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Navigating the U.S. Healthcare Regulatory Landscape for Wearable Devices

Complex Environment Includes Key Federal Agencies FDA, FTC, OCR, CPSC, CMS, and OIG

By David Hoffmeister, James Ravitz, Georgia Ravitz, Paul Gadiock, and Eva Yin

The wearable device market is emerging as a key player in big data and digital health. Worldwide sales of smart wearable devices are projected to become a $27 billion-plus market by 2022.[1] And savvy businesses have noticed. Wearable devices are being developed for a broad range of convenient healthcare monitoring and preventive medicine functionalities, including motion trackers, vital signs measurement such as electrocardiograms (ECGs), and smart clothing.[2] Many wearable devices are also integrating with telemedicine and telehealth to provide medical services, increasing the complexity of how these devices are regulated by the various agencies of the government. Key federal agencies that regulate wearable devices, their uses, distribution, and reimbursement include: the U.S. Food and Drug Administration (FDA), Federal Trade Commission (FTC), Office of Civil Rights (OCR), Consumer Product Safety Commission (CPSC), Centers for Medicare & Medicaid Services (CMS), and Office of Inspector General (OIG). Additionally, state governments may have similar or more restrictive laws than federal laws that regulate wearable devices and related services in the healthcare sector. Navigating these layered regulatory requirements both successfully and efficiently is critical to gaining a market advantage in this growing industry.

In This Issue

Navigating the U.S. Healthcare Regulatory Landscape for Wearable Devices.....Pages 1-5

A Conversation with Katharine Ku, Chief Licensing Advisor at WSGR.....Pages 6-7

The Role of Automation in Legal Practice.....Pages 8-9

Matthew J. Meyer Joins WSGR as Chief Client Corporate Development Advisor..... Page 9

Select Recent Life Sciences Client Highlights.....Pages 10-11

Upcoming Life Sciences Events..... Page 12

FDA

In general, the FDA regulates medical products (not services) under the Federal Food, Drug, and Cosmetic Act (FDCA). These medical products can include drugs, biologics, and medical devices. A "device" is defined by the FDCA as an "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man … or intended to affect the structure or any function of the body of man...."[3] Under this broad definition, the FDA regulates many devices offered over the counter and most devices used in a clinical setting, ranging from simple items like tongue depressors to complex implantable technologies.

However, not all medical devices are regulated by the FDA. Recent policy has exempted certain low risk medical devices intended for "general wellness" from FDA oversight. A general wellness product is defined as a product that: 1) is intended solely for general wellness use, and 2) presents a low risk to the safety of users and other persons. A general wellness product's intended uses, including claims as reflected in a manufacturer's promotional and marketing materials, must fall within one of two categories: 1) an intended use that relates to sustaining or offering

[1] Paul Lamkin, Forbes, Smart Wearables Market To Double By 2022: $27 Billion Industry Forecast, Oct 23, 2018, *available at* https://www.forbes.com/sites/paullamkin/2018/10/23/smart-wearables-market-to-double-by-2022-27-billion-industry-forecast/#2023a9dd2656.

[2] Haghi M, Thurow K, Stoll R. Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available Devices. Healthc Inform Res. 2017; 23(1): 4–15.

[3] 21 U.S.C. § 321(h).

Continued on page 2...

Continued from page 1...

general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions, or 2) an intended use that relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions. In the latter category, the use must be intended to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, (a) may help to reduce the risk of certain chronic diseases or conditions, or (b) may help living well with certain chronic diseases or conditions.[4] Not all wearable devices will fit these criteria, but those that do may be able to decrease associated FDA regulatory burden. However, even if the wearable device is not regulated by the FDA, it may still be under CPSC's oversight, as discussed in more detail below.

If the wearable device is indeed regulated by the FDA, the company must comply with a multitude of requirements, including registering the facility and listing the device with the FDA, implementing necessary controls such as current good manufacturing practices (cGMP), applying proper labeling, and conducting adverse event reporting. In many cases, manufacturers may be required to obtain premarket notification or approval from the FDA and/or undergo an FDA inspection before placing the wearable device into commerce. Applicable FDA requirements generally correlate to the risk presented by the wearable device, often inherent in the device's technology or interpreted from its intended use. Therefore, how a device is intended to be marketed can have a significant bearing on its path to commercialization, with opportunities to increase or decrease the level of scrutiny it receives from the FDA. As an additional layer, any mobile application (mobile app) component of wearable devices may be regulated as a separate device, requiring its own regulatory considerations. For example, in a 2017 warning letter, the FDA issued a warning letter to Opternative, Inc. for marketing its On-Line Opternative Eye Examination Mobile Medical App device in the United States without marketing clearance or approval, requiring the company to immediately cease commercial distribution of the device through its online website.[5]

Readers should keep in mind that the FDA's authority extends past the point when a wearable device first enters the market and continues to apply throughout the product's lifecycle, at times increasing postmarket regulatory burden. In a field of emerging technologies with at times fluid requirements, an ineffective regulatory analysis can lead to non-compliance with FDA regulations, potentially resulting in enforcement actions, penalties, and/or significant reputational and business loss. Conversely, skillfully maneuvering FDA pitfalls can help propel a wearable device out of the premarket stage and into users' hands with minimal FDA burden.

FTC and OCR

In addition to the FDA's postmarket requirements, wearable devices are also subject to regulation by the Federal Trade Commission, among others, once the product is commercialized. The FTC is an independent administrative agency that is tasked with protecting consumers under the FTC Act. This federal agency has investigative, law enforcement, and rulemaking authority, including protecting consumers' privacy and security. In particular, Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce."[6] In the context of internet-connected technologies, such as wearable devices, FTC can take legal action against companies that fail to maintain reasonable security measures and violate security and privacy standards.

Wearable devices that collect or track sensitive personal information are subject to general privacy laws, while those that collect or access protected health information may further be subject to the Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which is enforced by the Office of Civil Rights of U.S. Department of Health & Human Services (HHS). HIPAA generally prohibits the use and disclosure of individually identifiable health information created or received by Covered Entities, which include health plans, healthcare clearinghouses, and healthcare providers. Wearable devices that interface with Covered Entities or are integrated with telemedicine or telehealth may be subject to HIPAA as a Covered Entity or a business associate of a Covered Entity, and should conduct a thorough review of its privacy and security measures to ensure compliance with HIPAA.

Wearable devices that interface directly with consumers without involving Covered Entities have lower exposure under HIPAA, but are nonetheless subject to liability under general privacy laws and consumer protection laws that apply to all devices that access or track sensitive information. The FTC recommends such companies to be transparent in their data collection and use practices, including routine risk assessment; service provider oversight to ensure service providers have sufficient security measures; ongoing oversight, updating, and patching to ensure security standards are maintained; providing options to allow consumers to take control over their data; and providing heightened protections for

[4] FDA, General Wellness: Policy for Low Risk Devices, July 29, 2016, *available at* https://www.fda.gov/media/90652/download.
[5] FDA, Warning Letters, Opternative Inc., MARCS-CMS 532477, October 30, 2017, *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/opternative-inc-532477-10302017.
[6] 15 U.S.C. § 45(a)(1); *see also* FTC, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority, *available at* https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority.

FDA Regulatory Pathways for Medical Devices

Process Overview	Class I	Class II	Class III
Begin implementing Quality System Regulation (QSR, 21 Part 820) unless exempt.	Increasing risk profile Increasing complexity before commercial launch Overall cost for regulatory clearance/approval		
• Clinical studies are required for innovative Class II and III devices. • Obtain requisite state device manufacturing license/permit before commencing clinical studies, pursuant to state laws.	FY 2019 User Fees: • Annual establishment registration fee: $4,884 • 510(k) fee: $10,953 (standard); $2,738 (small business) • De Novo Classification: $96,644 (standard); $24,161 (small business) • PMA: $322,147 (standard); $80,537 (small business)		
Apply for an Investigational Device Exemption (IDE) and obtain pre-submission feedback from FDA on clinical studies; obtain IRB approval for clinical studies.	Subject to general controls only	Subject to general controls and special controls	Subject to general controls and premarket approval (PMA)
	Estimated time between submission and grant of clearance/approval		
	1 month	6-9 months	18-30 months
Prepare and submit 510(k) or PMA application; pay fee.	• Some require clearance via 510(k) premarket notification • Some are 510(k)-exempt	• Most Class II devices require clearance via 510(k) premarket notification • Some are 510(k)-exempt	• Premarket approval, including clinical studies, is required. • Some Class III devices may be cleared via 510(k) premarket notification • FDA inspects facility before issuing PMA. • Applicants may either submit a PMA or Product Development Protocol (PDP), or may petition FDA to reclassify the devices into Class I or Class II (through the De Novo process).
FDA issues clearance or approval letter.			
• Must be in full compliance with QSRs before commercial launch. • FDA may conduct random inspections for Class I and II devices. • FDA inspects facility before issuing PMA.	Not intended to be: • For use in supporting or sustaining life; • Of importance in preventing impairment to human life; and may not • Present a potential unreasonable risk of illness or injury		Generally intended to be used in supporting or sustaining human life or preventing impairment of human health, or that may present a potential unreasonable risk of illness or injury for which general controls and special controls are insufficient to provide reasonable assurance of the safety and effectiveness of a device, or for which there is insufficient information to make such a determination.
• Register establishment and list device in FDA database pursuant to 21 CFR Part 807; • Pay annual registration fee, must be renewed each year			
Prepare for commercial launch: • Implement a comprehensive healthcare compliance program; • Train all employees on healthcare compliance • Obtain other required state licensing or permit (e.g., device distribution and/or wholesale)	General controls including: 1. Adulteration; 2. Misbranding; 3. Device registration and listing; 4. Premarket notification; 5. Banned devices; 6. Notification and repair, replacement, and refund; 7. Records and reports; 8. Restricted devices; and 9. Good Manufacturing Practices (cGMP).	General and Special Controls. Special controls are usually device-specific and can include: 1. Performance standards 2. Postmarket surveillance 3. Patient registries 4. Special labeling requirements 5. Premarket data requirements 6. Guidelines	
Commercial launch	• Clinical studies of medical devices before obtaining required 510(k) or PMA are subject to investigational device exemption (IDE) regulations. Study sponsors must have an IDE before commencing human studies prior to clearance/approval.		

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sensitive information, such as health data.[7] Additionally, the FTC Bureau of Competition's recent launch of a new task force to monitor technology markets likely signals increased scrutiny of the digital health market.[8]

CPSC

Wearable devices that are not regulated by the FDA, such as general wellness products, may still be regulated by the Consumer Product Safety Commission, which is responsible for protecting the public from unreasonable risks, injury, or death associated with consumer products under the agency's jurisdiction, including products that pose a fire, electrical, chemical, or mechanical hazard. Further, the CPSC has jurisdiction over child resistant-packaging for all devices, including FDA-regulated devices. The CPSC's responsibilities include working with standards organizations, manufacturers, and businesses to develop voluntary standards, issuing and enforcing mandatory standards or banning certain hazardous consumer products, recalling products and arranging for repair, replacement or refund for recalled products, and researching potential hazards. For example, the Consumer Product Safety Improvement Act (CPSIA) addresses lead, phthalates, and third-party testing and certification, among other requirements, in consumer products. The Flammable Fabrics Act (FFA), which includes standards for certain textiles used in clothing, may apply to some wearable devices and smart clothing. In designing wearable devices, manufacturers should evaluate materials used in the devices, potential hazards to users and other people, including children, and potential for allergic reactions, especially for materials that contact the skin.

Additionally, manufacturers of wearable devices that use batteries should review CPSC's voluntary standards for batteries, including rechargeable batteries and lithium batteries, and best practices in the industry during product development phase to prevent potential hazards that may result in safety alerts, product recalls, personal injury, or product liability lawsuits. Potential hazards associated with batteries include overheating, fire, electrical shock, thermal burns, and exposure to alkaline battery electrolytes.

One example of a legal action taken by the CPSC against a wearable device manufacturer is the recall of Fitbit Force. In 2014, the wireless activity tracking wristband was recalled due to allergic reactions to the stainless steel casing, materials used in the strap, or adhesives used to assemble the product that resulted in redness, rashes or blistering where the skin contacted the tracker device.[9] A refund program was established as a remedy to address the recall.

CMS and OIG

Wearable devices and related healthcare services that are reimbursable by a federal healthcare program, such as Medicare or Medicaid, are subject to extensive regulation by CMS, which is part of the HHS. CMS implements policies that impact coverage and reimbursement for devices and related healthcare services, such as patient monitoring services and chronic disease management, billing policies, and program transparency policies, such as the Sunshine Act. With respect to program integrity, CMS often works closely with the Office of Inspector General, which enforces healthcare fraud and abuse laws, such as the False Claims Act (FCA), the Anti-Kickback Statute (AKS), and the Physician Self-Referral Law (Stark law). Wearable device companies that contract with healthcare providers or other referral sources should evaluate their business model for risks under these laws and potential for unlawful referral or inducement, as non-compliance with the healthcare laws discussed below can result in government investigation, criminal penalties, civil fines, and/or exclusion from federal healthcare programs.

The FCA (31 U.S.C. § § 3729-3733) makes it illegal to submit claims or cause false claims to be submitted for payment to Medicare or Medicaid that one knows or should know are false or fraudulent, and specific intent to defraud the government is not required. Further, filing false claims may result in fines of up to three times the damages incurred by the government. The civil FCA also contains a whistleblower provision that allows a private individual to file a lawsuit on behalf of the United States and provides for a percentage of damages recovered. Whistleblowers can be business partners, employees, customers such as hospital or office staff, consultants, patients, or competitors. Additionally, a claim that results from an illegal kickback or a violation of the Stark law may render it false or fraudulent, creating liability under the civil FCA along with other healthcare laws.

The AKS (42 U.S.C. § 1320a-7b(b)) is a criminal law that prohibits the knowing and willful payment of any remuneration to induce or reward patient referrals or business generated involving a product or service payable by the federal healthcare programs, including medical devices and durable medical equipment (DME), which encompasses certain general wellness products. Unlawful referrals include compensation or business arrangements that lead to overutilization, increased costs to federal healthcare programs, influence over medical decision-making, patient steering, and/or unfair competition. "Remuneration" is defined broadly to include anything of value, such as free products, compensation outside of fair market value, gifts, meals, or consultancy fees, unless it is expressly excepted or protected under a safe harbor.

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[7] FTC, Comments of the Staff of the Federal Trade Commission's Bureau of Consumer Protection, June 15, 2018, *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/comment-staff-federal-trade-commissions-bureau-consumer-protection-consumer-product-safety/p185404_ftc_staff_comment_to_the_consumer_product_safety_commission.pdf.

[8] FTC, Press Release, February 26, 2019, *available at* https://www.ftc.gov/news-events/press-releases/2019/02/ftcs-bureau-competition-launches-task-force-monitor-technology.

[9] CPSC, Fitbit Recalls Force Activity-Tracking Wristband Due to Risk of Skin Irritation, *available at* https://www.cpsc.gov/Recalls/2014/fitbit-recalls-force-activity-tracking-wristband.

To lower risks under the AKS, device companies should structure their business arrangements in accordance with one of the statutory exceptions or safe harbors under the AKS. Device companies whose products are reimbursable by a federal healthcare program, either as a separate payment or as part of a bundled payment, such as part of payment for a covered procedure, should thoroughly evaluate their interactions with healthcare providers and clinics, and structure their arrangements with healthcare providers and clinics to comply with applicable safe harbor requirements under the AKS.

The Physician Self-Referral Law (42 U.S.C. § 1395nn), also referred to as the Stark law, is a strict liability statute that prohibits physicians from referring patients to receive certain designated health services payable by a federal healthcare program from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Designated health services include durable medical equipment and supplies, which means wearable devices that are considered DME can implicate the Stark Law if a physician owns equity in the device manufacturer and also refers his/her patients to the device manufacturer.

Under the Sunshine Act (42 CFR § 403.900 *et seq.*), Open Payments is a national disclosure program intended to promote greater transparency and accountable healthcare system through public disclosure of certain payments or transfers of value made by applicable manufacturers and group purchasing organizations to covered recipients, such as physicians and teaching hospitals. Covered devices or medical supplies include devices or DME that require premarket notification or approval by the FDA and are covered by Medicare, Medicaid, or the Children's Health Insurance Program, either separately or as part of a bundled payment. Applicable manufacturers of such covered products must report annually to CMS' Open Payments certain payments or transfers of value provided to physicians or teaching hospitals. Reportable payments or transfers of value include consulting fee, speaker fees, honoraria, gifts, food and beverage provided by device companies' salespeople, payment for certain research activities, charitable contributions, royalty or license fees, grants, and space rental or facility fees. Manufacturers of devices that do not meet the definition of a covered product, such as general wellness products that are not regulated by the FDA, are not subject to the Sunshine Act. Thus, wearable device companies should design their products and plan their FDA regulatory strategies carefully and in view of potential downstream regulatory burdens as well as criteria for coverage and reimbursement, which may require FDA premarket notification or approval, as coverage/reimbursement by CMS, the largest healthcare payer in the United States, can be critical for business growth.

State Regulation

In addition to federal laws, many states have similar or, in some cases, more restrictive, anti-kickback, physician referral, transparency, or privacy laws that apply to medical devices, which add another layer of complexity to how wearable devices may be regulated. For example, Fitbit customers in various states have brought a class action lawsuit against the company under state consumer protection statutes, alleging the company falsely claimed its devices could track sleep schedules, citing an academic study that found the Fitbit devices over-counted sleep time by about 67 minutes per night when compared to the most accurate sleep-measuring technology.[10]

Manufacturers, distributors, and wholesalers of medical devices may be required to obtain state licensure or permit before engaging in commercial activities in a state. Therefore, wearable device companies should consult with counsel on state healthcare laws before commercial launch and business growth in new states.

Conclusion

The wearable device industry is well-positioned to take advantage of a consumer climate focused on convenience, efficiency, and data integration. What remains to be seen is which companies can distinguish themselves by navigating a complex regulatory environment while maximizing product potential. Given the prevalence of federal and state hurdles that are applicable to wearable device technology and use, a comprehensive regulatory compliance program can help springboard decisive companies into industry leaders.

David Hoffmeister
650-354-4246
dhoffmeister@wsgr.com

Georgia Ravitz
202-973-8806
gravitz@wsgr.com

Jamie Ravitz
202-973-8804
jravitz@wsgr.com

Paul Gadiock
415-947-2059
pgadiock@wsgr.com

Eva Yin
206-883-2572
eyin@wsgr.com

[10] Lauren Berg, Law360, Fitbit Class Attys Seek $7M Fees In Sleep-Tracker Deal, May 13, 2019, *available at* https://www.law360.com/articles/1158824; see *Brickman et al. v. Fitbit Inc.*, case number 3:15-cv-02077, in the U.S. District Court for the Northern District of California.

A Conversation with Katharine Ku, Chief Licensing Advisor at WSGR

Attorneys Vern Norviel and Charles Andres recently sat down with Katharine "Kathy" Ku, WSGR's new chief licensing advisor, to discuss questions and situations that come up in the licensing process. Kathy is an internationally recognized leader in the field of licensing and technology transfer, and spent almost three decades as the executive director of Stanford University's Office of Technology Licensing. Kathy's many accomplishments include implementation of the Cohen-Boyer DNA Cloning licensing program which contributed to the creation of the biotechnology industry, and her work on the document: *In the Public Interest: Nine Points to Consider in Licensing University Technology*. This document, which provides nine principles that continue to influence and guide university licensing, should be read by any start-up contemplating taking a university license.

Q: Why did you join Wilson Sonsini Goodrich & Rosati?
Kathy: It's a terrific firm with a great reputation for supporting start-ups. I can contribute by helping to pull technologies from universities and research organizations—and placing the technologies into start-ups. I hope to also enhance WSGR and client relationships with universities and with other partners.

Q: Why is licensing unique?
Kathy: Licensing is fundamentally a different transaction from many other legal transactions because a license—especially an exclusive license—is the basis for a long-term relationship. There aren't winners and losers in a license agreement—the agreement needs to be a win-win for both parties. If the parties have a bad relationship, the words in an agreement will not make solving a problem easier. In contrast, if the parties have a good relationship, problems and issues are easier to work out. I want WSGR and its clients to have the best possible relationships with universities.

Q: **What are some challenges of dealing with a tech transfer office?**
Kathy: Clients can be uncertain about how to work with a tech transfer office. Universities are usually thrilled to have a potential licensee but from a company perspective, it may be the first time a company is dealing with a university on a business transaction.

Q: What is important for staying on the good side of a university tech transfer office?
Kathy: It is essential for a company to establish a good relationship with the tech transfer office with regular and open communication. This is important in the early stages of the relationship, particularly during negotiations, because it sets the tone for future interactions. Both parties have an interest in commercializing the technology and both need each other to be successful. When the tech transfer office understands the challenges of commercialization and the company respects what the university hopes to accomplish, issues can be resolved.

Q: Let's talk about some of the ways you can help our clients.
Kathy: I can serve as a bridge between different cultures. I am practical and can offer advice based on the extensive situations and solutions that I've seen through my multi-decade career. I want to help enable our clients to do what they want to do—transfer or acquire IP through licensing. Very few licensing situations are completely straightforward, so I can work with WSGR attorneys/clients to come up with creative, workable, approaches.

Q: You have a broad network of technology transfer contacts throughout the country. How can that benefit the firm, its clients, and universities?
Kathy: Tech transfer colleagues know that I understand their business and concerns. It is easier to work with someone you already know—so I hope my network of contacts can help the firm, our clients, and the universities connect and conduct business effectively.

Q: What are some current trends in and around university licensing?
Kathy: Many universities have gap/proof-of-concept funds which can be used to do the one or two experiments that will help with proof-of-concept experiments that can convince a company to take a license. Typically, the funding per project is in the range of $25,000 to$50,000 and the total amount of money available to projects is limited. Companies should be aware of this.

In addition, many universities are helping start-ups start by providing business and legal advice or services. Some are raising venture funds which will be dedicated to the particular university's start-ups. This trend is finding its way into license provisions of these universities.

Many tech transfer offices have the responsibility to create a more entrepreneurial ecosystem for their region. Tech transfer offices are creating internal groups such as venture creation or business

development to focus on the different aspects of this broader technology transfer mission; it also means that these offices are growing rapidly and need to have people with different skills than previously required.

More than ever, universities are interested in the equity component of a license, including the anti-dilution and pre-emptive rights provisions. Particularly in biotech deals, they are focusing on the sublicensing clauses because they understand that partnering with big pharma is very likely. They are keenly aware of "change of control" provisions and want to participate in the upside if a company is acquired.

Q: Please talk a little bit about the evolution of university licensing.
Kathy: Tech transfer has "professionalized" over the years. There are training programs and best practices and discussion forums. Professionals cross over from industry business development/licensing to university tech transfer and vice versa.

Over the years, university tech transfer practitioners have come to realize that start-ups may be the best hope for technology commercialization, particularly when an inventor is passionate about developing the technology. Some universities have developed "express licenses" to make it very easy for a start-up to take a license.

Sometimes technology transfer creates potential perceived and/or actual conflicts of interest, so universities have had to develop robust conflict of interest policies and management processes for its researchers and for itself as an institution.

University licensing is becoming more about technology transfer in a much broader sense than in the past. Some universities, such as MIT and Stanford who are in entrepreneurial ecosystems, do not have to do much to encourage start-ups. But most universities throughout the world would like to create an entrepreneurial culture to transfer their technology to start-ups, to create jobs and a more economically vibrant region.

Q: What are some things that companies should be aware of in the Bayh-Dole Act?
Kathy: If a company licenses government-funded inventions from a university or accepts direct government funding for their own research via a grant or SBIR funding, the Bayh-Dole Act applies. Prior to Bayh-Dole, the U.S. government owned inventions funded by federal research dollars. In 1980, the Bayh-Dole law was created to spur the economy and encourage innovation by allowing recipients of government funding to retain title to inventions, but only if the recipient agrees to certain terms and conditions. If the recipient fails to comply, the government can take ownership of those inventions. Therefore, compliance is extremely important. Companies who are affected by the Bayh-Dole law should take their obligations seriously.

Q: Any last thoughts?
Kathy: The world is bursting with new and important innovations. If we all work together to play our part to help commercialize them, we can bring them more quickly to the marketplace to benefit society. That's a good thing!

PitchBook Ranks WSGR Among Top Firms in Q1 2019 VC Healthcare and Pharma Deals

In spring 2019, PitchBook ranked Wilson Sonsini Goodrich & Rosati among the leading law firms for U.S. venture financings in the first quarter of 2019. In particular, the venture capital data company's legal rankings for Q1 2019 issuer-side venture financing deals placed WSGR ahead of all other firms by the total number of rounds of equity financing raised on behalf of clients in the healthcare devices and supplies industry. The firm also ranked No. 2 in the: i) pharmaceutical and biotechnology; and ii) healthcare services and systems sectors. In general, WSGR was ranked No. 3 in PitchBook's list of the most active global law firms in VC transactions ranked by the total number of venture capital deals in Q1 2019.

The Role of Automation in Legal Practice

By Jeffrey Nagashima and David Wang

Lawyers constantly struggle against demands on both the timing and volume of work. Historically, they have only been able to offer clients two out of three of the following options when providing legal services: cheap, quick, and high quality. Advances in technology, in particular document automation, now enable legal services providers to offer clients all three choices simultaneously.

Lawyers can, and should be, developing a "technology-enabled practice." By using a growing number of legal software solutions, lawyers are now able to offer higher quality and more efficient legal services. Some legal software solutions focus on assisting lawyers with routine legal tasks such as document preparation or document review. Other legal software solutions assist with legal process management, such as facilitating document coordination among deal teams or preparation and collection of transaction document signatures. Typically, legal software solutions focus on outsourcing low value-adding routine legal tasks thereby reducing costs to clients and allowing lawyers to focus on high value-adding services.

Generally, document preparation involves a combination of high value-added sophisticated legal work and lower value-added clerical work. Specifically, selecting an appropriate precedent for a client's unique situation, drafting changes to the document based on business terms and current circumstances, and reviewing the document for off-market terms or conditions based on a lawyer's expertise would fall into the high value-added category. Lower value-added services would include simple formatting, spelling and reference checks, and directly inputting information or changes provided by clients in appropriate document locations. Historically, when a lawyer prepared a document they performed both a combination of these high and low value-added services; however, document automation provides a technical solution by automating low value-added work.

Through automation, documents will adjust automatically based on inputs provided by the lawyer without requiring the lawyer to revise the document in its entirety. This thereby dramatically reduces the drafting time, saving clients' money and allowing legal services providers to focus on higher value-added services. Furthermore, by outsourcing these tasks to legal software solutions, human error in document preparation is correspondingly reduced as the risk of transcription error falls.

Finally, the working template which is used as the model for each instance of a particular document, is typically prepared and regularly reviewed by a number of legal experts across various specialties. However, in a typical setting, cost considerations often make it impractical to have a large number of legal specialists weigh in on one off, fairly routine documents. Consequently, not only is it cheaper to create, but the final documentations is usually of higher quality.

For example, document automation software can now quickly convert a company formation input questionnaire into a package of company formation documents. Through the automation procedure, low value-added costs associated with this type of documentation preparation (i.e., inputting repeat information and ensuring consistency between documents) have been outsourced to the software solution. Similar document automation tools have been used by a number of law firms to automatically generate preliminary venture financing documents.

While document automation generally focuses on creating good "first drafts" of legal documents, other legal software solutions assist lawyers with their review of legal documents. These solutions can quickly analyzes a document and identifies a number of errors such as incorrectly defined terms or cross references errors and provides an intuitive dashboard to resolve them. Some software providers claim to reduce proofreading time by up to 90 percent.

Similarly, legal technology companies and law firms have developed a number of other software solutions to tackle a wide variety of legal issues. For example, cloud-based transaction closing software aims to improve the transaction closing process by allowing lawyers to check the status of transaction documents and automatically generate and track signature packages for clients. Comparable to other tools, this software tool also focuses on outsourcing a low value-added aspect of legal services allowing lawyers to work more efficiently and focus on higher value-added services. Even general use workplace productivity software has become integrated into legal practices to help teams track, organize, and manage their work. For example, task management tools can be created and allocated to team members who then update their progress in real time. This allows project managers to quickly identify the status of the project and allocate resources appropriately.

As legal software solutions continue to proliferate they mainly focus on the commoditized section of the legal services market. These software solutions usually include some type of automated standard form documentation, such as generating company formation documents or preparing generic commercial agreements from input questionnaires. Law firms have already started to provide these legal tools on a free-to-use basis under the theory that client use of their product would provide for opportunities to upsell more sophisticated legal services. For example, Wilson Sonsini Goodrich & Rosati has made available on the firm website a venture financing term sheet generator for anyone to use. This term sheet uses a cloud-based questionnaire and then generates a fairly complete first draft of a venture financing term sheet. Clients

and potential clients have been able to use this term sheet to go out and solicit initial expressions of interest or to build out their own knowledge of the various permutations of venture financing.

While more traditional technology companies and ex-law firm practitioners focus on providing these types of commoditized legal software solutions, law firms have begun to develop technology solutions for legal issues requiring deeper legal expertise. For example, WSGR's software development subsidiary, SixFifty, offers a technology solution, informed by WSGR's deep privacy and cybersecurity legal expertise, to help companies comply with the California Consumer Privacy Act (CCPA) which will come into effect January 2020. It can assist companies with preparing compliance documents, mapping consumer data flows, collecting and managing consumer requests. The service also provides CCPA training.

Overall, legal software solutions, particularly document automation, are continuing to grow in importance as part of a lawyer's practice. Developing a robust technology-enabled practice is becoming a key differentiator in the highly competitive legal services market and allows lawyers to focus on providing more value-added services to clients instead of spending time on low value-added tasks. Clients should, if they haven't already, start inquiring as to what tools counsel is using to facilitate their provision of legal services.

Jeffrey Nagashima
650-849-3437
jnagashima@wsgr.com

David Wang
650-849-3003
dawang@wsgr.com

Matthew J. Meyer Joins WSGR's Life Sciences Practice as Chief Client Corporate Development Advisor

On June 3, 2019, Wilson Sonsini Goodrich & Rosati announced that Matthew J. Meyer has joined the firm as chief client corporate development advisor. He will lead the firm's life science business advisory practice, and he will be based in San Francisco.

WSGR's life sciences business advisory practice is a newly formed, innovative resource aimed at providing start-up and emerging life sciences companies with insights, capabilities, and strategies to help them thrive and address some of their most challenging issues, including partnering, financing, operations, and commercialization.

Matt is an experienced executive who has held diverse roles of increasing responsibility across a wide range of private and public biopharma, med tech and precision medicine companies in the U.S. and Europe, including Pfizer, Novartis, CareDx and Counsyl. His leadership capabilities include delivery of strong commercial results, structuring and executing partnering transactions across the product life cycle and working with management teams and boards to address complex business issues.

Matt has been instrumental in the growth of multiple venture-backed, emerging life science companies which have gone on to private sales or IPOs. These companies had novel business models or game-changing technologies for which he helped achieve critical milestones.

"Matt's combined business development, partnering, commercial and investment experience, coupled with his extensive legal background in life science companies, is uniquely suited to lead this innovative business advisory practice," said Ian Edvalson, a WSGR partner and co-leader of the firm's technology transactions practice. "His level of insight into company formation, operations, and financing matters complements the expertise we offer our clients."

Matt earned his J.D. from the Villanova University School of Law, and received his B.A. in Government from Cornell University, cum laude.

For more information about WSGR's life science business advisory practice, contact Matt Meyer at 415-947-2097 or mjmeyer@wsgr.com.

Select Recent Life Sciences Client Highlights

Tilos Therapeutics to Be Acquired by Merck for Up to $773 Million
On June 10, 2019, Merck, a leading global biopharmaceutical company, announced that it has entered into a definitive agreement to acquire Tilos Therapeutics, a privately held biopharmaceutical company developing therapeutics targeting the latent TGFβ complex for the treatment of cancer, fibrosis, and autoimmune diseases. Under the terms of the agreement, Merck, through a subsidiary, will acquire all outstanding shares of Tilos for total potential consideration of up to $773 million, including an upfront payment as well as contingent milestone payments. WSGR is representing Tilos Therapeutics in the transaction. For more details, please see https://www.businesswire.com/news/home/20190610005054/en/Merck-Acquire-Tilos-Therapeutics.

Amicus Therapeutics and the University of Pennsylvania Announce Major Expansion of Gene Therapy Collaboration
On May 29, Amicus Therapeutics and the Perelman School of Medicine at the University of Pennsylvania announced a major expansion to their collaboration with rights to pursue collaborative research and development of novel gene therapies for lysosomal disorders and 12 additional rare diseases. The collaboration has been expanded from three to six programs for rare genetic diseases. In addition to these three new programs, a discovery research agreement provides Amicus with exclusive disease-specific access to rights to collaborate with Penn's Gene Therapy Program to develop potentially disruptive new gene therapy platform technologies and programs for the majority of lysosomal disorders and 12 additional rare diseases. WSGR represented Amicus Therapeutics in the transaction. More information is available at https://www.globenewswire.com/news-release/2019/05/29/1856150/0/en/Amicus-Therapeutics-and-the-University-of-Pennsylvania-Announce-Major-Expansion-of-Gene-Therapy-Collaboration.html.

Peloton Therapeutics to Be Acquired by Merck for Up to $2.2 Billion
Merck, a leading global biopharmaceutical company, and Peloton Therapeutics, a clinical-stage biopharmaceutical company, announced on May 21 that the companies have entered into a definitive agreement under which Merck, through a subsidiary, will acquire privately held Peloton in a deal potentially worth up to $2.2 billion. Peloton is focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α for the treatment of patients with cancer and other non-oncology diseases. The acquisition is expected to close in the third quarter of 2019. WSGR is representing Peloton in the transaction. Read more details at https://www.businesswire.com/news/home/20190521005432/en/Merck-Acquire-Peloton-Therapeutics-Bolstering-Oncology-Pipeline.

Concentric Analgesics Raises $76 Million in Series B Round
Concentric Analgesics, a clinical-stage biopharmaceutical company focused on developing and commercializing novel, non-opioid pain therapeutics, announced on May 21 that it secured $76 million in a Series B round of financing. The financing was led by Oracle Investment Management and included additional new investors Venrock Healthcare Capital Partners, Cowen Healthcare Investments, and Kern Whelan Capital. Concentric intends to use the proceeds from the financing to advance its lead product candidate, CA-008, a non-opioid therapeutic providing long-lasting pain relief after a single local administration, into late-stage clinical trials targeting the post-surgical market. WSGR represented Concentric in the transaction. The firm also represents the company in other various corporate and IP matters. For additional details, please see https://www.concentricanalgesics.com/concentric-analgesics-raises-76-million-in-series-b-financing.

Parvus Therapeutics Enters into Agreement with Genentech
Parvus Therapeutics, a biopharmaceutical company focused on the development of disease-specific immunoregulatory medicines to treat autoimmune diseases without impairing normal immunity, announced on May 16 that it has entered into a worldwide collaboration and license agreement with Genentech, a member of the Roche Group, to develop, manufacture, and commercialize novel Navacim™ therapeutics for the treatment of inflammatory bowel disease, autoimmune liver diseases, and celiac disease. WSGR represented Parvus in the transaction. For additional details, please see https://www.businesswire.com/news/home/20190516005018/en/Parvus-Therapeutics-Enters-Worldwide-Collaboration-License-Agreement.

Verve Therapeutics Raises $58.5 Million in Series A Financing
On May 7, Verve Therapeutics, a next-generation cardiovascular company, announced its launch to discover and develop therapies that safely edit the adult human genome to permanently reduce a person's risk of coronary artery disease, the most common form of heart disease and the leading cause of death worldwide. The company also announced that it raised $58.5 million in a Series A round of financing led by GV, with participation from ARCH Venture Partners, F-Prime Capital, and Biomatics Capital. In addition, Verve said that it has assembled a portfolio of key gene editing technologies, which includes a collaboration with Beam Therapeutics and license agreements with Harvard University and the Broad Institute of MIT and Harvard. Verve has also entered into a collaboration with Verily to develop and optimize nanoparticle formulations for therapeutic delivery. WSGR represented Verve in its Series A round of financing. The firm also represented the company in its collaboration agreements with Beam and Verily and its license agreements with Broad and Harvard. To read more, please

see https://www.businesswire.com/news/home/20190507005300/en/Verve-Therapeutics-Founded-Protect-Heart-Disease-Launches.

EverlyWell Raises $50 Million
EverlyWell, a digital health company, announced on April 16 that it has raised $50 million in a round of financing led by Goodwater Capital and Highland Capital Partners. Next Coast Ventures, NextGen Venture Partners, SoGal Ventures, and others also participated in the round. The company will use the funding to expand its digital platform and scale existing partnerships with leading brands like CVS and Humana. WSGR represented EverlyWell in the transaction. Please see https://www.prnewswire.com/news-releases/everlywell-raises-50-million-in-funding-to-accelerate-digitally-enabled-consumer-lab-testing-platform-300832314.html to read more.

Tessa Therapeutics Announces Collaboration with Merck
Tessa Therapeutics, a clinical-stage immunotherapy company focused on autologous and off-the-shelf, allogeneic therapies targeting solid tumors, announced on April 15 that it has entered into an agreement with Merck through a subsidiary to evaluate Tessa's armored human papillomavirus-specific T cell (HPVST) therapy in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with recurrent or metastatic HPV 16 and 18-positive cervical cancer. Under the agreement, Tessa will conduct a multi-center phase 1b/2 trial to evaluate the safety and efficacy of the combination. The trial is planned for initiation in the U.S., Singapore, and South Korea. WSGR represented Tessa Therapeutics in the transaction. For further details, please see https://www.prnewswire.com/news-releases/tessa-therapeutics-announces-collaboration-with-merck-investigating-the-combination-of-keytruda-pembrolizumab-and-virus-specific-t-cell-therapy-targeting-human-papillomavirus-in-cervical-cancer-300832067.html.

Twist Bioscience Announces Antibody Optimization Agreement with Pandion Therapeutics
On April 10, Twist Bioscience, a company enabling customers to succeed through its offering of high-quality synthetic DNA using its silicon platform, announced a new collaboration with Pandion Therapeutics to apply its antibody optimization platform to the targeting arm of a bispecific antibody. Pandion Therapeutics is a biotechnology platform company developing therapeutics to achieve localized immunomodulation to treat autoimmune and inflammatory disease. WSGR represented Twist Bioscience in the agreement. Please see https://www.businesswire.com/news/home/20190411005229/en/Twist-Bioscience-Announces-Antibody-Optimization-Agreement-Pandion for additional details.

Silk Road Medical Announces Closing of Initial Public Offering
On April 8, Silk Road Medical, a medical device company focused on reducing strokes through minimally invasive technology that safely and effectively treats carotid artery disease through "transcarotid artery revascularization," announced the closing of its initial public offering of 6,000,000 shares of common stock, and the full exercise of the underwriters' option to purchase 900,000 additional shares of common stock from the selling stockholders, at a public offering price of $20.00 per share. The gross proceeds from the offering were approximately $120 million, before deducting underwriting discounts and commissions and estimated offering expenses. The shares commenced trading on the Nasdaq Global Market on April 4 under the ticker symbol "SILK." WSGR represented Silk Road Medical in the offering. More information is available at https://investors.silkroadmed.com/news-releases/news-release-details/silk-road-medical-announces-closing-initial-public-offering-and.

Twist Bioscience and LakePharma Form Strategic Collaboration to Provide Antibody Discovery and Development Services
On April 4, Twist Bioscience, a company enabling customers to succeed through its offering of high-quality synthetic DNA using its silicon platform, and LakePharma, a leading U.S.-based biologics contract research, development, and manufacturing organization, announced a strategic collaboration to offer antibody discovery and development solutions to pharmaceutical and biotechnology customers. WSGR represented Twist Bioscience in the transaction. For more details, please see https://lakepharma.com/news/2019-04-04-twist-bioscience-and-lakepharma-form-strategic-collaboration-to-provide-antibody-discovery-and-development-services.

Arrinex Acquired by Stryker
Medical technology provider Stryker announced on February 25 that it has completed its acquisition of Arrinex, a Menlo Park-based medical device company that has developed a novel cryoablation technology for the treatment of chronic rhinitis, a condition that affects more than 24 million people in the U.S. each year. Terms of the deal were not disclosed. WSGR represented Arrinex in the transaction. Please visit https://www.globenewswire.com/news-release/2019/02/25/1741930/0/en/Stryker-acquires-Arrinex.html for additional details.

Peloton Therapeutics Raises $150 Million in Series E Round
Peloton Therapeutics, a drug discovery and development company advancing first-in-class oral medicines for cancer and other serious conditions, announced on February 20 that it has closed an oversubscribed $150 million Series E round of financing. The financing was led by RA Capital Management and was joined by new investors, including Eventide Asset Management, Biotechnology Value Fund, OrbiMed, EcoR1 Capital, Vida Ventures, Curative Ventures, and Driehaus Capital Management. Peloton's existing investors, including The Column Group, Nextech Invest, Topspin Fund, Tichenor Ventures, and Foresite Capital Management, also participated in the round. WSGR represented Peloton in the transaction. For more information, please visit https://www.businesswire.com/news/home/20190220005028/en/Peloton-Therapeutics-Secures-150-Million-Series-Financing.

Upcoming Life Sciences Events

Phoenix 2019: The Medical Device and Diagnostic Conference for CEOs
October 16-18, 2019
The Ritz-Carlton, Half Moon Bay
Half Moon Bay, California
https://phoenix.wsgrevents.com/

The 26th Annual Phoenix Conference will bring together top-level executives from large healthcare companies and CEOs of small, venture-backed firms for an opportunity to discuss critical issues of interest to the medical device industry today, as well as to network and gain valuable insights from both industry leaders and peers. This exclusive, two-day event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead.

WSGR Women in Life Sciences Reception
January 12, 2020
San Francisco, California

Held in conjunction of the J.P. Morgan 38th Annual Healthcare Conference, Wilson Sonsini Goodrich & Rosati's annual Women in Life Sciences Reception brings together women leaders in the life sciences industry for an energetic evening of networking with colleagues.

WSGR Biotech Reception
January 15, 2020
San Francisco, California

Wilson Sonsini Goodrich & Rosati's annual Biotech Reception, held to coincide with the J.P. Morgan 38th Annual Healthcare Conference, brings together industry leaders and innovators from around the globe for a lively evening surrounded by friends and colleagues in the life sciences field.

rEVOLUTION Symposium
April 1-3, 2020
LINE DC
Washington, D.C.
https://www.wsgr.com/news/revolution/

The rEVOLUTION Symposium has become the place to discuss the most important strategic problems facing pharma and biotech CSOs. We will examine the organization and management of R&D to uncover new disruptive discovery and development models and assess the continued impact of pricing, reimbursement, regulation, and globalization on our industry.

Casey McGlynn, a leader of the firm's life sciences practice, has editorial oversight of *The Life Sciences Report* and was assisted by Philip Oettinger, Elton Satusky, Scott Murano, and James Huie. They would like to take this opportunity to thank all of the contributors to the report, which is published on a semi-annual basis.


Casey McGlynn
(650) 354-4115
cmcglynn@wsgr.com


Philip Oettinger
(650) 565-3564
poettinger@wsgr.com


Elton Satusky
(650) 565-3588
esatusky@wsgr.com


Scott Murano
(650) 849-3316
smurano@wsgr.com


James Huie
(650) 565-3981
jhuie@wsgr.com

WSGR
Wilson Sonsini Goodrich & Rosati
PROFESSIONAL CORPORATION

650 Page Mill Road, Palo Alto, CA 94304-1050 | Phone: 650-493-9300 | Fax: 650-493-6811 | www.wsgr.com

Austin Beijing Boston Brussels Hong Kong London Los Angeles New York Palo Alto San Diego San Francisco Seattle Shanghai Washington, DC Wilmington, DE