

Factoring in Human Factors

By Shannon E. Clark, P.E., CEO, UserWise, Inc.

According to a recent *British Medical Journal* research report, the mean rate of death from medical error in U.S. hospitals is estimated to be over 251,000 people per year. Though many medical errors are due to medication errors, patient hand-offs, and issues with hospital processes, other errors are attributable to poor medical device design.¹ Human factors engineering plays an essential role in reducing the rate of these avoidable deaths and additional adverse outcomes.

The U.S. Food and Drug Administration (FDA) defines "human factors engineering" as:

"The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device

users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use."

Overall, the objective of human factors engineering is to minimize or eliminate human error through the design of the medical device. The FDA defines "use error" to mean:

"user action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by device failure and (3) did or could result in harm."

"Human factors" at the FDA is synonymous with usability risk reduction. The focus of usability risk reduction is to design a medical

device that minimizes risks related to human error. The errors of focus when reducing usability risks from most devices are usually cognitive in nature (i.e., not ergonomic in nature).

The need for usability testing is driven by FDA regulation 21 CFR 820.30(g), which states: "Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions." Usability validation testing is one type of design validation, and it includes bringing in end-users to simulate use of the final medical device in a simulated use environment.

There is a trend of increasing FDA enforcement of human factors requirements for medical device development and, correspondingly, increased adoption of human factors processes among medical device manufacturers.

In This Issue

Factoring in Human Factors..... Pages 1-4

An Interview with Justin Klein of New Enterprise Associates..... Pages 5-7

Life Sciences Venture Financings for WSGR Clients Pages 8-9

Patenting MedTech with Software – An Update for Inventors..... Pages 10-12

The Serious and Immense Impact of a Medical Device Hack Pages 13-17

Select Recent Life Sciences Client Highlights..... Pages 18-19

Upcoming Life Sciences Events.....Page 20

¹ Martin A. Makary and Michael Daniel, "Medical error—the third leading cause of death in the US," 353 *British Medical Journal* i2139, 2016.

Continued on page 2...

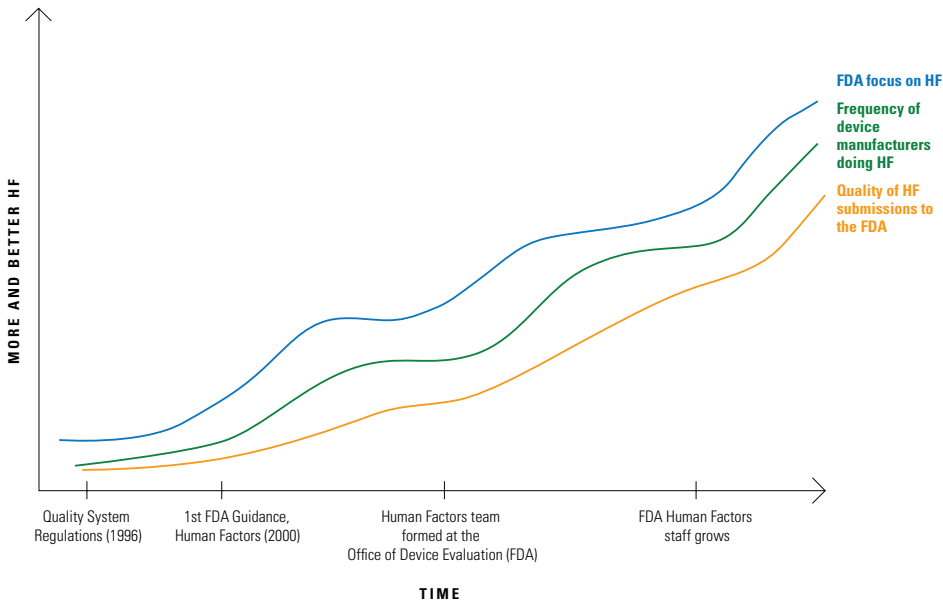
WSGR Ranked as No. 1 Life Sciences Law Firm

For the second consecutive year, Wilson Sonsini Goodrich & Rosati has been ranked No. 1 in the Life Sciences Law Firm Index, which identifies the most active and relevant firms for life sciences companies based on research conducted by Breaking Media, the publisher of *MedCity News*. Researchers compiled the index based on data in three research categories—corporate, intellectual property, and regulatory—and also incorporated information on firms' work with start-up companies and thought leadership contributions.

For more information, please visit <http://abovethelaw.com/2017/05/wilson-sonsini-tops-life-sciences-law-firm-index-for-2nd-straight-year/>.

Continued from page 1...

Figure 1: FDA Focus on Human Factors (HF) and Industry Response



*Adapted from "Human Factors/Usability for Medical Devices: An Historical Perspective," Ron Kaye Office of Device Evaluation, CDRH, Food and Drug Administration, NIST Workshop on Usability and HER Technology, June 7, 2011.

The FDA shared a graph titled "Center Effort on HF/Usability and Industry Response" in 2011 (Figure 1). The graph suggests that there was a low level of FDA focus on human factors when the quality system regulations were published in 1996. As a result, very few manufacturers were incorporating human factors processes when the FDA issued its first human factors guidance in 2000.

On February 3, 2016, the FDA updated its human factors guidance, *Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices* (originally published in 2000). The effect of the amended guidance has been rippling quickly through the medical device industry. While manufacturers of higher-risk medical devices began adopting the new human factors processes in 2011 and earlier, many new and established medical device

manufacturers continue to scramble to incorporate the new human factors process.

The FDA Human Factors Engineering Process

The FDA-recommended human factors process can be described in five steps, as depicted in Figure 2 below.

Step 1: User Research

The goal of user research is to help identify and refine design requirements by understanding the users and the use environments. The focus of user research is on making data-backed assumptions about who the end-users will be and how they will perceive and interact with the product in their context of use.

User research helps to identify design requirements by obtaining direct input from intended users. It reveals what people are really thinking and how people really behave through observation at point of use. The researcher evaluates environmental, social, and motivational aspects of the design. User research can include shadowing doctors, nurses, and technicians in various hospital settings and/or conducting one-on-one interviews to reveal user needs. For home-use medical devices, user research is particularly valuable for defining where the device may be used (e.g., Will they keep their device at their bedside or on a wet surface on their bathroom sink? What level of water ingress testing should we consider conducting?).

Step 2: Use-Related Risk Analysis

A use-related risk analysis is performed to:

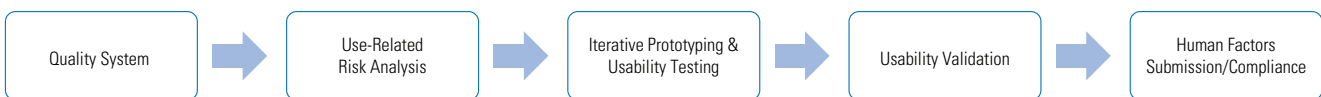
- Predict potential use errors and associated consequences for patients and users
- Identify risk control measures to make the design as error-proof as possible
- Identify use scenarios to examine during usability testing

The use-related risk analysis is a powerful tool to prioritize design efforts and tackle the most serious use errors first. Various use errors are prioritized according to how serious their consequences are, how frequently they occur, and how easily they can be detected by end-users.

It is best to eliminate the given use errors through the design of the device. If it is not possible to eliminate a use error through design, the following options are pursued, in order of preference:²

1. Guard against the use error

Figure 2: The FDA-Recommended Human Factors Process



² Content from ISO 14971:2007.

2. Warn against the use error
3. Information for safety
 - a. Labeling
 - b. Instructions for use
 - c. Training
4. Remove feature (least desirable)

Step 3: Iterative Prototyping and Usability Testing

Usability testing is conducted with early-stage prototypes to reveal the prototypes' strengths, weaknesses, and potential use errors. Usability testing includes observing intended users' interaction with the device to reveal potential use errors. Subjective feedback on the design is also collected from the usability study participants, but observation of end-users is usually the primary method for collecting data.

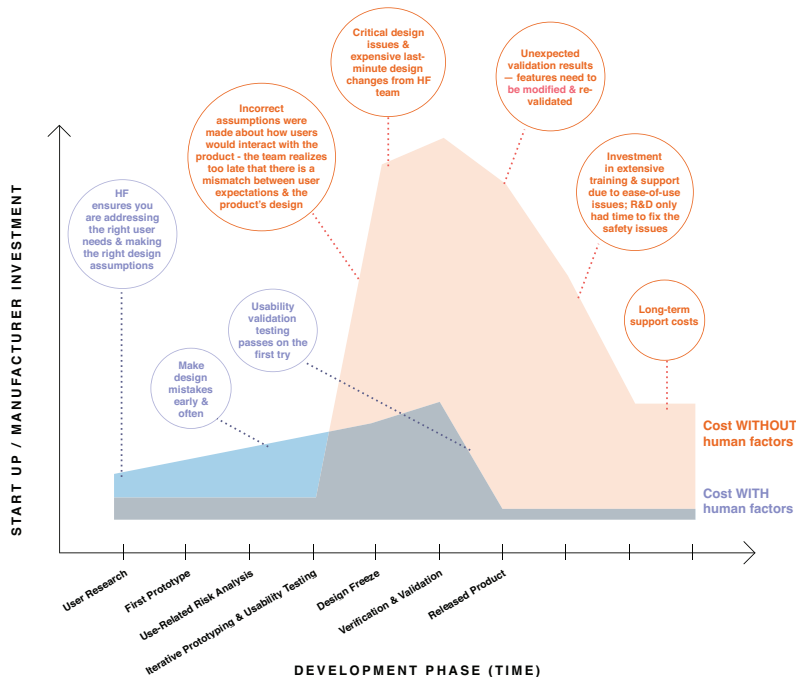
Multiple early-stage usability studies—called “formative usability testing”—are usually conducted. In response to each study, rapid modifications are made to the device design in an effort to improve the usability and reduce use errors. It is an iterative process consisting of three stages:

1. Conducting usability testing of early product prototypes
2. Identifying use errors
3. Guiding design changes to eliminate these use errors

These three stages are repeated until results from formative usability testing show that the design is ideal or that the use errors are minimized.

Investing in iterative prototyping and usability testing can save time and money in the long run. The process allows a company to “take shortcuts” toward an optimized product by allowing imperfect designs to fail more quickly. It is expensive to invest in tooling and manufacturing of final prototypes, and the human factors engineering process facilitates obtaining usability data using low-fidelity prototypes. By conducting multiple usability studies and refining the product cheaply and early on, the development team can progress

Figure 3: Cost of Medical Device Development With and Without Human Factors



to the next development phases with greater confidence.

Step 4: Usability Validation

At the end of the development process, usability validation examines user interactions with the device user interface to identify use errors that could result in serious harm.

Usability validation also demonstrates that mitigations in the use-related risk analysis are sufficient to minimize use errors.

Per FDA requirements, usability validation testing must include the following:

- At least 15 participants as representative intended users for each user profile
 - Participants cannot be internal employees
 - Participants must be U.S. residents (non-U.S. citizens can be included)
- All critical tasks (i.e., tasks associated with use errors that could lead to serious harm)
- Software and hardware configuration equivalent to the final design

- Changes post-validation may trigger the need for further testing or may require a justification for no further usability validation testing

- Test conditions that are sufficiently realistic to represent actual conditions of use

The results of the usability validation study are used to demonstrate the safety and efficacy of the device with respect to usability.

By conducting multiple usability studies and refining the product cheaply and early on, the development team can progress to the next development phases with greater confidence

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Step 5: Human Factors Submission/Compliance

A human factors submission report is prepared at the end of the human factors process. This report describes the full human factors process and explains how use errors were minimized.

A human factors engineering submission report is usually required for a pre-market approval (PMA) submission, and the FDA reserves the right to request the human factors engineering report for other types of submissions as well (e.g., 510(k)). UserWise recommends always submitting a human factors engineering submission report in order to expedite and streamline the FDA's review of a submission.

For compliance outside of the U.S., it is necessary to assemble a usability engineering file and compliance checklist for IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*.

UserWise recommends always submitting a human factors engineering submission report in order to expedite and streamline the FDA's review of a submission

Tips on Human Factors

Here are some common human factors pitfalls that UserWise has seen companies encounter:

- Not having a clear human factors strategy when meeting or corresponding with the FDA for the first time
- Assuming that your medical device requires usability validation testing when it could have been validated in another manner

- Combining human factors with pre-clinical work or a clinical trial—this may seem like a good idea at first, but it inevitably presents unique challenges
- Recruiting fewer than 15 end-users for validation—FDA human factors reviewers at the Office of Device Evaluation rarely accept fewer than 15 end-users per user type (i.e., 15 nurses and 15 surgeons in the case where both users use the device)
- Forgetting to mine the databases on FDA.gov to discover what recalls and medical device reports (MDRs) have been reported for similar products before communicating with the FDA—the FDA knows about the recalls and MDRs, so these should be well analyzed and thought through before corresponding with the FDA
- Inadequately resourcing a development project with designers who “know the user” and bake usability into a medical device
- Aligning incentives between R&D management and the goals of the marketing and sales organizations to encourage R&D to reduce on-market training and product support costs in the long term

Conclusion

Usability testing is a rigorous process that has become increasingly important for obtaining a 510(k) clearance or a premarket approval. Planning and testing during the early stages of product development can yield great benefits and efficiency in bringing a product to market. The human factors process can save huge amounts of research and development time and money, as well as minimize delays during an FDA submission, reduce the risk of product recalls, and reduce on-market training and maintenance costs.



Shannon E. Clark is the founder and CEO of UserWise, a consultancy that helps medical device manufacturers and start-ups to design safe and easy-to-use medical devices. The consultants at UserWise conduct usability testing for a variety of medical devices, ranging from surgical robots to home-use injection platforms. UserWise consultants also perform safety assessments to comply with U.S. and international regulations related to human factors.

Before founding UserWise in 2015, Shannon was a human factors engineer at Intuitive Surgical and Abbott Laboratories. She graduated in 2010 from UCLA with a B.S. in mechanical engineering and a technical breadth in technology management. Additionally, Shannon is a Certified Professional Industrial Engineer, holds two patents, and has written and published three books.

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About UserWise

Our mission is to inspire human factors engineering best practices within both Fortune 500 medical device companies and start-ups, and to facilitate the development of usable medical devices. We work with companies to fulfill any and all of the steps in the usability engineering process to facilitate the design of safe and usable medical devices. We offer risk analysis, usability testing, and compliance documentation, as well as corporate trainings and assistance navigating regulatory clearance.

To learn more, visit
www.UserWiseConsulting.com.

An Interview with Justin Klein of New Enterprise Associates



*Wilson Sonsini
Goodrich &
Rosati partner
James Huie
recently sat down
with Justin Klein,
a partner at
New Enterprise
Associates
(NEA), one of the*

world's largest and most active venture capital firms. Among other topics, Justin discussed NEA's mission and commitment to investing in early-stage companies, the current state of the healthcare investment industry, and the advice he'd offer to entrepreneurs. Below is a selection of highlights from their discussion.

Tell us about NEA. What's the firm's overall mission and how does NEA try to differentiate itself across its core markets?

NEA is a classically constructed venture capital firm. We're going to celebrate our 40th anniversary this year, making us one of the oldest and—because of our firm size and strategies—one of the largest, most active venture capital firms across all sectors. Technology innovation, which broadly includes categories like consumer or enterprise-oriented technologies and electronics, makes up a substantial portion of where NEA invests. And healthcare is the other major category in which we focus our efforts. Within each NEA investment fund, which we tend to raise every 2.5 to 3.5 years in regular cycles, we're committing about a third of our dollars to the healthcare space, which includes biopharma therapeutics, medical devices, and healthtech, as well as healthcare services and healthcare IT.

One of the things we prioritize as a capital partner to entrepreneurs is being in a position

to actively guide our portfolio companies to expand their market opportunities and scale with our capital and other resources over time. We raise some of the largest funds in the industry, and we believe that being able to invest capital at scale allows us to be an entrepreneur's partner throughout his or her company's lifetime, from seed and Series A stages all the way through growth equity, and potentially as they go public and beyond. What we've found is that in almost all of our sectors, it is increasingly capital-efficient to start a business and demonstrate early traction in multiple markets. But to really scale, a business continues to take resources, and NEA strives to be in a position where we can partner with those entrepreneurs early, help them craft and further expand their vision, and then be their lead financial partner for every step of the journey.

What are you looking for in your portfolio companies in terms of unique qualities or traits of success, particularly in the healthcare space?

In the healthcare space, we're most focused on investing in companies that present open-ended business opportunities, such as standalone businesses that could go public and self-finance over time, or those that become coveted acquisition candidates for some of the larger players in the industry. We like to build companies and franchise opportunities predicated on solutions that address significant unmet clinical needs, and do so at reduced costs. I think the pairing of those phrases is important. It's something we've been focused on for our entire history. To be something big, we believe a company really has to demonstrate evidence to convince all stakeholders to adopt new technologies or new ways of delivering healthcare.

Of course, we also look at other things like the nature of the unmet need, the clinical

development hurdles, the regulatory path, reimbursement/payment structures, and the go-to-market opportunities to commercialize something. These are all critical elements. Thematically, we try to stay open-minded, focusing on different subsectors, whether it's therapeutics, devices, or services, and over time we migrate toward the larger, open-ended opportunities in each category.

In the last few years, you've been a part of some of the largest-ever exits for venture-backed medical device companies. Looking forward, what opportunities do you see and what concerns you most about the current healthcare market?

Broadly, we remain very enthusiastic about investing in healthcare. We try to be mindful of things like economic and political cycles that could affect our portfolio companies and therefore our investments. If possible, we try to identify long-term secular trends that we think our companies will succeed in, regardless of some of the shorter-term market or political cycles.

Our system faces real challenges in terms of the affordability of—and access to—healthcare. We expect that to continue to be a very hot topic. Ultimately though, healthcare is one of the most important dimensions of a person's life. It's close to 20 percent of our GDP, and the opportunity for technology to improve clinical outcomes or reduce costs still remains fairly open-ended. We want to be careful not to invest in entities that bear significant political risks, where opinions about how to do things fall in or out of favor, which could completely derail an investment opportunity. But we do believe there are some durable trends that allow us to invest in a number of these companies and to support them from their earliest stages all the way through to being mature businesses.

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Do you feel like the healthcare industry is on an upward trend? Do you envision more activity in the next few years, or at least in 2017?

We're coming out of a significant bull market in the biopharma space as of a couple of years ago. Of course, there also have been some pullbacks along the way, but most people believe there can be a relatively healthy IPO window this year in multiple healthcare subsectors. Public market investors continue to look for growth opportunities in their portfolios, and strategic acquirers need to find revenue growth opportunities in new businesses to expand their markets, particularly after a period of consolidation among a lot of the big pharma and medtech companies. And we're seeing financing environments and acquisition/IPO discussions look fairly positive across all of our categories. So, we think it's going to continue to be a fairly healthy time in the ecosystem.

In January 2016, you gave an interview at the J.P. Morgan Healthcare conference where you underscored NEA's commitment to investing in early-stage companies and, specifically in your case, early-stage medical device companies. Can you offer some insights into NEA's reasoning and commitment to early-stage companies?

I recently did a quick tabulation of our medical device investment activity in our last two funds, and between those, we made 13 new investments, nine of which were at the Series A or seed stage, including companies that we seeded in incubators. Those numbers would probably surprise most folks, because overall, the medtech venture market has shifted away from pre-regulatory approval or pre-data-stage medical device companies since around 2008. On the contrary, we have deliberately tried to embrace that stage of investment because, one, there are still a lot of opportunities and, frankly, there is less competition from other investors investing in those deals. And two, at a high level, we're trying to invest in the parts of the medtech ecosystem where we as investors and our start-up companies have some competitive advantage. There can be

merits to a late-stage investment focus, but it's also important to recognize that there are competencies that big, established companies have in these channels, like commercial distribution or manufacturing, that are difficult for a start-up to compete with.

Where our companies excel is in identifying unmet needs, developing innovative products that have IP protection, and executing on a development plan that generates evidence for the FDA, payers, patients, and physicians to really embrace things and bring them to market. Some of our peers have moved away from earlier-stage investing, but I don't think that's irrational. From 2008 to 2012, particularly for medical devices, there were a lot of headwinds, particularly around the U.S. regulatory process. Although we've seen the regulatory climate become much more reasonable and predictable in recent years, that era was so taxing for investors and their portfolio companies that it's hard to stomach re-testing earlier-stage investment where capital requirements and timelines were extended pretty significantly, almost beyond the reach of a lot of our peers.

We are intentional in our strategy to raise relatively large funds, which gives us the ability to sustain our commitment to companies over the long term, and gives them the opportunity to complete the mission. When we invest in early-stage companies, we try to be very thoughtful about the total capital requirement and syndicate formation. I think maybe 10 to 15 years ago, we might have taken on some Series A innovations or technologies that would have required a series of multiple de-risking financings over time, whether it's validating technology development, clinical evidence, regulatory approval, reimbursement, or commercial traction. There are probably fewer of those types of opportunities we're willing to step up for. We try to find spaces where our companies are in an overall strong position to execute on a plan that answers really hard stakeholder questions relatively early in the process of building that company or funding that program.

What are some of the key events that you look forward to attending each year? Are there any new conferences that you're eyeing?

Annually, there are a handful of events I try to attend that are fairly spaced out during the course of the year. It probably starts in January with the J.P. Morgan Healthcare Conference, which is kind of the annual "must attend." There are a couple of conferences in the spring and early summer, whether it's WSGR's Medical Device Conference, the MedTech Investing Conference in Minneapolis, or Piper Jaffray's annual conference. Then, in the fall, there are some different events that investment banks or other industry groups put together, and those are a great way to keep in regular touch with people.

Throughout the year, I typically attend a handful of conferences that focus on clinical areas where we have active portfolio companies, such as cardiovascular disease, interventional pain, or personalized medicine. And sometimes I attend conferences that overlap the due diligence we're doing on a new space.

Outside of the U.S., are there any particular markets that you or your companies are most interested in?

As a firm, NEA is certainly global in its reach. Our interest in start-up companies, as well as the markets where they'll bring their innovations, is global. We have a very active investment practice in Asia, largely on the tech side, though we've made some select healthcare investments there over time. More recently, we've expanded our investment practice to include more opportunities in Europe. One of the companies I'm involved with is called FIRE1 (Foundry Ireland), which is an Ireland-domiciled medical device incubator that we funded in partnership with the Foundry, Lightstone Ventures, and Medtronic. Since creating the incubator, we've advanced the program to include an outstanding senior management team that's based on the ground in Ireland, and we're actively building the company there. Some other examples of

investments in our biopharma practice have been companies coming out of Western Europe and the UK, including Adaptimmune in the immuno-oncology space, NightstaRx in the gene-therapy space, and CRISPR Therapeutics in the gene-editing space. Overall, something like 90 percent of our dollars are committed to U.S.-domiciled companies. But we recognize that terrific innovation is happening all over the globe, and we're comfortable with backing teams based in those countries. We're working with them to build our companies across the Atlantic, sometimes opening offices and/or taking them public in the United States, and in other cases growing them for the long term, regardless of borders.

Do you have any advice for entrepreneurs who are looking to work with NEA or who may be trying to start a company for the first time?

First, I think it's encouraging that the past five years have been a fantastic time to start a company and raise capital for that company, whether it's in tech or healthcare. There's a lot of fundamental innovation happening in all sectors of the venture ecosystem that's creating tremendous opportunities for new businesses. We like to see entrepreneurs who are passionate about an area where they have a lot of deep experience. And in general, we try to support them, recognizing that their time is the most precious thing that any of us have to commit to one of these ventures. So, if it's an entrepreneur that really knows their space well and they've identified a problem and developed a technology-driven solution that we share an interest in, we'd love to talk to them as early as possible in the company's formation process. Whether or not we choose to invest can be affected by a variety of different considerations, but we look for opportunities to get involved where we can make an impact on that company's trajectory. That may mean funding them with the right amount of capital, or it may mean helping them set a vision that aims for something bigger or more expansive than they would have otherwise if they hadn't had that conversation.

It's often the case that we meet entrepreneurs but may not invest for three or four years. But along the way, we're able to track their progress and help provide introductions to folks who may join their team, or we may introduce other investors who get involved earlier than we do. Then, at the right opportunity, we'll sign up to lead a financing and, once we do, we are fully committed to them. Having those early conversations during that relationship-building process is fundamental, because these can be very durable partnerships. It's rarely an 18-month relationship; usually it's three, five, seven, or even 10 years, and hopefully what comes out of it is interest in doing it again. Around 60 percent or more of our investment opportunities are introduced to us through entrepreneurs or folks that we worked with in the past, and if we had a great experience together, we'd love to find that next venture to do it again and again.

I think that touches one last point. You've been an investor for quite some time now. What would you say the biggest differences are between being an investor now and being an investor when you first started?

From a personal perspective, this is my 11th year of investing and I've had the benefit of being part of NEA and working with some fantastic folks who came before me in our medical technology practice. I started at NEA as an associate, where I was entirely supporting other partners. Today I'm proud to be on a dozen boards and am actively trying to grow our medical device and healthcare technology investment practice with my colleagues in the service of our companies and our industry. With board responsibilities and other leadership opportunities outside of the firm, I've only become busier over time, which is great. It's been a fantastic experience.

In each of these investing climates, the markets move in cycles, whether it's related to politics or the economy, and there's always something to learn or figure out how to do better. It could be solving some sort of complicated financing or M&A transaction, or

creating investment opportunities that wouldn't otherwise exist. There are always new, creative ways to do this job better and be a better partner or entrepreneur. So, I don't know whether there have been dramatic differences from my first day to yesterday, but it's a continual process that's been a lot of fun.

Justin Klein joined NEA in 2006 and is a partner on the healthcare team. Justin focuses on medical device, healthcare technology, and biopharmaceutical company investments. He serves as a director of Advanced Cardiac Therapeutics, Cartiva, ChromaCode, FIRE1, Intact Vascular, Personal Genome Diagnostics, PhaseBio Pharmaceuticals, Relievant Medsystems, Senseonics (NYSE: SENS), VertiFlex, Vesper Medical, and VytronUS. Justin's past board memberships and investments include CV Ingenuity (acquired by Covidien), Nevro (NYSE: NVRO), Topera (acquired by Abbott), TriVascular (NASDAQ: TRIV, acquired by Endologix), and Ulthera (acquired by Merz). He is also a member of the advisory boards for Duke's Innovation & Entrepreneurship Initiative, the Johns Hopkins Center for Bioengineering Innovation & Design, and the National Venture Capital Association's Medical Industry Group and its Medical Innovation and Competitiveness Coalition (MedIC), as well as a member of AdvaMed's Business Development Committee.

Prior to NEA, Justin worked for the Duke University Health System—reporting directly to the hospital CEO on health system strategy, finance, and clinical service unit operations—as Duke built one of the nation's first and largest healthcare integrated delivery systems. Justin concurrently earned his M.D. from the Duke University School of Medicine and his J.D. from Harvard Law School. He has also served as a member of the board of trustees of Duke University, where he earned his A.B. in economics and his B.S. in biological anthropology and anatomy.

Life Sciences Venture Financings for WSGR Clients

By Scott Murano, Partner (Palo Alto)

The table below includes data from life sciences transactions in which Wilson Sonsini Goodrich & Rosati clients participated across the first and second halves of 2016. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the two six-month periods.

Life Sciences Industry Segment	1H 2016 Number of Closings	1H 2016 Total Amount Raised (\$M)	1H 2016 Average Amount Raised (\$M)	2H 2016 Number of Closings	2H 2016 Total Amount Raised (\$M)	2H 2016 Average Amount Raised (\$M)
Biopharmaceuticals	31	420.39	13.56	33	370.91	11.24
Genomics	5	31.01	6.20	5	32.30	6.46
Diagnostics	8	37.84	4.73	11	98.45	8.95
Medical Devices & Equipment	48	309.39	6.45	47	321.76	6.85
Digital Health	10	40.18	4.02	10	71.33	7.13
Healthcare Services	4	8.24	2.06	6	140.08	23.35
Total	106	847.05		112	1,034.83	

The data demonstrates that venture financing activity increased during the second half of 2016 compared to the first half of 2016 with respect to the total amount raised and the number of closings. Specifically, the total amount raised across all industry segments increased 22.2 percent from the first half of 2016 to the second half, from \$847.05 million to \$1,034.83 million, while the number of closings across all industry segments increased 5.7 percent, from 106 closings to 112 closings.

Notably, the industry segment with the largest number of closings—medical devices and equipment—experienced a slight decrease in number of closings, but an increase in total amount raised during the second half of 2016 compared to the first half. Specifically, the number of closings in medical devices and equipment decreased 2.1 percent, from 48 closings

to 47 closings, but the total amount raised increased 4 percent, from \$309.39 million to \$321.76 million. The industry segment with the second-largest number of closings—biopharmaceuticals—experienced an increase in number of closings, but a decrease in total amount raised during the second half of 2016 compared to the first half. Specifically, the number of biopharmaceutical closings increased 6.5 percent, from 31 closings to 33 closings, while the total amount raised decreased 11.8 percent, from \$420.39 million to \$370.91 million. Meanwhile, diagnostics, the industry segment with the third-largest number of closings during the second half of 2016, experienced increases in both number of closings and total amount raised; the number of closings increased 37.5 percent, from 8 closings to 11 closings, while the total amount raised increased 160.2 percent, from \$37.84 million to \$98.45 million. All

remaining industry segments (in descending order of 2H 2016 number of closings)—digital health, healthcare services, and genomics—were flat or up in number of closings and up in total amount raised during the second half of 2016 compared to the first half.

In addition, our data suggests that Series A and Series B financing activity compared to bridge financings and Series C and later equity financings increased during the second half of 2016 compared to the first half. The number of Series A closings as a percentage of all closings increased from 31.8 percent to 41.1 percent, while the number of Series B closings as a percentage of all closings increased from 15.9 percent to 17 percent. Offsetting those gains, bridge financing and Series C and later financing activity relative to all other financings decreased during the second half of 2016. The number of bridge financing closings as a percentage of all

Series A and Series B financing activity compared to bridge financings and Series C and later equity financings increased during the second half of 2016 compared to the first half

closings decreased from 31.8 percent to 26.8 percent, while the number of Series C and later financing closings as a percentage of all closings decreased from 15 percent to 10.7 percent.

Average pre-money valuations for life sciences companies increased for Series A financings and Series C and later financings, but decreased for Series B financings during the second half of 2016 compared to the first half. The average pre-money valuation for Series A financings increased 70.1 percent, from \$10.86 million to \$18.47 million; the average pre-money valuation for Series B

financings decreased 58.5 percent, from \$105.2 million to \$43.65 million; and the average pre-money valuation for Series C and later financings increased 18.6 percent, from \$120.97 million to \$143.45 million.

Other data taken from transactions in which all firm clients participated in the second half of 2016 suggests that life sciences is tied with services as the second-most attractive industry for investment. During that period, life sciences (as well as services) accounted for 24 percent of total funds raised by our clients, while the software industry—traditionally the most popular industry for investment—accounted for 29 percent of total funds raised.

Overall, the data indicates that access to venture capital for the life sciences industry increased from the first half of 2016 to the second half. It is also worth noting that financing activity during the first half of 2016 had increased significantly over the second half of 2015, and the second half of 2015 had increased over the first half of 2015—so the second half of 2016 represents the third consecutive six-month period of improved financing activity. Moreover, the second half of 2016 represents the second consecutive six-month period of improved financing

activity at the Series A stage in terms of number of closings. The second half of 2016 also saw an increase in pre-money valuations for Series A financings, unlike the prior six-month period, which witnessed an increase in number of Series A closings but a decrease in pre-money valuations. This suggests that companies are moving into a greater position

The second half of 2016 was the third consecutive six-month period of improved financing activity

of leverage at the Series A stage, as there are more Series A deals getting done and at relatively higher pre-money valuations.



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WSGR Ranked No. 1 for Q1 2017 Venture Financings

Dow Jones VentureSource recently ranked Wilson Sonsini Goodrich & Rosati as the leading law firm for U.S. venture financings in the first quarter of 2017.

Dow Jones VentureSource's legal rankings for Q1 2017 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. The firm is credited as the legal advisor in 61 rounds of financing, while its nearest competitor advised on 42 rounds of financing.

Of particular interest to *The Life Sciences Report*, WSGR ranked first for Q1 2017 issuer-side U.S. deals in the healthcare and medical devices and equipment industries.

Patenting MedTech with Software – An Update for Inventors

By John Shimmick (Associate, Palo Alto) and
Charlie Hagadorn (Associate, Seattle)

MedTech includes traditional medical devices and smart devices brought about by the tech revolution. From surgical robotics to apps for smart phones, smart devices and connectivity have forever changed the way we think of healthcare and how it is delivered.

Examples of computer-based medical devices include surgical robotic systems and lasers used for LASIK surgery. Additional examples include smart patches worn by patients for remote monitoring and 3D scanners used to plan orthodontic treatment. Even an iPhone programmed with the right app can transform a smart phone into a healthcare instrument.

The smart phone illustrated in the figure to the right is an example of many new MedTech devices. Often there is a local device, such as a smart phone, that has sensors or actuators that interact with the local environment. The local device also could be a spectrometer, a surgical robot, a laser eye surgery system, or a diagnostic instrument, for example. A local processor, such as a processor of the smart phone, is coupled to the local device or sensor within the device that may gather data from the local device and may control the local device. The local device transmits the data to a remote server in the cloud. The remote server can be configured to do much more than merely store data—it can be configured to perform analytics and machine learning, and offer guidance to the local device.

It is important to note that software can transform old or existing hardware into a new invention. For this reason, an update on recent case law and strategies for claiming MedTech



software in the United States may be of interest to inventors.

The Good News: Software Is Still Patentable

The United States requires that subject matter recited in the claimed invention be patent eligible. In particular, 35 USC § 101 defines “patent-eligible subject matter” as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” The Supreme Court has created judicial exceptions that preclude patentability under § 101 and held that laws of nature, natural phenomena, and abstract ideas do not qualify as patent-eligible subject matter. In recent years, several cases in the United States have cut back on the extent to which software can be patented because the claims at issue failed to recite patent-eligible subject matter.¹ The good news, however, is that software is still patentable in the United

States, provided that the claims are not directed to a judicial exception.²

Under *Alice*, courts will apply a two-part test. The first step is to determine whether the claim at issue is directed to a judicial exception such as an abstract idea. In step two, the court will consider whether the claims contain an “inventive concept” sufficient to “transform the nature of the claim into a patent-eligible application.”³ In assessing patentability under § 101, it is important that the court not oversimplify the claims.⁴ In *McRO*, the claims were directed to automated animation of lip synchronization to sounds. In particular, the claims were limited to rules that evaluate subsequences consisting of multiple sequential phonemes. These claims were held not to be directed to an abstract idea.⁵ If claims are directed to an abstract idea, the claims can still be found patentable, so long as they do not preempt the field. In general, courts will look at the technical problem being solved

¹ See, e.g., *Bielski v. Kappos*, 130 S. Ct. 3218, Supreme Court (2010); *Mayo Collaborative v. Prometheus Labs.*, 132 S. Ct. 1289, Supreme Court (2012); *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, Supreme Court (2014).

² See, e.g., *DdR Holdings, LLC v. Hotels. Com, LP*, 773 F. 3d 1245, Federal Circuit (2014); *ENFISH, LLC v. Microsoft Corp.*, 822 F. 3d 1327, Federal Circuit (2016); *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F. 3d 1299, Federal Circuit (2016).

³ *Alice*, 134 S.Ct. at 2355.

⁴ *McRO*, 837 F. 3d at 13133.

⁵ *McRO*, 837 F. 3d at 13133 at 1316.

and the solution presented with the claimed invention. In *Enfish*, the claims were directed to a self-referential table that was a specific type of data structure designed to improve the way a computer stores and retrieves data in a memory table feature. These claims were viewed as a particular implementation of a solution to a problem in the software arts, and were held not to be directed to an abstract idea.⁶

Some keys to success for software MedTech patents include emphasizing that the claimed subject matter:

- improves another technology or technical field;
- improves the functioning of the computer itself;
- applies the idea with, or by use of, a customized machine;
- includes a limitation other than what is well-understood, routine, and conventional in the field; and/or
- includes unconventional steps that confine the claim to a useful application.

MedTech IP features that can help secure patent eligibility include:

- providing solutions to problems that arise only in the context of the technology itself (problem did not pre-date the technology);
- improvements to efficiency that better utilize computing resources to handle massive data sets, enhance speed, or allow scale-up;
- sensors, external to the computer running the software, that must feed data to the software; and
- distinct machines, other than the computer running the software, that must communicate with each other.

U.S. Patent Office Subject-Matter Eligibility Resources

Over the past few years, the U.S. Patent Office has produced guidelines and other

resources for their examiners with respect to subject-matter eligibility under § 101 and related case law. The evolving guidelines address how examiners should formulate their subject-matter eligibility rejections under § 101 and how examiners should evaluate an applicant's response to such rejections. In addition, the U.S. Patent Office also compiles regularly updated summaries of § 101 subject-matter eligibility decisions from the U.S. District Courts, the Court of Appeals for the Federal Circuit, and the United States Supreme Court.

The U.S. Patent Office subject-matter eligibility page is available at: <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>.

If You Have a Killer App, Consider Patenting It

In general, the U.S. Patent Office will give patentable weight to software instructions that are stored on a tangible medium, such as an app. Given that software is patentable, an app that transforms a smart phone into more than a mere phone is still patentable, provided that the statutory requirements are met. In general, drafting the patent application and claims to address the technical problem solved by the software app can help with patentability, because the courts and the U.S. Patent Office often look to this when evaluating whether the claims recite patent-eligible subject matter as noted above.

In general, drafting the patent application and claims to address the technical problem solved by the software app can help with patentability

MEDTECH SOFTWARE MOVES FAST

Track One Prioritized Exam at the USPTO is a valuable tool to keep patents aligned with MedTech product and business cycles.

The traditional route to a U.S. patent takes 3-4 years. Sometimes this means that the patent is granted around the same time the claimed invention is phased out as obsolete or superseded by the next-generation product.

The Track One Prioritized Exam program allows a patentee to get a final disposition on patentability from the examiner within 12 months of the request for prioritized status being granted.

Under the traditional route, patents take much longer to issue:

- Average time to first action on the merits from filing = about 16 months
- Average time to final disposition from filing = about 26 months (56 months with one or more RCEs)
- Average number of office actions = 2.5

Compare to prioritized applications:

- Average time to first action on the merits from grant of request = about 4 months
- Average time to final disposition from grant of request = about 8 months
- Average number of office actions = 1.2

The bottom line is that, in the fast-moving MedTech space, we often recommend filing a non-provisional patent application under the Track One Prioritized Exam program.

⁶ *Enfish*, 822 F. 3d 1327 at 1339.

Continued on page 12...

Continued from page 11...

The claims can be written to cover the tangible medium that stores the software instructions of the app. These claims effectively cover the app that someone downloads onto their phone. For example, the claims can be directed to the software instructions of the app that control the local device and handle the processing and display of data.

Design Patents Can Protect Unique Devices and Graphic User Interfaces (GUIs)

The user display and interface that allows the user to interact with data are areas that may be patentable as well. Where a MedTech application includes a novel and non-obvious device or sensor and GUI, or way of presenting, summarizing, or formatting information, consider supplementing the utility patent application with a design patent application.

In general terms, a utility patent protects the way an article is used and works, while a design patent protects the way an article looks (the so-called “ornamental aspects”).

Where a MedTech application includes a novel and non-obvious device or sensor and GUI, or way of presenting, summarizing, or formatting information, consider supplementing the utility patent application with a design patent application

The ornamental appearance for an article includes its shape or configuration, along with the surface ornamentation applied to the article. Both design and utility patents may be obtained on an article if the invention resides both in its utility and ornamental appearance. U.S. patent law has evolved to allow the protection of the visual appearance of a GUI as “surface ornamentation” on the screen of a monitor or smartphone. This was first announced in *Ex Parte Strijland*, 26 USPQ 2d 1259 (BPAI 1992). New and non-obvious icons associated with GUIs are protectable via design patents. New and non-obvious aspects of the layout of the GUI, including the specific location of each element and even animations, are also protectable.

Design patents have other additional benefits:

- Speed – The typical time to a first office action is about 13 months and the average total pendency is about 20 months for a design application.
- Success – The allowance rate is about 84 percent for design applications.
- Global Scope – Many foreign jurisdictions have robust design protection regimes.
- Secrecy – Design applications do not publish unless and until they issue as an enforceable U.S. patent.
- Term – U.S. design patents have a term running 15 years from the date of grant.

Additional Strategies for Protecting MedTech

Many approaches can work, depending on the nature of the technology and the invention. In general, it is helpful to describe and claim the invention from several perspectives, including the local device and the remote server. For each of these, it can be helpful to have device

claims, method claims, and software claims (i.e., tangible medium claims). For example, the hardware that is used locally is often patentable. Examples of patentable hardware include specific tools used for surgical robotics, stents, and balloons that are used to treat patients. The general requirements for such inventions include novelty, non-obviousness, and utility. The system that is used locally, including the software, can also be patented, for example with a combination of hardware and software.

For software inventions, claims can often be written to cover how data is processed in the cloud (e.g., the server). In many instances, it can be helpful to have a hook between the server and the hardware. For example, if there is any special data from the local device that is being sent to the server, claims directed to the receipt and processing of this data with the server can provide useful points of distinction over the prior art.

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The Serious and Immense Impact of a Medical Device Hack

By David Hoffmeister (Partner, Palo Alto), Vern Norviel (Partner, San Francisco, San Diego, and Boston), Mark Solakian (Partner, Boston), Lou Lieto (Partner, Boston), Lydia Parnes (Partner, Washington, D.C.), Lawrence Perrone (Of Counsel, Washington, D.C.), Wendell Bartnick (Associate, Austin), Jennifer Fang (Associate, Boston), Prashant Girinath (Associate, Boston), Jake Gatof (Associate, Boston), and Charles Andres (Associate, Washington, D.C.)

On August 25, 2016, the investment firm Muddy Waters Research announced it had taken a short position in St. Jude Medical, Inc., and released a report suggesting a “strong possibility that close to half of” St. Jude revenues were about to disappear for a period of roughly two years because St. Jude’s implantable cardiac devices were allegedly vulnerable to cyber-attacks.¹ The report further stated that the cyber-attacks included crash attacks that cause devices to malfunction—including by apparently pacing at a potentially dangerous rate and a battery drain attack that could be particularly harmful to device-dependent users.²

The Muddy Waters report was largely based on analysis conducted by the cybersecurity company MedSec Holdings Inc. MedSec Chief Executive Officer Justine Bone suggested that St. Jude’s products had an “astounding” level of problems, including lack of encryption and authentication between devices, which could allow hackers to tap into implanted devices.³ MedSec had negotiated compensation tied to the success of Muddy Waters’ trade position, and Ms. Bone stated that partnering with Muddy Waters was the most powerful way to inflict pain on St. Jude for what she

called its “negligent level of attention to cybersecurity.”⁴

At the time of the Muddy Waters report, St. Jude was in the process of being acquired by Abbott Laboratories for \$25 billion. St. Jude shareholders were slated to receive, for each share of St. Jude common stock held, \$46.75 in cash and 0.8708 shares of Abbott common stock, representing about \$85 per

A host of different government agencies enforce laws that impose obligations on medical device manufacturers whose devices gather, store, or transmit information

St. Jude share, by the end of the year. In contrast, upon release of the Muddy Waters report, St. Jude stock closed at \$77.82, well below the deal value, leading analysts to speculate about the prospect of the acquisition by Abbott.

In response, St. Jude filed suit in the U.S. District Court for the District of Minnesota against Muddy Waters and MedSec, claiming that the allegations of cybersecurity vulnerabilities are false. St. Jude further alleged that the two companies used “false and misleading tactics” to scare patients, drop share prices, and make cash on the side as a result. St. Jude also released a

rebuttal report stating that the researchers at MedSec used “flawed test methodology on outdated software,” demonstrating a “lack of understanding of medical device technology.”⁵ As the case has proceeded, Muddy Waters has released additional videos and expert reports elaborating on its allegations. Abbott’s deal with St. Jude recently closed, and the company has continued to assert that these allegations are exaggerated and untrue.⁶

In this article, we explore select ramifications of a medical device hack, and provide some suggested practices for companies that offer medical devices to the public.

The Regulatory Landscape

Companies that manufacture and sell medical devices to the public face a complex regulatory landscape. A host of different government agencies enforce laws that impose obligations on medical device manufacturers whose devices gather, store, or transmit information.

HIPAA

For example, the Health Insurance Portability and Accountability regulations (HIPAA rules) issued and enforced by the Department of Health and Human Services (HHS) govern the privacy and security of protected health information (PHI).⁷ The HIPAA rules require implementation of reasonable and appropriate administrative, physical, technical, and organizational data security safeguards, including data security risk assessments, and ongoing risk management efforts to reduce cyber risks and vulnerabilities. Compliance with the HIPAA

¹ See <http://www.muddywatersresearch.com/research/stj/mw-is-short-stj/>.

² *Id.*

³ See <http://www.bloomberg.com/news/articles/2016-08-25/carson-block-takes-on-st-jude-medical-with-claim-of-hack-risk>.

⁴ *Id.*

⁵ See <http://www.reuters.com/article/us-st-jude-medical-cyber-idUSKCN11129K>.

⁶ Despite the company’s assertions that the allegations are exaggerated and untrue, the FDA contacted the company on April 12, 2017, and gave them 15 days to explain how it has addressed cybersecurity concerns.

⁷ The HHS regulations implementing the privacy and data security provisions of HIPAA are at 45 C.F.R. §§ 160, 164.

Continued on page 14...

Continued from page 13...

The FTC's enforcement actions require companies to implement and maintain data security programs that contain administrative, technical, and physical safeguards appropriate for the size and complexity of the business and the sensitivity of the personal information collected

rules is mandatory for device manufacturers that collect or transfer PHI.⁸

Device manufacturers and others that fail to comply with the HIPAA rules may face significant penalties. For example, in August 2016, HHS imposed a \$5.55 million penalty in a settlement with Advocate Health Care Network due, in part, to an alleged failure to conduct a data security risk assessment and to implement reasonable physical security measures. In roughly the same timeframe, HHS settled a case against Oregon Health & Science University (OHSU) that included a \$2.7 million civil penalty. The case was based on allegations that OHSU's risk assessment did not cover all electronic PHI that it maintained, and that OHSU did not reasonably and appropriately address documented vulnerabilities and risks in a timely manner. These settlements underscore the importance of conducting regular risk assessments, ensuring that the device manufacturer's data security mechanisms

meet ever-evolving threats, and confirming up-to-date HIPAA compliance.

The FTC

In addition to the specific rules that govern PHI, the Federal Trade Commission (FTC) has taken a similar approach to data security more generally. Relying on the very broad language in Section 5 of the FTC Act, which prohibits unfair and deceptive acts and practices in or affecting commerce, the FTC has brought over 60 enforcement actions against companies that allegedly failed to maintain adequate data security. Some of these actions were based on allegations that a company engaged in a deceptive practice if it did not have measures in place that matched the public representations it made about its data security efforts.⁹ Even without an affirmative representation, however, the FTC could challenge a device manufacturer's data security practices as unfair if the manufacturer failed to employ reasonable and appropriate measures to prevent unauthorized access to the information it collected.

The FTC's enforcement actions, virtually all of which are settlements, require companies to implement and maintain data security programs that contain administrative, technical, and physical safeguards appropriate for the size and complexity of the business and the sensitivity of the personal information collected from or about consumers. Similar to HHS, the FTC expects companies to engage in regular risk assessments. Device manufacturers should consider implementing data security plans that meet these standards and should review their public statements, including their privacy policies, to ensure that their practices are consistent with any public commitments.

The SEC

Public medical device companies should also consider whether a security vulnerability or data breach should be disclosed to investors and, by extension, to the U.S. Securities and Exchange Commission (SEC). The SEC has the authority to investigate possible violations of the federal securities laws, which include failures of public companies

Public medical device companies should consider whether a security vulnerability or data breach should be disclosed to investors and, by extension, to the SEC

to make adequate disclosures, withhold material information, and/or misrepresent to, or mislead, investors.¹⁰

In 2011, the SEC issued written guidance to public companies to assist them in "assessing what, if any, disclosures should be provided [to shareholders/investors] about cybersecurity matters." The guidance notes that "[a]lthough no existing disclosure requirement explicitly refers to cybersecurity risks and cyber incidents," if a public company experiences a "material cyberattack" it "would not be sufficient" for the company to merely disclose that a risk of cyber-attacks exists (i.e., via standard risk factors); rather, the public company may be required to disclose specifics regarding the cyber event and its potential costs and

⁸ The protocol that HHS uses in HIPAA compliance audits is available at <http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol/>.

⁹ For example, in January 2016, the FTC investigated and settled a case against Henry Schein Practice Solutions, Inc., for its alleged failure to provide industry-standard encryption of patient information despite advertising that it did so. *In re Henry Schein Practice Solutions, Inc.*, No. C-4575 (May 20, 2016).

¹⁰ While the SEC engaging in the regulation of cyber or security events may seem odd, it is not. The underlying facts of such securities violations related to a cyberattack or security vulnerability in a medical device likely do not undermine such authority. See Securities Act of 1933 (Securities Act), Sections 19 & 20, 15 U.S.C. §§ 77s, 77t; Securities Act of 1934 (Exchange Act), Section 21, 15 U.S.C. § 78u.

The Serious and Immense Impact of a Medical Device Hack

consequences. Outside of standard risk factor disclosure, the SEC recommends that companies review other disclosures such as the Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A), Business, Legal Proceedings, and Financial Statement sections.

In 2014, former SEC Commissioner Luis Aguilar publicly stated that cybersecurity is "of particular concern to the SEC" and that he hoped the disclosures discussed in the 2011 guidance "helped investors and public companies to focus and assess cybersecurity issues." Current SEC Chair Mary Jo White has reaffirmed the SEC's focus on cybersecurity.¹¹ Of course, the dispositive question in determining whether disclosure is required is whether the cyber-attack/security vulnerability is material to investors. In the recent past, many companies that have suffered large cybersecurity breaches have not reported these in their period or current reports on Form 10-K, 10-Q, or 8-K, and there have been a limited number of SEC enforcement actions for failure to disclose breaches.

Increasing scrutiny and public awareness of cyber incidents, however, could lead to a tightening of disclosure standards. Public companies should be careful to ensure proper disclosure.

The FDA

Finally, medical device companies should also consider the U.S. Food and Drug Administration's (FDA's) role in any medical device hack, especially where the hack could result in harm or death to patients.

The FDA regulates medical devices under, for instance, the Medical Device Amendments of 1976, and is keenly concerned with the safety and effectiveness of any medical

device. Recognizing that the cybersecurity of connected medical devices could present a growing problem, the FDA issued guidance on post-management security in 2016.¹² While the FDA's guidance touches on a number of areas, when evaluating post-market risk, the FDA encourages companies to:

- 1) monitor cybersecurity information sources for identification and detection of cybersecurity vulnerabilities and risk;
- 2) understand, assess, and detect the presence and impact of a vulnerability;
- 3) establish and communicate processes for vulnerability intake and handling;
- 4) clearly define essential clinical performance of the device to develop mitigations that protect, respond, and recover from the cybersecurity risk;
- 5) adopt a coordinated vulnerability disclosure policy and practice; and
- 6) deploy mitigations that address cybersecurity risk early and prior to exploitation.

The FDA has enforcement authority over medical device manufacturers. If a medical device: a) has uncontrolled risk, including a cybersecurity risk, to essential clinical performance that b) may reasonably cause serious adverse health consequences or death, then the manufacturer may be in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). FDCA violations may subject the device manufacturer to FDA enforcement actions, which can include the seizure and recall of medical devices.

Thus, if a medical device hack endangers the health or safety of patients, the medical device manufacturers should work with the FDA¹³ to mitigate the hacking-associated risks in an expeditious manner. Companies should be prepared to recall medical devices that contain the vulnerability, re-engineer the medical device or its software to remove the hacking vulnerability, and facilitate

communication shut-off of in-use medical devices until, for instance, a vulnerability-mitigating patch can be implemented.

Reporting obligations to various agencies of the federal and state governments, and mechanisms for addressing any FDA-mandated action, should be contained in the incident response plan that is prepared and in place ahead of any hack.

Plan of Action

Medical device hacks can have serious and wide-ranging repercussions: they can endanger patient lives, result in data breaches, materially affect stock prices, sour investor relationships, scuttle ongoing transactions, and tarnish a device manufacturer's reputation. Hackers may also attempt to use their ability to hack a device to extract a ransom in exchange for not harming patients relying upon the device, for providing information about how the hack is performed, or for containing or preventing a data breach.

To prepare for a possible intrusion, companies whose devices may be subject to hacking should develop an incident response plan. Companies should also create a culture that encourages and enables timely reporting, evaluation, and escalation of reports of a possible hack, regardless of the source. This can be achieved, for example, through comprehensive training of personnel and putting into place appropriate internal reporting mechanisms and structures.

In addition, companies should consider reviewing existing internal compliance policies, including those related to whistleblowing, to ensure these are designed to appropriately identify and address reports of information technology and cybersecurity issues. For example, whistleblowers and "white hat" hackers should have

¹¹ Earlier this year, the SEC hired Chris Hetner as its first Senior Advisor to the Chair for Cybersecurity Policy.

¹² See "Postmarket Management of Cybersecurity in Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff," FDA (Jan. 22, 2016), available at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf>.

¹³ Manufacturers regulated by the FDA may be required to report certain vulnerabilities under 21 C.F.R. parts 803, 806, and 1004.

Continued on page 16...

The Serious and Immense Impact of a Medical Device Hack

appropriate avenues to report potential cyber vulnerabilities.

Incident Response Plan and Team

The discovery of a hack is, at minimum, unsettling for any company. Senior managers are faced with making decisions under extreme time pressures, which can significantly impact the business.

In making these decisions, senior managers must be able to adjust in response to unfolding events and new information. Manufacturers may also have obligations to notify various government agencies such as the FDA and HHS, as well as affected individuals and their caregivers.¹⁴

Managing this effort can be complicated and uncertain, and being prepared is a significant factor in mitigating costs and damages associated with a hack. A key factor in security incident preparedness is developing an incident response plan. Supporting the centrality and importance of an incident response plan, research conducted by the Ponemon Institute shows that failure to have an incident response plan and team in place is a leading factor that can increase the incident costs and damages.¹⁵

Therefore, companies should draft, implement, and regularly test their incident response plans.¹⁶ Incident response plans typically include detailed instructions for the following:

- 1) Identifying and preparing the members of the incident response team. This includes determining, in advance, what roles and responsibilities key decision makers will have in the event of a hack.
- 2) Putting communication trees (e.g., phone trees) in place and pressure-testing them to ensure timely access to key decision makers in the event of a hack.
- 3) Cultivating good working relationships with law enforcement and relevant governmental agencies before any hack occurs (the first time law enforcement meets your team should not be after a hack occurs).
- 4) Understanding, implementing, and updating protective mechanisms required by different laws.
- 5) Identifying suspected incidents
- 6) Responding to suspected hacks from an IT perspective.
- 7) Bringing in outside legal and forensics experts; legal should be involved from the start.
- 8) Documenting a hack.
- 9) Mitigating damage from a hack.

- 10) Reporting response efforts to senior management.
- 11) Assessing legal and business risks from a security incident.
- 12) Determining breach notification obligations under applicable law and contracts. This includes state and federal government and agency reporting requirements, and their associated timeframes, as well as having a detailed plan for notifying health care providers and their patients.
- 13) If a ransom is demanded, deciding in advance the company's policy on ransom payment, keeping in mind that in some situations, the general policy may need to be adapted to meet incident specifics.¹⁷

Having and following an incident response plan helps an organization methodically take the proper steps while responding to an incident. Organizations with a plan will be able to more quickly assess the incident so that they can respond in a timely, cost-efficient, and effective manner.

Intellectual Property Considerations

Timely fixing or patching over the hack is

¹⁴ *FTC v. Wyndham Worldwide Corp.*, 12-CV-1365 (D. Ariz. 2012) (Complaint).

¹⁵ "Cost of a Data Breach Study: United States," Ponemon Institute (June 2016).

¹⁶ HIPAA requires regulated companies to have an incident response plan. HHS recently reached a settlement with the University of Mississippi Medical Center imposing a monetary penalty of \$2.75 million for HIPAA violations, including a failure to implement policies and procedures to address security incidents and a failure to properly notify individuals affected by a data breach.

¹⁷ Although this article does not deal with device design and manufacturing issues per se, companies should also consider taking steps to minimize the possibility of a device being hacked by: limiting the communication range of the device, using handshake protocols, making use of sophisticated encryption software, and allowing for external communication with the device to be shut off.

In addition, the FDA has provided draft guidance to medical device manufacturers to address pre-market concerns that networked medical devices may be vulnerable to cybersecurity threats that pose safety and effectiveness risks. See "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff," FDA (Oct. 22, 2014), available at: <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356190.pdf>.

While not legally binding, medical device companies are nevertheless strongly encouraged to follow the FDA's guidance, which, among other things, promotes the benefits of collaboration on and sharing of cyber risk information and intelligence with the medical device community through participation in an Information Sharing Analysis Organization.

The guidance also recommends using the National Institute of Standards and Technology Framework for Improving Critical Infrastructure Cybersecurity, and evaluating premarket risk by:

- identifying assets, threats, and vulnerabilities;
- assessing the impact of these threats and vulnerabilities on the device functionality and end-users/patients;
- assessing the likelihood of a threat and of a vulnerability being exploited;
- determining risk levels and suitable mitigation strategies; and
- assessing residual risk and risk acceptance criteria.

The Serious and Immense Impact of a Medical Device Hack

of paramount importance. But the ability to make hardware or software modifications that mitigate a hacking vulnerability may not simply be a technical problem. Any fix to a device's hardware or software should also not violate intellectual property to which the medical device manufacturer does not have rights. Thus, medical device manufacturers should maximize patent claim scope, strategically leverage licenses, and be aware of the relevant patent landscapes so as to create a "buffer" that allows for modifications that could be reasonably foreseeable in response to a hack.

Other Considerations

A medical device hack (or the possibility of a hack) raises diverse considerations beyond those discussed above. While it is not possible to address all of these, we point out three relevant examples as catalysts for further thought.

First, if a medical device manufacturer is involved in a transaction to sell the company, it should be careful in ensuring proper disclosure regarding the features and limitations of the medical device and proactively addressing any cybersecurity vulnerabilities to limit post-closing issues. The medical device manufacturer should also carefully consider how risk—in the form of indemnification—should be allocated after the deal closes.

Second, disclosure of a hack may put downward pressure on a medical device company's stock. To protect against hostile takeover at a vulnerable point, companies may want to consider implementing appropriate protective actions.

Finally, one way to minimize fallout from a hack is to control the narrative, which includes providing thoughtful responses, such as planned changes to address vulnerabilities. Strategic, clear, timely, and honest public

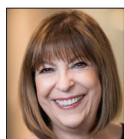
relations can help a company weather a hack. Any proposed communication, however, should be evaluated in light of the potential for the communication to be used in a future investor or patient lawsuit.

Conclusion

With the growth of medical devices that communicate wirelessly, share data, and can be adjusted or turned off remotely, the threat, reach, and potential fallout of hacking will continue to increase. Medical device manufacturers should proactively take steps to minimize the possibility of hacking, and have structures in place—including an incident response plan—to deal with a hack, should it occur.



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Ninth Circuit Affirms Dismissal of Securities Class Action Against Align Technology

On May 5, the U.S. Court of Appeals for the Ninth Circuit affirmed the dismissal of a securities class action filed against Align Technology, maker of the Invisalign teeth-aligning system. It's the first time the Ninth Circuit has ruled that the U.S. Supreme Court's decision in *Omnicare, Inc. v. Laborers Dist. Council Constr. Ind. Pension Fund*, which articulated the standards for pleading falsity of opinions, applies to Section 10(b) fraud claims of the Securities Exchange Act of 1934. It's also the first goodwill accounting case the Ninth Circuit has decided, holding that judgments about goodwill accounting should be treated as opinion statements. WSGR represented Align Technology and its former CEO and CFO in the matter. More information is available at <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/0517-align.htm>.

Outset Medical Announces \$76.5 Million in Funding

Outset Medical, a commercial-stage company delivering first-of-its-kind technology to the global dialysis market, announced on May 3 that it has raised \$76.5 million in a Series C round of equity funding. A new investor, funds advised by T. Rowe Price Associates, led the round, which also included participation from existing investors Fidelity Management & Research Company, Partner Fund Management LP, Warburg Pincus, Perceptive Advisors, and The Vertical Group. WSGR represented Outset Medical in the transaction. Please refer to <http://www.businesswire.com/news/home/20170503005383/en/Outset-Medical-Announces-76.5-Million-Funding-Innovative> for further details.

Advanced Cardiac Therapeutics Raises \$45 Million

Advanced Cardiac Therapeutics, a medical device company focused on developing a next-generation ablation catheter to treat cardiac arrhythmias, announced on May 2 that it has raised \$45 million in new equity funding led by Ajax Health alongside existing investor

New Enterprise Associates and new investor Questa Capital Management. WSGR represented Advanced Cardiac Therapeutics in the transaction. More information is available at <http://www.businesswire.com/news/home/20170502005519/en/Advanced-Cardiac-Therapeutics-Announces-45-Million-Funding>.

Savara Secures \$15 Million Loan and Security Agreement with Silicon Valley Bank

Savara, a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel therapies for the treatment of serious or life-threatening rare respiratory diseases, announced on May 1 that it has entered into a loan agreement—which provides for a \$15 million debt facility, \$7.5 million of which is immediately available to Savara—with Silicon Valley Bank. WSGR represented Savara in the transaction. Please refer to <http://www.prnewswire.com/news-releases/savara-secures-15-million-loan-and-security-agreement-with-silicon-valley-bank-300448508.html> for further details.

Savara Announces Closing of Merger with Mast Therapeutics

On April 27, Savara announced the closing of its previously announced merger with biopharmaceutical company Mast Therapeutics, under which the stockholders of Savara have become the majority owners of Mast, and the operations of Mast and Savara have combined. WSGR represented Savara in the transaction. For further details, please see <http://www.prnewswire.com/news-releases/savara-announces-closing-of-merger-with-mast-therapeutics-300447355.html>.

ChromaCode Raises \$12 Million in Series B Round

Molecular diagnostics company ChromaCode announced on April 27 that it has raised \$12 million in a Series B round of financing led by New Enterprise Associates with participation from Domain Associates and Okapi Ventures. The proceeds will be used to fuel development and establish the commercial infrastructure for the company's high-

definition polymerase chain reaction technology. WSGR represented ChromaCode in the transaction. For additional details, please see <http://www.prnewswire.com/news-releases/chromacode-raises-12-million-in-series-b-for-commercial-launch-and-appoints-alex-dickinson-as-executive-chair-300445858.html>.

Drchrono Raises \$12 Million

Drchrono, a provider of the electronic health record, practice management, medical billing, revenue cycle management, and healthcare application programming interface (API) platform, announced on April 6 that it has raised \$12 million in a Series A round of financing. The round was led by Runa Capital, with participation from Maxfield Capital, Quicken CEO Eric Dunn, and FundersClub. The proceeds will fuel the company's growth in larger healthcare organizations and revenue cycle management business. WSGR represented drchrono in the transaction. Please see <http://www.marketwired.com/press-release/drchrono-raises-12m-series-a-financing-round-build-medical-practice-future-2208370.htm> for further details.

Vital Therapies Announces Pricing of Public Offering of Common Stock

On March 22, Vital Therapies, a biotherapeutic company developing a cell-based therapy targeting the treatment of acute forms of liver failure, announced the pricing of an underwritten public offering of 8,750,000 newly issued shares of its common stock at a price to the public of \$4.00 per share, for gross proceeds of approximately \$35 million. WSGR represented Vital Therapies in the offering. Additional information is available at <https://globenewswire.com/news-release/2017/03/22/943085/0/en/Vital-Therapies-Announces-Pricing-of-Public-Offering-of-Common-Stock.html>.

AliveCor Raises \$30 Million Series D Financing

AliveCor, a leader in FDA-cleared mobile electrocardiogram technology for mobile devices, announced on March 16 that it has

Select Recent Life Sciences Client Highlights

raised \$30 million in a Series D round of financing led by Omron Healthcare with participation from Mayo Clinic and existing inside investors. WSGR represented AliveCor in the transaction. More details are available at <http://www.prnewswire.com/news-releases/alivecor-unveils-first-ai-enabled-platform-for-doctors-to-improve-stroke-prevention-through-early-atrial-fibrillation-detection-300424529.html>.

Vertiflex Completes \$40 Million Financing Round

On March 8, Vertiflex, a leading innovator of advanced, minimally invasive interventions for spinal stenosis, announced that it has completed a \$40 million round of financing led by new investors Endeavour Vision and H.I.G. BioHealth Partners, with participation from existing investors New Enterprise Associates, Thomas, Mc Nerney & Partners, and Alta Partners. WSGR represented Vertiflex in the transaction. For more information, please see <http://www.businesswire.com/news/home/20170308005249/en/Vertiflex-Completes-40-Million-Financing>.

First Circuit Reverses Dismissal of Amphastar Antitrust Suit

On March 6, the U.S. Court of Appeals for the First Circuit revived an antitrust suit brought by Amphastar Pharmaceuticals—a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products—against Momenta Pharmaceuticals and Sandoz that was previously dismissed by the U.S. District Court for the District of Massachusetts. WSGR is representing Amphastar in the matter. For further details, please see <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/0317-amphastar.htm>.

GRAIL Raises More Than \$900 Million in Series B Financing

GRAIL, a life sciences company whose mission is to detect cancer early, announced on March 1 that it has raised more than \$900 million through the first close of its previously announced Series B round of financing. The round was led by ARCH Venture Partners, with

participation from Johnson & Johnson Innovation and other world-class strategic pharmaceutical, technology, and financial investors. WSGR represented GRAIL in the transaction. Please refer to <https://globenewswire.com/news-release/2017/03/01/929515/0/en/GRAIL-Closes-Over-900-Million-Initial-Investment-in-Series-B-Financing-to-Develop-Blood-Tests-to-Detect-Cancer-Early.html> for more details.

Delinia to Be Acquired by Celgene

On January 26, Celgene, a global pharmaceutical company, and Delinia, a privately held biotechnology company developing novel therapeutics for autoimmune diseases, announced that they have entered into an agreement for the acquisition of Delinia by Celgene. Under the terms of the agreement, Celgene will make an initial payment of \$300 million and Delinia shareholders will be eligible to receive up to an additional \$475 million in contingent payments upon achievement of certain development, regulatory, and commercial milestones. WSGR represented Delinia in IP matters related to the transaction. Please refer to <http://ir.celgene.com/releasedetail.cfm?ReleaseID=1009217> for additional details.

KenSci Secures \$8.5 Million in Series A Round

KenSci, a healthcare data platform and machine learning-powered applications company, announced on January 25 that it has raised \$8.5 million in a Series A round of financing led by Ignition Partners with participation from Osage University Partners and Mindset Ventures. The proceeds will accelerate innovation for KenSci's machine learning platform and expand operations to support the company's rapidly growing customer base. WSGR represented KenSci in the transaction. For further details, please see <http://www.businesswire.com/news/home/20170125005319/en/KenSci-Secures-8.5M-Series-Funding-Fight-Death>.

ForSight VISION4 Announces Acquisition by Roche

ForSight VISION4, a privately held biotechnology company revolutionizing drug delivery for treatment of retinal diseases,

announced on January 10 that it has been acquired by Roche Holdings. Under the terms of the agreement, Roche has acquired ForSight VISION4 for an undisclosed upfront payment and additional earn-out payments related to development and commercial milestones. WSGR represented ForSight VISION 4 in the transaction. For additional information, visit <http://www.prnewswire.com/news-releases/forsight-vision4-inc-announces-acquisition-by-roche-300388249.html>.

Trefoil Therapeutics Raises \$5.2 Million

Trefoil Therapeutics, an early-stage biopharmaceutical company focused on developing a regenerative approach to corneal endothelial dystrophies and other diseases, announced on January 5 that it has raised \$5.2 million in a Series 1 round of financing led by Hatteras Venture Partners with participation from AJU IB Investment, Correlation Ventures, ExSight Capital, and InFocus Capital. WSGR represented Trefoil Therapeutics in the transaction. For more information, please see <http://www.mikeblaber.org/series1.htm>.

PvP Biologics and Takeda Announce Development Agreement Around Novel Therapeutic for Celiac Disease

On January 5, Takeda Pharmaceutical, a global pharmaceutical company, and PvP Biologics, a developer of an oral enzyme for the treatment of celiac disease, announced a global agreement for the development of KumaMax, a novel enzyme designed to break down the immune-reactive parts of gluten in the stomach. PvP will conduct all R&D through phase one proof-of-principle studies per a pre-defined development plan. Takeda will fund \$35 million for PvP's expenses related to the plan in exchange for an exclusive option to acquire PvP following receipt of a pre-defined data package. Upon PvP's successful completion of the development plan, Takeda may exercise its option to acquire PvP by paying an undisclosed fee as well as development and regulatory milestones. WSGR represented PvP in the transaction. Please see <http://www.businesswire.com/news/home/20170105005656/en/Takeda-PvP-Biologics-Announce-Development-Agreement-Therapeutic> for further details.

Upcoming Life Sciences Events

25th Annual Medical Device Conference

June 1-2, 2017
The Palace Hotel
San Francisco, California
<https://www.wsgr.com/news/medicaldevice>

Wilson Sonsini Goodrich & Rosati's 25th Annual Medical Device Conference, aimed at professionals in the medical device industry, will focus on understanding the challenges facing the medtech start-up today, and the strategies that are emerging to respond to these challenges. Through a series of topical panels, attendees will hear from industry CEOs, venture capitalists, industry strategists, investment bankers, and market analysts.

Phoenix 2017: The Medical Device and Diagnostic Conference for CEOs

October 18-20, 2017
The Ritz-Carlton, Half Moon Bay
Half Moon Bay, California
<https://www.wsgr.com/news/phoenix>

The 24th Annual Phoenix Conference will convene top-level executives from large healthcare companies and CEOs of small, venture-backed firms to discuss issues of interest to the medical device industry today, as well as to network and gain valuable insights from both industry leaders and peers.

Biotech Board of Directors and Senior Executives Reception

January 10, 2018
The San Francisco Museum of Modern Art (SFMOMA)
San Francisco, California

Wilson Sonsini Goodrich & Rosati's annual Biotech Board of Directors and Senior Executives Reception, held to coincide with the J.P. Morgan 36th Annual Healthcare Conference, is an exclusive networking event geared toward executives and directors of biotechnology companies.

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.



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