



legal matters

Inventive Gifts So, you have a great idea for a medical device and want to manufacture and sell it for the benefit of all the world...and hopefully yourself as well. It's time to shift from inventor to entrepreneur.

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Over the holidays many of us exchanged gifts with our family and friends—new personal organizers, video games, DVDs, and of course, the obligatory tie or sweater. In the clinical practice of medicine, often “gifts” come in the form of new medical devices introduced in the marketplace. Many of these devices, not surprisingly, are designed by physicians who foresaw the potential benefits the new device would have on their own practice and the practices of their colleagues.

Bringing a medical device to the marketplace can be a long and winding road. There can be unexpected peaks and valleys—and pot-

holes—that an entrepreneurial physician may confront. If you have an idea for a new medical device, you should think ahead and carefully plan an implementation strategy that addresses all the important issues. This will protect your investment in your invention and ensure that you continue to benefit from its sale and use.

One of the first issues to consider is your employment agreement if you are employed (rather than a sole proprietor). Similarly, if you are a co-owner/shareholder in a medical practice, you should review the professional corporation's

governing documents. These agreements could include seemingly innocuous language like, “Any remuneration earned by employee [shareholder] while in the employ of employer shall be forwarded to employer.” This language could provide that any remuneration a physician earns from the new medical device shall be the property of the employer. This is likely not what a physician inventor has in mind, and the employment agreement or operating documents should be amended accordingly.

Universities and academic hospitals usually have specif-

ic intellectual property (IP) right provisions in their physician employment agreements or reference these provisions as part of the institution's policies and procedures manual.

Entrepreneurial physician practices may also have specific intellectual property policies and procedures. These provisions could mean that any work, invention, or discovery that is authored, conceived, created, or made by the employee during the period of employment and related to the business of the employer is the property of the employer.

Often, a violation of the “remuneration clause” or the “IP clause” constitutes grounds for immediate termination of the employment agreement for cause—also likely not what a physician inventor has in mind.

The strategic business plan allows the physician entrepreneur to demonstrate his vision for successfully marketing the medical device.

Once the physician's contract issues have been reviewed, and amended if necessary, the physician entrepreneur can move forward with the business of bringing his new medical device to market.

Protect your idea

Properly protecting and licensing commercial rights for a new medical device is necessary for economic success. These commercial rights are protected through patents, trademarks, copyrights, and trade secrets.

Generally, a patent protects against the unauthorized use of an idea, a trademark protects the name or logo associated with a product or the good will of the business, a copyright protects the expansion of the idea, and a trade secret protects against an unauthorized disclosure of an idea.

Collectively, these four concepts are referred to as intellectual property. As a physician entrepreneur, you should take advantage of the available intellectual property rights to protect and defend against the unlawful infringement or theft of your new medical device. An attorney who has experience in intellectual property can help guide you and protect your interests.

Develop a plan and business model

In conjunction with protecting the idea, a physician entrepreneur needs to have a strategic business plan for the manufacture, sale, and marketing of the device. The strategic business plan has several purposes:

- First, it will help a physician create a "roadmap" for how the medical device can be successfully marketed and define objectives and realistic dates to achieve those goals.
- Second, the strategic business plan will allow the physician to articu-

late in a cogent manner his objectives for potential investors, lenders, and as importantly, potential customers for the medical device. The plan should answer several questions: What makes this medical device different from what is already in the marketplace? Which key constituencies are being targeted? How much time and money should it take to prepare the medical device to enter the marketplace?

- Third, the strategic business plan is imperative if the physician needs to raise or borrow money to fund the business venture. At the outset, most of these new businesses will likely have to rely on personal resources and the generosity of family and friends to fund the start-up costs since most commercial lenders are reluctant to invest in such projects unless they are well organized. However, even friends and family will want a solid business plan to support their investment. Most small businesses fail because they have too little capital to develop and market the product or business properly. A physician entrepreneur needs to identify the realistic capital needs of the business and understand the ways that new businesses are typically capitalized.

Developing a strategic business plan is often a critical self-assessment tool. No one enjoys highlighting the shortcomings or potential deficiencies of his idea, especially for a wider audience, but it is necessary to show that you have realistic expectations and have considered the idea's potential problems and drawbacks as well as its assets. The strategic business plan allows the physician entrepreneur to demonstrate his vision for successfully marketing the medical device and the resources that will be necessary to accomplish that goal. A well conceived,

comprehensive strategic business plan is a key to ensuring short and long-term success for the medical device.

In addition to developing the strategic business plan, the physician entrepreneur should consider establishing an appropriate legal entity for the business. There are a variety of options to consider: sole proprietorship, general partnership, limited liability partnership, limited liability company, or corporation. You will want to select a form of business organization that permits the maximum flexibility during the start-up phase of the company, minimizes federal and state income taxes, and finally, allows you a successful exit strategy, such as having the device or the company purchased by a larger company.

The FDA regulatory scheme

If the product is a medical device, as defined in the [Federal Food, Drug, and Cosmetic Act](#), it must be approved by the [U.S. Food and Drug Administration](#) (FDA) before it may be placed in commercial distribution. If the product does not fall within the definition of a medical device, the FDA does not have regulatory oversight.

Assuming your new device is actually a medical device and is regulated by the FDA, it will fall in one of three categories of medical devices.

Class I devices include items such as elastic bandages and examination gloves. These devices are subject to the least regulatory scrutiny through FDA's general controls. FDA has exempted almost all Class I devices from its premarket notification requirements. The premarket notification demonstrates to the FDA that the device to be marketed is as safe and effective (or substantially equivalent) to

a legally marketed device that is not subject to premarket approval. Forty-seven percent of all medical devices fall into this category. You need to confirm the device's status before you begin to market the device.

A Class II medical device must comply with all of the Class I general controls and special controls to provide assurances that the device is safe and effective. Class II devices include powered wheelchairs and some pregnancy test kits. According to the FDA, approximately forty-three percent of medical devices are Class II devices.

Class III devices are those devices that are purported to be for a use in supporting or sustaining human life, to prevent or help prevent the impairment of human health, or that present a potential unreasonable risk of illness or injury. Generally, Class III devices are those devices for which insufficient information exists to ensure safety and effectiveness through Class I general controls and Class II special controls. According to the FDA, approximately ten percent of medical devices are Class III devices. Class III devices are devices such as replacement heart valves and implantable pacemaker pulse generators.

Physician entrepreneurs and their advisers should work with FDA proactively throughout the device approval process. The key determinant for the FDA for approving a medical device to be marketed in the United States is that it be safe and effective. A variety of mechanisms may be used to prove a medical device is safe and effective, including the so-called 510(k) process, the premarket approval (PMA) process, and the product development protocol. If a physician is interested in using a new

medical device solely for investigational use on human subjects (clinical evaluation) and not for commercial distribution, a person may seek an investigational device exemption (IDE) from the FDA.

A great deal of information on this process is available at the FDA's Web page, www.fda.gov. You may undertake FDA approval on your own or employ an adviser to help you.

Getting paid by the payers

Even after getting FDA approval to market a medical device, there is no guarantee that the payers will reimburse the providers for using the medical device. There are two different payments that must be addressed—paying for the device itself, and paying the physician for performing the procedure in which the device is used. Physicians will purchase and use a device if it is worth their while. If a payer does not reimburse the provider for using a particular medical device, the physician entrepreneur will have to convince her provider colleagues that the cost of purchasing the device is warranted solely for clinical purposes—a difficult proposition in this era of diminished payments from payers and increasing expenses of running a medical practice.

The physician entrepreneur will need to pursue slightly different strategies with public and private entities to convince each payer to pay (hopefully, a reasonable amount) for a provider to use the new medical device. Medicare will require one strategy. Private health insurers will require another. Medicaid is different in every state. Approval from private insurers does not ensure that Medicare

will reimburse for the medical device, although the converse may be true.

A physician entrepreneur needs to focus on coverage decisions and payer reimbursement issues at the same time she is seeking FDA approval. Waiting until after final FDA approval has been achieved to start this process wastes valuable time and momentum for introducing the new medical device to the marketplace.

Finally, once a medical device has entered the marketplace, the physician entrepreneur's legal responsibilities do not end. The FDA regulates the device manufacturer's labeling and advertising of the device, monitors its good manufacturing practices, and imposes medical device tracking and reporting requirements upon the manufacturer. Depending on the nature of business arrangements between a physician entrepreneur and his colleagues, the physician entrepreneur may have to consider issues with the [Federal Anti-Kickback Statute](#) and [Stark Statute](#).

Like giving and opening gifts during the holidays, bringing a new medical device to market is fun and exhilarating. A physician entrepreneur must be sure, however, to take the necessary steps to protect her employment and intellectual property rights, develop a sound strategic business plan, and work proactively with the FDA and payers to help ensure the medical device is properly positioned for success in the marketplace. ■

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