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CALIFORNIA HEALTHCARE INSTITUTE

2013 CHI Federal Policy Agenda

FDA

Last year, Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA), which not only renewed critical FDA user fees, but instituted new mechanisms and procedures, agreed to by the Agency and industry, to promote biomedical innovation by enhancing industry-Agency communications, strengthening Agency performance reporting requirements, and improving product review process predictability, consistency and transparency. This year, it will be important for Congress to ensure that the law is being properly implemented and, just as important, to ensure the Agency has the funding -- through access to the user fees and congressionally appropriated funds -- be able to institute all the new improvements included in the measure.

In 2013, CHI Will

- Develop and publish CHI FDA Scorecard of key drug and device review process data, including updates to material published in CHI's two FDA reports as well as new data made available under new FDASIA reporting requirements.
- Work with delegation and committees of jurisdiction as part of FDASIA implementation oversight activities.
- Join with other stakeholders in addressing the importance of FDA funding, via access to user fees and congressional appropriations, and the consequences to biomedical innovation and patient care stemming from cuts to FDA funding under sequestration scenario.
- Monitor and engage as needed around other FDA-related issues, including biosimilars, the regulation of mobile health and related technologies, research-use only proposals, unique device identifier (UDI) policies, etc.
- Maintain and enhance CHI-FDA engagement by working with key Agency leadership on issues of mutual importance and interest, such as "big data," and the expansion of the CDRH-LifeScience Alley (MN) supported public-private partnership to advance device regulatory science initiative.

Coverage and Payment Issues

The ability for products to receive timely and appropriate coverage and reimbursement is critical to drug, device and diagnostics innovation and patient care. That is why it is important to protect programs that are working -- Medicare Part D and Part B programs for example -- from proposals that would undermine and weaken them. More broadly, in other areas, such as, comparative effectiveness research, CMS "coverage with evidence development" policies, and the need for modernized payment mechanisms for advanced diagnostic tests, policymakers must be sure to balance the need for responsible fiscal policy with the importance of protecting and promoting access to innovative medicines and technologies that improve patient and public health. Certain other policies, such as the Medicare Independent Payment Advisory Board (IPAB), fail to achieve this balance and instead favor blunt cost control mechanisms that threaten future innovation and patient care. In addition, regardless of the election outcome, numerous Affordable Care Act (ACA) provisions are likely to continue with implementation at the federal and state levels, including accountable care organizations (ACOs) and the exchanges. Finally, the drive towards "value-based" healthcare decision-making -- including coverage and payment policies -- is likely to continue,

making it increasingly important for innovators to participate in efforts to not only identify and shape policy proposals in this area but to develop and communicate a narrative that better contextualizes the issue as part of the broader biomedical R&D ecosystem.

In 2013, CHI Will

- Develop data and contextual narrative to better quantify and communicate the value of medical innovation.
- Inform and educate delegation members on the success of Medicare Part D, and the consequences to innovation and patient care that would result from proposals to weaken the program, such as expanding rebates to dual eligible and allowing the government to negotiate pricing.
- Inform and educate delegation members on the success of Medicare Part B, and the consequences to innovation and patient care that would result from proposals change the market-based Average Sales Price (ASP) system.
- Address issues such as comparative effectiveness research and CMS' coverage with evidence development policy in order to inform delegation members of their purpose, usage and, if misapplied, implications for biomedical innovation and patient access.
- Join efforts to modernize diagnostics coverage and payment policies and to inform delegation offices over the value of diagnostic technologies in informing healthcare decision-making and patient care.
- Continue to support efforts to repeal IPAB.
- Coordinate with CHI Sacramento office, membership and industry associations (AdvaMed, BIO, MDMA, PhRMA, etc.) regarding implementation of ACA provisions of significant importance, such as ACOs, value based purchasing, Medicaid expansion, the state exchanges, etc..

Science Funding

Together, industry, research universities and institutes, venture capital and the National Institutes of Health (NIH) comprise one of the most successful and important public-private partnerships in our country. For example, in 1973, research led by Herbert Boyer at the University of California - San Francisco and Stanley Cohen at Stanford led to the development of recombinant DNA technology. That research, supported by NIH funding, spawned an entire industry -- biotechnology -- which today continues to grow not only in California, but in states across the country and nations around the world. As we look to the future, we are confident that scientific breakthroughs will lead to similar cases -- if the "public" foundational element of the public-private partnership is sustained and strengthened. The continued vibrancy of the California and U.S. biomedical industry depends on many things -- such as those issues addressed above. But at its very foundation, it depends upon continued advances and progress in science that are fueled and driven by the NIH and other federally-funded science research. Therefore, it is imperative that Congress safeguard and sustain this critical public-private partnership and resulting improvements in patient care, public health, economic growth and job creation by protecting NIH funding as part of a thoughtful and deliberative approach to deficit reduction.

In 2013, CHI Will

- Develop and publish case studies illustrating the numerous benefits stemming from initial NIH funding, in terms of improvements to patient and public health, technology development, and

economic growth and job creation. For example, recombinant DNA and the sequencing of the human genome.

- Continue efforts to inform and educate delegation offices regarding the consequences to California's biomedical innovation ecosystem stemming from NIH funding cuts under the threatened sequestration scenario.
- Convene leaders from industry, the research community and policymakers to discuss models for improving research, discovery and development collaboration and partnerships.

Tax Policy and Reform

Sound tax policy can greatly influence life sciences investment, innovation and job creation -- and enhance global competitiveness -- by providing companies with important incentives to make high-risk investments, leading to the development of innovative, life-saving therapies and medical technologies. Unfortunately today, U.S. tax policy serves as a complicated and growing burden on companies competing in the increasingly intertwined and interconnected global economy. Issues ranging from the U.S.'s near-world high corporate tax rates, never-ending yearly angst over extension of the R&D tax credit and, most recently, a punitive excise tax on medical technologies at a time when we need more, not less, investment and innovation are just a few of the examples of the challenges and frustrations we face. For emerging companies, the challenges are even more direct -- venture capital and other investment dollars to start-up firms have been drying up, meaning that these entrepreneurial firms are struggling simply to keep their doors open. As discussions over comprehensive tax reform intensify, it will be critically important for policymakers to consider and incorporate proposals that recognize these and other challenges.

In 2013, CHI Will

- Continue efforts to inform and educate delegation members regarding the impact of the looming medical device excise tax on medical technology investment, innovation and job creation in California.
- Join in efforts to communicate and contextualize industry consensus positions around particular tax reform proposals.