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CALIFORNIA HEALTHCARE INSTITUTE

New Member "101":
FDA Regulatory Policies and Funding

History shows that a strong, science-based FDA and well-articulated, predictable and consistent regulatory process are essential to biopharmaceutical and medical technology investment, innovation and patient care. For most of its history, 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, with California front and center, become the global leader in medical device, pharmaceutical and biotechnology innovation. None of this would be possible without adequate congressional funding of the Agency.

Yet the FDA performs its work with relatively little resources – a base appropriations budget of approximately $2.6 billion. And in recent years, Congress has enlarged the Agency's scope into new fields – tobacco, biosimilars, drug compounding, anti-counterfeiting, antibiotics development, drug and device security, and more – and significantly added to its overall responsibilities and authority. Yet federal appropriations have largely failed to keep up with new mandates, forcing greater reliance on industry-funded user fees and creating more risk and uncertainty for biomedical inventors and investors in an already lengthy and expensive endeavor.

After industry, consumer groups, and FDA agreed the length of time from submission of a new drug application to a final review decision was taking far too long, Congress implemented "user fees" for drugs in 1992. User fees were extended to medical devices in 2002, and have more recently been implemented for generic drugs, biologics, biosimilars, animal drugs, and other product review activities. The agreements negotiated between industry and FDA aim to ensure faster, more predictable approval times, and specify that user fees are intended to supplement rather than replace congressionally appropriated funding to FDA. However, FDA today relies heavily on user fees to supplement congressional appropriations for its product review activities: industry user fees fund approximately 60-65% of the cost of FDA human drug and biologics review activities, and approximately one-third of the cost of FDA device and diagnostics review activities.

In 2012, Congress passed the *Food and Drug Administration Safety and Innovation Act (FDASIA),* which renewed critical FDA user fees and also 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. Unfortunately, temporary but meaningful reductions in the agency's budget due to sequestration, combined with chronic underfunding of the agency, slowed FDA's ability to properly implement the important provisions included in FDASIA. *(See CHI Backgrounder on the "FDA Safety Over Sequestration (SOS) Act")*

With the next round of user fee negotiations set to commence as soon as summer 2015, it is critically important that Congress ensure FDA has unfettered access to funding – in the form of appropriations and user fees – that will not only allow FDA to meet its Congressionally-mandated product review responsibilities, but for sustaining biomedical investment, innovation and improvements in patient care.

It is also important for Congress to evaluate FDA drug and device review and performance data to monitor FDASIA implementation and prepare for the next round of user fee negotiations. To this end, together with Boston Consulting Group (BCG), CHI developed and released two reports – one for biopharmaceuticals, and one for devices and diagnostics – taking a closer look at overall review times as well as performance trends across therapeutic areas. We believe these reports which rely on FDA's publicly available data will be key resources in identifying additional areas for improving review performance in the next round of user fee negotiations or as part of the House Energy & Commerce Committee's *21st Century Cures* initiative.

As Congress considers FDA funding levels and regulatory improvements in the 114th Congress, we respectfully urge your consideration of the following priorities:

- Increase FDA appropriations so that the agency has adequate funding to institute all the new improvements included in 2012's FDASIA, as well as any regulatory reforms that stem from the House Energy & Commerce Committee's *21st Century Cures* initiative.
- Cosponsor the *FDA Safety Over Sequestration (SOS) Act*, legislation to protect industry user fees paid to FDA from sequestration or other across-the-board spending cuts in future fiscal years.
- 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, including preserving the 12-year exclusivity incentive for innovative biologics and encouraging the agency to provide clear guidance on a number of key provisions, including biosimilars naming, labeling, indication extrapolation, and interchangeability.
- Continue exploring appropriate regulation of mobile health and related technologies, research-use only proposals, unique device identifier (UDI) policies for their important impacts on public health and innovation.