

Life Beyond FDA Clearance or Approval: The Reimbursement Challenge

By David Hoffmeister, Charles Andres, and
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To medical device manufacturers, winning premarket approval or 510(k) clearance from the U.S. Food and Drug Administration (FDA) is only half the battle. Securing adequate reimbursement from payers is just as important.

The rising cost of healthcare¹ is creating increased pressure, both politically and publicly, to shift reimbursement from a fee-for-service model to a value-based paradigm.² Here, we provide an overview of the healthcare

reimbursement landscape, and we offer several strategic considerations for medical device manufacturers that are planning to launch a new medical device and want to receive payment from payers.

Reimbursement Fundamentals: Coverage, Coding, and Payment³

Coverage

Coverage is the process and criteria used by a payer (e.g., Medicare, Medicaid, and private insurers) to determine whether or not to pay for a medical device provided to a patient. If a medical device is not covered, payers will generally not pay for the device.

Coverage decisions are primarily based on three factors:

1. Clinical and scientific data showing a demonstrated medical benefit to the patient
2. Whether the medical device provides improvement(s) over other currently available products

3. Whether the medical device is cost effective

Coding

Coding is the numeric (or alpha-numeric) language used by payers, hospitals, and physicians in the billing process (e.g., Healthcare Common Procedure Coding System or HCPCS) to describe covered products or services for medical procedures and conditions. As a general rule, it is better to have more—not fewer—codes associated with and appropriate to a medical device, and to have these codes match up with coverage.

Payment

Finally, payment is the money paid to healthcare providers (e.g., physicians, hospitals, and medical device companies) for the provision of products and services based on the permitted coverage. The road to the commercial success of a new medical device requires all three elements of the reimbursement process—coverage, coding, and payment—to work in sync.

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¹ In 2015, the U.S. spent \$3.2 trillion totaling 17.8 percent of the nation's gross domestic product on healthcare expenditure according to the Centers for Medicare & Medicaid Services (CMS). See: "NHE Fact Sheet: Historical NHE, 2015," CMC: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>.

² "Value-Based Reimbursement State-by-State," Change Healthcare, November 13, 2017. See: <http://mhsinfo3.mckesson.com/rs/834-UAW-463/images/Change%20Healthcare%20State-by-State%20VBR%20Study%202017%20report.pdf>.

³ Martha Christian & Melissa Martinson, "Getting Paid for All Your Hard Work: The Basics of Reimbursement for Healthcare Products and Services," Regulatory Affairs Focus, July 2002, pp. 5-10. See: http://www.prgweb.com/news/pdf/02_July_Focus_Christian.pdf.

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Formulating Reimbursement and Regulatory Strategies in Tandem

The payer—to a large extent—controls the destiny of a medical device in the marketplace. If payers will not pay for a medical device, the device may not be commercially viable. It is therefore beneficial to understand the types of evidence the payer weighs when determining whether to provide coverage, and gather and optimize such evidence at the same time that data is being generated to support regulatory approval or clearance.

Device manufacturers should therefore put themselves into the shoes of the patients and payers. Because value-based reimbursement is outcome-determined, the quality of life for patients must take center stage in new medical device designs. The payer—to a large extent—controls the destiny of the medical device in the marketplace.

Although different payers may have differing criteria when determining coverage, Medicare coverage has traditionally been the bellwether for other payers. Medicare, the federal health insurance program primarily

for people age 65 and older, is administered by the Centers for Medicare & Medicaid Services (CMS). CMS evaluates coverage based on published data for medical effectiveness in the Medicare population.

Legally, the Medicare program pays for products, services, and procedures that are “reasonable and necessary for the diagnosis and treatment of illness or injury, or to improve the functioning of a malformed body member.”⁴ In practice, CMS has struggled to interpret the meaning of “reasonable and necessary” when making coverage decisions.⁵ An operational definition promulgated by CMS is “evidence sufficient to conclude that the item or service improves clinically meaningful health outcomes in the affected Medicare beneficiary population.”⁶

Strategies for Achieving Approval and Securing Reimbursement

1. Include Medicare beneficiaries as test subjects

As a threshold matter, if the new medical device can be used in the Medicare population, the clinical development plan for the device should include Medicare beneficiaries as test subjects in order to seek coverage from Medicare.

CMS and private payers may rely on the following when deciding coverage:

- Peer-reviewed, published clinical data
- Real-world clinical efficacy data
- Independent assessment and evaluation of the new product
- Reactions, feedback, and practice guidelines from the physician community

- Cost-effectiveness analysis based on reasonable patient pools
- Other evidence of safety and efficacy

2. Capture cost-effectiveness data in as many ways as practical, including after approval or clearance

Post-approval clinical data derived from real-world patient populations may be particularly relevant and convincing in the eyes of CMS to answer the cost effectiveness question in an initial or expanded coverage evaluation.

3. Understand the tradeoffs between 510(k) and PMA

As the amount and type of clinical evidence required for premarket approval is generally greater and more stringent than for 510(k) clearance, PMA devices—all other things being

Post-approval clinical data derived from real-world patient populations may be particularly relevant and convincing in the eyes of CMS to answer the cost-effectiveness question.

equal—have an advantage over 501(k) cleared devices in the competition for coverage.

⁴ Social Security Act, Title XVIII, §1862(a)(1)(A), 42 U.S.C. §1395y(a)(1)(A). “Appendix B: An Introduction to How Medicare Makes Coverage Decisions,” Medicare Payment Advisory Commission (2003). See: http://67.59.137.244/publications/congressional_reports/Mar03_AppB.pdf.

⁵ Peter J. Neumann & James D. Chambers, “Medicare’s Enduring Struggle to Define ‘Reasonable and Necessary Care,’” *New England Journal of Medicine* 2012, 367 (19): 1775-1777.

⁶ Tamara Syrek Jensen & Louis B. Jacques, “Medicare Coverage: Engaging on Evidence,” *Regenerative Medicine* 2011, 6(6 Suppl.): 99-101. See: <https://www.futuremedicine.com/doi/pdf/10.2217/rme.11.60>.

4. Publish in high quality, peer reviewed journals

Because CMS evaluates peer-reviewed, published clinical data in making coverage decisions, journal publication of clinical and economic data for the new device gives the old phrase “publish or perish” a new meaning. Along these lines, publication in a more prestigious journal can also create a coverage evaluation advantage.

5. Plan ahead

Keeping the suggestions above in mind, manufacturers are better-off taking an early assessment of issues pertaining to reimbursement, and devising a reimbursement plan accordingly.

Adapting to the Value-Based Care Model

Healthcare reform, spearheaded by the Patient Protection and Affordable Care Act (ACA) and the Medicaid and CHIP Reauthorization Act (MACRA), catalyzed the conversion from fee-for-service to value-based care. Value-based care rewards health care providers with incentive payments for the quality of care they give to patients.⁷ Accordingly, value-based reimbursement programs use economics to improve the efficiency of healthcare and reduce costs by rewarding providers who produce better outcomes.⁸ The U.S. Department of Health and Human Services intends to allocate 50 percent of Medicare payments to value-based reimbursement by 2018.⁹

Device manufacturers should therefore put themselves into the shoes of the patients and payers. Because value-based reimbursement is outcome-determined, the quality of life for patients must take center stage in new medical device designs.

Likewise, because lowering the healthcare cost

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is the overarching goal of national policies, cost considerations should be built into the DNA of product research and development and tabulated in progress reports of product development. By listening to patients, physicians, and payers during the development process, manufacturers can build in the necessary “value” proposition into the new device, which will help ensure the device is adequately reimbursed, when launched.

Focusing on the collection of meaningful clinical outcomes during development can be a trump card during coverage evaluations. Notably, digital health, which is the

convergence between healthcare, genomics, and digital technologies, continues to be a fast-growing sector and may represent at least part of the answer to the paradigm shift in reimbursement.¹⁰ As a case study, a recent outcome-based, risk-sharing agreement between Medtronic and Aetna is an example of one way to adapt to this value-based model.¹¹

Conclusion

Value-based reimbursement is both a challenge and an opportunity for medical device manufacturers, and value-based reimbursement is here to stay. By understanding coverage, coding, reimbursement; and key drivers of coverage decisions, device manufacturers can meet the challenge of value-based reimbursement by providing clinically effective, cost-efficient patient outcomes, which in turn can result in medical device manufacturers getting paid.



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⁷ “Value-Based Programs” CMS. See: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html>.

⁸ Mary B. Hamel et al., “The Affordable Care Act at 5 Years,” *New England Journal of Medicine* 2015, 372 (25): 2451-2458.

⁹ Burwell M. Sylvia, “Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care,” *New England Journal of Medicine* 2015, 372(10): 897–899. See: <http://www.nejm.org/doi/full/10.1056/NEJMp1500445>.

¹⁰ “Digital Health Report - Fall 2017,” Wilson Sonsini Goodrich & Rosati, November 9, 2017. See: <https://www.wsgr.com/publications/PDFSearch/digital-health-report/Fall17/digital-health-report.htm>.

¹¹ Bill Berkrot, “Medtronic Deal with Aetna Ties Insulin Pump Payment to Patient Results,” *Reuters*, June 26, 2017. See: <https://www.reuters.com/article/us-medtronic-aetna-diabetes/medtronic-deal-with-aetna-ties-insulin-pump-payment-to-patient-results-idUSKBN19H1GB>.

Three Areas of Focus to Prepare for a Successful IPO in 2018

By Andrew Ellis and Philip Oettinger

Globally, 2017 was the biggest year for IPOs since 2007, both in terms of the number of deals (1,624 IPOs) and proceeds raised (\$188.8 billion), with 49 percent and 40 percent increases, respectively, compared with 2016. In the United States, there were 174 IPOs raising \$39.5 billion in 2017, which is an increase of 55 percent in volume and 84 percent in proceeds raised compared to 2016.¹ Biotech IPOs also had a good year, with 40 IPOs raising approximately \$4 billion in 2017 versus 28 IPOs raising approximately \$2 billion in 2016.² WSGR represented Denali Therapeutics Inc. (NASDAQ:DNLI) in the landmark biotech IPO of 2017, which raised approximately \$250 million in December 2017.³ Because of the momentum caused by Denali and others, we are encountering optimism from investment bankers and clients about the healthcare and biotech IPO market in 2018, and we have anecdotally seen more companies start the IPO process or contemplate an IPO in late 2017 and early 2018.

Completing an IPO is an enormous milestone for any company. Along with the excitement, liquidity, and attention, IPOs also bring the responsibility of Securities and Exchange Commission (SEC) reporting, increased regulatory burden and tougher public scrutiny. In order to prepare for these additional challenges, there are certain action items that we advise our clients to undertake before the IPO process begins. As it often takes time to implement these action items, we encourage clients to start early. These action items are important for any company, but are especially crucial for healthcare and biotech companies because, compared with their counterparts in other industries, they tend to be earlier stage and, in some cases, pre-revenue, which means they likely have less infrastructure to deal with

these challenges. Below are three main areas of focus to prepare for a successful IPO in 2018.

1. Build Up Your Financial and Reporting Team and Resources

The most important part of IPO preparedness is ensuring that you have sufficient internal financial resources. The chief financial officer (CFO) is the most important member of the finance

The most important part of IPO preparedness is ensuring that you have sufficient internal financial resources. The chief financial officer is the most important member of this team and the most important company representative during the IPO process.

team and the most important company representative during the IPO process. If you are contemplating an IPO and do not have a CFO with public company experience (or who is up for the challenge of learning on the job), hiring such a CFO should be your highest priority. This is important not only operationally, but also from a marketing perspective, as new investors will be looking for a CFO they can trust to run a public company, and other members of management and the board will be looking to the CFO to make

sure the company's financial performance is accurately reflected in order to communicate with investors and limit liability.

Particularly for companies with revenue, your second priority should be to consider hiring a controller, with a strong preference for someone with public company experience. An experienced controller can help ensure that you have the processes in place to meet public company reporting timelines and maintain internal accounting and control standards, which would enable the CFO to focus on higher-level matters. Other hires in the finance department may be necessary depending on the size and complexity of your accounting and finance functions, but these two are the most important.

For many of our healthcare and biotech clients, the CFO and/or the controller handle all SEC reporting matters, but for larger companies—or to fill a gap in public company experience on your financial team—you may want to consider hiring a SEC reporting manager. This individual is responsible for coordinating with your legal, accounting, and investor relations teams with respect to quarterly and annual reporting, XBRL, Section 16 filings, and other accounting and reporting matters, which frees up your CFO and/or controller to focus on their respective non-reporting functions on a daily basis.

A third position that can take a lot of lead time to fill is the Audit Committee Chair. Board members with financial experience are in high demand, and it is important to find someone whose style is compatible with the rest of the board. The SEC requires that every public company's audit

¹ [http://www.ey.com/Publication/vwLUAssets/ey-global-ipo-trends-q4-2017-de/\\$FILE/ey-global-ipo-trends-q4-2017.pdf](http://www.ey.com/Publication/vwLUAssets/ey-global-ipo-trends-q4-2017-de/$FILE/ey-global-ipo-trends-q4-2017.pdf)

² <https://www.fiercebiotech.com/biotech/biotech-ipo-roared-back-2017-but-what-will-next-year-bring>

³ <http://investors.denalitherapeutics.com/node/6366/pdf>

committee contains at least one “audit committee financial expert,” and, while it is not necessary that this individual becomes the Audit Committee Chair, it is typically preferable. We often see companies focus on finding their Audit Committee Chair before they even build out the finance management team below the CFO.

As the challenges facing your company grow, both due to internal growth and new regulatory and reporting burdens as a public company, your financial organization may need to upgrade from (in many cases) Microsoft Excel spreadsheets to a more scalable and efficient financial reporting technology solution. As you plan your SEC reporting and accounting processes, you should ask your auditors what they see as standard for a company of your size in your industry.

2. Assemble Your IPO Team

In addition to your internal hiring, you will need to evaluate and eventually choose a large external team to support you through the IPO process and as a public company, which should include the following:

- **Law Firm.** Your lawyers will guide you through the IPO process and can make assembling the rest of the external team easier, so you should engage a law firm as early in the process as possible. It is of utmost importance to hire a law firm with significant IPO experience because an experienced IPO lawyer can keep the timeline moving forward by anticipating next steps and can help you avoid numerous potential pitfalls. As a result, this may be an appropriate time for you to upgrade from your prior counsel. An experienced IPO lawyer will know first-hand what similarly situated companies have done in the various situations you will

face, which is especially crucial for the unique challenges that face healthcare and biotech companies.

- **Auditors.** It is at least as important, if not more important, to identify the right auditors to use for the financial statements in the S-1 and going forward as a public company. The big four audit firms are the obvious choices, but our clients have had good experiences with other audit firms as well. When choosing an auditor (and choosing whether or not your current auditor needs to be replaced), the key is to find one that: (i) your target investors will respect and trust, (ii) has geographical and/or industry expertise, if applicable to you, and (iii) is committed to your timeline. Auditors can also be a tremendous resource for advice on establishing or upgrading your internal controls and processes. Depending on how quickly after the IPO organizational meeting (org meeting) you want to make your first confidential submission, you may need to engage your auditors well before you engage any other external team members.
- **Underwriters.** Depending on your market (or sub-market), your choice of underwriters can have a huge impact on your IPO and subsequent trading. Similar to auditors, you should find underwriters that: (i) have relationships with your target investors to sell the offering, (ii) have analysts who are knowledgeable about the industry in which you operate and can write credible reports, (iii) have geographical and/or industry expertise, (iv) have the financial resources to be able to stabilize trading following the IPO, and (v) are committed to your timeline and share your vision as to how to present the company to potential investors. The analyst coverage

provided by the underwriters in your syndicate may make a big difference in the institutional ownership of your stock and the overall market interest in your business and is oftentimes the critical factor in choosing underwriters, especially in life sciences. Another area where it is important to be aligned with your underwriters on is valuation. If your lead underwriter does not share your idea of valuation, you may be setting yourself up for a confrontation later in the process when it is too late to change horses.⁴

- **Stock Exchange.** Although it may not seem like it, the stock exchange you choose is a service provider like your lawyer or auditor and is part of your external team. In addition to providing the exchange on which your stock is traded, they can help you by expediting their review when the timeline gets tight and often also commit resources to marketing matters or handle the investor relations portion of your website.⁵
- **Investor Relations.** An investor relations firm can help you field questions from investors, issue press releases, revise your website, and comply with various investor information requirements that will be applicable to you when your stock begins trading. In most cases, we recommend that our IPO clients engage an investor relations firm during the IPO process in order to ensure that the firm is onboarded before trading begins.
- **Financial Printers.** During the IPO process, your financial printer of choice will help assemble and submit your filings and will help process changes that are made to those filings during the IPO process. They also print the preliminary prospectuses that are delivered during your roadshow and the

⁴ Sometimes underwriters provide a necessary reality check on valuation, so it may not be an argument that is in your best interest to “win.” Just make sure you have these conversations early so there are no surprises later in the process.

⁵ Our clients often reserve a ticker symbol early in the process, but do not submit an application to an exchange until drafting has begun.

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final prospectuses that are delivered once you begin trading. This sounds simple enough, but to keep the machine running smoothly you need to choose an experienced printer that is focused on customer service.⁶

- *Other Consultants.* Depending on the needs of the company, you may need to engage one or more additional consultants before or during the IPO process. For example, for healthcare and biotech companies with limited finance personnel, it may make sense to hire a financial consultant to help prepare financials and with disclosure in the S-1. If your regulatory path is not yet certain, you may need to hire a regulatory consultant to help ensure your disclosure adequately reflects the risks in your business and matches realistic expectations regarding timeline and categorization. Consultants such as these can be engaged on an ad hoc basis and are not necessary for every company.

3. Create Public Company Infrastructure

Hiring internally and engaging external providers are important parts of the process, but it is just as important for you to gather your internal documentation, evaluate your internal process, and make necessary changes before and during the IPO process. There are many things to consider, but some key items you should address are the following:

- (a) *Policies.* Early in the IPO process, you should have your counsel create forms of the various policies you will need in order to operate as a public company, such as communications policies, insider trading policies, committee charters, whistleblower policies, codes of conduct, etc. Although only certain of these are required by rules or regulations,

there are several others that are considered best practices and can be an effective defense against any future claims regarding inadequate corporate governance. Review these forms of policies to understand them and think about (i) who would best fill each role within them and (ii) how they will actually be implemented. Take steps toward implementation during the IPO process so you are not overwhelmed on the first day of trading. Most importantly, make sure that any policies that are adopted are actually followed—it is better not to have a policy at all than to have one and not follow it.

- (b) *Financial and Accounting Operations.*

Leading up to the IPO, start and maintain the processes you will need in order to timely report your financials as a public company. Some clients even hold mock quarterly conference calls and practice closing the books according to accelerated timelines in order to prepare for being a public company. Discuss internal controls, Sarbanes-Oxley (SOX) compliance, and best practices internally and with your auditors. The importance of these steps is inversely proportional to the level of prior public company experience in your finance and accounting team.

- (c) *Executive Compensation.* If the company has not already done so, begin obtaining regular quarterly 409A valuations in order to establish the practice and defend the fair value of the equity awards you have granted leading up to the IPO. If equity awards are granted at less than fair value in the 12-18 months prior to an IPO, it may raise a “cheap stock” issue with the SEC or, even worse, cause the SEC to ask whether the board has fulfilled its fiduciary duties to stockholders in pricing options. If the

SEC determines that “cheap stock” was granted, then the company will need to take an accounting charge for the difference between the grant price and the fair value of that equity and in more serious cases it could lead to additional disclosure on option granting practices or delay effectiveness, if the SEC is uncomfortable with the price at which options were granted. Proper valuation at frequent intervals or in conjunction with major events (financings, acquisitions, etc.) on at least a quarterly basis 12-18 months prior to an IPO and adequate disclosure in the S-1 can minimize risk. In addition, make sure that there are no outstanding loans from the company to directors or officers prior to filing the S-1 in order to comply with Sarbanes-Oxley Section 402.

- (d) *Documentation.* Using a sample diligence request list provided by your counsel, begin compiling your diligence items in a data room (or locally in folders until you engage a data room provider) well in advance of the org meeting. This does two things: (i) it ensures that these documents are already organized and ready to upload when diligence needs to begin and (ii) it can reveal areas of weakness in your prior documentation that you can address before the IPO. Besides material agreements (licenses, manufacturing agreements, and the like), of particular importance are the company’s foundational documents and documents related to the issuance of equity or debt.
- (e) *Communication.* Make sure your external communications (your website, your social media, press releases, etc.) do not contain any statements that you cannot prove or that are not accompanied by appropriate disclaimers. It

⁶ There are some traditional options and more modern, software-based solutions to choose from. We are happy to discuss the differences to help you make an informed decision.

is important that your website and communications match the statements made in the S-1 in all material respects. Finally, ask your counsel for publicity guidelines that you can review and convey to your employees so they do not run afoul of SEC rules regarding communications during the IPO process.

(f) *Board of Directors.* This is not an action item for every company, but you should take some time to evaluate your current board. In order to establish a majority of independent directors or round out your areas of expertise, such as to add a financial expert to a science-heavy board, it may be in the company's best interest to add to or replace certain of your board members. In some cases, venture capital directors may need to rotate off of the board because their partnerships will not let them sit on public company boards. In other cases, you may have a vestigial early investor on the board, and the IPO is a natural time for them to move on. The CEO should take an active role, working with existing board members, to determine how many directors will be leaving, how many new directors need to be appointed, and the skillsets required by the directors to fill the board and committee roles. These can be difficult conversations to have, and good board members can be difficult to find, so starting early is important.

(g) *Your Story.* Before the first line of your S-1 is written, you should have an idea of how you want to tell your story. This will come in part from past presentations to investors and preliminary discussions with your underwriters, but special care should be given to the addressable market, how you compare to competitors, the unique way you solve an unmet need, what key metrics you use to evaluate your performance, and how you intend to use the IPO proceeds.

Conclusion

The mere exercise of preparing for an IPO can be a catalyst for a lot of positive change at a growing company. Many of our clients contemplating an IPO still have startup infrastructures, and major upgrades are necessary in order to operate like a large private company or a public company. Collecting diligence materials can illuminate missing documentation or faulty processes, thinking about accounting disclosure can refine how you recognize revenue, and the act of outlining your business section can refine the way you think about your business. In order to have a smooth IPO and avoid delays while managing risk, we recommend focusing on these three main areas prior to or early in the IPO process.

We look forward to a robust IPO market in 2018. For more information about any of these areas, or to begin a conversation about your planned IPO, contact Andrew Ellis, Philip Oettinger, or another WSGR attorney.

Collecting diligence materials can illuminate missing documentation or faulty processes, thinking about accounting disclosure can refine how you recognize revenue, and the act of outlining your business section can refine the way you think about your business.



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Target Product Profile: A Valuable Tool for Drug Development, Increasing Investment, and Building Multi-Layered Patent Estates

By David Hoffmeister, Vern Norviel, Charles Andres, and David Knapp¹

Drug development can be lengthy and expensive. In 2013, the Tufts Center for Study of Drug Development published a study estimating the total pre-approval cost of developing a new pharmaceutical to be \$802 million.² In a 2016 follow-up study, the same group estimated the total cost to have risen to \$2.6 billion.³ The authors' analysis showed that costs are increasing year-to-year significantly faster than inflation, and pointed to the failure rate of drugs tested in human subjects as being a major cost driver.⁴ Faced with these realities, drug developers need to leverage every available resource to improve their chances at success when entering clinical trials.

One such resource is the target product profile (TPP), a high-level drug-development roadmap that provides a summary of a clinical drug-development program described in terms of the labeling concepts. The TPP is a living, evolving document that offers significant benefits to a development program in terms of facilitating the U.S. Food and Drug Administration (FDA) development, approval, and licensing processes.

TPPs are also a powerful tool for building a robust patent portfolio, as the information in the TPP is useful for writing patent claims of varying scopes, and submitting

patent applications at different times. The information in TPPs can be helpful when preparing for discussions with potential investors. Additionally, some granting agencies now require submission of TPPs along with grant applications. For all of these reasons, we recommend that drug developers implement a TPP early in the development lifecycle, and regularly update the TPP as new information becomes available.

Preparation of a TPP is not required by the FDA as part of an Investigational New Drug Application (IND). Nevertheless, the FDA has published draft guidance encouraging use of a TPP and outlining its key parts and advantages.⁵ The FDA draft guidance approaches the TPP as a tool for strategic planning in drug development and facilitating communications between a drug sponsor and the FDA when seeking approval or licensing, and it suggests development of a TPP with those goals in mind.

One primary goal of the TPP is to define early in the development process the desired labeling of the final approved drug product as envisioned by the sponsor and investigators. Therefore, the TPP should include information corresponding to key sections of the desired final drug label, and ideally the final version of the TPP will be similar to the annotated draft labeling submitted with a new drug application or biologics license application.⁶

Sections to Include in a TPP

The FDA draft guidance proposes several potential sections for inclusion in a TPP, mirroring the sections that a sponsor would like to appear in the final package insert, such as:

- Indications and usage
- Dosage and administration
- Dosage forms and strengths
- Contraindications
- Warnings and precautions
- Adverse reactions
- Drug interactions
- Use in specific populations
- Drug abuse and dependence
- Overdosage
- Description
- Clinical pharmacology
- Nonclinical toxicology
- Clinical studies
- References
- How supplied/storage and handling
- Patient counseling information⁷

¹ The information herein is provided for informational purposes only and should not be taken as legal advice. Legal counsel should be consulted for questions regarding preparation of a Target Product Profile.

² DiMasi, et al., The Price of Innovation: New Estimates of Drug Development Costs, 22 *Journal of Health Economics* 151-185, 2003.

³ DiMasi, et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 *Journal of Health Economics* 20-33, 2016.

⁴ *Id.*

⁵ Guidance for Industry and Review Staff: Target Product Profile—A Strategic Development Process Tool, Draft Guidance, March 2007. See: <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080593.pdf>.

⁶ *Id.* at 2.

⁷ *Id.* at 5.

The dosage and administration, and indications and usage sections can be particularly useful for drafting patent claims.

Each section of the TPP should include pre-defined information based on the anticipated outcome of clinical testing. First, each section should feature the language that the sponsor hopes will appear on the final, approved label, based on the outcome of studies performed during pre-clinical studies and clinical trials. This may include alternative language representing the best case, most likely, and minimally acceptable versions of labeling language.

The TPP should also include a summary of completed or planned studies that will support the target label language. The TPP should not be viewed as a static document, but can and should be updated as studies are completed and additional data is gathered.⁸ The FDA draft guidance provides a template TPP reflecting the above recommendations.⁹ This information is also useful in building a patent estate. It is often worthwhile to draft and file additional patent applications, at different times, as information is updated and the TPP evolves.

Advantages of a Complete TPP

The advantages of preparing a complete TPP as described above are many. First, by preparing the TPP with the final, desired labeling language explicitly stated, the TPP can guide the internal design, conduct, and analysis of pre-clinical and clinical studies. The TPP thus serves as a planning tool to help sponsors and investigators design studies in the context of the desired final labeling, as well as to aid in the evaluation of whether the outcome of these studies will be sufficient to support the desired labeling. Use of a TPP in this way can help ensure that studies are designed with the best possible chance of supporting the desired label, and help guide an objective, realistic analysis of the study results.

Second, the TPP can help to guide discussions between sponsors and FDA review staff. A TPP written to include final drug labeling and a thorough summary of completed and planned studies helps the FDA understand the sponsors' specific goals. The TPP therefore allows the FDA to provide better feedback, and advice on what additional information to collect in clinical trials to meet the proposals described in the TPP.

Early preparation of a TPP allows drug sponsors and developers to maximize these benefits. By identifying the desired final labeling as early as possible, drug developers can avoid unnecessary expenditure of time and resources on studies that are extraneous to, or are not likely to support the desired labeling.

Early development of a TPP will also help guide review staff early in the clinical development process, maximizing the efficiency and benefit of review staff-sponsor discussions. Early TPP development is also useful when planning pivotal phase II trials. A successful phase II trial can bring in significant investment, and the TPP and Investigator's Brochure of the IND should be updated to maximize this possibility. Also, new patent claims drafted to efficacy can often be drafted and filed at this point.

Further, a TPP does not represent an implicit or explicit obligation on the sponsor's part to pursue or realize all stated goals, nor does the TPP constrain the sponsor to submit draft labeling in an NDA that is identical to language proposed in the TPP.¹⁰ Thus, there is no disadvantage to the early preparation of a detailed and goal-oriented TPP.

Ultimately, a thorough, label-oriented TPP prepared early in a company's drug-development cycle can help guarantee that clinical studies are designed to help ensure appropriate efficacy and safety data is generated, which in turn will help to

streamline and maximize the value of FDA meetings, and ultimately minimize the risk of late-stage drug-development failure. These benefits are consistent with needs of the modern-day drug developer, including:

- Reducing the time and cost of drug development
- Increasing the odds of getting a drug from development to market
- Maximizing investment in the company at the right times
- Building a robust, multi-layer patent portfolio

For questions regarding TPPs, clinical trials, patent portfolio development, investment, or any pharmaceutical-related question, please contact David Hoffmeister, Vern Norviel, or any member of the patents and innovation or FDA/life sciences practices at Wilson Sonsini Goodrich & Rosati.



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⁸ *Id.*

⁹ *Id.* at 11.

¹⁰ *Id.* at 3.

Life Sciences Venture Financings for WSGR Clients

By Scott Murano

The table below includes data from life sciences transactions in which Wilson Sonsini Goodrich & Rosati clients participated during the second half of 2016 and the first half of 2017. 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	2H 2016 Number of Closings	2H 2016 Total Amount Raised (\$M)	2H 2016 Average Amount Raised (\$M)	1H 2017 Number of Closings	1H 2017 Total Amount Raised (\$M)	1H 2017 Average Amount Raised (\$M)
Biopharmaceuticals	33	370.91	11.24	31	251.05	8.10
Genomics	5	32.30	6.46	4	13.19	3.30
Diagnostics	11	98.45	8.95	8	118.64	14.83
Medical Devices & Equipment	47	321.76	6.85	55	522.10	9.49
Digital Health	10	71.33	7.13	6	16.64	2.77
Healthcare Services	6	140.08	23.35	10	385.64	38.56
Total	112	1,034.83		114	1,307.26	

The data demonstrates that venture financing activity increased during the first half of 2017 compared to the second 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 26.3 percent from the second half of 2016 to the first half of 2017, from \$1,034.83 million to \$1,307.26 million, while the total number of closings across all industry segments increased 1.8 percent, from 112 to 114 closings.

Notably, the industry segment with the largest number of closings—medical devices and equipment—experienced an increase in the number of closings and in the total amount raised during the first half of 2017 compared to the second half of 2016. Specifically, medical devices and equipment increased 17 percent in the number of closings, from 47 to 55 closings, and more

Medical devices and equipment experienced an increase in the number of closings and total amount raised during the first half of 2017 compared to the second half of 2016.

significantly, increased 62.3 percent in the total amount raised, from \$321.76 million to \$522.10 million.

The industry segment with the second-largest number of closings—biopharmaceuticals—experienced a decrease in both the number of closings and in the total amount raised

during the first half of 2017 compared to the second half of 2016. Specifically, the number of closings in the biopharmaceuticals segment decreased 6.1 percent, from 33 to 31 closings, and the total amount raised decreased 32.3 percent, from \$370.91 million to \$251.05 million.

Meanwhile, the industry segment with the third-largest number of closings during the second half of 2016—diagnostics—experienced a small decrease in the number of closings, but an increase in the total amount raised. Specifically, the number of closings in the diagnostics segment decreased 27.3 percent, from 11 to eight closings, while the total amount raised increased 20.5 percent, from \$98.45 million to \$118.64 million.

The industry segment with the third-largest number of closings during the first half of

The number of closings in the healthcare services segment increased 66.7 percent, from six to 10 closings.

2017—healthcare services—experienced a significant increase in number of closings and in total amount raised. Specifically, the number of closings in the healthcare services segment increased 66.7 percent, from six to 10 closings, while the total amount raised increased 175.3 percent, from \$140.08 million to \$385.64 million. The two remaining industry segments (in descending order of number of closings during the second half of 2016)—digital health and genomics—were down in the number of closings and in the total amount raised during the first half of 2017 compared to the second half of 2016.

In addition, our data suggests that Series A and Series B financing activity as a percentage of all other financing activity decreased during the first half of 2017 compared to the second half of 2016. Specifically, the number of Series A closings as a percentage of all closings decreased from 41.1 percent to 37.4 percent, and the number of Series B closings as a percentage of all closings decreased from 17 percent to 16.5 percent.

Offsetting those losses, bridge financing and Series C and later-stage financing activity

compared to all other financings increased during the first half of 2017. The number of bridge financing closings as a percentage of all closings increased from 26.8 percent to 29.6 percent, and the number of Series C and later-stage financing closings as a percentage of all closings increased from 10.7 percent to 12.2 percent.

Average pre-money valuations for life sciences companies increased for Series B financings but decreased for Series A and Series C and later-stage financings during the first half of 2017 compared to the second half of 2016. The average pre-money valuation for Series A financings decreased 31.7 percent, from \$18.47 million to \$12.62 million; the average pre-money valuation for Series B financings increased 14 percent, from \$43.65 million to \$49.74 million; and the average pre-money valuation for Series C and later-stage financings decreased 29.4 percent, from \$143.45 million to \$101.31 million.

Other data taken from transactions in which all firm clients participated in during the first half of 2017 suggests that life sciences remains the second-most attractive industry for investment. For the first half of 2017, life sciences represented 25 percent of the total funds raised by our clients, while the software industry—traditionally the most popular industry for investment—represented 31 percent of the total funds raised.

Overall, the data indicates that access to venture capital for the life sciences industry increased during the first half of 2017 compared to the second half of 2016. It is also worth noting that financing activity

during the first half of 2017 represents the fourth straight six-month period of improved financing activity. And while early-stage financing activity as a percentage of all financing activity moderately decreased during the first half of 2017, later-stage financing activity is on the rise, marking an end to gains early-stage financing activity had been making over later-stage financing

Data taken from transactions in which all firm clients participated in during the first half of 2017 suggests that life sciences remains the second-most attractive industry for investment.

activity during the two prior six-month periods. We expect early-stage financing activity as a percentage of all activity to improve, as the later-stage companies begin to exit.



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Select Recent Life Sciences Client Highlights

Denali Therapeutics Announces Pricing of Initial Public Offering

On December 7, Denali Therapeutics, a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases, announced the pricing of its initial public offering of 13,888,888 shares of its common stock at a price to the public of \$18 per share. The company's shares began trading on the Nasdaq Global Select Market on December 8 under the ticker symbol "DNLI." WSGR advised Denali Therapeutics in the offering. To read more, please visit <http://investors.denalitherapeutics.com/node/6366/pdf>.

Semma Therapeutics Raises \$114 Million in Series B Financing

Semma Therapeutics, a biotechnology company focused on the development of novel regenerative medicines, announced on November 30 that it has raised \$114 million in a Series B round of financing co-led by Eight Roads Ventures and Cowen Healthcare Investments with participation from MPM Capital, F-Prime Capital Partners, ARCH Venture Partners, Novartis, Medtronic, JDRF T1D Fund, ORI Healthcare Fund, Wu Capital, 6 Dimensions Capital, and SinoPharm Capital.

Proceeds will be used to bring the company's lead development program, encapsulated stem cell-derived islets, through clinical proof-of-concept in patients and to continue exploration of other regenerative medicine therapeutics. WSGR represented Semma Therapeutics in intellectual property matters related to the transaction. To read more, please visit <http://www.semma-tx.com/media1/semma-therapeutics-raises-114-million-series-b-financing>.

Savara Announces Pricing of Public Offering of Common Stock

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 the pricing of an underwritten public offering of 5,250,000 shares of its common stock at a price to the public of \$7.85 per share on October 25. WSGR advised Savara in the transaction. To read more, please visit <http://savarapharma.com/investors/press-releases/release/?id=2311119>.

Mylan Invalidates Allergan's Patents on Restasis

Mylan announced on October 16 that the U.S. District Court for the Eastern District of Texas issued a 135-page decision finding that all asserted claims of the patents relating to Restasis invalid based on obviousness. The court, recognizing that Allergan's patent protection for Restasis ended in 2014, concluded that "Allergan is not entitled to renewed patent rights for Restasis in the form of a second wave of patent protection." WSGR represented Mylan in the matter. To read more, please visit <http://investor.mylan.com/releasedetail.cfm?ReleaseID=1044133>.

PW Medtech and China Biologic Announce Major Share Swap Transaction

On October 12, PW Medtech Group, a China-based company principally engaged in the development, manufacture, and sale of regenerative medical biomaterial and advanced infusion products, announced that it has entered into a share exchange agreement with China Biologic Products Holdings, a leading fully integrated plasma-based biopharmaceutical company in China. Pursuant to the share-exchange agreement, PW Medtech subscribed for 5,521,000 ordinary shares of CBPO in consideration of the entire issued share capital of Health Forward, for a total value of approximately \$513.5 million with a subscription price of \$93 per CBPO share. WSGR acted as U.S. and Hong Kong counsel to PW Medtech in the transaction. To read more, please visit <http://www.pwmedtech.com/upimage/ZXm1VAwT9Y.pdf>.

Recursion Pharmaceuticals Raises \$60 Million in Series B Financing

Recursion Pharmaceuticals, a biotechnology company that combines innovative biological science with artificial intelligence to discover new therapeutics at scale, announced on October 3 that it has raised \$60 million in a Series B round of financing led by Data Collective (DCVC), with participation from Lux Capital, Obvious Ventures, Advantage Capital, Felicis, Epic, AME, Mubadala, Menlo Ventures, CRV, Two Sigma, and other angel investors. WSGR represented Recursion Pharmaceuticals in the transaction. To read more, please visit <https://www.recursionpharma.com/press-release/recursion-pharmaceuticals-raises-60-million-industrialize-drug-discovery-using-artificial-intelligence/>.

NeoTract Acquired by Teleflex

Medical device company Teleflex announced on October 2 that it has completed its acquisition of NeoTract, a urology company focused on the treatment of BPH through its UroLift System. Under the terms of the agreement, Teleflex acquired NeoTract for an upfront cash payment of \$725 million at closing, and has agreed to pay up to an additional \$375 million upon the achievement of certain commercial milestones related to sales through the end of 2020. WSGR represented NeoTract in the transaction. To read more, please visit <https://www.businesswire.com/news/home/20171002005022/en/Teleflex-Incorporated-Completes-Acquisition-NeoTract>.

Peptilogics Raises \$5.5 Million

Peptilogics, a pre-clinical stage company utilizing an innovative peptide platform to treat multidrug-resistant bacterial infections, announced on September 29 that it has raised \$5.5 million in a Series A round of financing from Peter Thiel, Stefan Roever, and BlueTree Ventures, among other investors. The funding will fuel the expansion of the company and its eCAP platform, particularly the continued development of its first

clinical candidate in preparation for an IND submission in 2018. WSGR advised Peptilogics in the transaction. To read more, please visit <https://www.businesswire.com/news/home/20170929005064/en/Peptilogics-Set-Transform-Development-Antibiotics-Treatment-Multidrug-Resistant>.

Cofactor Genomics Announces \$18 Million in Funding

On September 18, Cofactor Genomics, a leading platform developer for RNA sequencing and expression analysis, announced that it has raised \$18 million in a round of financing led by Menlo Ventures, with major participation from Data Collective (DCVC) and Ascension Ventures, and additional participation from iSelect, Y Combinator, WSGR, and Stanford. WSGR represented Cofactor Genomics in the transaction. To read more, please visit <https://www.businesswire.com/news/home/20170918005287/en/Cofactor-Genomics-Announces-18M-Funding-Oversubscribed-Series-A>.

Third Circuit Affirms Dismissal of Securities Class Action Against Globus Medical

On August 23, the U.S. Court of Appeals for the Third Circuit affirmed the dismissal of a securities class action filed against Globus Medical, a medical device company that designs, develops, and sells musculoskeletal implants, particularly for spine disorders. The complaint alleged that certain risk disclosures relating to the possible negative impact on revenues from the loss of distributors for Globus' product were misleading because such a risk had already materialized when the company decided to terminate a significant distributor.

The complaint also alleged that the company's projections were false since they allegedly did not take into account the loss of revenue from the termination of the significant distributor. The Third Circuit held that the risk disclosures were not misleading because the plaintiff had failed to sufficiently allege that the termination of the distributor had any adverse effect on sales at the time the risk

disclosures were made. Further, the appeals court found that the plaintiff had failed to adequately allege that the challenged financial projections were misleading or what, if any, revenues of the terminated distributor were included in those projections. WSGR represented Globus, along with its CEO, CFO, COO, and Chief Accounting Officer, in the matter. To read more, please visit <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/0817-globus-medical.htm>.

Sientra Completes Acquisition of Miramar Labs

Sientra, a medical aesthetics company, announced on July 26 that it has completed the previously announced acquisition of Miramar Labs, a global medical device company dedicated to bringing innovative and clinically proven applications to treat unmet needs in the aesthetic marketplace, for an aggregate transaction value of \$20 million in upfront cash, plus contractual rights for potential contingent payments of up to \$14 million in cash upon the achievement of certain milestones. WSGR represented Miramar Labs in the transaction. To read more, please visit <http://investors.sientra.com/news/news-details/2017/Sientra-Completes-Acquisition-of-Miramar-Labs/default.aspx>.

Federal Jury Decides in Favor of Amphastar in Patent Infringement Dispute

On July 21, following a two-week trial, a federal jury in the District of Massachusetts returned a verdict for Amphastar Pharmaceuticals, a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable and inhalation products, in a patent infringement suit. The plaintiffs, Momenta Pharmaceuticals and Novartis AG's Sandoz unit, sued Amphastar for infringement in September 2011 in the U.S. District Court for the District of Massachusetts.

At trial, the plaintiffs alleged that Amphastar's testing of its generic enoxaparin sodium drug

product infringed U.S. Patent No. 7,575,886 (the '886 patent'). The jury returned a verdict finding that the '886 patent was invalid for lack of enablement and lack of adequate written description. The jury also found that the plaintiffs had waived their ability to enforce the '886 patent against Amphastar because of the plaintiffs' inequitable conduct before the U.S. Pharmacopeia. WSGR represented Amphastar at trial. To read more, please visit <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/0717-amphastar.htm>.

Silk Road Medical Raises \$47 Million

Silk Road Medical, a company dedicated to alleviating the devastating burden of stroke through surgical innovation, announced on July 18 that it has raised \$47 million in a new round of financing led by Norwest Venture Partners and funds managed by Janus Capital Management with participation from Warburg Pincus, The Vertical Group, and CRG. WSGR represented Silk Road Medical in the transaction. To read more, please visit <https://www.prnewswire.com/news-releases/silk-road-medical-announces-47-million-financing-led-by-norwest-venture-partners-and-funds-managed-by-janus-capital-management-llc-300488844.html>.

WuXi Biologics Completes IPO on the Hong Kong Stock Exchange

On June 13, WuXi Biologics (Cayman), a leading open-access R&D capability and biologics technology platform company, announced that it has completed its initial public offering of 192,982,500 shares at an offering price of HK\$20.60 per share, for a total offering size of approximately HK\$3.98 billion. WSGR acted as U.S. and Hong Kong counsel to WuXi Biologics in the offering and listing. To read more, please visit <https://www.wuxibiologics.com/wuxi-biologics-is-officially-listed-on-the-hong-kong-stock-exchange>.

Savara Announces Closing of Public Offering of Common Stock

On June 7, Savara announced the closing of an underwritten public offering of 9,034,210 shares of its common stock at a price to the public of \$4.75 per share, which included

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613,157 shares upon the partial exercise of the underwriters' option to purchase additional shares of Savara common stock at the public offering price, less the underwriting discounts and commissions. The aggregate gross proceeds from the offering, before deducting the underwriting discounts and commissions and offering expenses, were approximately \$42.9 million. WSGR represented Savara in the offering. To read more, please visit <http://savarapharma.com/investors/press-releases/release/?id=2279673>.

NanoString Technologies Announces Closing of Public Offering

NanoString Technologies, a provider of life science tools for translational research and molecular diagnostic products, announced on June 6 that it has closed its underwritten public offering of 3,450,000 shares of its common stock at a price of \$16.75 per share, which includes the exercise in full by the underwriter of its option to purchase an additional 450,000 shares of NanoString's common stock. Net proceeds from the offering were approximately \$56.5 million. WSGR represented NanoString in the

offering. To read more, please visit <http://investors.nanostring.com/releasedetail.cfm?ReleaseID=1029274>.

GRAIL Merges with Cirina

GRAIL, a life sciences company whose mission is to detect cancer early when it can be cured, announced on May 31 that it has entered into a definitive agreement to combine with Cirina, a privately held company that is also focused on the early detection of cancer. WSGR advised GRAIL in the transaction. To read more, please visit <https://globenewswire.com/news-release/2017/05/31/1003871/0/en/GRAIL-and-Cirina-Combine-to-Crete-Global-Company-Focused-on-Early-Detection-of-Cancer.html>.

Saluda Medical Secures AU\$53 Million in Series D Financing

Saluda Medical, a medical device company developing a platform of closed-loop neuromodulation technologies based on neural response to stimulation, announced on May 30 that it has secured AU\$53 million in an all-equity financing round led by Action Potential Venture Capital (APVC), a venture

capital fund of GlaxoSmithKline created to invest in companies that are pioneering bioelectronic medicines and their enabling technologies, with participation from existing investors, including Medtronic PLC, also participated in the round. WSGR represented APVC in the transaction. To read more, please visit <https://www.prnewswire.com/news-releases/saluda-medical-secures-au53-million-in-series-d-financing-300464918.html>.

SR One Co-Leads Investment in TP Therapeutics' \$45 Million Series C Financing

TP Therapeutics, a clinical-stage biopharmaceutical company focusing on addressing oncology drug resistance, announced on May 23 that it raised \$45 million in a Series C round of financing co-led by corporate healthcare venture capital fund SR One, Lilly Asia Ventures, and OrbiMed Advisors with participation from Cormorant Asset Management and SV Tech Ventures. WSGR is representing SR One in the transaction. To read more, please visit <https://www.businesswire.com/news/home/20170523005576/en/TP-Therapeutics-Closes-45M-Series-Financing>.

Healthcare Innovations Venture Investment Forum

On December 6-8, 2017, WSGR held its third Healthcare Innovations Venture Investment Forum in Austin, Texas. The event connected investors with promising life sciences start-ups from a variety of industry sectors, including diagnostics, therapeutics, medical devices, and digital health.

Over the course of three days, more than 150 innovative life sciences companies from across the country met privately with over 50 top-tier life sciences investors. Additionally, during breakfast, lunch, and receptions,

companies were able to network with investors and fellow entrepreneurs.

"Investment in life sciences is tremendously robust, and great ideas can be well-financed today," said WSGR partner, Vern Norviel.

"This investment environment now creates the opportunity to make enormous advances. Technologies such as immunotherapy, gene editing, cell therapy, and inexpensive DNA sequencing are making changes in patient treatment that were unimaginable a few years ago."

WSGR hosted its first venture forum in Palo Alto, California, in 2016, and a second forum in Boston, Massachusetts, in conjunction with the Harvard Innovation Lab, in Spring 2017. The therapeutics sector made up 40 percent of the more than 370 company submissions to the forum this year, followed by medical devices at 33 percent, and digital health at 26 percent.

Upcoming Life Sciences Events

26th Annual Medical Device Conference

Friday, June 22, 2018
Palace Hotel
San Francisco, California

Wilson Sonsini Goodrich and Rosati's 26th Annual Medical Device Conference will feature industry experts discussing key issues facing today's early-stage medical device companies. Through a series of topical panels, attendees will hear from industry CEOs, venture capitalists, industry strategists, investment bankers, and market analysts. The conference will kick off with a dinner on June 21.

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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