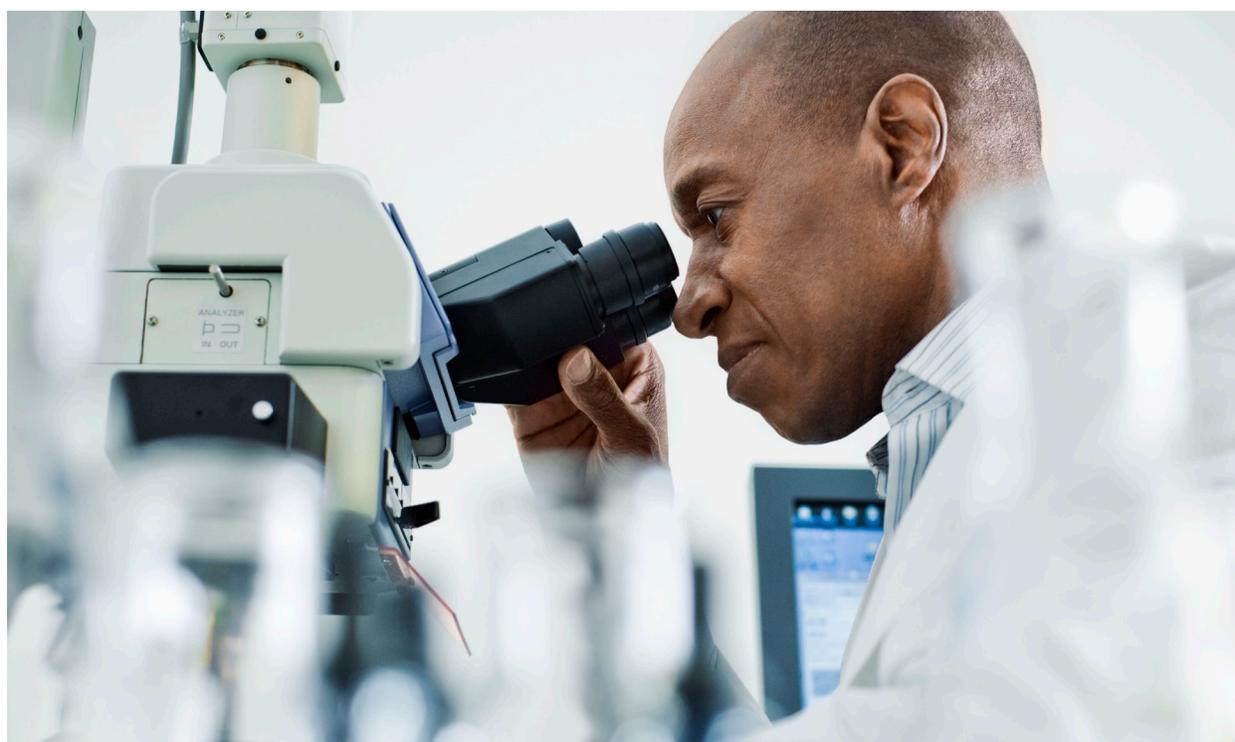


## Forward look

# Top regulatory midyear trends for 2014 in life sciences



## Foreword

This publication is part of the Deloitte Center for Regulatory Strategies' inaugural cross-industry series on the year's Top Regulatory Trends. This annual series provides a forward look at some of the regulatory issues we anticipate will have a significant impact on the market and our clients' businesses throughout the year – and beyond. For 2014, we are providing regulatory perspectives on the following industries and sectors: Banking, Securities, Insurance, Energy and Resources, and Life Sciences.

The issues outlined in each of the five reports will serve as a starting point for the crucial dialogue surrounding regulatory challenges and opportunities in 2014 and will assist executives in staying ahead of the trends and requirements. We encourage you to share this whitepaper with the senior executive team at your company. In addition, please feel free to share your questions and feedback with us at [centerregstrategies@deloitte.com](mailto:centerregstrategies@deloitte.com).

Best regards,

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The regulatory landscape in life sciences is expected to be increasingly challenging and uncertain. Regulatory authorities continue to increase their compliance, oversight and enforcement activities for existing laws. Meanwhile, lawmakers and agencies are introducing new rules and requirements that will significantly affect how life sciences companies do business. In this dynamic environment, organizations continue to invest significant time, resources and effort to achieve compliance – even while certain parts of the regulatory environment are still unfolding.

Here is a look at what we believe are six of the most important regulatory trends for the rest of 2014 – and beyond. This is not an exhaustive list, but we think addressing these issues should be at or near the top of the regulatory agenda.

**1. Patient safety and enforcement:** *Regulatory agencies around the world are increasingly scrutinizing business practices that put patients at risk.*

Patient safety continues to occupy a prominent place on the health policy agenda and is garnering renewed regulatory interest in order to improve health outcomes by improving care processes and ensuring quality of care.<sup>1</sup>

In life sciences, there has been increased interest by large pharmaceutical companies in utilizing social media analytics to monitor their products. Key stakeholders in the industry — including patients, healthcare providers and insurance companies — interact using social media on a daily basis. As a result, there is a wealth of data on the internet that pertains to a company's product safety, effectiveness and reputation. Even before regulators get involved, pharmaceutical companies are working to stay ahead of potential risks and lawsuits by leveraging social media data to prevent adverse event discussions.

Counterfeit medicines and digital pharmaceutical marketing also present rising challenges related to patient safety. With the continued rise in prescribed and non-prescribed counterfeit medicines entering the legitimate supply chain, governments are developing new regulations and increasing levels of vigilance over life sciences stakeholders to help manage patient risk. Several key international organizations, including the World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC), Interpol and the World Customs Organization (WCO), are all attempting to address the global counterfeit medicines issue. However, their enforcement capability is limited. Enhanced global health governance and shared responsibility are needed to promote global health security, combat transnational pharmaceutical crime and — most importantly — ensure safe access to medicines.<sup>2</sup>

Electronic direct-to-consumer advertising (eDTCA) is helping to globalize the pharmaceuticals marketplace. However, inadequate governance mechanisms and unregulated expansion of eDTCA are creating public health threats and putting patient safety at risk. Addressing these issues will require global governance strategies that engage a wide range of sectors — from public health and law enforcement to information technology.<sup>3</sup>

**2. Increasing emphasis on transparency:** *Patient advocacy groups and regulators are increasingly pushing for greater transparency in the relationships between life sciences companies and health care providers.*

A number of factors including health care reform and increased cost pressure have led to calls for increased disclosures and transparency in the relationships that life sciences companies have with health care providers. However, it has been argued that “[b]ias from financial ties is the problem, and disclosure does not solve it.”<sup>4</sup>

As part of the Affordable Care Act, the Physician Payments Sunshine Act (PPSA) went into effect in August 2013, requiring providers to disclose compensation they receive from manufacturers of pharmaceutical and biological drugs, medical devices and medical supplies. Although the burden of collecting and reporting data rests on the life sciences companies, providers are advised to maintain their own documentation.<sup>5</sup> The PPSA is meant to inform patients of financial relationships their doctors might have with the drug and device industry, allowing them to make informed decisions on how those relationships could affect their course of treatment.<sup>6</sup> This transparency initiative creates new civil penalties, over and above the legal penalties associated with the Stark Law and anti-kickback laws that continue to apply to physicians and life sciences companies.<sup>7</sup>

While some might argue that the PPSA is already changing the landscape — as demonstrated by the decline in payments to health professionals for promotional speeches — the impacts thus far only highlight the need for life sciences and health care companies to maintain rigorous compliance programs to minimize the potential of engaging in unethical or illegal practices.<sup>8</sup> Compliance programs should closely examine physician relationships and the incentives that drive them, which will require transparent information sharing along with a full understanding of the associated risks.

**3. Greater collaboration between regulators and businesses:** *Today’s Food and Drug Administration (FDA) is actively making an effort to help companies get new drugs approved in a more timely manner.*

In an effort to bring new products to market earlier, the FDA has recently shown an increased desire to collaborate with businesses to accelerate the approval process and increase drug development efficiency. By collaborating with the agency during the initial stages of drug development, companies can better align their clinical development programs with the FDA’s current thinking and standards. To this end, the FDA has developed extensive written guidance that provides a detailed account of pharmaceutical companies’ successes and failures, during drug development.

One example of the FDA’s increased collaborative spirit occurred in October 2013, when pharmaceutical companies consulted closely with the FDA while developing direct-acting antiviral drugs to treat Hepatitis C. These drugs show great promise and are now making their way to the marketplace.<sup>9</sup> Another example is when the FDA and the University of Arizona joined forces in 2005 to form the Critical Path Institute (C-Path). C-Path’s mission is to bring together academia, industry and regulatory agencies to help improve the quality and efficacy of drug development by creating standard testing processes. C-Path members include representatives from the FDA, scientists from the life sciences industry, researchers from the National Institutes of Health (NIH), regulators from around the world, and professors and students from academia. This collaboration has already delivered benefits and helped align the viewpoints of industry, academia and regulatory agencies.<sup>10</sup>

Judging by the developments to date, collaboration will likely continue to play an increasingly pivotal role in new product development — at least in the near term. However, collaboration between the FDA and life sciences companies presents a number of potential risks. One risk involves uniform data elements. If companies do not all use the same data nomenclature, it could lead to miscommunication, inefficient processing of information and misinterpretation of results. Another risk involves ownership rights. Specifically, who owns the rights to intellectual property generated through collaboration? While it may ultimately be in the best interests of life sciences companies to work collaboratively with the FDA, companies will likely need a well-developed strategy to ensure collaboration risks are identified and managed wherever possible.

**4. Accelerated product approvals:** *The FDA and its global counterparts are fast-tracking new drugs that address unmet needs.*

Regulatory agencies around the world are streamlining and accelerating their approval processes for drugs that appear to offer benefits over available therapies for serious or life-threatening diseases.<sup>11</sup> As of July 2010, there had been 35 oncology drugs that received accelerated approval from the FDA, of which 26 were converted to regular approval. This resulted in an average time savings of 4.7 years per drug.<sup>12</sup>

There are two common pathways to accelerated drug approval. The first involves using a single-arm trial developed from historical controls with no approved drug as a control. The second compares a single-arm trial to a drug that has already been approved (a comparative trial). To qualify for accelerated approval, the drug being studied must demonstrate superior efficacy, tolerability and consistency.<sup>13</sup> Some drugs might have efficacy comparable to an approved drug but utilize a different delivery mechanism, raising questions about consistency. This can be a major barrier to accelerated approval.<sup>14</sup>

Upon receiving accelerated approval, pharmaceutical companies are required to conduct post-approval clinical trials with due diligence to confirm that the drug provides clinical benefit, as predicted by the surrogate endpoint. If not, regulations allow the drug to be removed from the market. This requirement was created to address FDA concerns that ineffective drugs might be approved with insufficient or poorly conducted trials that fail to confirm clinical benefit. Congress has recently given the FDA authority to impose penalties of up to \$10 million on pharmaceutical companies for lack of due diligence in post-approval trials. Although the FDA believes this will effectively address the problem,<sup>15</sup> only time will tell. In the meantime, pharmaceutical companies need to ensure they have the governance structures, processes and procedures in place to design and conduct robust post-approval trials.

A key question that has not been fully explored is whether accelerated approval actually speeds up the availability of products in the marketplace.<sup>16</sup> Some academic researchers argue that completing a study for regular approval might actually be faster than completing an initial study for

accelerated approval, followed by a post-approval study — unless the post-approval study is a direct continuation of the initial study. It could be that the time savings associated with accelerated approval is not as impressive as it once seemed.

**5. Technology:** *There has been a recent push by the FDA and other regulatory agencies to identify strategies to regulate the use of emerging technologies, including mobile medical applications, cloud computing, medical telemetry and network medical devices.*

Technology continues to play an important role in health care by improving access and quality of care, while lowering costs. Advances in mobile apps, cloud computing, telemetry, and cybersecurity for medical devices demonstrate the value and promise of technology in modern health care. However, unintended consequences and risks in areas such as patient safety, privacy and security also accompany these technologies, creating the need for proactive oversight and regulation.

On September 25, 2013, the FDA released long-awaited final guidance on its plan to regulate mobile medical applications. The guidance is meant to inform manufacturers, distributors and other entities about how the agency will apply its regulatory authority to certain mobile apps considered to be medical devices and that could pose a risk to patient safety.<sup>17</sup> While the guidance addresses some key questions about FDA regulation, there are outstanding concerns within the mobile medical app community — including uncertainty about device classification, what data is needed to support a market filing, and what constitutes a minor, iterative change to a regulated application. All of these issues present significant challenges for mobile app makers.<sup>18</sup>

Cloud computing is another technology for which the regulatory landscape in life sciences is still being defined. Cloud provides computing and storage resources as a service to end-users over a network. Key features include: widespread network access, resource pooling, rapid elasticity and on-demand self-service. Cloud services can be deployed in a variety of ways, including (1) public cloud, which is provisioned for open use by the general public, (2) private cloud, which is provisioned for exclusive use by a single organization, (3) community cloud, which serves

a specific community, and (4) hybrid cloud, which mixes and matches multiple cloud models. Key issues and risks for cloud in life sciences include: patient safety, product quality, data integrity, privacy and protection, vulnerability and change management. All of these risks must be mitigated and managed. Limited regulatory guidance and experience with cloud computing creates additional challenges for life sciences companies pioneering the use of cloud.

A third technology receiving a lot of attention from regulators is medical telemetry, which provides the ability to send and receive important diagnostic information, and to remotely conduct medical analysis. The market value of this industry segment is expected to surpass \$45B by 2018, with a compound annual growth rate of 17 percent.<sup>19</sup> Wireless medical telemetry is commonly used to monitor a patient's vital signs with radio frequency communication, so patients do not have to be tethered to a bedside monitor with a hard-wired connection. This technology operates using specific frequency bands that the Federal Communications Commission (FCC) has allocated for the Wireless Medical Telemetry Service (WMTS). The FDA recently released guidance recommending manufacturers use the WMTS for all products not yet introduced into the market.<sup>20</sup> Operating devices within the designated frequency bands should reduce the risk of electromagnetic interference for vital medical telemetry signals.<sup>21</sup>

Last but not least, networked medical devices such as patient monitors, infusion pumps and ventilators have the potential to transform healthcare through wireless capabilities and sophisticated software. However, these technologies can also present significant patient safety and security risks, including vulnerabilities to hacking, unauthorized access and malware infections. These threats are fast, complex and constantly evolving, creating a need for robust governance, risk identification and risk management.<sup>22</sup> On June 13, 2013, the FDA released guidance on cybersecurity for medical devices and hospital networks, recommending medical device manufacturers and health care facilities take steps to assure that appropriate safeguards are in place to reduce the risk of failure due to cyber-attack. An attack could be initiated by the introduction of malware into the medical equipment, or by unauthorized access to configuration settings

in medical devices and hospital networks.<sup>23</sup> Medical Device Security Leaders (MDSLs) must understand their organization's risk exposure, adopt a risk management framework and increase security education awareness among stakeholders to mitigate the risks associated with networked medical devices.

**6. Secure supply chain:** *The FDA has passed regulations requiring all medical devices sold within the U.S. to have a Unique Device Identifier (UDI).*

In September 2013, the FDA published UDI regulations to support patient safety and supply chain security requirements.<sup>24</sup> The rule aims to enable accurate device identification by requiring a unique identifier for every medical device sold in the U.S. market. As part of the UDI system, the FDA is creating the Global Unique Device Identification Database (GUDID), which will include a standard set of basic identifying elements for every device with a UDI.<sup>25</sup> Manufacturers are responsible for submitting and maintaining their own data in the database, and must fully comply with the UDI rule by September 24, 2014.<sup>26</sup>

Integrating UDI across the entire health care infrastructure is a critical step toward Digital Health. UDI system implementations enhance patient safety and support improved regulatory compliance, post-market surveillance, standard device documentation, recall management, clinical and operational efficiency and health care cost savings.<sup>27</sup> However, the full benefits of UDI can only be achieved if all stakeholders — from manufacturers to health care providers to patients — implement UDI systems throughout their workflow systems.<sup>28</sup> This will require continued research, education of multiple stakeholders, and external support, such as effective regulations and meaningful incentives.<sup>29</sup>

In the pharmaceutical industry, track and trace solutions are used to protect the integrity and authenticity of drugs throughout the supply chain.<sup>30</sup> Tracking is forward-looking and involves knowing the current location and future destination of a particular drug within the supply chain at all times. Tracing is backward-looking and involves knowing the historical locations, time spent at each location, record of ownership, packaging configurations

and environmental storage conditions of a particular drug.<sup>31</sup> Track and trace solutions provide the foundation for improved patient safety by giving manufacturers, distributors and pharmacies a systematic method to detect and control the key risks of supply chain security: counterfeiting, drug diversions and improper handling.<sup>32</sup> Deploying track and trace solutions can enhance the top and bottom line by boosting efficiency in the supply chain and distribution channel, improving compliance and reducing the frequency of theft and counterfeiting.

The six trends highlighted above are likely to have a significant impact on the life sciences industry for the rest of 2014 — and beyond. Although the regulatory environment continues to evolve, the general direction seems to be toward increased compliance requirements, scrutiny and enforcement. For life sciences companies, the overarching challenge will be finding ways to achieve compliance without creating excessive drag on the business.

## Endnotes

- <sup>1</sup> Mello MM, Kelly CN, Brennan TA. Fostering Rational Regulation of Patient Safety. *Journal of Health Politics, Policy and Law*, 2005; 30(3):375-426.
- <sup>2</sup> Mackey TK, Liang BA. Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism. *BMC Medicine*, 2013; 11:233.
- <sup>3</sup> Mackey TK, Liang BA. Pharmaceutical digital marketing and governance: illicit actors and challenges to global patient safety and public health. *Globalization and Health*, 2013; 9:45.
- <sup>4</sup> Jerome Kassirer, *Medicine's Obsession with Disclosure of Financial Conflicts: Fixing the Wrong Problem*, in SCIENCE AND THE MEDIA: DELGADO'S BRAVE BULLS AND THE ETHICS OF SCIENTIFIC DISCLOSURE, 79, 79 (Peter Snyder, et al., eds., Academic Press 2009).
- <sup>5</sup> Robeznieks, Andis. "Reform Update: Aug. 1 brings deadline to report physician payments" *Modern Health care* 29 Jul. 2013. Web. 12 Nov. 2013.
- <sup>6</sup> Cleary, Kelly M. "Physician Payment Sunshine Act: How Hot Could it Get in the Sun?" *Bloomberg Law* 1 Dec. 2013. Web. 2 Dec. 2013.
- <sup>7</sup> Freeman, Greg. "How the Physician Payment Sunshine Act Could Affect Practice Revenue" *Managed Care Contracting & Reimbursement Advisor* 10 Oct. 2013. Web. 2 Dec. 2013.
- <sup>8</sup> Ornstein, Charles. "Drugmakers Slash Spending On Doctors' Sales Talks" *ProPublica*, 4 Mar. 2014. Web. 4 Mar. 2014.
- <sup>9</sup> Murray, J. et al. FDA. Guidance for Industry Chronic Hepatitis C Virus Infection: *Developing Direct-Acting Antiviral Drugs for Treatment*. Oct 2013
- <sup>10</sup> Woodcock, Janet, and Raymond Woosley. "The FDA Critical Path Initiative and Its Influence on New Drug Development." *Annu. Rev. Med.* 59 (2008): 1-12.
- <sup>11</sup> Johnson JR, Ning Y-M, Farrell A, Justice R, Keegan P, Pazdur R. Accelerated approval of oncology products: the Food and Drug Administration experience. *J Natl Cancer Inst.* 2011; 103(8):636-644.
- <sup>12</sup> Ellenberg SS. Accelerated Approval of Oncology Drugs: Can We Do Better? *J Natl Cancer Inst.* 2011; 103(8), 616-617.
- <sup>13</sup> Johnson JR, Ning Y-M, Farrell A, Justice R, Keegan P, Pazdur R. Accelerated approval of oncology products: the Food and Drug Administration experience. *J Natl Cancer Inst.* 2011; 103(8):636-644.
- <sup>14</sup> Ellenberg SS. Accelerated Approval of Oncology Drugs: Can We Do Better? *J Natl Cancer Inst.* 2011; 103(8), 616-617.
- <sup>15</sup> *ibid*
- <sup>16</sup> *ibid*
- <sup>17</sup> "Mobile medical applications: Guidance for industry and food and drug administration staff." FDA. 25 Sept. 2013. Web. 31 Dec. 2013. <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>
- <sup>18</sup> Alerts and Updates: Mobile Medical Apps Guidance." Duane Morris. 4 Oct. 2013. Web. 31 Dec. 2013. [http://www.duanemorris.com/alerts/mobile\\_medical\\_apps\\_guidance\\_5037.html#1](http://www.duanemorris.com/alerts/mobile_medical_apps_guidance_5037.html#1)
- <sup>19</sup> "Rise of medical telemetry." CIOL. 23 Sept. 2013. Web. 31 Dec. 2013. <http://www.ciol.com/ciol/news/196263/rise-medical-telemetry/page/1>
- <sup>20</sup> "Guidance for Industry – Wireless Medical Telemetry Risks and Recommendations." FDA. 27 Sept. 2000. Web. 31 Dec. 2013. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070920.htm>
- <sup>21</sup> "Wireless Medical Telemetry Systems." FDA. 13 Aug. 2013. Web. 31 Dec. 2013. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/WirelessMedicalDevices/ucm364308.htm>
- <sup>22</sup> "Issue Brief: Networked medical device cybersecurity and patient safety: Perspectives of health care information cybersecurity executives." Deloitte Center for Health Solutions. 2013. Web. 31 Dec. 2013. [http://www.deloitte.com/view/en\\_US/us/Insights/centers/center-for-health-solutions/eff8b79b48031410vgnVCM2000003356f70aRCRD.htm](http://www.deloitte.com/view/en_US/us/Insights/centers/center-for-health-solutions/eff8b79b48031410vgnVCM2000003356f70aRCRD.htm)
- <sup>23</sup> "FDA Safety Communication: Cybersecurity for Medical Devices and Hospital Networks." FDA. 13 Jun. 2013. Web. 31 Dec. 2013. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm356423.htm>
- <sup>24</sup> GS1. How to comply with Unique Device Identification (UDI). [http://www.gs1.org/health\\_care/udi](http://www.gs1.org/health_care/udi)
- <sup>25</sup> U.S. Food and Drug Administration. Unique Device Identification (UDI). <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>
- <sup>26</sup> PTC, Product & Service Advantage. Unique Device Identification (UDI) Requirements for Medical Devices. <http://www.ptc.com/topics/unique-device-identification/>
- <sup>27</sup> Wilson NA, Drozda J.. Value of Unique Device Identification in the Digital Health Infrastructure. *JAMA*. 2013; 309(20), 2107-8.
- <sup>28</sup> *ibid*
- <sup>29</sup> *ibid*
- <sup>30</sup> Frost & Sullivan. Track & Trace Pharmaceuticals Do It Before You Must –But Do It Right. 21 July, 2010.
- <sup>31</sup> Koh R, Schuster EW, Chackrabarti I, Bellman A. White Paper Securing the Pharmaceutical Supply Chain, 1 June, 2003.
- <sup>32</sup> *ibid*

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