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WHITE PAPER

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Regulatory Developments Life Sciences Companies Should Expect in the New Presidential Administration

2017 and beyond promises to be a time for continued evolution for life sciences companies doing business in the United States. This Jones Day *White Paper* contains a summary of several major issues that life sciences companies should monitor as the new Presidential Administration begins its governance, and relevant regulatory and legislative actions are implemented. The topics include: FDA Leadership; Funding and Deployment of Resources; Drug Pricing Issues; Taxation Initiatives; Research Harmonization and Modernization; Patient Experience Data and Real World Evidence; Biosimilars; “Off-label” Promotion; Potential Health Care Enforcement Activity; and Digital Health.

TABLE OF CONTENTS

FDA LEADERSHIP	1
FUNDING AND DEPLOYMENT OF RESOURCES	1
DRUG PRICING ISSUES	2
Drug Pricing Control Efforts	2
Drug Pricing Transparency Initiatives	2
Medicare Part D Coverage Gap	2
TAXATION INITIATIVES OF INTEREST TO LIFE SCIENCES COMPANIES	3
RESEARCH HARMONIZATION AND MODERNIZATION	3
Research Rule Harmonization	4
Reduction of Grant Funding Administration	4
Modernizing Clinical Trials	4
PATIENT EXPERIENCE DATA AND REAL WORLD EVIDENCE	5
BIOSIMILARS	5
“OFF-LABEL” PROMOTION	6
POTENTIAL HEALTH CARE ENFORCEMENT ACTIVITY	7
DIGITAL HEALTH	8
LAWYER CONTACTS	9
ENDNOTES	10

2017 and beyond promises to be a time for continued evolution and uncertainty for life sciences companies doing business in the United States. In addition to the potential changes in policy typically posed by a transition in Presidential Administration, life sciences companies are now carefully watching a number of “game-changing” regulatory and legislative actions, including potential impacts from congressional consideration of the [future of the Affordable Care Act](#) (“ACA”),¹ as well as the near-term and long-term implementation of the recently enacted 21st Century Cures Act (“Cures Act”).² Also on the regulatory agenda in 2017 is the proposed reauthorization of important user fee programs administered by the Food and Drug Administration (“FDA”).

In addition, continued conversations are anticipated regarding complex issues such as drug pricing, off-label promotion, and biosimilar development.

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FDA LEADERSHIP

Essential to implementation of the incoming President’s agenda is the appointment of senior leaders in the executive departments and administrative agencies responsible for implementing the agenda. With respect to the FDA, such leadership comes from the Secretary of the U.S. Department of Health and Human Services (“HHS”) and the Commissioner of the FDA. President-elect Trump has announced his intention to nominate Rep. Tom Price (R-GA), an orthopedic surgeon and six-term congressman, as the Secretary of HHS. Rep. Price’s appointment will be subject to Senate confirmation.

As of the date of this report, President-elect Trump is yet to officially announce potential candidates for the FDA Commissioner position. The current FDA Commissioner, Robert Califf, MD, garnered bipartisan support for his appointment, being confirmed on a vote of 89-4.³ As a matter of historical

precedent, however, every sitting FDA Commissioner has been replaced by a new president, with the exception of Dr. David Kessler, who served as FDA Commissioner under both the Bush and Clinton Administrations (1990–1997).

Beyond the political appointees, leaders of the FDA’s nine centers and offices have historically had great subject matter power and autonomy to oversee their respective product areas, reporting either directly to the Commissioner or to a Deputy Commissioner. It is unclear whether incoming Agency leadership will change this historical norm.

In addition, the internal structure of FDA may undergo change as a result of the Cures Act, which requires the Secretary of HHS to establish one or more “Intercenter Institutes” within FDA for a major disease area or areas. The Secretary is required to implement procedures for extensive collaboration and coordination across the major FDA centers, the Center for Drug Evaluation and Research (“CDER”), the Center for Biologics Evaluation and Research (“CBER”) and the Center for Devices and Radiological Health (“CDRH”) with respect to such disease area or areas. At least one such institute must be established within one year of enactment of the Cures Act.⁴

FUNDING AND DEPLOYMENT OF RESOURCES

The Cures Act increases FDA funding by \$550 million over five years, targeting development of new tools and programs and enhancing scientific capacity at FDA. The funding is, however, subject to ongoing congressional appropriation.⁵

How Agency resources are deployed in the new Administration remains to be seen, but the President-elect has indicated new regulations will not be a high priority. In his “Contract with the American Voter,”⁶ President-elect Trump set forth “a requirement that for every new federal regulation, two existing regulations must be eliminated.” In a video message outlining actions he would take within the first 100 days in office, President-elect Trump reiterated this commitment.⁷

However, the Contract with the American Voter also provides that, while a goal is the elimination of “FDA red tape,” “... there are over 4,000 drugs awaiting approval, and we especially want to speed the approval of life-saving medications.” This suggests that the new Administration desires for FDA

resource deployment to be focused on expedited approval of important medicines.⁸

Additional funding policies are likely to arise during congressional consideration of the reauthorization of the prescription drug, medical device, generics and biosimilars user fee programs, each of which expires in September 2017. User fees represent a substantial portion of FDA's operating budget.⁹

DRUG PRICING ISSUES

Drug Pricing Control Efforts

Many individuals in the United States have identified prescription drug pricing as a significant concern.¹⁰ In a recent press conference, President-elect Trump continued earlier calls from his campaign for drug pricing reform and suggested creating “new bidding procedures.”¹¹ Soon thereafter, Senator Bernie Sanders echoed the President-elect's sentiments, issuing a series of tweets suggesting “price gouging,” a need for “policing” of drug companies, implementation of policies to support “buy[ing] safe medication abroad,” and for “Medicare to negotiate prices.”¹² Congress has recently been focused on the subject, including hearings and investigations. On December 21, 2016, the Senate Special Committee on Aging released a report and findings from its bipartisan investigation related to drug pricing practices by companies.¹³ In the report, the committee raised concerns that current market pressures have resulted in a “business model that harms patients, taxpayers and the U.S. health care system.”¹⁴

As the new Administration takes office, drug pricing controls may be a unique area presenting opportunities bipartisan legislation.¹⁵ However, some Republican leaders have historically and consistently expressed concern that “bidding” and other types of “price control” legislation should be opposed because of its negative impact on innovation and business.¹⁶ In 2015, a number of U.S. senators introduced legislation aimed at addressing the cost of prescription drugs and authored multiple pieces of bipartisan legislation to improve consumer protection relating to drug prices.¹⁷

The last time legislation was presented to permit Medicare to negotiate prescription drug prices was in 2007.¹⁸ The proposed bill would have revised the “noninterference provision” of the Social Security Act, which prohibits the Secretary of Health and

Human Services from participating in negotiations with or related to drug manufacturers.¹⁹ When the proposed legislation was last reviewed by the Congressional Budget Office, the proposed negotiation power was expected to have a “negligible effect on federal spending” for covered Medicare Part D drugs.²⁰

Drug Pricing Transparency Initiatives

During the 2015–2016 state legislative sessions, a number of states introduced bills to require prescription drug cost and price transparency.²¹ As part of these legislative efforts, states typically focused on transparency by prescription drug manufacturers, health insurers, and pharmacy benefit managers.²² Of these state efforts, Vermont was the first state to pass legislation requiring manufacturers to disclose costs or explain pricing practices.²³ This trend for increased state-level legislative efforts to promote pricing transparency will likely continue; federal electors may also take up efforts and legislation to require disclosure of manufacturer costs and pricing.

Medicare Part D Coverage Gap

Effective in 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003²⁴ established a voluntary, outpatient prescription drug benefit (under Medicare Part D). This benefit is provided through private prescription drug plans (“PDPs”) that offer drug coverage. As structured, private drug plans bear some limited financial risk for the coverage provided by the plan, but most program costs are addressed through federal subsidies designed to encourage Medicare beneficiary participation and to keep prescription drug benefits affordable.

Since 2006, the Medicare Part D program has been modified through a series of statutes, including the ACA, as amended.²⁵ The ACA amended the Medicare Part D program by addressing a long-standing coverage gap concern in which Medicare beneficiaries faced increased out-of-pocket costs (frequently referred to as the “doughnut hole”). By 2020, the ACA is set to gradually close the doughnut hole coverage gap through a combination of manufacturer discounts and government subsidies. If the ACA is appealed in a way that affects closing this gap, legislators likely will revisit reform options to address the Medicare Part D drug benefit issue. If the coverage gap is not addressed by ACA replacement legislation, manufacturers may face additional pressures from consumers related to drug costs and increased demand for patient assistance programs to avoid, delay, or defray costs resulting from the coverage gap.

TAXATION INITIATIVES OF INTEREST TO LIFE SCIENCES COMPANIES

The incoming Administration has made business tax reform an explicit priority. It is too early to predict what will be enacted, but significant information may be gleaned from the President-elect's campaign website (the "Trump Proposal")²⁶ and tax reforms proposed in the House Republicans' plan released by House Speaker Paul Ryan last year (the "House GOP Blueprint").²⁷ Both favor a significant rate-cutting and base-broadening change in the taxation of business income. Both would significantly impact life science companies.

The Trump Proposal and the House GOP Blueprint articulate an intent to limit the availability of tax deductions and credits, particularly those tailored for "special interests." Both plans provide an exception from this goal in order to retain a *research and development* tax credit, but do not indicate any intent to keep other deductions and credits applicable to life sciences companies (such as the orphan drug credit).

The Trump Proposal and the House GOP Blueprint propose to compensate for the elimination of deductions and credits by lowering the corporate tax rate. The Trump Proposal would lower the rate from 35 percent to 15 percent, while the House GOP Blueprint calls for a rate of 20 percent. Both the Trump Proposal and the House GOP Blueprint would repeal the corporate alternative minimum tax.

The Trump Proposal would allow companies engaged in manufacturing in the United States to elect to immediately expense capital investments (rather than amortize the cost over the property's useful life) or deduct corporate interest expense, but not both. The House GOP Blueprint is not elective; the cost of business investments (other than land) would be immediately expensed and corporate interest deductibility would be disallowed except to the extent of interest income.

Both the Trump Proposal and the House GOP Blueprint contain proposals for international tax reform. This is one of the most controversial areas of business tax reform, and may not be implemented as quickly as rate-cutting or repeal measures. President-elect Trump has not provided much detail on his campaign website except that he would impose a one-time 10 percent deemed repatriation tax on accumulated offshore earnings. The House GOP Blueprint would also impose

a current tax on accumulated offshore earnings, generally at a rate of 3.5 percent (increased to 8.75 percent to the extent of offshore cash) payable over eight years. Additionally, the House GOP Blueprint would introduce a 100 percent exemption for dividends received by a U.S. company from its foreign subsidiaries. This would effectively transition the United States from a "worldwide" system of taxation (taxing U.S. companies on worldwide earnings) to a "territorial" system limited to taxing U.S. earnings.

Furthermore, the House GOP Blueprint would introduce rules intended to impose tax on a destination basis. Details regarding the mechanics and implementation of this tax have not been formally supplied by the drafters of the House GOP Blueprint as of the date of this report, but it seems to provide as follows. Regarding imports, U.S. tax deductions would be disallowed for tangible property, services or intangible property purchased from outside the United States. Regarding exports, U.S. tax deductions would be allowed for domestic input purchases and labor costs, but the proceeds of the sale of any property, services, or intangible property outside the United States would not be taxed in the United States. House Speaker Paul Ryan has referred to this tax as a border adjustment tax intended to level the trade playing field for the United States relative to other countries. The President-elect is not committed to this approach, but he is discussing it with congressional lawmakers. He has alternatively proposed levying a U.S. tax on goods imported by companies that have shifted production out of the United States

Finally, the medical device excise tax and the branded pharmaceutical fee (effectively a tax, although not labeled as such) were enacted as part of the ACA and help fund the subsidies and credits provided by the ACA. Both may be repealed as the incoming Administration focuses on the ACA as one of its first priorities.²⁸ As of the date of this report, the ACA has not yet been repealed.

The cumulative effect of these various tax initiatives will affect investment and transaction strategies.

RESEARCH HARMONIZATION AND MODERNIZATION

Through the enactment of the Cures Act, Congress underlined efforts to reduce the administrative burdens for researchers and grant recipients, modernize the conduct of clinical trials, and direct the harmonization of regulations and policies

among federal agencies that fund and regulate research. It is anticipated that implementation of the Cures Act provisions and other modernization initiatives at federal agencies will continue to be a key focus under the incoming Administration.

Research Rule Harmonization

Under Section 3023 of the Cures Act, the Secretary is directed to harmonize differences between HHS and FDA human subject regulations²⁹ within the next three years.³⁰ Specifically, such efforts are to focus on modifying regulations to reduce regulatory duplication and unnecessary delays, modernizing processes for clinical trials conducted at multiple sites, and protecting vulnerable populations participating as research subjects.

Section 3023 also seeks to streamline institutional review board (“IRB”) review of research by facilitating joint or shared review and the use of independent IRBs. This is consistent with other evolving federal agency policies regarding IRBs.³¹ Related, Section 3024 of the Cures Act also provides FDA with additional authority to modify or waive informed consent requirements for clinical trials involving minimal risk.³²

The Cures Act “harmonization” mandate continues some efforts already underway between HHS and FDA. For example, HHS and FDA recently issued a jointly developed final guidance on the use of electronic informed consent in research.³³

The Cures Act goal of modernizing the regulation of human subject research occurs in the midst of HHS’s approximately five-year effort to finalize comprehensive revisions to the “Common Rule,” the HHS human subject regulations, that apply to federally funded or supported research and cover approximately 20 federal agencies.³⁴ A proposed final version of such comprehensive revisions was submitted for review to the Office of Management and Budget (“OMB”) on January 4, 2017.³⁵ OMB completed review of the proposed final version, which is set to publish on January 19, 2017.³⁶

Notably, the proposed Common Rule revisions have generated significant controversy, especially as related to the proposed stringent requirements regarding research involving biospecimens.³⁷ Even if the rule is finalized it is unclear whether it may be among the rules potentially targeted by the incoming Administration for revocation.³⁸ Any uncertainty regarding the revisions to the Common Rule will necessarily impede

the Cures Act mandate for harmonization thereof with FDA research regulations.

The Cures Act also contains a number of provisions related to privacy which will need to be considered in light of existing HIPAA³⁹ regulations and the privacy provisions of the Common Rule (as revised). For example, Section 2036 requires the Secretary of HHS to clarify its current position regarding the extent of an individual’s ability to authorize use of his or her protected health information for future research.⁴⁰

Reduction of Grant Funding Administration

The Cures Act contains provisions designed to alleviate administrative and conflict of interest requirements for grant funding recipients. Section 2034 requires the Secretary of HHS to lead federal research funding agencies in a review of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting.⁴¹ Key considerations for this review include modifying reporting timelines, and the requirements for financial interest disclosures to ensure that such disclosures are relevant to awards that will directly fund the research and to reduce the frequency of reporting.⁴² Section 2034 also calls for measures to reduce the administrative burdens on primary awardees of grants from the National Institutes of Health (“NIH”) with respect to the monitoring of grant sub-recipients.

These provisions would necessarily require reconsideration of the revised regulations issued by HHS in 2011, which were designed to tighten financial conflict of interest rules for institutions and researchers.⁴³

Modernizing Clinical Trials

Consistent with its emphasis on advancing the precision medicine initiative and expedited approval pathways for important medicines, the Cures Act provides for innovative means for clinical trial design and the data development in support of product approval. Action on certain of these items may begin as early as this year.

Section 3021 requires the Secretary of HHS to issue new guidance to assist sponsors in utilizing complex adaptive and other novel clinical trial protocols for new drugs and biologics. The guidance is to include feedback from FDA as to how novel protocols will satisfy the substantial evidence test and how sponsors may obtain feedback from FDA on technical matters

related to modeling and simulation. A public hearing must be held within 18 months of enactment of the Cures Act and a draft guidance issued no later than 18 months thereafter.⁴⁴

Section 3011 requires the Secretary of HHS to establish a process for the qualification of “drug development tools,” as requested by an applicant, for use in supporting or obtaining approval for, or the investigational use of, a drug or biologic. These tools may include biomarkers, clinical outcome assessments and “any other method, material or measure that the Secretary determines aids drug development and regulatory review...”⁴⁵ This is a longer-term measure, as draft guidance must be issued within three years of enactment of the Cures Act.

PATIENT EXPERIENCE DATA AND REAL WORLD EVIDENCE

In recent years, FDA has increasingly exhibited its interest in engaging with patient advocacy groups to further development of medicines for unmet medical needs, particularly in the rare disease space. The Cures Act adds support for this approach and also an expansion of the type of data that may support the approval of new products.

Following approval of a drug or biologic, which such approval occurs at least 180 days after enactment of the Cures Act, the Secretary is required to make a public statement regarding any patient experience data submitted and reviewed as part of the application for approval.⁴⁶ Further, FDA is required to develop a long-term plan and guidance documents regarding the collection and use of patient experience data in drug development. At least one such guidance document must be issued in draft form within 180 days of enactment. “Patient Experience Data” includes data that are collected by persons such as family members, caregivers, disease research foundations, researchers, and drug manufacturers and that are intended to provide information about patients’ experience with a disease or condition, including (i) the impact of the disease or condition, or a related therapy on patients’ lives and (ii) patients’ preferences regarding treatment of such disease or condition.⁴⁷

One of the more controversial provisions of the Cures Act requires the Secretary to establish a program to evaluate the use of so-called “real-world evidence” to support marketing approval for a new indication of a previously approved

drug and to satisfy post-approval study requirements.⁴⁸ Significantly, “real-world evidence” means data regarding the potential benefits or risks of a drug based on sources “other than randomized clinical trials.”⁴⁹ Implementation of this program will begin with the Secretary’s establishment of a “draft framework,” which is required to be issued not later than two years after enactment of the Cures Act.⁵⁰

BIOSIMILARS

In 2016, FDA approved three biosimilars: Pfizer/Celltrion’s Remicade® (infliximib) biosimilar Inflectra® in April, Sandoz’s Enbrel® (etanercept) biosimilar Elrezi® in August, and Amgen’s Humira® (adalimumab) biosimilar Amjevita™ in September.⁵¹ The biosimilar approval pathway was made possible by the Biologics Price Competition and Innovation Act (“BPCIA”) as title VII of the ACA. As noted above, the ACA has been a focal point for President-elect Trump on the campaign trail and a candidate for repeal and replacement under the new Administration. However, there has been no indication from the President-elect or legislative leaders that the BPCIA is expected to be part of actions taken on the ACA.

While the BPCIA may or may not be retained as a part of any broader revision or repeal of the ACA, FDA policies and actions in the new Administration may nonetheless implicate biosimilar products, particularly through the Agency’s interpretation of the BPCIA and subsequent implementation of the rules and policies affecting naming, pricing, and interchangeability. While FDA recently finalized guidance on the clinical pharmacology data to support biosimilarity to a reference product and non-proprietary names including an FDA-designated suffix devoid of meaning, much work remains in the Agency’s hands to form policy and approve products in the coming years, including finalizing guidance on the key concept of what it takes for a product to be interchangeable.⁵²

In addition to the regulatory front, a Trump-nominated Supreme Court Justice may be in place when the Court begins hearing issues arising under the BPCIA, though it is difficult to predict how quickly a nominee could navigate the confirmation process and be appointed. What is recognized, however, is that given the significant litigation occurring and likely to occur under the BPCIA, there will likely be a need for the Supreme

Court to review additional court decisions interpreting the scope of the BPCIA.

At least one significant biosimilar case is pending before the Supreme Court this term. The case involves the first interpretations of the BPCIA by the Federal Circuit and regards a Sandoz biosimilar of Amgen's Neupogen. Sandoz petitioned the Court for review of part of the 2015 decision while Amgen has submitted a conditional cross-petition requesting review of another part of the decision should Sandoz's petition be granted.⁵³ Sandoz seeks review of when a biosimilar applicant can provide an effective "notice of commercial marketing," which the BPCIA states must issue at least 180 days before the biosimilar enters the market. Amgen's conditional cross-petition challenges the Federal Circuit's ruling that the patent dance is optional. In June 2016, the Supreme Court asked the Solicitor General to provide comments on both petitions.

In December, the acting Solicitor General filed an amicus brief recommending that the petition and cross-petition be granted, arguing that the Federal Circuit's decision on the 180-day delay was incorrect. The Federal Circuit held that a biosimilar maker can only give effective notice of commercial marketing after the biosimilar product is licensed by FDA, meaning that the first sale of a biosimilar cannot occur sooner than six months after FDA's approval (for additional insight on the 180-day notice of commercial marketing for biosimilars, see [Jones Day Commentary](#)). On January 13, 2017, the Court granted cert to both the petition and cross-petition.⁵⁴ The case is expected to be argued in April 2017.

Beyond U.S. implications, biosimilars and biologic protections have global implications. In a video message outlining actions he would take within the first 100 days of office, President-elect Trump stated his intent to withdraw from the Trans-Pacific Partnership ("TPP") "from day one." In lieu of the TPP, Trump indicated he would "negotiate fair bilateral trade deals" with foreign countries. Withdraw from the trade deal has ramifications to available protections for innovator biologics within the 12 Pacific Rim nations, including Canada, Mexico, Japan, Australia, New Zealand, and Malaysia (for an analysis of the anticipated impact of the TPP on the U.S. life sciences industry, see [Jones Day Insights](#)).

The final text of the TPP agreement requires signatory countries to provide a minimum of five years of exclusivity, and in some instances eight years of exclusivity, to biologics, defined

as "a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition." The United States argued for 12 years of protection, while five other countries came to the table offering no protections. The incoming Administration has not addressed whether and to what extent these protections could or would be negotiated as part of a bilateral trade agreement.

"OFF-LABEL" PROMOTION

The extent to which life sciences companies may or should be permitted to promote their products for "off-label" uses in the United States has come into increased focus in recent years. Further developments in this area may be anticipated, as a result of FDA's recent public hearings on the subject, as well as the policy approach of the incoming Administration.

As a general rule, once FDA approves or clears a drug or device for marketing, physicians may lawfully prescribe such product for any indication. For many years, however, FDA has aggressively interpreted the misbranding provisions of the Federal Food, Drug, and Cosmetics Act ("FDCA") to restrict manufacturers' ability to make off-label uses known to physicians.⁵⁵ The end result is that while virtually any other speaker may lawfully promote the benefits of an off-label use, the government continues to use regulatory and legal enforcement measures, including prosecution, for any manufacturer who promotes an off-label use of a drug or device.⁵⁶

This selective restriction on speech has raised First Amendment concerns. In a key 2012 case the Second Circuit Court of Appeals interpreted the FDCA's misbranding provision "as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs."⁵⁷ Since that time, FDA has appeared reluctant to litigate off-label promotion cases, presumably for fear that other courts would reach similar results.⁵⁸

Very recently, there have been other U.S. district court decisions favorable to manufacturers. In *Amarin Pharma, Inc. v. U.S. Food & Drug Administration*, the U.S. District Court for the Southern District of New York entered a preliminary injunction permitting a manufacturer to offer truthful, non-misleading statements about the off-label use of a drug.⁵⁹ And in *United States v. Vascular Solutions, Inc.*, the U.S. Department

of Justice's prosecution of a medical device manufacturer for off-label promotion concluded in a not-guilty verdict.⁶⁰ Notably, in that case, the government offered a jury instruction stating that it is "not a crime for a ... company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device."⁶¹

Notwithstanding the results in the previously mentioned cases, manufacturers and their officers remain subject to risk for off-label promotion of pharmaceuticals or medical devices. In July 2016, in *United States v. Facticeau*,⁶² a jury convicted two company executives of misbranding charges related to the alleged distribution of a medical device for an unintended use. At the same time, the jury acquitted those executives of companion charges alleging false or fraudulent speech. Post-trial briefing raising the First Amendment issue is now pending in the U.S. District Court for the District of Massachusetts.⁶³

In addition to what manufacturers take from these court decisions, further developments in off-label enforcement may come from evolving FDA policy, as informed by the incoming Administration. In November 2016, FDA held a two-day public hearing related to communications by manufacturers and their representatives regarding FDA regulated drugs and devices, including licensed biological products for humans and animal drugs.⁶⁴ FDA has stated that it is "engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved/cleared medical products, and the input from this meeting will *inform FDA's policy development* in this area."⁶⁵ FDA recently extended the comment period for related docket submissions from January 9, 2017, through April 10, 2017, clearly placing future decisions about the policy with the new Administration.

Adding another layer to the discussion on where FDA draws the promotional line is Section 3037 of the Cures Act, which expands the scope of permissible drug manufacturer discussion of certain health care economic information. Since the passage of the Food and Drug Administration Modernization Act of 1997,⁶⁶ the misbranding provision of the FDCA granted a limited safe harbor for a manufacturer's communication of health care economic information. However, manufacturers generally did not utilize the safe harbor, as the Agency's position was that health care economic information making a claim *inconsistent* with a product's approved labeling could be considered misbranding.

While questions remain regarding FDA's implementation, Section 3037 on its face expands: (i) the definition of health care economic information;⁶⁷ (ii) the audience to which manufacturers may promote health care economic information (expanding to include payors in addition to formularies and similar groups with knowledge and expertise in the area of health care economic analysis carrying out responsibilities for the selection of drugs for coverage or reimbursement); and (iii) the necessary correlation between the health care economic information provided and the product's approved indication (relaxing the standard to allow health care economic information that "relates" to an indication, rather than limiting the safe harbor to information that "directly relates" to an indication).

While the Cures Act maintains the "competent and reliable scientific evidence" standard, health care economic information must be accompanied by "a conspicuous and prominent statement describing any material differences" between the health care economic information and the product's approved label.⁶⁸

Notably, the open regulatory docket and ongoing policy consideration has not prevented FDA from asserting that certain product promotion is misleading and taking enforcement action against product promotion consistent with existing standards. For example, in December 2016, FDA's Office of Prescription Drug Promotion, often seen as the harbinger for promotional enforcement matters, issued two warning letters and four untitled letters regarding misleading product promotion, following a relatively light regulatory enforcement year—there were only five letters issued by the Office from January to November 2016.⁶⁹ To what extent the incoming Administration will pursue off-label promotion may depend in significant part on the selected leadership of FDA (see FDA Leadership Section above).

POTENTIAL HEALTH CARE ENFORCEMENT ACTIVITY

There have been no signals from the incoming Administration on any reforms or changes in health care enforcement against the life sciences industry. In recent years, across both Democratic and Republican Administrations, there has been an increase in enforcement, with a substantial amount of enforcement by both federal and state government regulators being driven by private "whistleblowers" and their counsel seeking bounties on recoveries for violations of

the False Claims Act (“FCA”),⁷⁰ involving arrangements that potentially violate the complex regulations coming out of the Stark⁷¹ and Anti-Kickback (“AKS”)⁷² laws. It is not expected that enforcement activities will change course, particularly at the state level, as many states face increasing financial and other pressures that will likely continue to escalate regardless of the positions taken by the incoming Administration. (For perspective on how the new Administration will affect state attorney general activity, see Jones Day *White Paper*, “[What Impact Will the New Trump Administration Have on State Attorney General Activity?](#)”)

Congress is considering some modifications to the Stark law, which is usually applied against the provider community, but currently there are no proposed reforms to the FCA and AKS law, which are aggressively used against life sciences companies. Reforms are needed, including: (i) modifying the burden of proof to a higher standard of proof of violation of the AKS before it can be used to support an FCA claim; (ii) calculating damages on the government’s actual loss; (iii) requiring employee whistleblowers to exhaust internal compliance procedures and reporting before filing an FCA suit; and (iv) removing the threat of exclusion from federal health care programs without a finding of fraud. It is unclear at this time if the new Administration would support these reforms.

DIGITAL HEALTH

The broadly used and little-defined term “digital health” generally encompasses both telehealth and health IT. In this context, telehealth is a delivery method for health care services using technology and thereby expanding access and promoting collaboration beyond traditional “bricks & mortar” care models, while health IT encompasses the powerful method of analyzing and using digital data to advance care and health-related information. Given the acknowledged potential for incorporating digital health methods within precision medicine initiatives and clinical trials, the growing number of life science companies investing in, partnering with, and pursuing digital health opportunities are likely to benefit from any policies that further the digital health industry as a whole.

A number of medical organizations expect both telehealth and health IT to benefit from policies likely to be advanced by

the new Administration and Congress.⁷³ Digital health enables health care companies to advance efficiency when delivering care, collaboration among caregivers, patients, and industry stakeholders, and access to health care providers and health-related information, among other goals. Such advancements have and should continue to decrease the cost of care while maintaining high standards, and perhaps advancing the standard of care, given population health learning and virtual collaboration among health providers.

Accordingly, many anticipated health care policies of the new Administration are likely to require health providers to produce greater results with less revenue (or, at least less “set revenue” in value-based models) while also advancing access to and quality of care.⁷⁴ While not specifically mentioned by the new Administration as a policy target, digital health—a primary driver for efficiency and access regardless of geographic limitations—is likely to be an indirect beneficiary of stated health care policies advanced by the new Administration.

Recent increased industry activities and legislative advancements around digital health and risk-based programs are expected to continue in an Administration with stated goals of reducing regulations, driving value, advancing consumer independence, and developing big infrastructure projects.⁷⁵ Several of these themes are apparent in the digital health related provisions of the Cures Act. From a digital health perspective, the Cures Act appears to promote four objectives:

1. Interoperability by transitioning from “meaningful use” to a “trusted exchange network.”
2. Reduction of compliance burdens and costs while advancing value oriented participation.
3. Transparency through provider information, payor requirements, and consumer access to medical information.
4. Telehealth and coordinated care payment and best practices via studies commissioned as a result of Cures.

While not part of the Cures Act, with respect to infrastructure, some in the digital health industry quickly point to broadband expansion as a potential national-oriented infrastructure program that could significantly advance digital health by providing increased video streaming capabilities for telehealth solutions (not to mention beneficial technology advancements for other industries and consumers).⁷⁶

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our “Contact Us” form, which can be found at www.jonesday.com/contactus/.

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ENDNOTES

- 1 [Patient Protection and Affordable Care Act](#), Pub. L. No. 111-148, 42 U.S.C. § 18001 et seq. (2010) (“ACA”).
- 2 [21st Century Cures Act](#), Pub. L. No. 114-255, 130 Stat. 1033 (2016) (“Cures Act”).
- 3 Eric Palmer, “[FDA Commissioner Califf Has Supporters Who Hope Trump Will Keep Him](#),” FiercePharma, Dec. 1, 2016.
- 4 Cures Act § 3073, 130 Stat. at 1136 (to be codified at 21 U.S.C. § 391 et seq.).
- 5 *Id.* at § 1002. See Robert M. Califf, M.D., “[21st Century Cures Act: Making Progress on Shared Goals for Patients](#),” FDA Voice Blog (Dec. 13, 2016).
- 6 Donald J. Trump, “[Donald Trump’s Contract with the American Voter](#)” (Oct. 22, 2016).
- 7 Transition 2017, “[A Message from President-Elect Donald J. Trump](#),” YouTube (Nov. 21, 2016).
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- 9 Gillian Woollett & Jay Jackson, “[FDA Has Received \\$7.67 Billion from Manufacturers to Fund Drug Review](#),” Avalere, Aug. 15, 2016.
- 10 Paula Tironi, “Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs,” 19 *Annals of Health Law* (2010), 311.
- 11 *The New York Times*, [Donald Trump’s News Conference: Full Transcript and Video](#) (Jan. 11, 2017),.
- 12 Sanders, B. [SenSanders]. (2017, Jan. 11). Trump is right: pharma is “getting away with murder.” But do Trump and Republicans have the guts to police drug companies and lower prices? Retrieved from [Twitter](#); They must allow Americans to buy safe medication abroad, which is sold at substantially lower cost, and enable Medicare to negotiate prices. Retrieved from [Twitter](#); The epidemic of price gouging in the drug industry is an obscenity! The cost of prescriptions has become its own health hazard. Retrieved from [Twitter](#).
- 13 United States Senate, Special Committee on Aging, *Committee Report of Bipartisan Drug Pricing Investigation* (Dec. 21, 2016).
- 14 *Id.*
- 15 [Letter to President-elect Donald Trump from Sens. Al Franken and Sherrod Brown](#), December 20, 2016, (last visited Dec. 21, 2016).
- 16 R. Roubein, S. Chacko, “[Trump Opens a Can of Worms with Blast at Drugmakers](#)” (Jan. 13, 2017),.
- 17 Safe and Affordable Drugs from Canada Act that would require the Food and Drug Administration to establish a personal importation program that would allow individuals to import a 90-day supply of prescription drugs from an approved Canadian pharmacy; Preserve Access to Affordable Generics Act would expand consumers’ access to the cost-saving generic drugs they need and increase competition between drug manufacturers and choices for consumers by helping to put an end to “pay for delay” deals-the practice of brand-name drug manufacturers using anti-competitive pay-off agreements to keep more affordable generic equivalents off the market; Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act to deter pharmaceutical companies from blocking cheaper generic alternatives from entering the marketplace; Medicare Prescription Drug Price Negotiation Act of 2015, that would enable Medicare to negotiate for the best possible price of prescription medication.
- 18 [Civic Impulse](#). (2017). S. 3 — 110th Congress: Medicare Prescription Drug Price Negotiation Act of 2007.
- 19 *Id.*
- 20 [Letter to Hon. J. Dingell](#), Chairman, Committee on Energy and Commerce from Congressional Budget Office (Jan. 10, 2007).
- 21 National Conference of State Legislatures, *2015–2016 State Legislation to Require Prescription Drug Cost and Price Transparency* (Nov. 7, 2016).
- 22 *Id.*
- 23 Vermont Legislature, Act No. 165 (S.216) (effective June 2, 2016).
- 24 MMA, P.L. 108-173.
- 25 P.L. 111-148; P.L. 111-152.
- 26 Donald J. Trump for President, *Tax Plan*, <https://www.donaldjtrump.com/policies/tax-plan> (last visited January 17, 2017).
- 27 Paul Ryan, “[A Better Way for Tax Reform](#),” (Jun. 24, 2016).
- 28 See Jones Day *White Paper*, “[The Future of the Affordable Care Act](#)” (Nov. 2016).
- 29 Specifically, parts 50, 56, 312 and 812 of title 21 of the Code of Federal Regulations, and subpart A of part 46 of title 45.
- 30 Cures Act § 3023(d), 130 Stat. at 1098 (to be codified at 21 U.S.C. § 289).
- 31 See, e.g., NIH, “[Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#)” (June 21, 2016).
- 32 Cures Act § 3024(a),(d), 130 Stat. at 1099 (to be codified at 21 U.S.C. § 360j(g)(3)).
- 33 HHS, FDA, “[Use of Electronic Informed Consent, Questions and Answers, Guidance for Institutional Review Boards, Investigators, and Sponsors](#)” (Dec. 2016).
- 34 See Federal Policy for the Protection of Human Subjects; Proposed Rules, 80 Fed. Reg. 53933 (Sept. 8, 2015).
- 35 See [Federal Policy for the Protection of Human Subjects; Final Rules](#).
- 36 See [Federal Register](#) pre-publication of [Final Rule on Federal Policy for the Protection of Human Subject](#).
- 37 See Dylan Scott, “[Scientists Fight Obama Plan to Require Patient Consent to Use Blood, Biopsies in Research](#),” Stat News, May 16, 2016; Rebecca Skloot, “[Your Cells. Their Research. Your Permission?](#),” *The New York Times*, Dec. 30, 2015.
- 38 See Jeannie Baumann, “[White House Takes Final Steps to Revamp Medical Research Rule](#),” BNA News, Jan. 6, 2017.
- 39 The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat 1936 (1996) (“HIPAA”); and The Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 110–185, 122 Stat. 619 (2008) (“HITECH Act”).
- 40 Cures Act § 2063, 130 Stat. at 1080-81 (to be codified at 42 U.S.C.A. § 1320d–2).
- 41 *Id.* at § 2034.

- 42 *Id.* at § 2034(a)(2).
- 43 See Public Health Service regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F); and Responsible Prospective Contractors (45 C.F.R. Part 94).
- 44 Cures Act § 3021(b)(3), (b)(4), 130 Stat. at 1096 (to be codified at 21 U.S.C.A. § 355 NOTE).
- 45 *Id.* at § 3011(e)(5)(C).
- 46 *Id.* at § 3001(b).
- 47 *Id.* at § 3001(c).
- 48 *Id.* at § 3022(a).
- 49 *Id.* at § 3022(b).
- 50 *Id.* at § 3022(c).
- 51 Only two biosimilars are currently available in the U.S. market, Sandoz's Zarxio[®] product approved in 2015 and Inflectra[®]. Notably, both launched prior to resolution of related patent disputes. Although the FDA approved Erelzi[®] in August 2016, Sandoz has not yet launched its biosimilar product; related litigation is pending in the District Court for the District of New Jersey. Similarly, Amgen has not yet launched its Amjevita biosimilar, which is currently the subject of pending litigation in the District Court for the District of Delaware.
- 52 HHS, FDA, [Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product, Guidance for Industry](#) (Dec. 2016); HHS, FDA, [Nonproprietary Naming of Biological Products, Guidance for Industry](#) (Jan. 2017). HHS, FDA, [Considerations in Demonstrating Interchangeability With a Reference Product, Guidance for Industry Draft Guidance](#) (Jan. 2017).
- 53 *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), petition for cert. filed by Sandoz, 84 U.S.L.W. 3455 (U.S. Feb. 16, 2016) (No. 15-1039); petition for cert. filed by Amgen, 84 U.S.L.W. 3549 (U.S. Mar. 21, 2016) (No. 15-1195).
- 54 *Id.*
- 55 See 21 U.S.C. § 352.
- 56 See, e.g., FDA Untitled Letter to Supernus Pharmaceuticals, Inc., Oct. 31, 2016 (alleging a product video provides evidence that Oxtellar XR is intended for a new use for which it lacks approval, and for which its labeling does not provide adequate directions for use), and *United States of America v. Biocompatibles Inc.*, No. 16-MJ-710, settlement announced (D.D.C. Nov. 7, 2016) (Medical device manufacturer pled guilty to misdemeanor charge of introducing a misbranded medical device into interstate commerce and was sentenced to pay \$8.75 million criminal fine, \$2.25 million criminal forfeiture, and \$25 million to resolve civil allegations under the False Claims Act. FDA cleared the device for embolization, a process in which the flow of blood to liver tumors is stopped or reduced. Through a separate company, Biocompatibles marketed the device to deliver chemotherapy drugs).
- 57 *United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012).
- 58 Indeed, FDA chose not to appeal the Second Circuit's decision. However, in a later case, *Amarin Pharma, Inc. v. U.S. Food & Drug Administration*, FDA attempted to argue the decision was limited to the particular facts of *Caronia*. This subsequent argument by FDA in the Second Circuit was not successful.
- 59 *Amarin Pharma, Inc. v. U.S. Food & Drug Administration*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). The government subsequently settled this litigation, agreeing that "Amarin may engage in truthful and non-misleading speech promoting the off label use" of its product and that "under *Caronia*, such speech may not form the basis of a prosecution for misbranding." Stipulation & Order of Settlement at 2, *Amarin*, 119 F. Supp. 3d 196 (S.D.N.Y. Mar. 8, 2016) (No. 15-cv-03588) (Doc. 84).
- 60 *United States v. Vascular Solutions, Inc.*, No. 5:14-CR-00926 (W.D. Tex. 2016).
- 61 *United States v. Vascular Solutions, Inc.*, No. 5:14-CR-00926 (W.D. Tex. Jan 7, 2016) (Doc. 172), Proposed Jury Instructions at 31.
- 62 *United States v. Facticeau*, No. 1:15-cr-10076 (D. Mass. Aug. 31, 2016).
- 63 E.g., Mem. of Law in Support of Defs.' Mot. for Judgment of Acquittal or, Alternatively, a New Trial, *United States v. Facticeau*, No. 1:15-cr-10076 (D. Mass. Aug. 31, 2016) (Doc. 484); Government's Opp'n to Defs.' Mot. for Judgment of Acquittal or, Alternatively, a New Trial, *United States v. Facticeau*, No. 1:15-cr-10076 (D. Mass. Sept. 30, 2016) (Doc. 497); Reply Mem. in Further Support of Defs.' Mot. for Judgment of Acquittal or, Alternatively, a New Trial, *United States v. Facticeau*, No. 1:15-cr-10076 (D. Mass. Oct. 17, 2016) (Doc. 501).
- 64 [Transcript of Day 1 of the meeting; transcript of Day 2 of the meeting; access to the archived webcast of the public meeting.](#)
- 65 See Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments, 81 Fed. Reg. 60,299 (Sept. 1, 2016) (emphasis added).
- 66 Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) ("FDAMA").
- 67 Section 3037 defines "health care economic information" to mean "any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention." Cures Act § 3037, 130 Stat. at 1105 (to be codified at 21 U.S.C. § 352). This definition goes beyond the previous provision at 21 U.S.C. § 352(a), which provides "any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."
- 68 Cures Act § 3037, 130 Stat. at 1105 (to be codified at 21 U.S.C. § 352).
- 69 FDA, Office of Prescription Drug Promotion, [2016 Warning Letters](#) (last accessed Dec. 29, 2016).
- 70 31 U.S.C. §§ 3729-3733.
- 71 42 U.S.C. § 1395nn.
- 72 42 U.S.C. § 1320a-7b.
- 73 The American College of Physicians expects a Trump Administration to advance telehealth and initiatives under the Medicare Access & CHIP Reauthorization Act ("MACRA"). John Gregory, ["ACP Promises to Oppose Trump if Policies Hurt Physicians,"](#) Health Exec, Nov. 18, 2016. Other policy analysts indicate a likely expansion of Health IT and telehealth in a Trump Administration. Jessica Davis, ["HIMSS' Trump Presidency Predictions: No Complete ACA Repeal,"](#) Telehealth, Cybersecurity, Healthcare IT News, Nov. 16, 2016.

- 74 In the stated Healthcare Reform policy of the Trump/Pence campaign, “the Affordable Care Act ... resulted in runaway costs [and] greater rationing of care...,” thus the new Administration states that they “will broaden healthcare access, make healthcare more affordable and improve the quality of the care available to all Americans.” Donald J. Trump, “[Healthcare Reform to Make America Great Again](#)” (as of January 9, 2016).
- 75 In addition to Cures Act, a number of bi-partisan efforts advanced digital health as part of the 114th Congress. Although not enacted, a number of legislative activities sought to advance digital health, including S. 1465 (H.R. 2799)—the “FAST” Act (amending Medicare for purposes of expanding access to stroke services via telehealth methods), S. 1778 (H.R. 3081)—the “TELE-MED” Act (permitting certain Medicare providers licensed in a state to provide services via telemedicine to certain Medicare beneficiaries in a different state), and S. 2170 (H.R.2516)—“VETS” Act (improving the ability of health care professionals to treat veterans via telemedicine).
- 76 See Juliet Eilperin and Steven Mufson, “[Trump Team Plans for Infrastructure ‘Task Force’ to Advance Top Spending Priority](#),” *The Washington Post*, Dec. 20, 2016 (noting broadband as a likely component of a Trump Administration infrastructure program). Another article provides an overview of the recent legislative and regulatory advances for broadband and bipartisan priority of the topic. Cathy Sloan, “[One Bipartisan Priority: Broadband Internet Access Infrastructure](#),” *The Hill*, Dec. 13, 2016.

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