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Fall 2017

## Wearables and Warranties

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# DIGITAL HEALTH REPORT

FALL 2017

WSGR Wilson Sonsini Goodrich & Rosati  
PROFESSIONAL CORPORATION

## Introduction

Driven by the convergence between healthcare, genomics, and digital technologies, digital health is a fast-growing sector with important implications for individuals to institutions, alike. Whether its hospitals and health systems using electronic medical record management and outcomes metrics to improve care, parents using wearables to monitor children with diabetes, or harnessing precision medicine to design therapies to attack specific tumors, the digital health industry represents a market that is poised for exponential growth.

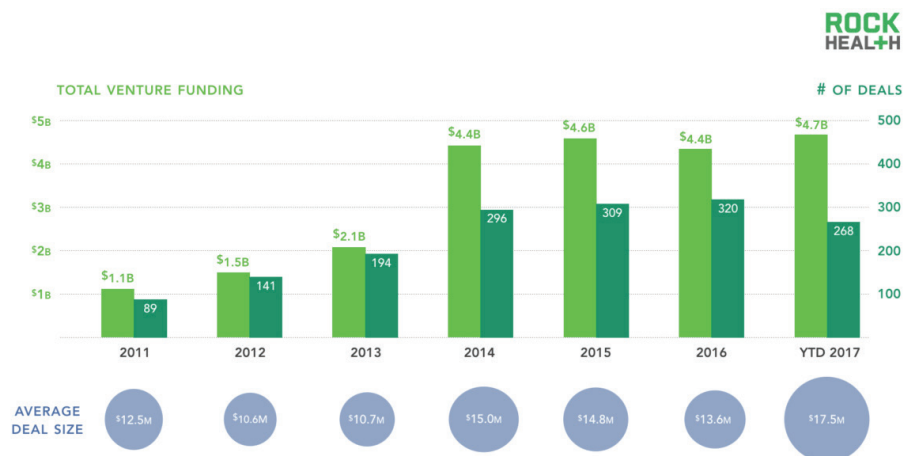
WSGR is pleased to share our initial Digital Health Report, which is aimed at providing digital health participants with timely insight and updates on trending topics and the many novel and intertwined legal and business issues that permeate this exciting and growing field.

We'd appreciate your feedback on our report, especially if you have suggestions on topics you'd like us to consider for future issues. If you have any comments or questions, please contact your existing WSGR attorney(s) or any of the attorneys listed as authors in our report.

### IN THIS ISSUE

<b>Introduction</b> .....	Page 1
<b>2017 Year in Review</b> .....	Pages 1-4
<b>Patents &amp; Trade Secrets</b> ....	Pages 4-5
<b>Wearables &amp; Warranties</b> .....	Page 6
<b>21<sup>st</sup> Century Cures Act</b> .....	Pages 7-8

## 2017 Is Already the Biggest Year Ever for Digital Health Investment



Source: Rock Health Funding Research, Q3 2017<sup>1</sup>

By Andrew Ellis

If you regularly follow innovation in the healthcare industry, it is no surprise that digital health investing has been strong since 2014. According to data from Rock Health, investment in digital health more than doubled to \$4.4 billion in 2014 from just \$2.1 billion in 2013. Investments remained at similar levels for the next two years, logging \$4.6 billion and \$4.3 billion in 2015 and 2016.<sup>1</sup> Startup Health, another digital health organization that tracks venture funding in the sector, uses a broader definition of digital health and recorded nearly double the amount of

investment, but shows the same trend from 2014 through 2016.<sup>2</sup>

Digital health has continued to strengthen in 2017. Rock Health and Startup Health data through Q3 2017 shows that 2017 has already reached \$4.7 billion and \$9.0 billion, respectively, exceeding any prior year of digital health investing. In addition, 2017 is also on pace to exceed the number of digital health funding deals in 2016, according to data from both providers.

In comparison, although venture investing in all industries is on pace

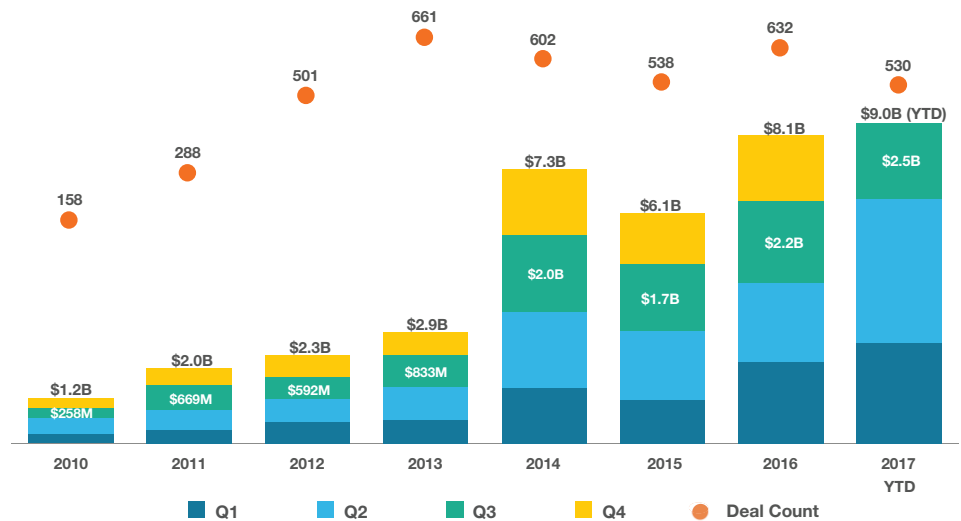
1 See: [https://rockhealth.com/reports/in-biggest-year-of-digital-health-funding-women-ceos-emerge-as-q3-2017-winners/?utm\\_source=Rock+Weekly&utm\\_campaign=937aff9ab-Rock\\_Weekly\\_10\\_2&utm\\_medium=email&utm\\_term=0\\_e44ef774d4-937aff9ab-90916197&mc\\_cid=937aff9ab&mc\\_eid=f-0877c04a2](https://rockhealth.com/reports/in-biggest-year-of-digital-health-funding-women-ceos-emerge-as-q3-2017-winners/?utm_source=Rock+Weekly&utm_campaign=937aff9ab-Rock_Weekly_10_2&utm_medium=email&utm_term=0_e44ef774d4-937aff9ab-90916197&mc_cid=937aff9ab&mc_eid=f-0877c04a2).

2 See: <https://www.startuphealth.com/marketing/insights/51631>.

(Continued on page 2)

## 2017 Is Already the Biggest Year Ever . . . (continued from page 1)

to beat 2016 levels, according to the PricewaterhouseCoopers MoneyTree Report,<sup>3</sup> with approximately \$55 billion invested through Q3 2017, compared with approximately \$60 billion for all of 2016, it has not already exceeded full-year 2016 levels. This demonstrates that digital health investing is not merely riding the general venture investment wave, but is showing unique growth in the current environment. We are excited and encouraged by the confidence that investors continue to show in digital health and believe there are a few notable trends that are important.



### Investment Trends Through Q3 2017

#### Regulatory Environment

Even more impressive than the numbers is the environment in which these investments took place. With a new president and multiple attempts by Congress to repeal or modify key components of the Affordable Care Act, 2017 has been an uncertain healthcare environment to say the least.

The resilience of digital health investment in an uncertain regulatory environment is notable, but the regulatory environment may be improving. In general, certainty may be higher in the near and intermediate terms as Congress appears ready to turn away from healthcare in order to focus on tax reform and other items on the agenda. More specifically, the passage of the 21<sup>st</sup> Century Cures Act in December 2016<sup>4</sup> laid the groundwork for digital health regulatory reform measures, and the first material step in that direction has come in the form of the Digital Health Innovation Plan, which was announced on July 27, 2017.<sup>5</sup>

Source: Startup Health Insights, Q3 2017

The Digital Health Innovation Plan:

- Introduces a new paradigm for digital health regulatory review, demonstrating a developer-centric approach rather than a product-centric approach. This may allow certain developers to “pre-certify” their product based on historical quality measures and market such products with little or no regulatory review.
- Promises forthcoming guidance on matters such as mobile medical applications, medical data, and medical image storage and retrieval software, and clinical decision support software. With the overarching goal of reducing regulatory burdens on the fast-moving digital health industry, these measures may have a positive effect on the regulatory environment that would embolden additional investment in the rest of 2017 and beyond.

#### Digital Health Megadeals

As the aggregate amount of digital health investment has grown, so has the size of investments. According to Rock Health, there were three digital health investments of \$100 million or more in 2016,<sup>6</sup> but 2017 has already claimed eight such investments. Startup Health shows a slight decline in early-stage funding deals with a sharp increase in Series C and D deals, adding that Q3 2017 had more mid-stage and late-stage funding deals than any other Q3 on record. In addition, Startup Health shows an increased average round size from approximately \$15 million to approximately \$18 million in 2016 and year-to-date 2017.

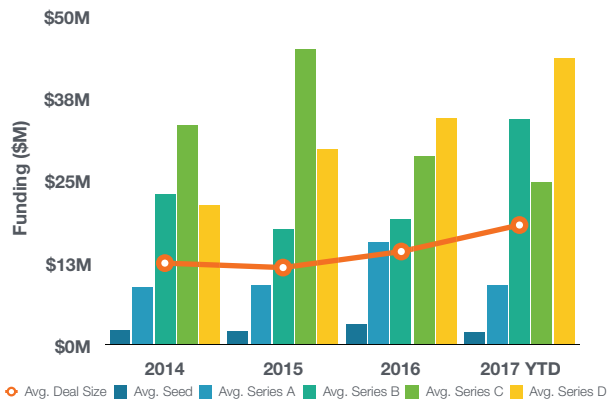
There may be multiple reasons for the emergence of the digital health megadeal. First, it may simply reflect confidence in the long-term value of digital health, the ability of the FDA to streamline regulatory processes, and the current positive economic macroenvironment. Second, it may simply indicate a maturing

3 See: <https://www.pwc.com/us/en/technology/moneytree/explorer.html#/>.

4 See our WSGR Alert on the 21<sup>st</sup> Century Cures Act: <https://www.wsgr.com/WSGR/Display.aspx?SectionName=publications/PDFSearch/wsgralert-21st-century-cures-act.htm>.

5 See: <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>.

6 See: <https://rockhealth.com/reports/2016-year-end-funding-report-a-reality-check-for-digital-health/>.



Source: Startup Health Insights, Q3 2017

industry, where the winners have been identified, and investors are focusing their investment dollars. Third, it may actually be a side effect of relatively few exits for digital health companies in 2017, forcing investors to create enough runway for these companies to continue operations rather than seek an exit.

**Where Are the Exits?**

Rock Health reports a multi-year downtrend in the number of M&A transactions in digital health, with 146 digital health deals reported at the close of Q3 2015 versus 112 and 83 through Q3 2016 and Q3 2017, respectively. Because so many of these transactions do not publicly disclose the acquisition price—in Q3, only 16 out of 83 had a disclosed transaction amount—it is difficult to determine the full meaning of these reduced numbers.

The reduced number of M&A transactions has not been alleviated by IPO activity in 2017. There were six digital health IPOs in 2015, three in 2016, and none through Q3 2017. In fact, according to Rock Health, 2017 may be the first year since 2012 without a digital health IPO, even though several digital health companies like iRhythm, Teladoc, and Tabula Rasa have performed quite well since their IPOs.

However, there is a silver lining in these numbers. First, because of the rising number of digital health megadeals raising private funds, there are more mature digital health companies with high valuations that may make attractive IPO candidates or may attract large buyouts in future years. Second, continued investment in digital health despite

the declining number of M&A and IPO transactions may indicate a longer-term investor focus, which is yet another sign of maturity for the digital health space that helps create stability.

**A Shift from B2C to B2B**

Rock Health recently published an interesting survey of 85 digital health entrepreneurs regarding business-to-consumer (B2C) and business-to-business

(B2B) business models.<sup>7</sup> Thirty-four percent of the businesses they surveyed started out with B2C business models, and 61 percent of those eventually changed their business model to either B2B2C (a hybrid model of B2B and B2C) or B2B. Only 14 percent of the companies that Rock Health surveyed still employed a B2C business model. The largest investments of 2017 so far also reflect a B2B focus, as evidenced by the chart below.

Why does this business model change affect investment trends? One of the downsides of a B2C business model in digital health has always been that it is a crowded space, and from the results of the Rock Health survey, it appears that B2B is also becoming increasingly crowded. When any space becomes crowded, the increased competition can have a negative effect on revenue and sales cycles, but this effect may be especially pronounced in digital health given the long B2B sales and implementation cycles in the healthcare space.

NUMBER OF \$100M+ DEALS  
Q1-Q3 2017



Company Category	2017 Round	Year Founded
Outcome HEALTH Consumer health information Sells to: Providers, life science firms	\$500M Goldman Sachs, CapitalG	2006
PELOTON Connected fitness equipment Sells to: Consumers	\$325M Wellington, KPCB, True Ventures	2012
23andMe Personal health tools and tracking Sells to: Consumers, pharma	\$250M Sequoia Capital	2006
MODERNIZING MEDICINE EMR Sells to: Physician practices	\$231M Warburg Pincus	2010
PatientPoint Consumer health information Sells to: Providers	\$140M Searchlight Capital Partners, Silver Point Capital	1987
Alignment Healthcare Population health management Sells to: Consumers, providers	\$115M Warburg Pincus	2013
patientslikeme Patient community Sells to: Pharma	\$100M iCarbonX	2005
sharecare Consumer health information Sells to: Employers, health plans, providers	\$100M Summit Partners	2010

Source: Rock Health Funding Research, Q3 2017

<sup>7</sup> See: <https://rockhealth.com/reports/streamlining-enterprise-sales-in-digital-health/>.



## 2017 Is Already the Biggest Year Ever . . . (continued from page 3)

Several WSGR clients have reported that, while a target company or hospital may find their product attractive, they simply do not have the bandwidth in their infrastructure to onboard multiple digital health solutions in a given year. Until the digital health industry matures into a phase of consolidation, the fragmented nature of digital health solutions may exacerbate these infrastructure limitations and delay revenue from new customers, as more companies enter the B2B space.

### What's Next?

There are a lot of things to be excited about in digital health. The industry appears to be maturing, as evidenced by more later-stage investments and larger deal sizes. The regulatory and economic macroenvironment, while imperfect, looks favorable at this time. Several high-profile recent digital health IPOs are performing well in the public markets. Most importantly, the fact that aggregate digital health investment in 2017 has already

exceeded 2016 is an encouraging vote of confidence by investors.

However, despite the strong numbers, there are some headwinds: M&A and IPO activity have trended down since 2015, and Q3 investment amounts were less than the very large Q2 numbers. It remains to be seen whether the strength of 2017 will continue to build momentum into 2018 or will prove to be short-lived, but there is ample evidence to support an optimistic view.

## Patent and Trade Secret Protection in Digital Health

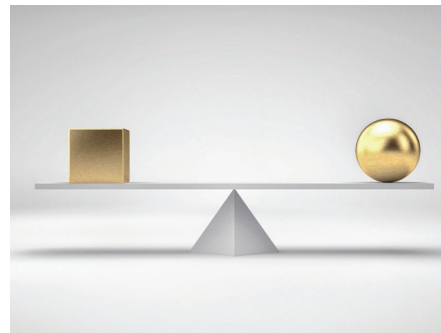
By *Ali R. Alemozafar and Charles T. Graves*

Practically all digital health companies are founded on the basis of ideas. For example, your company may have several ideas around a smart watch data-collecting sensor that tracks heart rate using algorithm software. The software draws correlations from the data as an actionable output. Such ideas are often subject to patent and trade secret protection, which is a key part of enabling continued growth for your company, including investment and downstream acquisition.

Understanding what warrants patent and trade secret protection is important. Additionally, selecting the kind of protection that is right for you is a careful balance between several considerations. Below are some frequently asked questions to provide you with guidance along the way.

### What Is a Patent?

A patent is a government right that excludes others from practicing the patented invention for a period of 20 years, creating a limited monopoly. To



be granted a patent, the ideas being patented need to be disclosed in a patent application in sufficient detail to permit the skilled person reading the patent to practice the patented invention. This often requires disclosing certain details of the secret sauce.

### What Is a Trade Secret?

A trade secret is generally information, including a formula, pattern, compilation, program, device, method, technique, or process that both:

- Derives independent economic value, actual or potential, from not being generally known to the public and others who can obtain economic value from its disclosure or use

- Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy

There are many famous examples of ideas that have been maintained as trade secrets, such as the formula for Coca-Cola. The term of a trade secret is theoretically indefinite so long as the underlying ideas remain secret.

### Which Ideas Are Suitable for Trade Secret Protection?

A company may pursue trade secret protection for ideas that can be effectively kept a secret. The company should establish an internal policy to maintain secrecy. Trade secret protection may enable the company to keep its ideas a secret and maintain first-mover advantage, which may be important in an uncrowded segment of digital health.

Trade secret protection may not be suitable if the ideas are subject to publication, may be readily reverse-engineered, or derived independently by another company in a fast moving area of digital health.

**What Is the Duration of Trade Secret Protection Versus Patent Protection?**

Trade secret protection is indefinite but thin, while patent protection is time-limited but thick. However, if an idea that is maintained as a trade secret is developed independently by a competitor, made public, or is reverse-engineered, then the trade secret protection may no longer be available.

On the other hand, while the period for patent protection is limited to 20 years, the patent may be used to stop a competitor from practicing the invention covered by the patent, regardless of whether the competitor independently derives the invention.

**When Would It Make Sense to Pursue Patent Protection?**






Ideas that are generally difficult to protect under trade secrecy may be better suited for patent protection. For example, if an idea may be readily reverse-engineered or derived independently, then patent protection may be the more suitable type of protection.

**What Are the Benefits of Pursuing a Patent?**

A patent may protect ideas regardless of whether such ideas are subsequently reverse-engineered or derived independently by others. In addition, a patent may enable a third party, such as an investor or acquirer, to place concrete value on a company’s ideas. This may be important for early-stage companies seeking financing.

With a trade secret, such value may be more difficult to show, given that the value of a trade secret is based on the underlying ideas not being generally known to the public or others.

**Factors to Consider When Pursuing Patent or Trade Secret Protection**

	Patent	Trade Secret
<b>Subject Matter</b> 	Process, machine, manufacture, or composition of matter	Information, including a formula, pattern, compilation, program, device, method, technique, or process
<b>Legal Threshold</b> 	Right subject matter, new, and non-obvious	Reasonable efforts to maintain secrecy
<b>Term</b> 	20 years	Indefinite
<b>Upside</b> 	Protect ideas regardless of reverse-engineering or independent derivation by others Allows third parties to place concrete value on ideas	Keep ideas a secret and maintain first-mover advantage
<b>Risk</b> 	Patent application typically published and reviewed with no guarantee of a patent	Ideas reverse-engineered, derived independently, or made public Difficult to place concrete value on ideas

**What Are the Risks When Pursuing Patent Protection?**

To be granted a patent, the idea being patented needs to be disclosed in a patent application, which is filed with a patent office and typically published. The patent application is reviewed by the patent office to determine whether the idea being patented meets a requisite legal threshold, including whether the idea is the right subject matter, new, and non-obvious.

An idea directed to a process, machine, manufacture, or composition of matter may be the right subject matter for a patent. This review may involve a technically and legally intensive negotiation process with the patent office, called patent prosecution.

Some ideas are more difficult to patent than others. For instance, ideas around algorithms or health data are generally more difficult to patent than ideas around hardware. If the patent office finds that an invention being patented is directed to an abstract idea, a law of nature, or a natural

phenomenon, then they may find that it is not directed to the right subject matter for a patent.

There is no guarantee that a patent will be granted from a patent application. A risk with pursuing patent protection is that a patent application can be made public without giving the company any patent protection. In this circumstance, the ideas in the patent application will be dedicated to the public.

**Can You Take a Hybrid Approach and Pursue Both Trade Secret and Patent Protection?**

A company may keep certain aspects of its technology as a trade secret, while pursuing patent protection around others. For example, a digital health company has software with a particular machine learning algorithm and a sensor for collecting data. The company may keep the machine learning algorithm as a trade secret and pursue patent protection around the sensor.

## Wearables and Warranties

By Rachel Landy and Jennifer M. Halbleib



The last few years have seen an explosion of wearable digital health products. Where a doctor's visit used to be required for a basic check-up, now a patient's health status is increasingly at his or her fingertips. We have the ability to track fitness levels, monitor lung and heart capacity, check skin temperature, and observe blood pressure with a simple wearable device.

Product warranties give consumers confidence that these devices will perform as expected. But overzealous marketing can also be interpreted as implied warranties that the manufacturer never intended, which expose the manufacturer to potentially significant liability. This is especially the case with devices used to track disease or improve health. Liability may arise under a number of theories, including false or deceptive advertising, as well as under warranty law.

### ABCs of Express Warranties

Consumer wearables are often accompanied by express warranties—promises made by the manufacturer or retailer to the consumer about the functionality of a wearable device. For example, a warranty may state that the

manufacturer warrants against defects in materials and workmanship of the product in its original packaging, but only when the product is used normally for its intended purpose. Any warranty also will include information on how to submit a claim and the consumer's remedy, if there is a defect.

### Legal Framework for Warranties

In drafting a consumer warranty, it is important to keep in mind the basic legal framework. Consumer warranties are governed at the federal level by the Magnuson Moss Warranty Act (MMWA). Notably, the MMWA does not require that a warranty be provided with a consumer product. Instead, it sets forth certain requirements for any written warranty that is provided including:

- A description of the product that is covered, and any parts that are excluded (e.g., any thirdparty batteries)
- The remedy in the event of a breach of warranty and who bears which costs (e.g., the cost of shipping the product back to the warrantor)
- The effective date of the warranty (e.g., the date a product is purchased from an authorized retailer)
- How long the warranty lasts (e.g., 5 years from purchase)
- A prohibition on disclaiming certain implied warranties

Some states have additional statutes that supplement the MMWA. If you are contemplating business in a specific state, it is important to review any relevant state statute. For example, California's Song-Beverly Act includes terms that apply specifically to health devices. Under the Song-Beverly Act, "assistive devices", intended to assist consumers with physical disability, injury, or disease treatment are subject to more strict warranty requirements. For instance, warrantors of most types of assistive devices must adhere to specific replacement terms in the event of a defect.

### Marketing Missteps: Unintended Implied Warranties

In addition to express warranties, warranties can be implied by the official product description or marketing. It can be easy to inadvertently run afoul of the warranty statutes by making claims in marketing materials that look like warranties or promises as to how a device will work, but are simply intended to be promotional. For example, in 2015, a group of consumers brought a class action suit against Fitbit, alleging that Fitbit's marketing of its sleep-tracking functionality—which included promises about specific results—breached the implied warranty of merchantability under the MMWA, and also constituted deceptive and unfair trade practices, among other things. The plaintiffs argued that the messaging in Fitbit's product packaging did not accurately reflect the device's capabilities. All claims survived a motion to dismiss last year and the litigation is ongoing. Similarly, in 2015, Nike settled a class action alleging similar claims against its FuelBand product, including the product's inability to accurately track calories and steps.

### Best Practices

When bringing a product to market, it is important to consider the following to avoid claims that the MMWA or any related state laws were violated:

- Ensure that any warranty is drafted in compliance with the MMWA and any relevant state statute(s)
- Disclaim accuracies of any specific results in end user license agreements
- Review marketing and promotional materials carefully to make sure the language does not imply any promises as to effectiveness of a device

# The 21st Century Cures Act: Clinical Decision Support Software Regulation

By David Hoffmeister and Charles Andres<sup>1</sup>

The sophistication and importance of software intended for use in the medical field and in medical applications continues to grow at a dizzying pace. For example, a robot surgeon in Italy successfully performed an unassisted 50-minute surgery to treat a patient with atrial fibrillation, a heart condition.<sup>2</sup> The robot's software contained data from about 10,000 real-world surgeries, and before operating solo, the robot previously performed assisted procedures on at least 40 people.<sup>3</sup> Specialized software running surgical robots represents just one area of this growth.

Another essential area is diagnostic software, which can make diagnoses independently of a healthcare provider or act as a diagnostic aid to providers. ARK Investment Management estimates that the total global addressable market for diagnostic software could reach \$16 billion.<sup>4</sup> With so much at stake, both in terms of patient outcomes and market share, all software developers—including diagnostic software developers—should understand how medical software is regulated in the United States.

The U.S. Food and Drug Administration (FDA) has the authority to regulate some software as a medical device. It is important for developers to know if their software meets the definition of a

medical device, how it will be regulated, and whether regulatory approval or clearance is required before it can be commercialized.<sup>5,6</sup>

## Background on the Act

The 21<sup>st</sup> Century Cures Act was signed into law on December 13, 2016.<sup>7</sup> Section 3060 of the act amends the Federal Food, Drug, and Cosmetic Act (FDCA) to exclude certain software from the definition of a medical device. This is important because the excluded software—so long as certain conditions are met—is exempt from FDA regulation, creating a faster and more certain path to market. Clinical decision support software (CDSS) is one of these exclusions.

## CDSS Exclusion

CDSS can aid healthcare professionals in making diagnoses. Providers, like radiologists, who make diagnoses based on images face several difficulties. They need to review images from potentially hundreds of patients daily and often in stressful settings such as an emergency room, which may create decision fatigue.

Additionally, image blur and regions of overlapping tissues can contribute to incorrect diagnostic decisions. These factors and others can cause healthcare professionals to order unnecessary medical procedures, such as a skin biopsy for a lesion that turns out to be non-cancerous. This exposes the patient to increased medical risks and increases the

cost burden on healthcare payers.

Section 3060 of the act,<sup>8</sup> which is relevant to CDSS, recites in part that the definition of medical device shall *not include* software for the purpose of:

- (i) . . . Analyzing . . . medical information about a patient . . . ; and
- (ii) Supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and
- (iii) Enabling such healthcare professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such healthcare professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

If the CDSS meets the criteria in Section 3060, the CDSS has a statutory safe harbor, with the FDA not having jurisdiction to regulate it.

It is crucial to note that there are two broad situations, or exclusions, where CDSS can nevertheless be regulated by the FDA as a medical device. The first is where software “is intended to acquire, process, or analyze a medial image or signal from an in vitro diagnostic device or

1 The information herein is provided for informational purposes only and should not be taken as legal advice. Legal counsel should be consulted for questions regarding the regulation of software as a medical device and the 21<sup>st</sup> Century Cures Act.

2 Evan Blass, “Robot surgeon performs world's first unassisted operation,” *Engadget*. See: <https://www.engadget.com/2006/05/19/robot-surgeon-performs-worlds-first-unassisted-operation/>.

3 *Id.*

4 James Wang, “Deep Learning Based Diagnostics: Unlocking a \$16 Billion Market,” *ARK Invest*, December 22, 2016. See: <https://ark-invest.com/research/deep-learning-based-diagnostics>.

5 In the case of robot surgeons, a company may need to get separate clearance or approval for both the hardware (e.g., the robot) and the software running the robot.

6 Mobile medical application developers should also be familiar with the FDA's regulatory framework for mobile medical applications. The FDA issued a Mobile Medical Applications guidance in 2015. The definition of medical device in the guidance is outdated, so the guidance should be consulted with caution.

7 Pub. Law. No. 114-255.

8 21 U.S.C. § 360j(o)(1)(E).



## The 21st Century Cures Act . . . (continued from page 7)

a pattern or signal from a signal acquisition system.”<sup>9</sup> For example, software that makes diagnostic recommendations based on the analysis of a medical image (e.g., CT, radiographs, or MRI) would not be entitled to the Section 3060 safe harbor. Rather, these CDSS products would require approval or clearance by the FDA.

The second exclusion, where the FDA can regulate and take the CDSS of the regulatory safe harbor, includes the following:

- (i) The Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences if it does not operate as intended; and
- (ii) The software function has been identified in a final order issued by the Secretary under subparagraph (B).<sup>10</sup>

To meet the criteria above, various factors are required to be considered, and certain procedural due process requirements must be adhered to.<sup>11</sup>

### Summary

CDSS will play an increasingly important role in the day-to-day practice of medicine. Developers of CDSS should understand how their CDSS will, or will not, be regulated by the FDA. Consulting early with regulatory counsel can help clarify the regulatory status of CDSS products.

<sup>9</sup> *Id.*

<sup>10</sup> 21 U.S.C. § 360j(o)(3)(A).

<sup>11</sup> 21 U.S.C. § 360j(o)(3)(B) and (C).

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