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Top FDA Issues for Hospitals and Health Systems



BY NATHAN BROWN AND MARLEE GALLANT

With the rapid pace of innovation in medical technology, hospitals and health systems are increasingly engaged in activities regulated by the Food and Drug Administration. New laws implemented by FDA carry important opportunities, and risks, for hospitals and health systems. Below we identify six important FDA issues that health care facility managers, compliance officials and lawyers should consider in 2015.

1. Digital Health Technology: Mobile Applications and Clinical Decision Support Software

Hospitals' and health systems' use of new mobile applications (apps), clinical support software and other digital health tools is growing rapidly. In many cases, hospital clinicians are developing their own digital tools for use in their practices or to market to other clinicians. These new technologies hold great promise for health care, by improving diagnostic capabilities, aiding treatment therapies, providing physicians with faster and more precise clinical data, and helping patients to manage their conditions and communicate with their providers. But digital health software also raises new

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regulatory questions, and potential risks for hospitals that use or develop digital health tools.

Software and mobile technology that aids in treatment or diagnosis is potentially a medical device subject to FDA regulation, and sometimes requires premarket clearance. Whether software or a mobile app is a medical device depends, in large part, on its intended use, which is determined both by explicit promotion and marketing and other implicit factors.¹ Under the Food, Drug and Cosmetic Act (FDCA), a medical device includes any instrument or other related article intended to diagnose, cure, mitigate, treat, prevent or affect the structure or any function of the human body.²

With advances in health technology and new regulatory oversight, the FDA is increasingly important for hospitals' success.

FDA has recognized that this broad definition would potentially sweep under regulation many helpful, but low-risk health-related apps; at the same time, the agency has expressed concern that software intended for higher risk medical uses should have the same assurance of safety and effectiveness that traditional devices must provide. FDA has issued several policies in

¹ A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Food, Drug, and Cosmetic Act § 201(h), 21 U.S.C. § 321(h).
² *Id.*

the last couple of years to address some of the key areas of uncertainty:

- **Mobile Medical Apps.**³ FDA defines mobile medical apps as mobile apps that meet the definition of a medical device and are either intended (1) to be used as an accessory to a regulated medical device or (2) to transform a mobile platform (such as a mobile phone) into a regulated medical device.⁴ Examples include:

- o An app that displays data from a bedside monitor;
- o An app that allows control of inflation and deflation of a blood pressure cuff and
- o An app that uses an attachment to a mobile platform to measure blood glucose levels.

FDA is currently exercising regulatory oversight over only health-related apps that meet this definition of a mobile medical app—meaning that these types of apps are potentially subject to FDA premarket review and other device requirements. Other apps are subject to enforcement discretion.

- **Medical Device Data Systems (MDDS).**⁵ MDDS are software or other technology that transmits, transfers, converts formats, stores or displays data from a medical device, as long as the transmission is not supporting active patient monitoring.⁶ MDDS do not perform other functions, such as controlling the connected medical device or interpreting data. For example, software that merely stores historical blood pressure information for later review by a health care provider, or that transmits data from a glucose monitor to a provider (unless the data is intended for real-time review), would constitute an MDDS. Although MDDS and related technologies are medical devices under the law, FDA recently announced that it would not enforce compliance with regulatory controls applicable to MDDS, medical image storage devices and medical image communications devices, due to the low risk they pose to patients in comparison to the potential benefit in advancing digital health.

- **General Wellness Apps.**⁷ FDA recently issued draft guidance to inform industry that it intends to exercise enforcement discretion with respect to low-risk, general wellness products. General wellness products are (1) intended for general well-

ness⁸ use only and (2) present a very low risk to users' safety. For example, mobile apps that allow users to record daily energy expenditure, or apps that monitor and track food intake to promote healthy choices and alert health care providers of dietary activity are for general wellness. FDA does not plan to evaluate whether these products are medical devices or, if they are devices, subject them to applicable regulatory requirements.

More broadly, FDA, in collaboration with the Federal Communications Commission (FCC) and the Office of the National Coordinator for Health Information Technology (ONC), has proposed an overall framework for the regulation of all health IT.⁹ The agencies identified three categories of health IT: (1) administrative health functions; (2) health management health IT functions and (3) medical device health IT functions—the final category being the one subject to FDA regulation.¹⁰ Administrative health IT functionalities include billing and claims processing, practice and inventory management and scheduling, which pose little to no risk to patient safety, eliminating the need for additional FDA regulatory oversight.¹¹ Health management functionalities include, but are not limited to, health information and data exchange, data encounter documentation, electronic access to clinical results, most clinical decision support, medication management and electronic communication and coordination. Some health management tools likely qualify as medical devices, and the proposed framework indicates that many clinical decision support technologies would fall within this category. FDA has proposed not to exercise oversight over products with these functionalities. Notably, however, FDA is also expected to issue a specific policy concerning clinical decision support tools. Finally, medical device IT functionalities include, for example, computer-aided detection software, remote display or notification of real-time alarms from bedside monitors and robotic surgical planning tools.¹²

Although FDA has provided a hands-off approach to certain digital health technologies, the distinction between an unregulated app and one that requires FDA premarket review as a medical device can be a fine one. It is important for health systems to maintain centralized oversight of the development and use of such tools in the health care setting. Providers should maintain protocols for assessing regulatory obligations and potential risks before adding any health-related software to the clinical environment.

³ FDA, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015), <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>.

⁴ *Id.* at 7.

⁵ FDA, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf>.

⁶ *Id.* at 5.

⁷ FDA, General Wellness: Policy for Low Risk Devices: Draft Guidance for Industry and Food and Drug Administration Staff (Jan. 20, 2015), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf>.

⁸ FDA defines a “general wellness product” as one that has “(1) an intended use that relates to a maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use claim that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.” *Id.* at 3.

⁹ FDA, FCC & ONC, FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework (April 2014), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

¹⁰ *Id.* at 3.

¹¹ *Id.*

¹² *Id.* at 4.

In many cases, FDA regulatory oversight can be avoided by modulating the intended uses of the software product or ensuring clinician involvement in the ultimate treatment decision. For digital health technology that is not currently subject to FDA oversight, hospitals should ensure proper functionality of the technology and appropriate integration into their systems. For instance, sponsors of MDDS no longer need to comply with device regulatory controls or register with FDA, but hospitals should nevertheless ensure that MDDS used by the hospital are fully interoperable with connected medical equipment and EHRs and will transmit patient data in a timely and accurate manner. Similarly, mobile apps that are used for treatment or for patient interactions must be validated to ensure proper functionality and that they perform as intended—whether or not they are FDA-regulated.

2. Cybersecurity

Cybersecurity breaches in the retail and insurance industries have received more public attention, but there is growing awareness of the security vulnerabilities in medical device software and other digital health software. In short, hospital systems are not as secure as they should be. Medical devices and data systems are becoming more interconnected, and are subject to a variety of risks. First, hackers may intend to steal valuable information that is available on, or accessible through, a medical device. Hackers are interested in an increasingly wide variety of information—not just patient medical records, but other clinical information and intellectual property. Medical devices are also at risk from hackers intending to bring financial or reputational harm to the manufacturer—or to the hospital or other user facility that depends on that equipment. The U.S. Department of Homeland Security is also investigating about two dozen cases of reported cybersecurity flaws in medical devices that hackers could exploit to harm patients themselves.¹³

In addition to risks from intentional hacking, networked systems and devices are vulnerable to software failures, malware and viruses. This is not a hypothetical concern. Medical device security breaches have jeopardized the integrity of hospital information technology systems, disrupted medical device operations and limited provider access to patient data. In particular, interference with medical device functioning can lead to inaccurate readings, misdiagnosis or over- or underdosing.

In an effort to improve the cybersecurity of medical devices, FDA has been collaborating with other federal agencies to communicate with hospitals, medical device developers and other stakeholders about vulnerabilities. The agency recently issued guidance framing expectations for device manufacturers concerning the incorporation of security principles throughout the development process.¹⁴ The guidance emphasizes the need for early implementation of security safeguards and

¹³ Jim Finkle, *U.S. Government Probes Medical Devices for Possible Cyber Flaws*, Reuters (Oct. 22, 2014), <http://www.reuters.com/article/2014/10/22/us-cybersecurity-medicaldevices-insight-idUSKCN0IB0DQ20141022>.

¹⁴ FDA, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff* (Oct. 2, 2014), <http://www.fda.gov/downloads/MedicalDevices/>

preparations for system updates. FDA recommends that medical devices limit access only to trusted users, ensure content is secure and incorporate threat detection features.

Hospitals should evaluate their cybersecurity risks to ensure the integrity, accuracy and accessibility of clinical data and patient data, and work with device makers to ensure proper safeguards and implement protocols for identifying and responding to breaches. Equally important, hospitals should develop feedback mechanisms to identify potential cyber vulnerabilities and the problems they might cause. Existing hospital procedures would likely result in identification and reporting of actual adverse events related to a medical device.¹⁵ However, hospitals should also consider less direct implications from security breaches, such as undermined functionality. They should also consider potential adverse consequences before they occur. Even seemingly minor intrusions, such as the introduction of cookies or malware, can undermine data speed, accuracy or availability in ways that could have adverse economic or regulatory consequences—and possibly lead to patient harm.

3. Drug Shortages

Drug shortages can create unexpected and urgent problems for hospitals. Such shortages put patients at risk by forcing deviations from treatment regimens, compromising medical procedures and rationing of medications. The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) requires drug manufacturers to notify FDA of manufacturing interruptions that could lead to drug shortages at least six months prior to the date of the drug discontinuance or interruption, or as soon as it is “practicable.”¹⁶ The law requires FDA to distribute information to health care providers, implement a mechanism for health care providers to notify FDA of a shortage and maintain a drug shortage database.¹⁷ Despite these new provisions, many shortages have caught FDA and the public by surprise, and shortages often end up lasting longer, and having a more severe impact, than manufacturers, providers or FDA anticipate.

FDA does have several tools to mitigate shortages. FDA can expedite inspections and reviews of preapproval submissions from other possible manufacturers, work with other sponsors of approved drugs to increase production, exercise temporary enforcement discretion for new sources of medically necessary drugs, coordinate with the manufacturer to determine the root cause

[DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf](http://www.fda.gov/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf).

¹⁵ FDA regulations require hospital user facilities to report specific information known about deaths related to a medical device as soon as practicable, but within 10 work days after becoming aware of the incident. 21 C.F.R. § § 803.3; 803.30. Hospital user facilities must also report serious injuries that may have resulted from a medical device. *Id.* Specific reporting requirements may be found at 21 C.F.R. pt. 803, available here: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=803>.

¹⁶ Food, Drug, and Cosmetic Act § 506C, 21 U.S.C § 356c.

¹⁷ For current and resolved drug shortages and discontinuations reported to FDA, please see FDA’s Drug Shortage’s website, available at the following link: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>. Shortage notifications and updates may be reported to the FDA at drugshortages@fda.hhs.gov.

of the shortage and review possible risk mitigation strategies for remaining inventory.¹⁸ Nevertheless, FDA often lacks full and timely information about the scope and consequences of supply disruptions. Hospitals and clinicians can provide valuable input to FDA, which the agency welcomes, concerning the presence of a potential drug shortage, the impact it has on patients and possible amelioration strategies. Early, proactive communication with the agency is an important way to minimize the impact of shortages on patients.

4. Laboratory Developed Tests

Laboratory developed tests (LDTs), or “home-brew” tests, are revolutionizing clinical practice. Clinical laboratories within hospitals often develop these tests on their own for use in their health system. According to one estimate, 100,000 LDTs are used in clinical practice today, many of which are developed or used by hospital laboratories.¹⁹ LDTs have generally gone unregulated by FDA, as long as they are developed and used within an individual certified lab. However, the rapid growth of this industry and concerns about lack of parity with traditional diagnostics tests that are subject to FDA oversight have led the agency to propose a new framework for LDTs. The agency has expressed concern that certain high-risk LDTs may rely on insufficient evidence, produce inaccurate results or lead to patients being over- or undertreated.²⁰ In draft guidance, FDA has asserted authority to regulate LDTs as medical devices under the FDCA, and has proposed a risk-based, phased-in approach to requiring premarket clearance or approval for many LDTs.²¹

Under the proposed framework, the agency would prioritize enforcement based on the level of risk associated with different categories of LDTs. FDA would continue to exercise enforcement discretion with respect to certain types of LDTs, such as those used for forensic purposes. For other low-risk LDTs, FDA would impose some device requirements, such as medical device reporting, but not enforce others, such as premarket review. Tests subject to this partial enforcement discretion include “Traditional LDTs,” LDTs used for rare diseases and LDTs for unmet needs.

For other, higher-risk LDTs, FDA proposes full compliance with device requirements but plans to phase in its oversight. It will initially focus its oversight efforts on (1) LDTs with the same intended use as a cleared or approved companion diagnostics; (2) LDTs with the

same intended use as an FDA-approved Class III medical device and (3) certain LDTs used for determining the safety or efficacy of blood or blood products.²² The agency proposes to enforce premarket review requirements for new LDTs in these categories upon publishing the final guidance, and will delay enforcement for currently marketed products in these categories for one year.²³

Regardless of the risk category, all manufacturers of LDTs, except for LDTs for law enforcement and certain LDTs associated with transplantation, must comply with manufacturing requirements, such as adverse event reporting.²⁴ Developers of LDTs must also notify FDA of their LDTs and provide basic information about them, and begin compliance with medical device reporting requirements relating to adverse events and malfunctions, within six months after FDA publishes the finalized guidance.²⁵ FDA plans to complete phased-in enforcement of premarket review requirements for Class III devices within five years from finalizing the guidance, and within nine years for Class II devices.²⁶ Nevertheless, under the proposal, sponsors of LDTs would potentially have to notify FDA of their tests and begin medical device reporting much sooner—within six months of the final guidance.

Timing of the FDA’s release of the final guidance is unclear. Regulation of LDTs is the subject of legislative attention in Congress, and many of the advanced diagnostics that will feature prominently in the President’s Precision Medicine initiative²⁷ are currently marketed as LDTs. Given the changing regulatory framework for LDTs, hospitals should closely follow congressional and FDA action. Hospitals must carefully evaluate the regulatory implications for the diagnostic tests that they develop, and for other LDTs on which they depend—both under FDA’s current, hands-off approach, and under the proposed LDT framework.

5. Pharmaceutical Compounding

Hospitals frequently rely on compounded drugs when approved formulations are not available in the necessary dosage forms or concentrations. Ninety-two percent of hospitals use compounded sterile drugs, with roughly 85 percent of those hospitals purchasing at least some of these products from outside pharmacies.²⁸ The 2012 tragedy caused by a contaminated version of a compounded sterile injectable focused atten-

¹⁸ FDA, FDA Facts: Drug Shortages in the United States, <http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM373078.pdf>.

¹⁹ Comment Letter from Ass’n of Am. Med. Colls. to Comm’r Margaret Hamburg, M.D., U.S. FDA re Docket No. FDA-2011-D-0360 for Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (Feb. 2, 2015), available at <https://www.aamc.org/download/423626/data/aamccommentsonfdaproposedguidanceonldts.pdf>.

²⁰ See FDA, Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (Oct. 3, 2014), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf> [hereinafter FDA, LDT Draft Guidance].

²¹ *Id.*

²² *Id.* at 24.

²³ *Id.*

²⁴ See 21 C.F.R. pt. 803 for more information about manufacturing reporting requirements.

²⁵ LDT Draft Guidance, *supra* note 20, at 17.

²⁶ *Id.* at 26.

²⁷ Francis Collins, M.D., Ph.D. & Harold Varmus, M.D., A New Initiative on Precision Medicine, 372 *New Eng. J. Med.* 793, 793 (2015), available at http://www.nejm.org/doi/full/10.1056/NEJMp1500523?query=featured_home&: For more information about the President’s Precision Medicine Initiative, please see NIH, *Precision Medicine Initiative*, <http://www.nih.gov/precisionmedicine/> (last visited April 12, 2015).

²⁸ HHS, OIG, Memorandum Report: High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them, OEI-01-13-00150 (Apr. 10, 2013), <https://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf>.

tion on the potential dangers from drugs compounded under unsafe conditions.²⁹

The Drug Quality and Security Act of 2013 (DQSA) clarified the federal and state oversight roles over pharmacy compounding, and created a new category of FDA-regulated “outsourcing facilities” to engage in larger-scale compounding of sterile drugs for use in hospitals and other provider settings.³⁰ Under section 503A of the FDCA, as clarified by the DQSA, pharmacies may generally compound drugs based on a specific prescription for an individual patient, subject to restrictions on compounding certain products and the use of certain ingredients.³¹ Pharmacy compounding is limited to 5 percent of total prescription orders or to amounts specified in a Memorandum of Understanding (MOU) between the relevant state and FDA.³² The agency has issued a draft MOU for states to consider that would limit compounding under section 503A, and interested stakeholders may submit comments until June 19, 2015.³³ The DQSA also amended the FDCA to allow for higher volume, sterile compounding by “outsourcing facilities” under section 503B. Section 503B allows these federally registered facilities to compound drugs for hospital and physician use, without individual prescriptions, subject to certain restrictions and labeling and reporting requirements.

Questions remain, however, about FDA’s recent oversight activities and the safety of compounded products. State pharmacy boards are also in the process of developing their own approaches to the regulation of these new outsourcing facilities, and many states are also revisiting their restrictions on pharmacy-based compounding. Hospitals must exercise due diligence in determining the best sources for their compounded drug needs, and in evaluating the compliance record and practices of their outsourcers and pharmacies. Hospitals should also ensure that their own in-house compounding practices comply with federal and state laws. In particular, it would be advisable for hospitals to consider whether they may need to register as outsourcing facilities, if their pharmacies compound medications for interstate use. Currently, it is unclear whether (and how) FDA intends to enforce the requirements for pharmacy compounding under section 503A to pharmacies within an interstate health system.

6. Biosimilars

The Biologics Price Competition and Innovation Act (BPCIA), part of the Affordable Care Act, creates a

pathway to market for biological products that are “bio-similar” to, or “interchangeable” with, a reference FDA-licensed biologic.³⁴ Biosimilars are manufactured with the goal of closely mirroring a licensed reference biological product—complex medicines manufactured from living organisms. While the introduction of biosimilars into the marketplace presents new and exciting opportunities for hospitals to achieve cost-savings, hospitals must also be aware of several key implementation issues that will affect the availability of biosimilars and their coverage and reimbursement.

- **“Interchangeable” Versus “Biosimilar.”** In making purchasing and formulary decisions related to biosimilars, hospitals should be aware of the difference between the interchangeability standard and the biosimilarity standard. Under the BPCIA’s abbreviated pathway, FDA can approve a biosimilar if it is “highly similar to” the reference biological product. In addition, FDA can deem a biosimilar product “interchangeable”—a more stringent standard—if the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient. FDA recently approved the first biosimilar biologic, Zarxio, a biosimilar version of Amgen’s Neupogen (filgrastim).
- **CMS Reimbursement Policies.** Hospitals must also monitor reimbursement issues related to biosimilars as they enter the market. CMS recently issued guidance documents on payment policies relating to Medicare Parts B³⁵ and D.³⁶ The agency has yet to issue such guidance for payment in the hospital outpatient setting, but it could be forthcoming in the 2016 Hospital Outpatient Prospective Payment System Proposed Rule, which is expected in July.
- **Biosimilar Substitution Standards.** Hospitals should also closely track pharmacy substitution laws related to biosimilar products, which many states have enacted or are presently considering. These laws would generally authorize pharmacists to prescribe a biosimilar product in lieu of the biologic in certain circumstances. A related unresolved question concerns how biosimilars will be named, and the extent to which their use of differential naming will impact substitution and prescribing patterns. Hospitals should anticipate needing to make potential changes to their ordering and tracking processes to accommodate biosimilars.

²⁹ See CDC, *Multistate Outbreak of Fungal Meningitis and Other Infections*, <http://www.cdc.gov/hai/outbreaks/meningitis.html> (last visited April 12, 2015) (reporting over 60 deaths resulting from the 2012 fungal meningitis outbreak linked to a compounded sterile drug).

³⁰ The Drug Quality and Security Act of 2013 amended the Food, Drug and Cosmetic Act. Drug Quality and Security Act of 2013, 21 U.S.C. § 351 et seq.

³¹ Food, Drug and Cosmetic Act § 503A, 21 U.S.C. § 353a.

³² 21 U.S.C. § 353a(b)(3).

³³ FDA, Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration (Feb. 19, 2015), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM434233.pdf>. Comments may be submitted by mail or electronically through the following link: <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1459-0001>.

³⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7001-03, 124 Stat. 119, 804-821 (2010).

³⁵ Dep’t of Health and Human Servs., CMS, MLN Matters No. SE1509: *Food and Drug Administration Approval of First Biosimilar Product* (March 31, 2015), available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1509.pdf>.

³⁶ Letter from Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group, CMS to Part D Sponsors re Part D Requirements for Biosimilar Follow-On Biological Products (Mar. 30, 2015), available at <https://www.pharmamedtechbi.com/~media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2015/March/Part%20D%20biosimilars.pdf>.

Although many important regulatory issues have yet to be resolved, biosimilars promise to be a force for market-disrupting change in the coming years.