropriately.

Similarly, recognizing the significant differences between traditional pharmaceutical drugs and biologic products, which are highly complex products derived from living proteins, CHI supports enactment of an FDA pathway for the approval of follow-on biologics, or biosimilars. That pathway must be science-based, emphasize patient safety, and promote continued biotechnology innovation.

In 2010, CHI will:

- Work to quantify and demonstrate the economic and human consequences of an increasingly unpredictable and risk averse regulatory environment at the FDA.
- Support enactment of biosimilars legislation with strong science, safety, and pro-innovation (i.e. data exclusivity) provisions. Monitor and engage as a follow-on biologics pathway framework is implemented at the Food and Drug Administration.
- Address concerns and consequences resulting from potential changes to 510(k) process.
- Work with key delegation members to address concerns with removing preemption for Class III medical devices.

### **Patent reform**

Proposals to reform U.S. patent law have included provisions (apportionment of damages, post grant "second window," failure to address inequitable conduct) that would dramatically undermine patent certainty and quality, upon which life sciences investment and innovation depend. Recently, patent reform discussions have exposed the fault lines between two key California industries – biomedical and high technology – on many of these issues. As a result, engaging the entire California delegation has been important to protect the interests of the biomedical industry in any patent reform discussions.

In 2010, CHI will:

- Support efforts to promote quality improvements at the PTO
- Lead efforts emphasizing consequences to biomedical research and innovation across the sector – research universities, small venture capital-backed firms, and industry leaders – if patent reform lowers patent certainty and value.

### **Research Funding**

The Obama administration and Congressional leadership, including Speaker Nancy Pelosi, have repeatedly remarked that science funding much be a top priority in order to restore the United States' position as a research innovator. Indeed, research funding from the National Institutes of Health (NIH) and other agencies has long proven critical to advancing biomedical innovation in California and nationwide.

In 2010, CHI will:

- Work with the California delegation and administration to support consistent, strong, and sustained growth in science funding.
- Illustrate that funding (NIH, NSF, etc.) is a proven investment to promote innovation, save lives, and encourage economic growth and job creation.

## **Tax Issues**

In 2009, CHI played a critical role in addressing the consequences to medical technology investment and job creation in California stemming from the proposed medical device manufacturers tax provision of healthcare reform. In the wake of this and other taxes and fees levied on the life sciences sector in order to fund healthcare reform, 2010 will see CHI uniquely positioned to address the impact of federal tax proposals on the industry in California as part of general tax reform or particular proposals related to deficit reduction, economic stimulus and the like.

In 2010, CHI will:

- Monitor proposed corporate tax reform proposals in order to address their impact on California's biomedical sector in terms of competitiveness, continued research and development, and job creation.

## **Other Issues**

- **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.
- **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.
- **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.