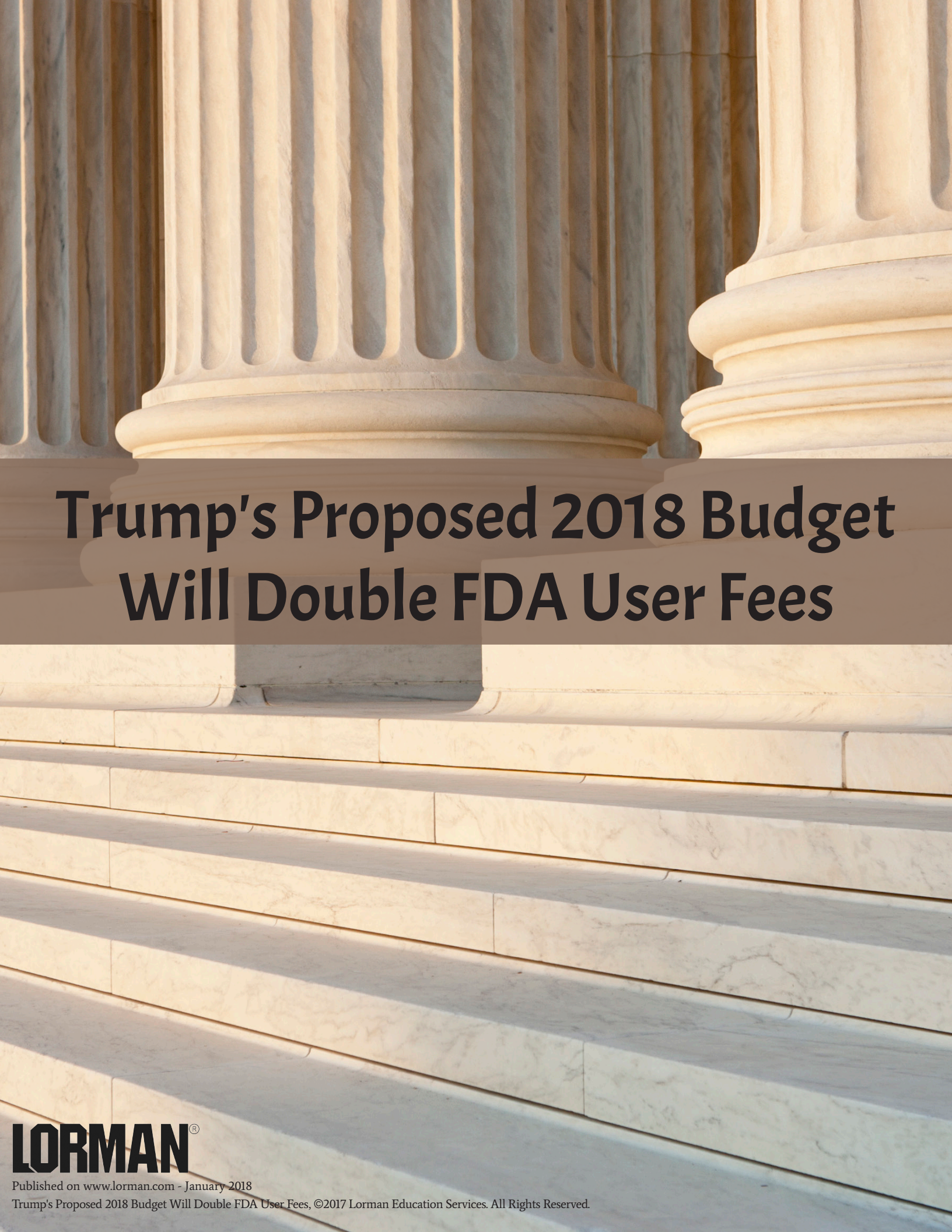

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Published on www.lorman.com - January 2018

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Trump's Proposed 2018 Budget Will Double FDA User Fees

28 MARCH 2017 LAW360 Written for David Rosen and Jason Drori

During his speech last month to a joint session of Congress, President Trump called out the U.S. Food and Drug Administration for its "slow and burdensome approval process." Those comments came on the heels of Trump's roundtable with drug company CEOs in the White House Roosevelt Room, during which he assured that "[w]e're going to streamline the FDA ... and you're going to get your products either approved or not approved but it's going to be a quick process. It's not going to take 15 years."

A few weeks later, on March 16, 2017, the Trump Office of Management and Budget released its budget blueprint for fiscal year 2018. The administration's America First: A Budget Blueprint to Make America Great Again sparked controversy for proposing $54 billion in cuts to discretionary spending, including a nearly 18 percent ($15.1 billion) cut to the U.S. Department of Health and Human Services to "help focus resources on the highest priority research." To offset the shortfall in funding, OMB's budget "recalibrates" medical product user fees to FDA for premarket review by increasing them to over $2 billion. Meanwhile, current user fee levels negotiated under the Prescription Drug User Fee Act will sunset this fall.

OMB's stated justification for the user fee hike? "In a constrained budget environment, industries that benefit from FDA's approval can and should pay for their share." Notably, however, "the Budget includes a package of administrative actions designed to achieve regulatory efficiency and speed the development of safe and effective medical products." These "administrative actions" have yet to be revealed, though Trump's "two out, one in" executive order may provide some insight into the administration's thinking.

Although Trump's budget blueprint lacks specifics and is subject to change and approval in Congress, some politicians, regulators and drug industry stakeholders have cried foul over the proposed user fee increase. Congressman Frank Pallone, who represents New Jersey's 6th District — home to several large pharmaceutical companies — lambasted the proposal, warning that it would "endanger our nation's pipeline of innovative drugs and medical devices by ... altering revenue streams for FDA from stable, appropriated funding to increased user-fee funding" and jeopardize FDA's ability to "carry out critical activities to ensure the safety and effectiveness of our drug supply." The Alliance for a Stronger FDA, a consumer protection agency focusing on science-based regulation, called Trump's budget request for the FDA "neither wise nor realistic," in part because "the drug and device industries have recently completed user fee agreement negotiations with FDA, concurring upon an appropriate amount of industry fees to support agency improvements." The Association for Accessible Medicines, formerly the Generic Pharmaceutical Association, likewise was "concerned by any proposal to raise user fees dramatically beyond what was agreed to in the recently concluded user fee negotiations." And rightfully so, as generic drugs have lower profit margins than brand-name products, and generic companies generally file more new drug applications. Generics thus stand to bear a greater proportion of any fee increase.

In fact, a 100 percent increase of FDA user fees would scrap the revenue targets carefully negotiated by the FDA and industry as part of the fee reauthorization process and potentially push fee totals above half of the FDA's total funding. As such, the increase, if adopted, would undermine the overall purpose of the FDA's user fee programs, which is to supplement, not supplant, traditionally appropriated funding for the FDA's review and approval of drugs (PDUFA, GDUFA), biosimilar products (BsUFA), and medical devices (MDUFA).

Further, whether raising user fees will speed regulatory approval or jumpstart innovation at best is an open question. The FDA already has implemented four approaches intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions. These are fast track, breakthrough therapy, accelerated approval and priority review. And despite complaints that the FDA's drug review is unworkable and slow to approve new pharmaceutical therapies, FDA data shows a consistent downward trend in review times for new drug applications for standard and priority drugs at least since the implementation of PDUFA I in the fall of 1992. For comparison purposes, "[a]verage review times by FDA have been consistently faster than regulatory agencies in other countries. Indeed, 76 percent of the new drugs approved by Japan, EU and FDA from 2009 to 2013 were approved first by FDA." Accordingly, the stated justification for Trump's fee-shifting strategy seemingly is based on a popular but "distorted view of the world"; specifically, "that there's this big logjam of wonder drugs that's having to work its way slowly through a thin hallway full of persnickety bureaucrats — if only we could open those floodgates!" But this isn't actually the case.

To hasten drug approval even more, the FDA must find and hire qualified staff to review applications, which the agency acknowledges is a challenge. Qualified applicants often are few and far between, and training them is time and resource-intensive without any guarantee of retention. In fact, once trained, many FDA staff can find higher-paying jobs in industry. As the head of FDA's Center for Drug Evaluation and Research, Janet Woodcock, recently told the House Energy and Commerce Committee, "[m]ost of these are doctors and scientists, they're almost all at the PhD or MD level. The physicians are generally sub-specialists[,] hard to find people ... heavily

recruited into other jobs ... and so I would expect we would start to lose people very early."

Responding to OMB's requested "recalibration" of fees, the Senate HELP (Health, Education, Labor, Pensions) Committee held the first of a two-part hearing on March 21 regarding the need to reauthorize existing FDA user fee agreements. During his opening statement, Committee Chairman Lamar Alexander echoed Dr. Woodcock's concern over FDA "brain drain," predicting that "[i]f we do not move quickly to reauthorize these agreements, in late July, the FDA will be forced to begin sending layoff notices to more than 5,000 employees to notify them that they may lose their job in 60 days." That would mean "an FDA reviewer who gets started reviewing a cancer drug submitted to the agency in April would be laid off on October 1, before the reviewer is able to finish his or her work." The consequences of such dramatic turnover are self-evident: a smaller workforce struggling to keep pace with increasingly complex medical products. The HELP Committee reconvenes for part two of its hearing on April 4.

Increased user fees also would create a barrier to entry for small and medium-sized enterprises — e.g., startup and specialty drug makers and medical device companies comprising much of the life sciences industry. These companies often have little or no sales revenue; however, they usually are on the cutting edge of medicine and biotechnology, developing new medical therapies for serious illnesses, from cystic fibrosis to Parkinson's disease. Rather than "speed the development of safe and effective medical products," as Trump promised, delaying or preventing companies like these from bringing their medicines to market would deter competition and stifle innovation.

Ultimately, Trump's preliminary budget proposal may be the opening salvo in an unpredictable negotiation process with Congress. Time will tell. In the meantime, we will continue to monitor and report on the rejiggering of FDA user fees and the "administrative actions" Trump and OMB promised would "achieve regulatory efficiency" at FDA and for FDA-regulated industries.

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