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# Practicing Innovation: Special Device Commercialization Considerations for Innovators Who Continue Practicing

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The medical device industry is special in that product innovation can occur "in the field"—practicing medical professionals are uniquely positioned to understand both the physiological and patient need for a medical device. Yes, large, multi-national corporations and small-medium enterprises (SMEs) develop medical devices from innovation all the way through commercialization. But many of these entities have come to realize the value in seeking out medical device inventions from practicing professionals as a supplement to their internal or contracted research and development efforts. This article will discuss the basics of medical device commercialization, with a focus on those issues that impact a practicing healthcare professional in unique ways.

## Product Innovation and Design

The Food, Drug, and Cosmetic Act (FDCA) defines a "device" as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary

> intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[1]

In general, if medical claims are made about a product, it is considered a medical device and will be regulated by the U.S. Food and Drug Administration (FDA). Practicing healthcare professionals are likely familiar with the FDA's deference to the practice of medicine and to physicians' ability to use approved medical products (drugs and devices) for new uses or purposes without obtaining specific FDA approval for each and every new use. However, FDA regulations may be applicable to physicians well before a device is legally commercialized.

The concept for a new medical device may stem from an improvement to an existing device or to fill a need in existing healthcare practice. Whatever the impetus for the new medical device idea, a practicing professional should consider two fundamental issues—intellectual property protection and design controls. First, intellectual property protection is the cornerstone of any future collaboration or relationship between the practicing innovator and a larger corporation. The practicing innovator should analyze whether patent protection is appropriate (versus reliance on trade secret protection alone) for the particular device. Obtaining a patent is not always the best strategy. A patent permits the owner to exclude others from making, using, offering for sale, or selling the patented product. This right to exclude others is not always useful, particularly if an existing product patent is broad enough to include features of the new device. In that case, the practicing innovator may be excluded from using his or her own patented invention. The need for trademark or copyright protection should also be assessed.

Second, the device design should be developed and documented according to FDA requirements. This proactive attention to FDA requirements will add value to the device by saving future collaborators or purchasers of the device significant time and money. Ultimately, the medical device manufacturer will need to "establish and maintain procedures to ensure that design requirements address the intended use of the device, including the needs of the user and the patient."[2] Design controls are based upon quality assurance and engineering principles. Because most practicing innovators are not engineers, attention to clear and accurate documentation of the physical and performance requirements of a device is important. Design changes should also be clearly documented with a rationale for the change. This documentation of the innovative process should be taken with an eye toward the intellectual property strategy chosen, since disclosure of an invention may impact timing for patent submissions.

## Evaluation of New Devices

Once a practicing innovator has moved the concept for a medical device from idea to prototype, the next step may be to test the device to determine if it works as envisioned. What many practicing innovators do not realize is that such "investigations" are regulated by FDA if the investigation or research involves one or more human subjects to determine either the safety or the effectiveness of the medical device.[3] Investigational devices include new and previously untested devices, in addition to modifications to legally marketed medical devices. FDA's requirements for investigational devices serve to protect human subjects, as described in 21 C.F.R. Part 50. All clinical evaluations of an investigational device must have an Investigational Device Exemption (IDE) in place *before* initiation of the study.[4] An IDE can be obtained directly from an Institutional Review Board (IRB) for non-significant risk devices, but significant risk devices must also have FDA approval.[5] Significant risk devices include those that are implantable, life sustaining, important to diagnosis, or present a risk to health and safety.[6] Conducting an investigation under an IDE requires informed consent from all patients, labeling reflecting that the device is for investigational use only, monitoring of the study, and maintenance and submission of required records and reports.

There are exemptions to the FDA's requirements for obtaining an IDE. An IDE is not required if the device is intended solely for veterinary use or will be used only for research on laboratory animals. Certain diagnostic devices do not require an IDE if the device is noninvasive, does not require invasive sampling, does not introduce energy (such as ultrasound or x-ray) into the patient, and is not used alone (without confirmation) for diagnosis. Finally, "custom devices" are exempt from IDE requirements. A "custom device" is one that is not generally available to, or generally used by other physicians or dentists; is not generally available in finished form for purchase or for dispensing upon prescription; is not offered for commercial distribution through labeling or advertising; and is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice. There is a fine line between a practicing innovator's making use of a custom device and investigating a new device that may later be commercialized.

## Options for Partnering Relationships

A practicing innovator may decide to leave the practice of medicine and pursue commercialization of the new medical device. More often, however, the practicing innovator wishes to continue practicing his or her profession, collaborate to bring the new medical device to market, and hopefully generate an income stream in doing so. For these practicing innovators, there are a number of options for strategic partnering. Solutions for practicing innovators typically fall into three categories:

(1) An asset sale;

(2) Licensing the device (with or without a royalty); and/or

(3) Entering into consulting or services arrangements with a commercial manufacturer.

### Asset Sale

The practicing innovator may seek to sell assets to a commercial enterprise. The assets to be sold may be just the intellectual property alone, but could also include any documentation

relating to the new medical device, all prototypes produced thus far, any regulatory approvals (such as an IDE or any FDA clearances or approvals), and any documentation relating to clinical investigation of the new device. One benefit of an asset sale is that it works to define a clear end to the relationship—closing. Asset purchase agreements will include a series of representations and warranties by the practicing innovator (seller) establishing the intellectual property ownership and compliance with laws, as well as setting forth financial terms of the purchase. Comprehensive indemnity provisions will be included to account for one party's bad acts or mistakes, especially those made in the representation and warranty provisions. Both parties will typically seek to ensure that the other can "make good" on the indemnity if a problem occurs in the future.

Asset purchase agreements also tend to include covenants and conditions precedent to control the behavior of the buyer and seller prior to closing. The agreement may limit the parties' ability to discuss the arrangement publicly before closing and may require joint press releases post-closing. Typically, the practicing innovator will be constrained by a non-compete and a non-disclosure provision, so as not to compete with the purchaser. This typical corporate restriction can be particularly stifling for a practicing innovator who intends to continue practicing medicine and who may be intending to use the new medical device in their practice after marketing approval from the FDA is obtained. A thorough review of the restriction and potential impact on the innovator's scope of medical practice is warranted.

The medical device company with whom the practicing innovator is dealing may seek to gain an advantage through a bifurcated purchase price. That is, a certain percentage will be paid at the closing, while the balance will come due at a specific milestone, usually FDA clearance or approval of the medical device. Such bifurcation can be expected when the purchaser is carrying all of the risk for obtaining regulatory approval or commercializing the device. Practicing innovators should be aware that typical clearance for a Class II medical device through the 510(k) submission process typically takes six to nine months. If the medical device is a Class III or otherwise requires the more stringent PMA, the time frame could be twenty-four months or longer.

One way the innovator can maintain leverage to ensure that the second payment is ultimately received and discourage the purchaser from simply squatting on the technology is to include a time restraint on the second payment. This would either require that the second payment be made within a set timeframe or structure the arrangement with an automatic reversion clause. The automatic reversion clause could state specific conditions which upon failure, will either return the purchased assets to the seller or require a penalty lump sum payment (usually much larger than the second purchase price payment).

## License

A license, whether exclusive or not, must also clearly define the specific item(s) to be licensed. The license itself attaches to a property ownership interest and can include tangible and intangible items such as patents, trademarks, copyright, goodwill associated with a business (if a separate business enterprise exists), documents, buildings, etc. If the innovator did not act alone in developing the device, he or she may need to obtain a license from the co-owner(s) before further licensing the product. If intellectual property protections have not been secured (either because a patent has not been sought or has not yet issued), the practicing innovator should clearly define what constitutes the scope of the innovation, including whether specific aspects of the technology are retained for the innovator to use freely later.

Licenses also may include a non-competition clause (or reference a separate non-competition agreement) similar to those found in an asset purchase agreement. A distinguishing characteristic of a license is the non-permanent nature of the transfer. Unlike an asset purchase, a license is characterized by specific permissions to use, sell, develop, offer to sell, etc. A license can be limited in scope (Worldwide or United States only? Exclusive or non-exclusive?) and length (One year? Five years?). The practicing innovator may be able to restrict further use of the product by prohibiting further sublicenses, thereby ensuring that only the original licensor has rights to the technology.

Another distinguishing characteristic of a license is royalty payments. In addition to one or more milestone payments (usually set at either product development benchmarks or product sales milestones), a license typically includes a royalty payment expressed as a percentage of "Net Sales" or, in some cases, "Gross Sales." Royalties calculated on Net Sales are typically sought by the licensee, carving out any product refunds, rebates, taxes, freight, or other costs associated with the sale or distribution of the product. Such a carve-out effectively forces the licensor to "cover" these costs by reducing the total amount upon which the royalty is based. In order to enforce the royalty payment requirements, the licensor is granted access to a regular financial statement and given rights to audit those statements, usually at his or her own expense. In most cases, practicing innovators must report royalty payments as income for tax purposes, and the licensee may request copies of such filings for its records. In some cases, a practicing innovator may set up a separate corporate entity to receive these royalty payments and license fees, thereby keeping the profits segregated.

A license allows the practicing innovator to retain some modicum of control over their invention and has almost infinite possibilities for customization based on the circumstances.

## Consulting or Services Arrangements

Either alone or as an adjunct to an asset purchase or license, a consulting arrangement permits the practicing innovator to remain involved in product development and provides the medical device company with access to under-developed ideas that may become future medical devices. Such arrangements are the most collaborative of the options discussed here, yet simultaneously the most difficult. Consulting agreements with practicing innovators who continue to practice medicine while consulting with medical device companies are under intense scrutiny from a variety of fronts.

Consulting agreements are infinitely flexible, permitting anything along the spectrum from daily collaboration on product development to infrequent review and input. These arrangements are likely to raise issues under the Anti-Kickback Statute (AKS) and, therefore, are typically structured to meet the personal services and management contracts safe harbor or include specific prohibitions on the practicing innovator's use of the very product they invented.[7] AKS prohibits the knowing and willful solicitation, offer, or receipt of any remuneration in return for: (1) the referral of an individual to a person for furnishing of an item or service that may be reimbursed under a federal healthcare program; or (2) purchasing, leasing, ordering, or arranging for the same for any item or service which may be paid for under a federal healthcare program.[8]

Although it may be tempting to combine a consulting arrangement with a license—whether to keep the license costs down while adequately reimbursing the inventor or in an attempt to be efficient in drafting—such a combination is not always advisable. In order to fall within the regulatory safe harbor, these consulting arrangements must:

- Be in writing (and be signed);
- Cover all aspects of the services to be provided by the practitioner during the term;
- Be for a term of one year or longer;
- Specify the services to be provided;
- Be limited to services that are necessary to accomplish the commercially reasonable business purpose; and
- Provide for compensation that is set in advance and consistent with fair market value.

These regulatory restrictions suggest that such an agreement be entered into only in those circumstances where the practicing innovator will be providing definable consulting services to the medical device company. Many times, a device company may seek to exercise additional control over an innovator through a consulting agreement. Practicing innovators should take heed, as recent enforcement trends demonstrate that governmental enforcement of AKS captures both physicians and the medical device company with whom they have contracted.[9] If definable services cannot be identified and structured to meet the safe harbor, it may be more appropriate to adjust the asset purchase price or increase the licensee fee or royalty payment than to convey additional monetary value through a consulting agreement.

## Options for Direct Commercialization

For those practicing innovators who wish to maintain maximum control over their recent innovation, direct commercialization of the medical device may be an attractive option. Such entrepreneurial spirits face the same hurdles as other start-up companies—securing needed financing to complete clinical testing, ensure appropriate FDA approval of the products, and eventually secure contract manufacturing or supply arrangements to actually manufacture the device.

Taking this approach is markedly different from maximizing a new technology through partnerships. It means actually running the business and being ingrained in the medical device industry. This conflation of roles can be especially challenging for an innovator who wishes to continue practicing medicine. Managing conflict of interest, ensuring appropriate financial disclosure, and avoiding potential bias suddenly become daily considerations.

A practicing innovator may seek many of the traditional avenues for financing a start-up company—family and friends, angle investors, or venture capital. They might also seek innovation or research grants from the National Institutes of Medicine, Small Business Administration or, in some cases, through public financing or tax-exempt bonds.

Some states' restrictions on corporate practice of medicine may force a practicing innovator to establish a separate corporate entity to commercialize the medical device. Even if it is not required, it often is advisable to do so. Again, anti-kickback restrictions are implicated when a practicing innovator holds an interest in a medical device company and the available safe harbors should be evaluated to ensure that the relationship between the medical practice role and the medical device commercialization role are balanced and legal.

## Conclusion

Medical device innovators who wish to continue the practice of medicine face unique hurdles in developing profitable arrangements to commercialize their innovations. But such arrangements are possible, despite stringent regulatory compliance requirements and aggressive statutes designed to protect federal and state healthcare programs from overutilization and conflicts of interest. Proactive assessment of these restrictions and development of solutions with the help of competent legal counsel is essential since the practicing innovator is often at a disadvantage in bargaining power and negotiation of these arrangements.

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1 21 U.S.C. § 321(h) [FDCA § 201(h)].
2 21 C.F.R. § 820.30.
3 21 C.F.R. § 812.3(h).
4 21 C.F.R. Part 812.
5 Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies; *available at* www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf.
6 21 C.F.R. § 812.3.
7 42 C.F.R. S 1001.952(d).
8 42 U.S.C. S 1320a-7b(b).
9 Physicians Under the Microscope: The Anti-Kickback Law: Practical Steps To Take in an Aggressive Enforcement Environment; General Surgery News, July 2009, p. 10.