

## 2009 FEDERAL POLICY PRIORITIES

### Comparative effectiveness research

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, CHI will:

- Address the complexities of CER through issue briefs, case studies, meetings and other activities.
- Ensure that CER legislation and related policies do not interfere with patients' access to the best treatments and reflect the values and concerns of biomedical innovators.

### Follow-on biologics

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 2009, CHI will:

- Produce high-quality information to inform the debate, including material addressing appropriate clinical data requirements for biosimilar products, the science and safety factors behind potential determinations of interchangeability, adequate years of patent protection and data exclusivity, and the impact of various biosimilar approaches on the broad biotechnology ecosystem.
- Work to gather support for enactment of biosimilars legislation that balances the need to preserve innovation and protect patients while lowering drug costs.

### FDA preemption

In February 2008, the U.S. Supreme Court decision in *Riegel v. Medtronic* ruled that Class III medical device makers who have been granted approval by the FDA are preempted from state tort claims under federal law. In November 2008, the Supreme Court heard arguments in *Wyeth v. Levine*, a related case that pertains to drug preemption. Following the Riegel ruling, legislation was introduced to overturn the decision.

In 2009, CHI will:

- Address concerns that subjecting device manufacturers to conflicting state-law obligations would generate widespread regulatory confusion and discourage investment and research into potentially life-saving technologies while simultaneously undermining the FDA and providing no real safety benefits for the public.

### Patent reform

Proposals to reform U.S. patent law 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.

In 2009, CHI will:

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

### **Science research and education**

Research funding from the National Institutes of Health (NIH) is critical to improving public health and advancing biomedical innovation. Similarly, funding from agencies such as the National Science Foundation is important in addressing critical math and science education and workforce development needs of the biomedical industry.

In 2009, CHI will:

- Work directly and in partnership with other stakeholder groups to illustrate how funding of NIH is a proven investment that promotes innovation, saves lives and encourages economic growth.
- Support efforts to develop or improve federal programs addressing science and math education at all levels, especially those that are based upon partnerships with industry.

### **Other issues**

- **Gift disclosure:** CHI will address legislation requiring manufacturers to disclose payments or other transfer of value to physicians, emphasizing the need for any federal disclosure mechanism to create a uniform national standard and prevent a patchwork approach by all 50 states.
- **Health disparities:** CHI will conduct outreach and education about the California's life sciences industry'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.
- **Coverage and reimbursement policies:** CHI will address proposals by CMS or Congress to ensure that coverage and reimbursement policies are reasonable, accurate, sensitive to patients' needs, and adequate to encourage future innovation. CHI will 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 regulation:** CHI will support efforts to modernize the diagnostics regulatory and payment frameworks. CHI will address the consequences of policies that threaten to make the overall FDA regulatory review process more cumbersome, complicated and uncertain. CHI will support coalition efforts to ensure Congress adequately funds the FDA.
- **Compulsory licensing:** CHI will address the risks and consequences of compulsory licensing threats worldwide.
- **Business incentives:** CHI will participate in coalition activities to support the permanent extension of the R&D tax credit, reforms to current federal Net Operating

Loss (NOL) restrictions, and loosening the Small Business Innovative Research (SBIR) grant program restriction on venture capital owned firms.

- **Drug pedigree:** CHI will support efforts to develop a uniform federal pedigree standard founded upon a phased-in, standards-based and technologically neutral approach.