NAVIGANT

ISSUE *BRIEF*

PERSPECTIVES FOR
THE HEALTHCARE INDUSTRY

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THE PRESIDENT'S 2017 BUDGET: KEY PROPOSALS AFFECTING LIFE SCIENCES

In February, President Obama sent an FY 2017 budget to Congress that at once supports innovation in the life sciences and presents significant challenges to manufacturers' abilities to deliver on that innovation. While it is unlikely the budget will be approved, the many proposals within it set the tone of negotiations and establish the priorities for the future of our nation's healthcare. They should, therefore, be carefully considered.

The president's budget includes significantly increased funding for initiatives that will help the life sciences industry continue discovering and developing important new medicines for patients with life-altering and life-threatening diseases. This includes $680 million to expand clinical trials for health disparity populations, pursue new vaccine technology, and fund exceptional opportunities in cancer research as part of the Cancer Moonshot Initiative as well as $33.1 billion to support biomedical research at the NIH (including $300 million for the Precision Medicine Initiative study and $195 million for the Brain Research through Advancing Innovative Neurotechnologies [BRAIN] Initiative). The budget also supports new FDA approval pathways, including $75 million to enable FDA to help advise the NIH on developing new cancer vaccines, diagnostics, and combination treatments.1,2 While this increased funding and support is encouraging, what is not clear is whether it is sufficient to achieve a significant impact in the market.

Furthermore, the budget includes an additional $43 million (for a total of $877 million) across several agencies to support the Administration's National Action Plan for Combating Antibiotic-resistant Bacteria. Though overall CDC funding is reduced by 3.6% in the FY 2017 budget, an additional $200 is proposed to continue establishing an outbreak surveillance network to track drug-resistant strains and set up state-level resistance prevention programs.1,3 As the World Health Organization (WHO) warned in 2011, developing new antibiotics is a "race against time" as antimicrobial resistance continues to increase while the pipeline of new antibiotics continue to dry up.4 This remains true today. Life sciences companies and advocacy organizations must continue to make the argument for better incentives to solve this critical healthcare issue, including significant funding for new drug R&D.

BALANCING THE NEED FOR REDUCED COST AND INCREASED TRANSPARENCY WITH THE NEED FOR CONTINUED INNOVATION

Pharmaceutical manufacturers of innovative products, including biotech, may face increased difficulties to commercialize their assets. Should the 18 provisions aimed at reducing drug costs, increasing the availability of generic drugs and biologics, and increasing transparency contained in this year's budget be approved, it will hamper the very innovation the budget strives to achieve.

Two such provisions that life sciences companies should watch closely are 1) a proposal to reduce exclusivity for biological products from 12 to seven years and prohibit both exclusivity extensions based on minor formulation changes and pay-for-delay agreements between branded and generic/biosimilar manufacturers and 2) a proposal to require pharmaceutical manufacturers to publicly disclose production costs, including R&D investment as well as payer discounts for specific high-cost drugs.1

As industry organizations PhRMA and BIO have stated, mandating public disclosure of proprietary information and reducing intellectual property incentives carries a high risk of undermining competition, reducing incentives for innovative development, and making it difficult for manufacturers to recoup their enormous investments in innovation.5,6

Manufacturers can, and should, also work together toward greater self-regulation, transparency, and education around the cost of drugs in order to comply with government requirements while improving trust in the life sciences industry and ensuring continued innovation. Key action steps include:

- Embracing the spirit of the transparency provisions put forth in the president's budget, while working with government to ensure that they do not hamper innovation.
- Strongly and publicly denouncing unwarranted price increases.
- Educating providers, patients, payers, and the public on the fact that while specialty drugs that offer breakthroughs in highly-complex disease are often much more expensive than traditional drugs, they also often offer much greater value to patients—and require far more funding, time, and risk from manufacturers.7,8 It is imperative that we build a common understanding that it can take nearly an entire generation and hundreds of millions of dollars to prove that a drug or device is safe and effective, making new product development an extremely risk endeavor.

ENSURING CONTINUED SUPPORT FOR INNOVATION AMID THE SHIFT TO VALUE-BASED REIMBURSEMENT

The industry must also monitor proposals that would lead to fundamental changes in Medicaid and Medicare access and reimbursement. One such proposal is the creation of a federal-state Medicaid negotiating pool for high-cost drugs. This proposal will allow CMS and participating state Medicaid programs to partner with a private sector contractor to negotiate supplemental rebates from drug manufacturers.1

Additionally, the budget includes several proposals that modify drug reimbursement and rebates for Medicare Parts B and D. These include, but are not limited to, increasing the rebates manufacturers are required to pay under Part B, increasing the branded drug discount for Part D beneficiaries from 50 to 75% starting in 2018 (closing the Medicare Part D coverage gap three years earlier than under current law), lowering payment for Part B drugs administered in the physician office and outpatient settings from 106% to 103% of the average sales price, and creating a development process for coverage with evidence for Part D that would require manufacturers of certain identified drugs to undertake further clinical trials and data collection to support use in the Medicare population and for any relevant subpopulations identified by CMS. 1

These proposals create additional challenges to manufacturers' ability to recoup their significant investments while also furthering the ongoing shift toward value-based drug pricing and reimbursement.

This shift raises significant new challenges to manufacturers in their negotiations with payers including Medicare and Medicaid. Among these challenges is the question of how to successfully track the necessary health measures and outcomes in specific patients to determine value-based pricing and reimbursement, particularly when it comes to measures and outcomes that are more difficult to track, such as re-hospitalization, due to the potential for multiple causation factors. This has been shown to be complex and costly even in systems with centrally managed health data such as the NHS in the UK and will likely prove far more difficult in the US, where decision-making and data-tracking are much more fragmented.

An additional concern is how this shift may impact the need for innovation in areas of continued need. As we shift toward value-based payment, more growth will be focused in areas like oncology, immunology, and rare diseases, which have greater immunity to these pricing pressures. But there is still unmet need in other areas like cardiology and antibiotics, where large populations are needed for drug evaluation and trials are immensely expensive. Will this push then stall innovation in those areas, who will continue to innovate, and what will be the incentive for continued innovation?

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Although this particular budget may never be approved, it is certain that manufacturers must work together with government, payers, and other stakeholders to address cost and value while also supporting innovation and the development of new medicines and technologies that address important medical needs affecting patients and their families. This includes advocating for the economic analysis of both the short-term and long-term value of new technologies as well as for the support needed to help bring exciting new technologies now in development to the market. It also includes investing in real world evidence initiatives that will help demonstrate the impact of drugs and devices in specific patient populations. Ultimately, a much deeper understanding of populations, and the integration of science and value, will become increasingly necessary to address some of the impending market changes.

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