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Building a Better Mousetrap: A Physician's Guide to Commercializing a Medical Device Invention

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What is the issue? Innovation in medical diagnosis and treatment often comes from practicing physicians, who conceive of better approaches through caring for patients. Physicians who want to share those innovations by creating a commercial medical device face a number of business and legal challenges.

What is at stake? In addition to the time and expense of product development, business organization, and regulatory approval, physicians entering the medical device business will want a business model that is sustainable, not one that will encounter challenges or lead to legal scrutiny and potential sanctions.

What should attorneys do? The surest path to success is a business plan that systematically identifies and sequentially addresses the challenges and enlists the appropriate experts. In this Practice Resource, the authors provide practical suggestions for developing a business through which a physician may commercialize a new medical device that he or she has invented.

Thomas N. Bulleit et al., *Building a Better Mousetrap: A Physician's Guide to Commercializing a Medical Device Invention*, J. HEALTH & LIFE SCI. L., Oct. 2018, at 78. © Published by the American Health Lawyers Association, www.healthlawyers.org/journal.

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Introduction

Your client, a practicing physician group, has identified a medical need, conceived a new treatment or diagnostic that would aid in patient care, and has asked you to help bring it to commercial life.¹ As a health law attorney, you know that this enterprise will involve expertise in several health law subspecialties: protection of intellectual property, business organization and finance, regulation by the U.S. Food and Drug Administration (FDA), compliance, and third-party payment. You are also aware of the various legal issues that will need to be addressed:

- **Protect the Intellectual Property:** The device, and any subsequent company that licenses or owns the device, will have little value if anybody can duplicate the product. Is the intellectual property protectable, and if so, what are the means for doing so? Has a “freedom to operate” analysis been conducted to ensure your client’s product does not infringe on the intellectual property of a third party?
- **Create the Business and Secure Funding:** What is the business model? When, after thorough consideration, you believe the compliance risks can be navigated, address key issues inherent to creating this type of new business, e.g., housing the invention, securing financing, and protecting the client medical practice from liability.
- **Product Development and FDA Oversight:** Develop the product for marketing. Most commercial medical devices will require some research and testing to show safety, effectiveness, and ultimately clearance or approval from the FDA.

¹ The focus of this Practice Resource is on the commercialization of a medical device invented by a physician or physician group without obligation to assign to an employer or other funding source. A number of different issues may arise if a hospital or academic medical center (AMC) owns the medical device invention by a doctor, by virtue of an assignment signed by the doctor upon hire. For example, additional institutional interests could include laws and regulations on tax exemption, technology transfer, or labor/employment. Because of the greater complexity, this Practice Resource does not address the institutional perspective. Instead, the discussion will focus on the practical aspects of how a doctor-inventor commercializes his or her medical device invention, with occasional reference to what might be different if an employer were involved.

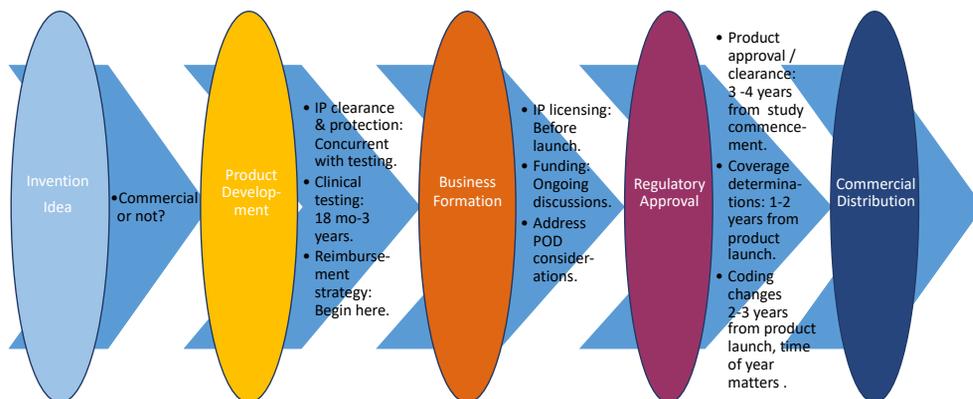
- **FDA and Anti-kickback Law Compliance:** A sustainable business model requires navigating through FDA and other health regulations that directly and indirectly impact product marketing. Avoiding the indicia of a physician-owned distributor (POD) and providing truthful, non-misleading claims that are consistent with FDA labeling are key elements.
- **Coverage and Reimbursement:** Is there a market? Even the most innovative technologies will have a hard time gaining acceptance in the absence of third-party payer coverage and reimbursement.

This Practice Resource will provide step-by-step guidance for creating a viable business for the purpose of commercializing an innovative medical device invented by a practicing physician.

The Medical Device Development Life Cycle

Although many aspects of building a new medical device to market will proceed simultaneously, there remains a general order to how the lengthy process unfolds. From conception of the idea to commercial distribution, the entire process likely will take at least 3-4 years. Obtaining market acceptance, third-party payer coverage, and reasonable reimbursement often takes longer. The process generally will look more or less as depicted in Figure 1.

Figure 1—Commercializing a New Medical Device: The Life Cycle



Protecting Intellectual Property

Developing and marketing a medical device product requires intellectual property (IP) protection and clearance. IP protection should be one of the inventor's first priorities, as it helps ensure the exclusive right to commercialize the medical device. This section provides an overview of available options of IP protection and how to effectively manage and leverage IP assets.

Patent

A patent is an exclusive right granted by the government for an invention. The invention can be a product or a process that provides a new technical solution to a problem.² Patents are typically the most important form of IP protection for medical devices. To be patentable, an invention has to be new,³ useful,⁴ and have an inventive step that is not obvious to someone having ordinary knowledge and skill in the subject.⁵

A medical device may be protected as either a utility patent or a design patent, or both. To qualify as a utility patent, the medical device must be innovative in some functional aspects; while a design patent can be something new for the ornamental appearance of a product. It is much easier to obtain a design patent than a utility patent. A utility patent is protected for 20 years, and a design patent is protected for 10 years. The patent holder has the right to exclude others from commercially exploiting the invention; however, this does not necessarily give the patent holder the full right to use the patented invention, and licenses from third parties may still be required.

Before filing a patent application, the inventor should conduct a patentability search (preferably with the assistance of patent professionals). A patentability search looks into whether there are any publications (either protected by third-party IP or in the public domain) or prior public uses that cover the key

2 See WIPO, *Patents*, www.wipo.int/patents/en/ (last visited June 23, 2018) and USPTO, *General Information Concerning Patents*, www.uspto.gov/patents-getting-started/general-information-concerning-patents (last visited June 23, 2018).

3 35 U.S.C. § 102.

4 *Id.* § 101.

5 *Id.* § 103.

technical features of the device. This search is also helpful with patent drafting as it helps delineate the boundaries between the invention and the prior art.

Trade secret

If the medical device cannot be easily reverse-engineered (i.e., easily deconstructed to reveal the essence of the invention's design or architecture), the inventor might consider protecting the technology as a trade secret rather than a patent. Information may be protected as a trade secret if it derives independent economic value from not being generally known by the public, and the owner has taken reasonable measures to keep such information secret.⁶ Reasonable measures to preserve the secrecy of trade secrets include limiting access to such information to necessary personnel and using [confidentiality agreements](#). In addition to the product designs, other types of information that may be protected as trade secrets include marketing plans, cost and pricing information, and customer lists.

Trade secret protection and patent protection are mutually exclusive, and the inventor must choose what works best for the medical device. While the term of patent protection is limited and requires public disclosure of the invention, it gives the patent holder exclusive right even against independent developers of the same technology. In contrast, trade secret protection lasts as long as the information remains secret, but the protection will be lost if it is disclosed or if others independently develop the same technology.

Trademark, copyright, and data

When the medical device product is ready for the market, a distinctive brand name will enable physicians and consumers to identify the origin of the product. A trademark may or may not be registered, though registration provides additional benefits. A trademark may be registered with the U.S. Patent and Trademark Office (PTO) once it is used in commerce or through an “intent to use” process before the trademark is introduced into commerce. As

⁶ 18 U.S.C. § 1839.

for copyright, the Copyright Act gives automatic protection when the work is created regardless of registration. For a medical device company, works protected by copyright may include documentation of product development, user manuals, product catalogues or any relevant publications, as well as any software or firmware included on or with the device. The inventor should consult data privacy and security professionals if the medical device or its related application collects sensitive personal information from users.

Managing and Making Use of Intellectual Property

Protecting IP is among the most important steps in commercializing an invention. This section highlights the importance of sharing information about a new invention only when appropriate confidentiality protections are in place, and engaging the right level of IP protection early on. Issues regarding ownership, agreements, monetization of IP assets, and enforcement are factors that should be considered and addressed to ensure IP protection.

Intellectual property ownership

The default rule under U.S. patent law is that the rights in a patented invention belong to the inventor. A company may not automatically claim ownership to the invention created by its employees or contractors, but may require them to assign their rights through contracts. A physician-inventor should be cognizant of any existing obligations (whether by contract or policy) to assign inventions to his or her employer, especially if the physician-inventor was involved in research and development work for a hospital or research institute.

If an employer, like a hospital or academic medical center (AMC), owns the patent, and [a business entity is set up to commercialize the invention](#), the employer may grant a license to the company (usually an exclusive license), in exchange for payments, usually including royalties, and sometimes equity interests in the company. When an invention is co-developed by two or more individuals or institutions, each co-inventor owns an equal and undivided interest in the entire patent. Unless agreed upon otherwise, each joint owner may use and exploit the patent without the consent of and without accounting

to the other joint owners. A co-inventor situation emphasizes the importance of appropriate assignments and contracts. When engaging vendors and consultants, such as prototype developers or other parties that may contribute a component to the device, an IP assignment agreement or provision should be put in place to make sure all IP arising from the contractual relationship belongs to the medical device owner.

Confidentiality and non-disclosure agreements

Confidentiality agreements should be put in place with all personnel, business partners, and potential investors who have access to such confidential information. It is crucial to keep ideas and product designs protected from disclosure to the public during the prototype stage. An early disclosure could jeopardize patentability. When collaborating with academic institutions, inventors should take special caution on the subject of publications and should always request the right to review the proposed publications to protect confidential information.⁷ The inventors should also keep detailed records of the research and development of the medical device, which might become important evidence of inventorship later on.

Exploiting or monetizing intellectual property assets

Monetizing IP assets will require **formation of a business entity** that can commercialize the medical device and sell the IP-protected products. The newly-formed company may also license its IP to other companies, typically for some combination of upfront, milestone, and royalty payments. Another very common business model among life science startup companies involves selling the IP assets, or even the entire business, to a strategic buyer after a proof of concept.

⁷ See PETER J. OGDONIK, *MEDICAL DEVICE DESIGN: INNOVATION FROM CONCEPT TO MARKET* 305 (Academic Press 2012).

Enforcing intellectual property

A patent is infringed when a third party makes, uses, sells, offers to sell, or imports a product covered by the patent without the consent of the patent holder. The business entity formed to commercialize the invention may consider adopting a market monitoring program later on, but should at least have an internal procedure so that employees can report any potential infringement. If the company identifies an infringer, the company should consider engaging IP counsel, who may recommend sending a cease and desist letter as a first step. In most cases, settling the dispute is far more cost-effective than IP litigation.

Forming a Business Entity and Securing Funding

Choosing the right business entity and allocating shareholder rights depends on a variety of factors. Perhaps chief among these is identifying and securing future funding, so as to make the business attractive to investors or lenders. This section discusses in greater detail key factors to consider regarding entity set-up, shareholder rights, and funding.

Forming the business entity

A business entity will offer statutory protection from personal liability and help the inventors better handle the risks of developing and commercializing a new medical device product. Figure 2 provides a checklist of key steps and decisions that should be considered when setting up a business entity.

Figure 2—Business Formation Checklist

1. Entity Type:

- *Limited Liability Company (LLC)*: The LLC is tax-efficient as a “pass-through” entity with no corporate-level tax. An LLC also offers more flexibility to craft specifically tailored economic agreements and business control rights without having to abide by all of the rules that govern these aspects of corporations.

Figure 2 continued on next page.

Figure 2—Business Formation Checklist continued

- *C Corporation*: The C corporation is the most popular entity type, as it typically provides sufficient business flexibility and allows for diverse funding options; however, it also can be more inefficient in regards to taxes and maintenance.
 - *S Corporation (Small Business Corporation)*: Like the LLC, the S corporation has no corporate tax; however, it only allows one class of stock and up to 100 owners, which may be less attractive for outside investors.
2. Jurisdiction of Incorporation:
- *Delaware*: The most popular legal home for corporations in the U.S. due to its well-developed body of corporate law, court system, and efficient state administrative systems.
 - *Home State*: Under certain circumstances, it can be more administratively efficient for a startup to incorporate in the state where it actually does business.
3. Incorporation Process:
- Draft the certificate of incorporation and file it with the secretary of state;
 - Draft the statement (or action) of the incorporator, which may include adopting the by-laws and electing initial directors (the physician-inventor may want a board seat);
 - Prepare initial acts of the board of directors, including electing initial officers, accepting subscriptions for and issuing stock, and authorizing shareholder's agreement (if applicable);
 - Address shareholder rights (see Figure 3 regarding funding sources); and
 - Issue stock.

Figure 2 continued on next page.

Figure 2—Business Formation Checklist continued

4. Post-incorporation Matters:

- Apply for an Employer Identification Number (EIN) with the IRS;
- Establish a company bank account;
- Obtain appropriate insurance coverage for the company;
- Obtain appropriate ongoing accounting and legal services for the company; and
- Enter into key agreements with its employees, consultants, and founders, including non-disclosure agreements, intellectual property assignment agreements, and potentially non-compete and non-solicitation agreements.

Rights among shareholders

A key element of forming the business is finding a balance between treating the founding inventors fairly, and creating an attractive vehicle to attract the investment capital necessary to develop the product. Consider the following components in your efforts to strike the right balance between inventors and investors.

Reverse vesting of founders' stock

Equity of founders often comes in the form of “restricted stock.” Restricted stock will be subject to vesting restrictions, pursuant to which the founder will own all shares up front, but such shares will remain “unvested” and therefore subject to repurchase by the company until time passes or specified milestones occur. Restricted stock can help ensure that each individual founder remains committed to the company and “earns” his or her share of ownership; venture capital investors frequently require founders to subject their shares to such vesting restrictions. The tax treatment of restricted stock is complex, however, and founders should consult with tax advisors and consider a federal 83(b) election.

Shareholders' agreements

Another very important arrangement regarding the rights among the founders is the initial shareholders' agreement, sometimes called a "founders' agreement." Such an agreement typically sets forth the company's control and decision-making mechanisms when there are multiple founders and/or investors, including shareholder voting rights and election of directors. These initial shareholder agreements may also set forth drag-along rights (the right of majority shareholders to force minority shareholders to participate in the sale of the company), rights of first offer (a contractual obligation of a shareholder to offer the sale of his or her shares to other shareholders before offering the same to a third party), and co-sale rights (a right of shareholders to join in a sale of equity by another shareholder to a third party).

Institutional owners

Much physician-led innovation in the medical device field may arise in the context of an academic medical center. As noted earlier, when an AMC employs the physician-inventor, it likely will have required assignment of the invention as a condition of employment. AMCs will have conflict-of-interest policies that often lead to imposition of a management plan that will place constraints on the role that inventors may have with the company selected to commercialize the invention. These constraints may include restricting the types of research the inventors may engage in, excluding inventors or others involved with the company from AMC or hospital purchasing decisions, and disclosing to patients and others the physician-inventor's financial interests.

Securing funding for the business

How much funding the company will need depends on many factors, a major factor being the company's particular business model. In some cases, the employer of the physician-inventor, often a hospital or academic medical center, owns the intellectual property rights in the medical device, and may help found the new company as well as provide funding needed to develop the medical device products. More often than not, however, the new company

needs to consider other sources of outside funding. It is important to keep in mind that investors are looking for the best risk-adjusted returns they can get for their money and often have very different areas of focus. Figure 3 below includes a comparison of the major sources of funding available for a medical device start-up company.

Figure 3—Funding Sources

	Friends and Family	Angel Investors	Venture Capital	Government Grants	Bank Loans
Investors/ Grantors	Usually are unsophisticated investors. Beware of inviting additional referring physicians to invest (see AKS Considerations).	Typically financially-sophisticated and wealthy individuals who are often themselves successful entrepreneurs.	Professionally-managed investment firms (can be individuals too, but this is very rare). VCs come in two forms: traditional VC and strategic VC.	Federal or state governments. Major grantors in the medical device field include the National Institutes of Health (NIH) and Small Business Innovation and Research (SBIR).	Banks
Form of Investment	Usually in the form of loans, but can also come in the form of equity in the business.	Loan or security convertible into stock upon consummation of the company's first equity financing involving an outside evaluation.	Equity, usually in the form of preferred stock.	Grant award	Loans
Stage of Business to be Involved	Seed stage	Seed stage	Early stage (usually several years into the business with evidence of progress and revenue potentials).	Various stages	Not likely to be available to speculative startups that do not yet have significant assets or revenues.

Figure 3 continued on next page.

Figure 3—Funding Sources continued

	Friends and Family	Angel Investors	Venture Capital	Government Grants	Bank Loans
Involvement in Business Management	Usually not involved.	Angel investors usually do not take on management positions, but may provide beneficial guidance to the company and introduce their experience and contacts in the relevant industries.	The VC often takes an active role in the management of the business. Strategic VCs usually also contribute relevant business resources and industry expertise.	Usually none, but specialized audits may be required to confirm government funding is being used appropriately.	None.
Legal Terms	Usually no formal legal agreements involved.	The terms and documentation of this type of financing tend to be simple and cost-effective.	Complete set of investment agreements with more fulsome investor rights and more investor-favorable deal terms.	Usually government standard forms.	Usually standard loan agreement and security agreement from the bank.

Approval or Clearance at FDA

A physician seeking to develop and commercialize a medical device must satisfy requirements administered by the FDA.⁸ Under the Food, Drug, and Cosmetic Act (FDCA)⁹ and implementing regulations, the FDA imposes requirements on the total life cycle of medical devices, from premarket product development to postmarket surveillance.¹⁰ Physicians are often at the cusp of medical product

⁸ Physicians may be subject to other regulatory authorities if the devices are imported or exported.

⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9 §§ 301–399i [hereinafter *FDCA*].

¹⁰ This Practice Resource does not examine the regulatory pathways and requirements related to physicians who (i) intend only to use the device in his or her practice, (ii) intend only to customize a commercially available device and use it on fewer than five patients per year, (iii) intend only to use a commercially available device in an off-label manner as part of his or her practice of medicine, or (iv) intend only to use an investigational device on a compassionate use basis.

technology innovation because of their direct and constant visibility into unmet patient clinical needs. Physicians may fill a single gap in clinical care with a customized device,¹¹ off-label use of a marketed device,¹² or seek compassionate use of an investigational device.¹³ Such uses of existing devices are beyond the scope of this Practice Resource, as is the use of a new device invented by the physician but used only in his/her own medical practice.¹⁴

If, however, a physician identifies a recurring use in medical product technology, he or she may seriously consider developing a medical product to meet that clinical need, be it an entirely new technological design or concept or a modification to an existing technology. It is important to keep in mind that during the early phases of concept development, physician-inventors should begin identifying and understanding the FDA regulatory pathway to which the device would be subject. Early meetings with FDA to discuss potential avenues to market, including the associated data requirements, may offer predictability with respect to how FDA would plan to regulate the device. Predicting and planning for the regulatory requirements that will attach to product development will avoid substantial delays that could result if FDA expects more data than the physician-inventor expected. The following section addresses in greater detail regulation, research and development, and commercialization of a medical device.

11 For more information on FDA's custom device exemption pathway, see FDA, CUSTOM DEVICE EXEMPTION: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 24, 2014), available at www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm415799.pdf.

12 Section 1006 of the FDCA permits a health care practitioner to prescribe or administer a legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. FDCA § 396.

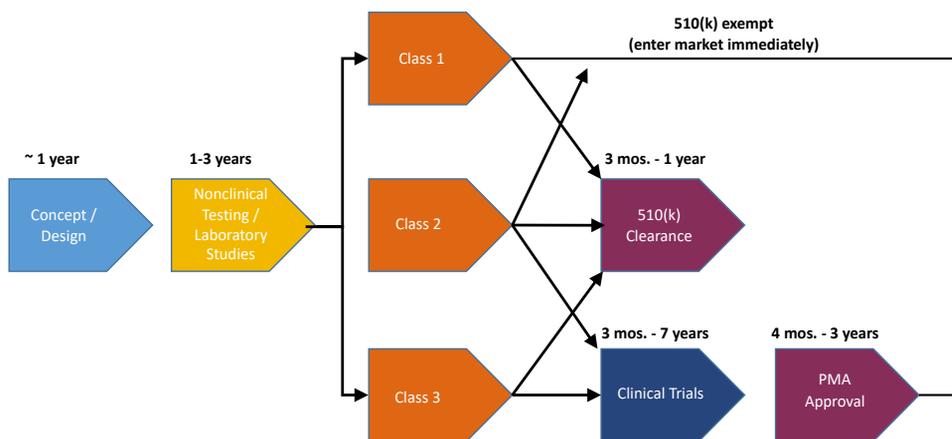
13 Compassionate use is a statutory mechanism by which FDA will allow access to investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. FDA requires that certain conditions be met, such as the patient experiencing a life-threatening or serious disease or condition and there being no generally acceptable alternative treatment for the condition. For additional information, see FDCA § 360bbb.

14 See e.g., 21 C.F.R. § 807.63(d).

Overview of how FDA will regulate your medical device

To bring a medical device to market, a physician-inventor must satisfy applicable FDA regulatory requirements associated with the type of device. The timeline for developing and commercializing a medical device may be significant depending on the type of device being pursued. A high-risk device that requires a clinical study may take an additional seven years of development as compared to a low risk device. The FDA life cycle is illustrated generally in Figure 4:

Figure 4—The FDA Life Cycle



FDA's framework for regulating medical devices is divided into three classes based on the risks and intended use of the device type: Class I (low risk devices), Class II (moderate risk), and Class III (high risk). FDA assigns each type of device to one of the three classes based on the level of regulatory controls that are needed to provide a reasonable assurance of the device's safety

and effectiveness.¹⁵ Not surprisingly, Class I devices are subject to minimal FDA requirements while Class III devices must satisfy rigorous requirements. A Class III device (such as a pacemaker) is more likely to cause harm if it fails to perform as intended as compared to a Class I device (such as a manual toothbrush). All medical devices regulated by FDA must satisfy general controls, which generally govern postmarket responsibilities. Devices that require premarket review (generally Class II and Class III) must be properly tested before FDA will allow them to enter commercial distribution. While FDA does not regulate early exploratory testing of medical devices, FDA does establish requirements to regulate nonclinical laboratory research as well as clinical studies. In general, Class III devices¹⁶ (and approximately 20% of Class II devices)¹⁷ will require clinical research data to support a marketing application.

Researching and developing your medical device

A physician may begin the product development phase when he or she sketches the design of the device on a napkin. Even though FDA does not directly regulate that early concept activity, the physician should begin thinking about FDA oversight as early as possible. Specifically, concept documents that result from early exploratory and utility research and testing, though not themselves FDA-regulated, may develop into design input requirements that will become part of the overall design controls of the device. Design controls apply to Class III, Class II, and certain Class I devices.¹⁸

15 FDCA §§ 360c–360c-1.

16 See *id.* § 360c(a)(1)(C).

17 See *Continuing America's Leadership: The Future of Medical Innovation for Patients: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions* 8 (2015) (statement of Jeffrey Shuren, Director, Ctr. for Devices & Radiological Health (CDRH)), available at www.help.senate.gov/imo/media/doc/Shuren3.pdf (“About 80% of all 510(k)s contain only non-clinical data.”).

18 Class I devices that are subject to design controls are (i) devices automated with computer software, and (ii) fall under one of five specific device types (tracheobronchial suction catheter, non-powdered surgeon's glove, protective restraint, manual radionuclide applicator system, and radionuclide teletherapy source). See 21 C.F.R. § 820.30(a)(2).

Determining the regulatory pathway for the device

There is no handbook that lays out the classification and regulatory pathway of every type of device. Instead, developers must rely on a combination of research and expert advice.

First, search FDA's product classification database and learn the classification regulation number and device class of the device type. The classification regulation is a provision in Title 21 of the Code of Federal Regulations (C.F.R.) that describes the product and sets forth the regulatory pathway. However, there are limitations to the scope of the classification regulation such that if a particular device has a different intended use or operates using a different fundamental scientific technology as compared to other legally marketed devices in that device type, the classification would not apply.

Second, FDA offers feedback through two primary mechanisms: pre-submission process and 513(g) requests. Under FDA's pre-submission program, developers can request feedback regarding potential or planned research or product applications. FDA generally provides written feedback within 70 days of the request. Developers could also submit a formal request for feedback under section 513(g) of the FDCA. Under section 513(g), any person can request from FDA information respecting the classification of a device or the applicable requirements under the FDCA, and FDA will respond within 60 days. The 513(g) request should contain a description of the device, the intended use of the device, and proposed labeling. Although FDA's feedback under the pre-submission and 513(g) processes is non-binding, it does represent the current thinking of the agency and should be weighted accordingly. Finally an inventor may seek external assistance. FDA consultants and law firms offer services to aid developers in determining the appropriate regulatory pathway.

Nonclinical testing

Physicians developing medical devices will first become subject to FDA regulatory responsibilities during the conduct of nonclinical testing. Under

regulations known as Good Laboratory Practice (GLP) requirements, FDA governs nonclinical product development, which follows on the heels of basic exploratory studies, such as characterizing the physical properties of the device and determining the device's potential utility. GLP requirements apply to "nonclinical laboratory studies," which include in vivo and in vitro experiments that study a device prospectively in a test system (defined as any animal, plant, microorganism, or subpart thereof) under laboratory conditions to determine safety.¹⁹ FDA's GLP regulations establish minimum basic requirements for nonclinical studies, which include animal studies,²⁰ to address, among other topics, personnel, facilities, equipment, study reports, and standard operating procedures (SOPs).²¹ Noncompliance with GLP requirements could prompt FDA to issue a violation letter or, more seriously, reject the affected data submitted as part of a marketing application.

Clinical testing

A physician-inventor whose device successfully passes nonclinical laboratory testing may seek next to subject the device to clinical testing involving human subjects if clinical data are required to support the marketing of the product. For example, 510(k)-exempt Class I devices rarely require clinical data, and 510(k)-subject Class II devices require clinical data in only about 20% of submissions.²² As the party who initiates the clinical study, the physician would

19 *Id.* § 58.3.

20 For further information on the use of animal studies to develop medical devices, see FDA, GENERAL CONSIDERATIONS FOR ANIMAL STUDIES FOR MEDICAL DEVICES: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Oct. 14, 2015), available at www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM466358.pdf.

21 At a high level, nonclinical laboratory studies, which include animal studies, must employ qualified personnel with appropriate training, must assign one individual to be the study director with overall responsibility for technical conduct of the study, and must designate a quality assurance unit to monitor and inspect the study for GLP and protocol compliance. Equipment used during the nonclinical laboratory study must be of appropriate design, be properly maintained, and be accurately calibrated.

22 See *Continuing America's Leadership: The Future of Medical Innovation for Patients: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions* 8 (2015) (statement of Jeffrey Shuren, Director, Ctr. for Devices & Radiological Health (CDRH)), available at www.help.senate.gov/imo/media/doc/Shuren3.pdf ("About 80% of all 510(k)s contain only non-clinical data.").

act as the regulatory sponsor of the study.²³ The physician need not carry out the functions and responsibilities of the sponsor, and instead may engage a contract research organization (CRO) to serve as the study sponsor. Importantly, however, FDA would not hold a CRO responsible for noncompliance of sponsor obligations, but rather the physician would remain ultimately accountable to FDA.²⁴ Physicians may choose to delegate all, some, or none of the sponsor obligations to a CRO. In general, a sponsor is responsible for (i) selecting qualified investigators and providing them with the information they need to conduct the investigation properly, (ii) ensuring proper monitoring of the investigation, (iii) ensuring that institutional review board (IRB) review and approval are obtained, (iv) complying with investigational device exemption (IDE) requirements, and (v) ensuring that any reviewing IRB and FDA are promptly informed of significant new information about the study.²⁵

In addition to deciding which sponsor obligations to fulfill, if any, the physician-inventor also must determine whether to serve as an investigator in the clinical study.²⁶ An investigator actually conducts the clinical investigation and immediately directs the administration or use of the device,²⁷ and is responsible for, among other obligations, (i) ensuring that an investigation is conducted according to investigational plan and applicable FDA regulations, (ii) protecting the rights, safety, and welfare of subjects under the investigator's care, (iii) controlling the investigational devices (e.g., assuring that the devices are not administered to individuals not properly enrolled in the study), and (iv) ensuring that informed consent is obtained.²⁸ Many physicians who initiate medical device research act as the sponsor-investigator and, as a result, assume regulatory responsibilities for complying with both sponsor and

23 21 C.F.R. § 812.3(n).

24 The physician could seek to hold the CRO contractually liable for any damages suffered as a result of the CRO's negligence, depending on the indemnification and liability provisions.

25 21 C.F.R. § 812.40.

26 Other laws may apply to the conduct of clinical research, such as the HIPAA Privacy Rule, the Common Rule (45 C.F.R. pt. 46, applicable to studies federally funded or conducted at institutions that apply Common Rule to all research regardless of funding), state laws (especially governing genetic testing), and other country laws (if research is conducted outside the U.S.).

27 21 C.F.R. § 812.3(i).

28 *Id.* § 812.100.

investigator FDA requirements.²⁹ As noted earlier, where there is an AMC owner, the AMC will consider whether an inventor serving as an investigator on a clinical trial is appropriate given the inventor's financial interest in the outcome of the trial. An AMC may find that this conflict is manageable by requiring that research participants be informed about the financial interest, and that the data from the study have some independent, objective review and analysis to minimize the potential for bias.

For medical device studies, FDA requires satisfaction of good clinical practice (GCP) requirements related to informed consent,³⁰ IRB oversight,³¹ certain investigator financial disclosures that could represent a conflict of interest,³² and investigational device exemption (IDE) requirements.³³ FDA's informed consent requirements require that investigators obtain the legally effective informed consent of subjects or their legally authorized representatives.³⁴ Although investigators interact directly with prospective subjects to obtain consent, the physician-inventor, most familiar with the design and manufacture of the device, as well as other clinical and nonclinical data regarding its safety and effectiveness, generally would be responsible for developing the consent form.³⁵ FDA's IRB requirements ensure that a

29 Any physician who elects to act as an investigator of the study should adopt rigorous measures to ensure regulatory compliance, such as undertaking robust training on applicable regulatory requirements, ensuring complete, accurate, and contemporaneous documentation, and installing sufficient personnel support, including sub-investigators and clinical research staff, to carry out the study. The physician-inventor also should address any potential conflicts of interests, or the appearance of a conflict of interest, that may arise in cases where the physician-inventor is either the sponsor or investigator.

30 21 C.F.R. pt. 50.

31 *Id.* pt. 56.

32 *Id.* pt. 54.

33 *Id.* § 812.2(c).

34 Notably, recent legislation allow IRBs to waive consent for certain minimal risk research if the IRB finds, among other factors, that waiver of consent will not adversely affect the rights and welfare of the subjects and that the study could not practicably be carried out without the waiver or alteration.

35 21 C.F.R. § 50.25 (the consent form must describe, among other aspects of the study, the procedures, reasonably foreseeable risks or discomforts, reasonably expected benefits to subject or others, appropriate alternative procedures or courses of treatment, extent to which confidentiality will be maintained, voluntariness of participation, and ability to withdraw at any time without penalty).

qualified institutional or commercial entity reviews, approves, and maintains oversight over the proposed study. To approve a prospective study, the IRB must determine, among other things, that risks to subjects are minimized; the risks are reasonable in relation to anticipated benefits and the importance of knowledge to be gained; and the selection of subjects is equitable (e.g., burdens of research do not disproportionately affect a vulnerable population). The IRB conducts continuing reviews (usually annually) to ensure that the study is still safe and being conducted ethically.

FDA's IDE regulations set forth a triumvirate division of medical device studies: significant risk (SR) studies, non-significant risk (NSR) studies, and IDE-exempt studies. The regulatory requirements attendant to each type of medical device study vary based on the risks posed by the investigational device. An SR study involves an investigational medical device that is, for example, intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.³⁶ An SR study requires the submission to FDA of an IDE application, which must contain sufficient nonclinical and other clinical testing data, as well as information about manufacturing and product design, to allow FDA to determine that the risks to subjects would be outweighed by expected benefits and that the study is scientifically sound.³⁷

In contrast, a physician-inventor who sponsors an NSR study is not required to submit to FDA an IDE application in advance of commencing the research, but instead must meet abbreviated requirements such as appropriate device labeling, recordkeeping, and reporting to FDA and the reviewing IRB(s). An IDE-exempt study is not subject to IDE requirements except potential investigator disqualification proceedings for serious or repeat noncompliance.³⁸ To be IDE-exempt, the study must involve an in vitro diagnostic device that is, among other things, noninvasive and is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.³⁹

36 *Id.* § 812.3(m).

37 *Id.* §§ 812.20, .30.

38 *Id.* § 812.2(c).

39 *Id.* § 812.2(c)(3).

Commercializing your medical device

If the device concept and prototype survive nonclinical and clinical testing, a physician-inventor may decide to commercialize the device for broader clinical use. To bring the device to market, the device must comply with the applicable premarket review process as well as general controls (Class II devices also must comply with special controls, such as patient registries and special controls guidance documents).

*Premarket review processes*⁴⁰

Most Class I and some Class II devices are exempt from submitting a premarket application to FDA, known as 510(k)-exempt device types. 510(k)-exempt devices may enter the market without submitting a marketing application in advance.⁴¹ In general, Class II devices are subject to 510(k) notification requirements to demonstrate that the new device is “substantially equivalent” to a legally marketed device. “Substantial equivalence” means that the new device has the same intended use as the legally marketed device, is as safe and as effective as the legally marketed device, and does not raise new questions of safety or effectiveness. If no legally marketed device exists to which the device at issue can be considered substantially equivalent, the FDCA would automatically classify the device into Class III, unless the sponsor submits a de novo petition to FDA to down-classify the device to Class I or Class II.⁴² A de novo petition provides FDA with nonclinical and clinical data to support the safety and effectiveness of the device when subject to general and, if applicable, special controls. The most rigorous marketing application is a premarket approval application (PMA), to which most Class III devices are subject. A PMA requires sufficient valid scientific evidence, often in the form of an

40 FDA also provides another regulatory pathway for devices intended to benefit patients with rare diseases or conditions, known as the humanitarian device exemption. A rare disease is defined as a disease or condition that affects fewer than 200,000 people in the United States. For further information, *see id.* pt. 814 subpt. H.

41 There are limitations, however, on whether a device would be exempt from 510(k) notification requirements, such as the device may not differ significantly in intended use or technological characteristics as compared to other devices in that generic class.

42 *See id.* § 360c.

adequate and well-controlled clinical investigation, along with nonclinical laboratory study data, to demonstrate to FDA that there is a reasonable assurance of the device's safety and effectiveness for the proposed intended use.

Postmarket obligations

A physician-inventor who satisfies the applicable premarket review process is also subject to minimum FDA requirements governing labeling, establishment registration, product listing, manufacturing, adverse event reporting, removals, and corrections. Device labeling must be truthful and nonmisleading, and must include adequate directions for use and any warnings needed to ensure the safe and effective use of the device.⁴³ Another general control is registration and listing,⁴⁴ which are generally administrative and nonsubstantive in nature and obligate a device company to register its establishment and list its commercially available devices with FDA. The information allows FDA to track recalled products as well as plan routine and targeted facility inspections.

One of the most critical aspects of device development is establishing and implementing manufacturing practices, referred to as the quality system regulation (QSR).⁴⁵ The QSR framework addresses the range of product manufacturing activities, from product design to complaint handling. Device manufacturers must establish methods and procedures to design, produce, and distribute devices that meet the manufacturer's quality system requirements. Another vital aspect of device regulation is FDA safety surveillance framework that requires manufacturers to notify FDA of events of (i) serious injury or death caused or contributed to by a medical device, or (ii) malfunctions that, if they were to recur, would be likely to cause or contribute to a serious injury or death.⁴⁶

43 See *id.* pt. 801.

44 See *id.* pt. 807.

45 See *id.* pt. 820.

46 See *id.* pt. 803 (FDA's medical device reporting framework).

Marketing Essentials: FDA and Anti-Kickback Considerations

FDA regulates the promotion of medical devices primarily under its authorities to prevent misbranding and adulteration of products. Advertising and promotional claims must be truthful, non-misleading, and consistent with the FDA label. The other key form of regulation of medical device marketing comes from the Anti-Kickback statute (AKS).⁴⁷ The AKS deals with improper financial incentives for those in a position to purchase, order, or lease (or arrange for or recommend the purchase, order, or lease) of medical devices used in the treatment of federal health care program patients. Institutional providers, like hospitals, are of course often the purchasers, but in many cases it is the physicians who perform procedures using medical devices who “arrange for or recommend” those purchases.

FDA regulation of marketing and promotion⁴⁸

A number of factors impact the marketing and promotion of a medical device, such as whether the device is investigational or 501(k)-exempt; premarket review requirements; and whether promotion is for off-label use.

Research phase

FDA does not permit the commercialization, promotion, or representation as safe or effective of an investigational medical device.⁴⁹ During the research phase of development, the device may be required to bear labeling that describes clearly its investigational status.⁵⁰ This obligation “ensures that

47 42 U.S.C. § 1320a-7b(b).

48 FDA has jurisdiction over labeling of all medical devices and the advertising of “restricted” devices. *See FDCA*, §§ 351, 360j. FDA restricts devices upon regulation or by order. However, FDA often relies on advertising and promotional claims to establish evidence of the intended use of the device. The Federal Trade Commission has primary authority for the advertising of non-restricted devices.

49 21 C.F.R. § 812.7.

50 *See, e.g., id.* § 812.5(a) (“An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with 801.1), the quantity of contents, if appropriate, and the following statement: “CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.”).

investigational devices are not advertised before their claims are established⁵¹ and claims are established after FDA vets and authorizes them as part of a marketing submission. FDA permits a device developer to make known the availability of the investigational device through an exhibit (e.g., medical or scientific conference) for the purpose of recruiting clinical investigators.⁵² The claims, however, cannot state or imply that the device is reliable, safe, or effective for uses being investigated, and the physician cannot sell the investigational device.

Postmarket phase

Depending on the premarket review requirements for the device, the physician may be required to submit labeling to FDA for review before commercialization. Specifically, FDA reviews the device labeling, including performance, safety, and effectiveness claims and indications for use, for 510(k) and PMA submissions. FDA does not conduct a review of product labeling for 510(k)-exempt devices, but such devices must be intended for a use that falls within the classification regulation for that device type. Advertising or promoting a 510(k)-exempt device for a new or significantly different intended use would subject the device to a 510(k) submission requirement. FDA prohibits claims that are false, misleading, or inconsistent with FDA-required labeling.⁵³ Claims that could arguably be false or misleading include those that (i) are supported by outdated data, (ii) use data related to a different patient population, (iii) suggest clinical benefit based solely on in vitro or animal data, or (iv) overstate the safety or efficacy. FDA's prohibition on off-label promotion bars a manufacturer from claiming the device is for a new intended use that is not part of the FDA required labeling. Products promoted for off-label use would be considered in violation of the FDCA and would

51 Medical Devices; Procedures for Investigational Device Exemptions, 45 Fed. Reg. 3732, 3741 (Jan. 18, 1980) (to be codified at 21 C.F.R. pts. 16, 20, 809, & 812).

52 FDA, PREPARING NOTICES OF AVAILABILITY OF INVESTIGATIONAL MEDICAL DEVICES AND FOR RECRUITING STUDY SUBJECTS (Mar. 19, 1999), available at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073585.pdf>.

53 See FDA, MEDICAL PRODUCT COMMUNICATIONS THAT ARE CONSISTENT WITH THE FDA-REQUIRED LABELING — QUESTIONS AND ANSWERS: GUIDANCE FOR INDUSTRY (June 2018), available at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537130.pdf.

present significant enforcement risk. Importantly, however, a physician may use a product in an off-label manner as part of the practice of medicine, but could not promote the product for such use.⁵⁴

AKS considerations

All financial relationships between medical device makers and ordering physicians (e.g., consulting and royalty agreements) are subject to AKS scrutiny. If a physician uses his or her referrals to the hospital as leverage to get the hospital to buy devices in which the physician has a financial interest, the AKS is implicated. Responsible medical device makers typically adopt a compliance program that regulates all potential sources of referring physician remuneration such as grants, meals, hospitality, free product, contracts for services, and royalties. Generally, device makers that follow the HHS Office of Inspector General's (OIG) program for voluntary compliance programs⁵⁵ and the AdvaMed Code of Ethics for Interactions with Health Care Professionals⁵⁶ will navigate these relationships without AKS violations; however, these longstanding areas of scrutiny pale in comparison to the key area of physician financial involvement with a medical device that has emerged in the last several years: avoiding the characteristics of an “inherently suspect” physician-owned distributor (POD) whose business model is primarily the POD's sale of devices ordered or influenced by the physician-owners to the hospitals and ambulatory surgery centers where the physicians refer their patients.

Why worry about PODs?

The last few years have not been kind to physician ownership of medical device companies. To name but a few prominent voices on the subject of PODs:

54 FDCA § 396.

55 See, e.g., *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003), available at <https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf> (n.5 indicates that many components are applicable to medical device makers).

56 AdvaMed, *Code of Ethics*, www.advamed.org/issues/code-ethics/code-ethics (last visited June 23, 2018).

- OIG issued a Special Fraud Alert (SFA) on Physician-Owned Entities, calling them “inherently suspect” under the AKS⁵⁷ and subsequently issued two reports concluding that PODs do not save money and do lead to overutilization of covered services;⁵⁸
- The Senate Finance Committee⁵⁹ and the Medicare Payment Advisory Commission⁶⁰ both advised that dealings with PODs be curtailed or eliminated; and
- Multiple large hospital systems took these warnings to heart, adopting policies that prohibit, or greatly restrict purchasing from PODs.⁶¹

Although most of the negative attention has focused on implantable medical devices, the SFA makes clear that this is because implants tend to be physician-preference items. Further, many of the anti-POD policies adopted by hospitals in the last few years have not been limited to implantable devices. Accordingly, whenever a device is one for which physicians play an important role in product selection, a POD analysis is in order. The good news is that for a medical device company that truly aims to commercialize a new product beyond the initial physician-inventors/investors, following the three guiding

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- 57 DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., SPECIAL FRAUD ALERT: PHYSICIAN-OWNED ENTITIES, at 3 (Mar. 2013), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/pod_special_fraud_alert.pdf [hereinafter *2013 Special Fraud Alert*].
- 58 DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., SPINAL DEVICES SUPPLIED BY PHYSICIAN-OWNED DISTRIBUTORS: OVERVIEW OF PREVALENCE AND USE, (Oct. 2013), available at <https://oig.hhs.gov/oei/reports/oei-01-11-00660.pdf> [hereinafter *2013 OIG Report*]; DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., MEMORANDUM REPORT: OVERLAP BETWEEN PHYSICIAN-OWNED HOSPITALS AND PHYSICIAN-OWNED DISTRIBUTORS (Aug. 13, 2015), available at <https://oig.hhs.gov/oei/reports/oei-01-14-00270.pdf>.
- 59 S. FIN. COMM. MINORITY STAFF, PHYSICIAN OWNED DISTRIBUTORS (PODs): AN OVERVIEW OF KEY ISSUES AND POTENTIAL AREAS FOR CONGRESSIONAL OVERSIGHT, at 2 (June 2011), available at www.finance.senate.gov/imo/media/doc/POD%20Analysis%20June%202011.pdf; S. FIN. COMM. MAJORITY STAFF, PHYSICIAN OWNED DISTRIBUTORSHIPS: AN UPDATE ON KEY ISSUES AND AREAS OF CONGRESSIONAL CONCERN, available at www.finance.senate.gov/imo/media/doc/Combined%20PODs%20report%202.24.16.pdf.
- 60 MEDICARE PAYMENT ADVISORY COMM., REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM (June 2017), available at www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.
- 61 E.g., LHP Hospital Group Inc.; Hospital Corporation of America (HCA); Intermountain Health; Tenet Healthcare Corporation.

principles listed in Figure 5 can help avoid the key characteristics that make a POD arrangement suspect:

Figure 5—Guiding Principles for POD Avoidance

- **Ownership:** *Limit physician ownership to the inventors and, if needed for initial funding, perhaps a small number of collaborating early adopters. Seek subsequent finance from non-physicians.*
- **Customers:** *Seek to make the physician-owners a minor part of the customer base. Shrink annually the percentage of sales ordered by the physician-owners.*
- **Referrals:** *Do not condition patient referrals on purchasers' use of POD-supplied products.*

The growing negative chorus

PODs first reached industry and public attention (invariably negative) in the first decade of our new century,⁶² with OIG speaking out in 2006 in a letter to AdvaMed expressing serious concerns with physician-owned implant companies under the AKS.⁶³ Two years later, Centers for Medicare and Medicaid Services (CMS) considered amending the Stark physician self-referral regulations to address PODs and similar entities,⁶⁴ noting that PODs and similar physician-owned entities may “serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for

62 *E.g., Nicole DiMaria, Arrangements With Physician-Owned Medical Device Distribution and Purchasing Companies – A Compliance Risk for Hospitals?*, 11 HOSPS. & HEALTH SYS. RX, 1 (Apr. 2009), available at www.csglaw.com/B8D11B/assets/files/News/dimaria_hhsapr09.pdf.

63 Letter from Vicki L. Robinson, Chief, Indus. Guidance Branch, Office of Inspector Gen., Re: Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

64 Medicare Program; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23528, 23695 (Apr. 30, 2008) (“we are soliciting public comments as to whether our physician self-referral rules should address POCs and similar physician owned companies more specifically”).

nothing more than ordering medical devices or other products that the physician-investors use on their own patients,” and in some cases may run afoul of the Stark statute.⁶⁵ This chorus of negative attention culminated in the issuance of a Special Fraud Alert on PODs in 2013⁶⁶—one of only fourteen such warnings OIG has issued. Later that same year, OIG released a report on POD prevalence and use based on claims billed to Medicare demonstrating that in fact, when hospitals began buying from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall, and costs did not come down.⁶⁷

The past few years have also seen federal enforcement against PODs. In 2014, the U.S. Department of Justice (DOJ) filed a civil case against the California-based Reliance Medical Systems, LLC POD, two related distributors, and several of their investors, including one physician, for potential kickbacks and submission of false claims.⁶⁸ The DOJ also filed criminal charges related to the POD activities. In January 2017, one of the individuals was sentenced to 235 months (almost 20 years) in prison for his role in the POD.⁶⁹ In connection with his guilty plea, the physician-owner admitted, among other acts, that he had convinced his hospital to purchase spinal implant devices from a POD to use in his own surgeries, and that he used more devices than were medically necessary in order to generate more sales revenue, resulting in serious bodily harm to his patients.⁷⁰

When is a physician-owned device maker a POD?

The SFA adopts a broad definition of POD as “any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices [including] entities that purport to design or manufacture . . . their

65 *Id.*

66 *2013 Special Fraud Alert.*

67 *2013 OIG Report.*

68 Complaint, United States v. Reliance Med. Sys., LLC, Case No. 14-6979 (Nov. 5, 2014).

69 Press Release, Dep’t of Justice, Detroit-Area Neurosurgeon Sentenced to 235 Months in Prison for Role in \$2.8 Million Health Care Fraud Scheme (Jan. 9, 2017), available at www.justice.gov/opa/pr/detroit-area-neurosurgeon-sentenced-235-months-prison-role-28-million-health-care-fraud.

70 *Id.*

own medical devices or instrumentation.⁷¹ OIG goes on to point out that it does not want to discourage innovation, but that claims of product superiority will not overcome the inference that the investment is intended to induce the physician to order the company's product.⁷² Thus, although there seems little doubt that a simple distributor of other companies' products, which cannot claim to be an innovator, is in a weaker position, it also cannot be said that just because a physician-owned company has developed a new product, it will avoid POD scrutiny.

On the other hand, the mere fact of physician ownership is not enough to create an "inherently suspect" POD. To begin with, some start-up businesses with physician owners may be able to satisfy the requirements of the AKS safe harbor for investments.⁷³ Most of these requirements relate to treating physician-investors like other investors, but many companies fall short on the requirement that no more than 40% of the business may be owned by referring physicians or persons or entities providing items or services (e.g., management), and no more than 40% of the revenues may come from physician-owner referrals.⁷⁴ While the second of these tests ought to be a goal of any device maker, it may not be true at the beginning, and the first requirement may be difficult even longer term. In addition, the requirement that investment return be proportional to capital investment may be tricky where the physician-inventor's contribution is of uncertain value.

If safe harbor protection is not available or is uncertain, the SFA identifies a number of features of a POD that render it "inherently suspect." The list in Figure 6 contains a fairly complete list of what OIG considers "suspect characteristics." With a few exceptions (highlighted in blue in Figure 6 below), it should not be difficult to organize and operate the business without raising concern regarding the presence of such suspect characteristics.

71 2013 *Special Fraud Alert*, at 1, n.1.

72 *Id.* at 4.

73 42 C.F.R. § 1001.952(a)(2).

74 *Id.*

Figure 6—OIG’s List of Suspect Characteristics of a POD

- Selecting investors because they are in a position to generate substantial business for the POD.
- Physician-owners are required, pressured, or actively encouraged to recommend the purchase of POD devices.
- The POD retains the right to re-purchase a physician-owner’s interest if the physician fails to purchase sufficient POD devices.
- The physician-owners are few in number, so that the value of a particular physician-owner’s referrals closely correlates with that physician-owner’s return on investment.
- The physician-owner alters his or her medical practice after or shortly before investing in the POD (e.g., by performing more surgeries, more extensive surgeries, or switching to the POD’s devices).
- The size of the physician’s investment in the POD varies with the expected or actual volume or value of devices used by the physician.
- Financial distributions are not in proportion to ownership interest, but rather the actual volume or value of devices used by the physician.
- Physician-owners condition referrals to hospitals or ambulatory surgery centers (ASCs) on the purchase of POD devices (either through coercion, promises, or exclusive purchase arrangements).
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory, or employ personnel.

Figure 6 continued on next page.

Figure 6—OIG’s List of Suspect Characteristics of a POD continued

- The POD does not maintain continuous oversight of all distribution functions.
- The physician-owners fail to disclose their ownership interests to hospitals and ASCs.
- The POD exclusively services the physician-owners’ patient base.
- The POD distributes extraordinary returns on investment compared to the level of risk involved.

If the business is formed with the three guiding principles in mind (as illustrated in Figure 5), most of the “suspect characteristics” simply will not be present, including those that are highlighted as exceptions in Figure 6 (because they could in some aspects seem to appear in such a company). For example, the following behaviors or actions describe scenarios that should not be considered suspect even though they may appear otherwise:

- **Selecting investors for referrals:** If the only physician-owners are the inventors, and the business plan is to make those owners only a minor part of the customer base, this inference of intent will not be present.
- **Product recommendations by the owners:** If the business plan is broad commercialization and the only physician-owners are the inventors, requiring or encouraging referrals from the doctors will be unnecessary, and recommendations alone will not be suspect.
- **Right of repurchase:** This is commonplace in a closely-held business, and should not be suspect if the business is not built on referrals from the physician-inventors.
- **Change in practice:** It is unquestionable that the physician-inventors will want to make use of their invention; only when ownership is offered to non-inventors to capture their referrals should this be suspect.

- **Number of physician-owners:** If sales are broadly beyond the inventor-physicians, investment return will not correlate with their use of the product.

The duration or longevity of suspect characteristics is another factor that impacts POD concern for properly-constructed companies that include physician-inventors (and even a small number of early adopters) as owners. Although OIG's analysis on PODs does not make explicit reference to the longevity of the suspect characteristics, the agency's historical approach to the issue of investment suggests that duration could be central to deciding whether a physician-owned entity merits enforcement. In promulgating the investment safe harbor in 1991, OIG made a point of recognizing that a venture may pass through a stage where it has too many physician-investors without meriting enforcement:

We emphasize that it is highly unlikely we will pursue an investigation of a joint venture where it complies with all the other standards in this safe harbor, is out of compliance with this 60-40 percent investment standard based on its prior fiscal year data, but is making a good-faith effort to reach compliance with this standard based on data showing compliance on a monthly basis for the most recent months of operation.⁷⁵

Applying this perspective, it seems clear that the essence of what makes a POD "inherently suspect" is when ownership by physician customers is not just an early stage in the company's growth but rather, is the continuing, long term business strategy. This interpretation would be consistent with the history of medical device invention in the U.S., which as OIG recognizes, has always relied heavily on physician involvement as inventors and early adopters. In 2008, Gregory Demske, then Assistant Inspector General for Legal Affairs at OIG (now Chief Counsel to the Inspector General), cited heart valves, pace-makers, and medical lasers as examples of medical devices that resulted from physician innovation:

⁷⁵ 56 Fed. Reg. 35952, 35968 (July 29, 1991).

In the development of new technologies and products, the interaction between device manufacturers and health care professionals can be especially valuable because physicians play an essential role in the development, testing, and extensive training involved in producing effective and safe medical devices, such as heart valves, pacemakers, and medical lasers.⁷⁶

Although operationalizing all of the principles discussed in this section requires diligence, medical device makers that follow OIG compliance guidance and the AdvaMed Code generally will avoid serious AKS concerns. POD status is the principal AKS risk facing the physician-inventor in commercializing a medical device. Assuming the inventor wants to remain an owner of the business, the business should be modeled after the three guiding principles illustrated in Figure 5 to target customers who are not owners, and reserve ownership opportunities for investors who are not customers.

Coverage and Reimbursement

Who pays for a new medical device once it receives FDA clearance? Even the safest, most effective device may not achieve commercial success without a reimbursement strategy. Unless the cost is insignificant or the technology significantly reduces costs of medical care, customers and investors likely will not purchase and/or be interested in medical technologies for which reimbursement is unavailable. Establishing reimbursement will require strong relationships with specialty societies, a sound body of U.S.-published empirical evidence of efficacy, and support from physicians and practitioners. In addition, the coverage, coding, and payment processes take time, so it is important to start early in establishing and following a reimbursement strategy; in some instances, this process may take longer than obtaining

76 *Surgeons for Sale: Conflicts and Consultant Payment in the Medical Device Industry: Hearing Before the S. Special Comm. on Aging*, 110th Cong. 7 (2008) (statement of Gregory E. Demske, Assistant Inspector Gen. for Legal Affairs, Dep't of Health & Human Servs.).

FDA marketing approval.⁷⁷ Thus, a comprehensive reimbursement strategy, including the employment or retention of reimbursement experts and appropriate contacts with relevant specialty societies should be early-stage components of the development of a new medical device.

Payment, coding, and coverage

There are three main elements for device reimbursement: coverage, coding, and payment:⁷⁸

- **Payment determines a device maker's pricing strategy:** Are providers eligible to receive additional reimbursement for using the device? What are the settings in which the new device will be used?
- **Coding identifies when a device is used and the professional reimbursement for performing the associated procedure:** Is the new device (or the procedure in which it is used) clinically different from current procedures?
- **Coverage dictates whether a device is eligible for payment:** Is access to the new device reasonable and necessary (and, potentially, cost effective) for each payer's patient population?

Figure 7 illustrates this process, explained in more detail below. A medical device maker may approach the elements in any order; however, a favorable

77 A parallel process, announced by HHS in 2011, allows manufacturers of new Class III devices to seek a CMS national coverage determination in parallel with FDA premarket approval. See 76 Fed. Reg. 62808 (Oct. 11, 2011) (establishing pilot program); 81 Fed. Reg. 73113, 73114 (Oct. 24, 2016) (extending program indefinitely). As of December 2017, only two devices (a colorectal cancer test and a next generation sequencing test) have been approved under the parallel process. See Michael Mezher, *FDA, CMS: Second Parallel Review Decision Ever for NGS Test*, Regulatory Affairs Prof'l Soc'y (Dec. 1, 2017), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/12/fda,-cms-second-parallel-review-decision-ever-for-ngs-test>. As discussed herein, a national coverage determination is not required to receive reimbursement from CMS and parallel review does not impact the process for establishing a new code for the procedure associated with the device.

78 See CTRS. FOR MEDICARE & MEDICAID SERVS., INNOVATORS' GUIDE TO NAVIGATING MEDICARE: VERSION 3, at 3–4 (2015), available at <https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf> [hereinafter *Innovators' Guide*].

coverage decision from each payer is required to obtain reimbursement.⁷⁹ Coding changes may be necessary in order for a new device to be competitive with existing products. What payments a medical device maker can expect to receive from customers will be determined based on a combination of coding and coverage, as well as market demand for the medical device.

Figure 7—Timeline for Establishment of New CPT Code



Payment

With very rare exceptions, Medicare and most private payers reimburse hospitals and other facilities on a bundled basis that does not include a separate payment for using a specific medical device.⁸⁰ In some instances, the CMS will provide additional, temporary payments to hospitals to support the use of new, expensive technology that is not yet reflected in bundled

⁷⁹ *Id.* at 5.

⁸⁰ See *Innovators' Guide*, at 32.

prices.⁸¹ However, CMS often rejects requests for add-on payments on the basis that the new technology does not offer a substantial clinical improvement over existing devices.⁸²

Physicians do not receive separate reimbursement for medical devices used in a clinic or hospital setting. Physicians do, however, receive compensation on a per-procedure basis that takes into account the time, effort, and costs associated with a specified procedure. Obtaining a new procedural code and estimate of the professional effort associated with a new medical device is therefore highly relevant to a device's commercial success.

Coding

New coding becomes important where use of the device involves a new procedure or adds measurably to the provider's expense in performing an existing procedure. Medicare and private payers use three main standardized code sets to process claims: (i) the International Classification of Diseases, 10th Edition (ICD-10), which is used for diagnosis and inpatient hospital procedures; the American Medical Association's (AMA) Current Procedural Terminology (CPT), which covers procedures and services performed by physicians; and Healthcare Common Procedure Coding System (HCPCS), which incorporates CPT codes and is used in CMS billing.

Most new procedures and diagnoses will be covered under an existing ICD-10 code. Obtaining appropriate CPT coding for a procedure associated with a new device should therefore be a priority. Obtaining a new CPT code for a procedure that is associated with a device requires FDA approval. The device maker also must show that the procedure is distinct from procedures

81 See 42 U.S.C. § 1395ww(d)(5)(K)–(L) (new technology add-on payments for inpatient procedures); see also 42 C.F.R. § 419.66 (transitional pass-through payments for outpatient procedures).

82 See Kerry Young, The Commonwealth Fund, *Medicare Rejects Most Bids for New Technology Add-On Payment*, Aug. 5, 2015, available at www.commonwealthfund.org/publications/newsletters/washington-health-policy-in-review/2015/aug/aug-10-2015/medicare-rejects-most-bids-for-new-technology-addon-payment.

covered under current CPT codes, is commonly performed in the U.S., and is supported by U.S.-based peer-reviewed literature.⁸³

Proposals for new or revised CPT codes may be submitted by specialty societies, individual physicians, hospitals, third-party payers, or other interested parties, including device makers.⁸⁴ The CPT Editorial Panel meets three times per year (generally in February, May, and October). Requests must be submitted three months prior to an upcoming meeting.⁸⁵ Prior to submitting a request to the CPT Editorial Panel, a device maker may choose to work with a relevant specialty society. The specialty society may require materials to be submitted well in advance of a CPT Editorial Panel meeting submission deadline.⁸⁶ Thus, it is important for a device maker to establish relationships with a relevant specialty society well in advance of the device's expected date of commercial availability.

Following a meeting, the Editorial Panel may add a code, reject a code, or submit it for further study. The code also may be withdrawn by its proponent in order to submit additional supporting materials. If a proposal is granted at a spring meeting, the update will generally be included in the fall CPT update and effective January 1 of the next year. If the proposal is granted at the fall meeting, the new code will be included in the CPT update for the subsequent year.

Following approval, the AMA's Relative Value Scale Update Committee (RUC) may provide a resource-based relative value scale (RBRVS) recommendation regarding the work associated with the new CPT code to CMS.⁸⁷ The

83 See AMA, Coding Change Application at 1-3 (June 6, 2017), available at <https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-category2-application.pdf>.

84 See AMA, *The CPT Code Process*, www.ama-assn.org/practice-management/cpt-code-process (last visited June 24, 2018).

85 *Id.*

86 See, e.g., AM. ACAD. OTOLARYNGOLOGY-HEAD AND NECK SURGERY, AAO-HNS NEW TECHNOLOGY PATHWAY REQUESTS: POLICIES AND PROCEDURES (May 2015), available at www.entnet.org/sites/default/files/aaohns_new_technology_pathway_requests_policies_and_procedures_may_2015.pdf.

87 See AMA, 2018 RVS UPDATE PROCESS, at 5, available at www.ama-assn.org/sites/default/files/media-browser/public/rbrvs/ruc-update-booklet_0.pdf.

RUC uses the clinical vignette submitted as part of the CPT process to solicit specialty society feedback on the new code.⁸⁸ RUC recommendations submitted to CMS by February 10 of each year, which include most codes approved by the Editorial Panel during the previous calendar year, will be considered as part of CMS's annual Physician Fee Schedule (PFS) update.⁸⁹

Coverage

As the largest payer in the United States, coverage decisions by CMS often guide private payers' determinations of whether a new device will be covered. Section 1862(a)(1) of the Social Security Act prohibits Medicare payments for "items or services which . . . are not reasonable and necessary . . ."⁹⁰ Private payers make their own determinations, but generally if Medicare decides that coverage is reasonable and necessary, private payers eventually will follow suit.

In many instances, a device may be covered under prior CMS decisions to cover procedures that are similar to the procedure associated with a new device. In the absence of coverage for analogous procedures, CMS and its regional claims administration contractors (MACs) have overlapping authority to determine coverage for an item or service.⁹¹ National Coverage Determinations (NCDs) serve as generally applicable rules for similar items or services, whereas Local Coverage Determinations (LCDs) allow a MAC to make case-by-case determinations of coverage for individuals.⁹² LCDs are often the route of choice because they provide more than one bite at the coverage apple, although that may lead to coverage in some areas but not in others.

Seeking an NCD is a higher-risk strategy. A favorable NCD provides Medicare coverage nationwide, but an unfavorable decision precludes coverage altogether. A medical device maker generally should consider requesting an

88 *Id.* at 5–7.

89 See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, 81 Fed. Reg. 80170, 80271 (Nov. 15, 2016).

90 42 U.S.C. § 1395y(a); see also CMS, *Medicare Coverage Determination Process*, www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html (last visited June 24, 2018).

91 See 42 U.S.C. §§ 1395ff(f)(2)(B), 1395y(l) (National Coverage Determinations).

92 See Medicare Program; Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48164, 48165 (Aug. 7, 2013).

NCD only if the medical necessity of the device is supported by a persuasive body of evidence. If a device maker submits a formal request for an NCD, CMS generally has six months to review the request and post a draft decision memorandum; however, CMS may elect to conduct a “Technology Assessment” (TA) or refer the matter to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). In either case, CMS will receive an additional three months to post the draft decision memorandum.⁹³ Once posted, CMS will collect public comments for thirty days and issue its final decision within sixty days following the end of the comment period.⁹⁴

CMS also has the option to issue an NCD that is “Coverage with Evidence Development” (CED). The purpose of CED is to determine whether the item or service is appropriate for specified conditions and Medicare beneficiary populations.⁹⁵ A CED will require additional data collection, such as clinical trial data, as a condition of coverage.⁹⁶

The future of reimbursement

CMS is currently implementing new payment systems that are intended to transition payment from fee-for-service to value-based payments. These pilot programs do not modify the payment systems described above; however, the programs do implement various forms of risk sharing between CMS and providers with respect to care quality, outcomes, and cost-effectiveness. Medical device makers should evaluate whether a new device offers opportunities to support providers participating in value-based purchasing initiatives. **J**

93 42 U.S.C. § 1395y(l)(2).

94 *Id.* § 1395y(l)(3).

95 *Id.*

96 CMS, *Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development* (Nov. 20, 2014), www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27 (last visited June 24, 2018).



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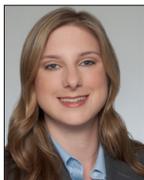


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