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Ramesh Iyer

Children's Hospital of Philadelphia; Perelman School of Medicine, University of Pennsylvania

Jeremy Solomon

Perelman School of Medicine, University of Pennsylvania

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Summary

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- It is important to follow ethical standards in starting and managing a company. Ethical shortcuts may yield short-term benefits but pose substantial risk in the long run, including the potential for ethical and financial malfeasance.

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Laws and Ethics in relation to Medical Entrepreneurship

Ramesh Iyer, MD,¹ and Jeremy Solomon²



Topic Relevance by Timeline

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- It is important to follow ethical standards in starting and managing a company. Ethical shortcuts may yield short-term benefits but pose substantial risk in the long run, including the potential for ethical and financial malfeasance.

Introduction

According to one study, major contributors to increasing healthcare costs are fraud and abuse; in 2009, fraud and abuse associated with wasteful healthcare represented approximately 3%–10% of healthcare costs (Price and Norris). The government is committed to law enforcement with healthcare-specific legislation. Combating fraud and abuse imposes additional costs for law enforcement and physician oversight.

While one may believe that the behavior of entrepreneurs who do not follow the law is rooted in a weak moral compass, the truth is a bit more complicated. Lapses in following the law are often rooted in lack of awareness of the regulations or the implications of not following them (Krause). Some entrepreneurs believe “moral shortcuts” in entrepreneurship are a tool necessary for their company’s survival. For others, these shortcuts are a rite of passage and considered proof of their

¹ Children’s Hospital of Philadelphia; Perelman School of Medicine, University of Pennsylvania

² Perelman School of Medicine, University of Pennsylvania

grit in the “fake it till you make it” culture of some entrepreneurship communities. The consequences of law breaking, regardless of whether it is by commission or omission, may destroy careers. In this chapter, we will explore some of the healthcare laws that academic entrepreneurs should be familiar with. We will also discuss one case in which an entrepreneur’s immoral behaviors, though intended to sustain the business, ultimately led to its downfall.

Challenges Facing the Academic Entrepreneur

The typical entrepreneur’s goal is to maximize the commercial potential in the shortest possible time without getting “scooped” by a competitor. Many academic entrepreneurs carry on with their faculty/staff/student roles while innovating and developing ideas. In the health entrepreneurship space, some play the role of healthcare provider and business entrepreneur simultaneously. Academic medical institutions have compliance offices to guide academics in how to manage these dual roles legally. However, as these institutions are large and complex, it is incumbent upon the academic entrepreneur to have an awareness of key statutes and agencies that regulate these issues and to maintain an awareness of what planned or current entrepreneurial activities might be covered by regulations.

Agencies Involved in Regulating Healthcare

As an academic entrepreneur, one may have to deal with multiple agencies that will ultimately reimburse for or purchase the invented goods and services. It is ideal to forge a successful partnership with them at the outset. The main healthcare agencies and what they regulate are included below.

Department of Health and Human Services (HHS)

The HHS (www.hhs.gov) is responsible for the regulation of interstate medical issues and administration of health services in the country. Further, the HHS delegates the approval and regulation of pharmaceuticals and devices (through the Food and Drug Administration) and the administration of the Medicare and Medicaid programs (along with the individual state governments) through the Centers for Medicare and Medicaid Services (CMS).

Food and Drug Administration (FDA)

The FDA (www.fda.gov) is responsible for ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use, are safe and effective before approval. Generally, these products require FDA approval before they can be sold in the United States. The FDA will consider efficacy and side effects of a product (often from studies provided by the manufacturer) prior to approval. The FDA has an Office of Criminal Investigations (“FDA-OCI” or “OCI”), which investigates crimes involving the production and sale of food and drugs. It is not uncommon for medical entrepreneurs whose innovations include

novel drug molecules (including biologics) or new devices that revolutionize medical treatment to have significant interaction with the FDA for approval of newer technologies (see the chapters “Overview of Device Development” and “Overview of Drug Development”).

Center for Medicare and Medicaid Services (CMS)

The CMS (www.cms.gov) administers Medicare and works with states to enable them to administer Medicaid. The CMS develops billing codes that cover a vast range of potential medical procedures and treatments so that providers billing the government under these programs can indicate what type of work or service was performed and receive reimbursement. Every year, over \$1 trillion is administered by the CMS (Verma). Fraud against the CMS is most commonly investigated by the Department of Health and Human Services Office of Inspector General (HHS-OIG). The largest client (buyer of healthcare) in the healthcare industry is the CMS, and thus it is very likely that academic entrepreneurs and their startups would have significant dealing with this federal agency if their innovations translate into healthcare products (drugs or devices).

National Institutes of Health (NIH)

The NIH (www.nih.gov) funds a variety of scientific research across medical fields through research conducted at NIH facilities and through the provision of grants to researchers outside of government. The NIH is a major source of funding for academic entrepreneurs for early research before more substantial funding is secured through private sources.

Overview of Healthcare Laws Relevant to Medical Entrepreneurs

Some of the healthcare laws that entrepreneurs must keep in mind are listed below (this list is not all-inclusive; academic entrepreneurs are advised to carefully research additional local regulations) (Fleps):

Stark Law

Example: A successful business venture provides medical services or devices for treatment. If patients are referred by the entrepreneur’s physician spouse to the business venture or to any medical provider who provides the new service, they may have violated the Stark Law, unless that service falls within one of the statute’s exceptions.

The Stark Law (42 U.S.C. 1395nn, “Limitation on Certain Physician Referrals”), also known as the **Ethics in Patient Referrals Act**, has one basic intent: to prohibit practitioners from referring Medicare or Medicaid patients to any designated health service with which either they or their immediate family members have a direct or indirect financial arrangement. It applies to doctors of medicine, osteopathy, dental medicine, dental surgery, podiatry, optometry, and chiropractic medicine. The financial relationship in question can involve an exchange of cash, services in kind, or

any other item or element of value. Originally enacted in 1989, expanded in 1993, and entering a third phase in 2007, this so-called self-referral ban applies regardless of whether the designated health services in question are themselves Medicare- or Medicaid-related.

The law restricts referrals to such designated health service categories as clinical laboratories, physical therapists, occupational therapists, speech and language therapists, radiation therapists, and radiology and imaging laboratories. It also covers non-coded categories such as hospital services, durable medical supplies like prosthetic or orthotic devices, home health providers, and outpatient prescription medications. Since the Stark Law is a strict liability law (i.e., compliance is mandatory), one could violate it without meaning to do so. Therefore, regardless of intentionality, sanctions and penalties will still apply.

Penalties for violation of the Stark Law include:

- Disallowing any entity that has furnished designated health services subsequent to a forbidden referral from billing Medicare, Medicaid, the patient, or a third-party provider.
- Compelling the designated health services provider to refund any monies received as the result of a disallowed referral.
- Denying payment by Medicare or Medicaid for designated health services performed in violation of Stark Law regulations.
- Imposing civil penalties of up to \$24,478 for each claim submitted in defiance of the Stark Law (*Medicare Fraud and Abuse: Prevent, Detect, Report*).
- Enforcing fines as high as \$100,000 for those who engage in circumvention schemes to make an end run around the law's provisions (*Medicare Fraud and Abuse: Prevent, Detect, Report*).
- Excluding offenders from future participation in Medicare and Medicaid programs.

Stark Law exceptions: The statute lists exceptions to the Stark Law for such categories as office space or equipment rental, ownership of publicly traded mutual funds and securities, physician recruitment, prepaid health plans, referrals to academic medical centers, and bona fide employment agreements.

Anti-Kickback Statute

Example: An academic entrepreneur has devised a new valve that can be used for cardiac surgery. They offer to take a local cardiac surgeon (who implants these devices at their hospital) for an expensive dinner and pay the surgeon as a “consultant.” The entrepreneur may have violated the Anti-Kickback Statute.

The federal Anti-Kickback Statute (42 U.S.C. 1320a-7b(b)), passed by Congress in 1972, is a criminal statute that prohibits the exchange of (or offer to exchange) anything of value in an effort to induce (or reward) the referral of federal healthcare program business. This broadly drafted statute establishes penalties for individuals and entities on both sides of the prohibited transaction.

For medical entrepreneurs, there can be no material incentive (financial or otherwise) placed for increasing sales when federal healthcare dollars are involved. In short, under the “one purpose” test, “if one purpose of the payment was to induce future referrals, the [M]edicare statute has been violated” (“United States v. Greber, 760 F.2d 68”).

Penalties for violation of the Anti-Kickback Statute: Conviction for a single violation under the Anti-Kickback Statute may result in a fine of up to \$100,000 and imprisonment for up to five years (*Medicare Fraud and Abuse: Prevent, Detect, Report*). In addition, conviction may result in exclusion from participation in federal healthcare programs. Absent a conviction, individuals who violate the Anti-Kickback Statute may still face exclusion from federal healthcare programs at the discretion of the Secretary of Health and Human Services. The government may also assess civil money penalties, which could result in treble damages plus \$50,000 for each violation of the Anti-Kickback Statute (Office of Inspector General, Department of Health and Human Services).

“Safe harbor” regulations exempt certain practices from being treated as Anti-Kickback Statute violations. Safe harbors address the following types of arrangements: investment interests, space rental, equipment rental, personal services and management contracts, sale of practice, referral services, warranties, discounts, employees, and group purchasing organizations. The HHS and CMS are in the process of revising the safe harbors to enable better innovation in the medical community.

False Claims Act

Example: During initial trials, the innovation of a new biologic molecule has a 50% cure rate for a disease. The academic entrepreneur exaggerates this success as 70% to improve the sales of the drug, and CMS is one of the clients buying the drug for use by Medicare patients. The entrepreneur has violated the False Claims Act and is liable.

Under the False Claims Act (31 U.S.C. 3729 – 3733), any person who knowingly presents a false or fraudulent claim for payment or approval, knowingly makes a false record or statement material to a false or fraudulent claim, or conspires to commit a violation of the above, is liable to the United States government.

The term “knowingly” means that a person has actual knowledge, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. The statute does not require proof of specific intent to defraud.

Penalties for violation of the False Claims Act: Conviction may result in a civil penalty of up to \$29,927, plus three times the amount of damages that the government sustains because of the false claim (*Medicare Fraud and Abuse: Prevent, Detect, Report*). The defrauding entity may also be barred from participating in CMS programs for a significant period of time, which often amounts

to a death sentence for some innovators. Additionally, a *criminal* False Claims Act (18 U.S.C. 287) allows for additional fines and imprisonment for those convicted of violations.

Academic Entrepreneurs: Mental State and Liability

Within the framework of the above regulations, it is important to keep in mind that most fraud and abuse crimes have two basic elements: the act or the crime and the mental state or a culpability requirement (Fleps). The culpability required varies by offense, and many possible offenses have different culpability levels and different punishments. For example, false claim submissions to a federal health program by a device manufacturer can happen in many ways. One false claim might result from a simple oversight of the paperwork, which typically would be considered “negligent.” If the entrepreneur willfully neglected responsibility, this would increase the severity of the crime and typically be considered “reckless.” Of course, intentionally misleading claims would increase culpability.

The various states of culpability include:

- **Specific Intent:** The defendant acted with a specified purpose and was aware of the surrounding circumstances that would enable their intended outcome. There was a conscious effort to commit the specific fraud.
- **General Intent:** The defendant meant for the action or fraud to occur, but may not have been aware of specific surrounding circumstances and may not have intended the result. A common example of this might be an entrepreneur’s exaggeration of device capabilities without a specific intent to mislead a customer.
- **Knowledge:** The entrepreneur knew that a certain device or drug would not work for a certain situation, was practically certain what would happen with a high probability, but continued to promote its use in the specific condition. This includes willful blindness, which is when a defendant is aware of a high probability of a particular thing but intentionally ignores the facts. Often “knowingly” is coupled with “intentionally” disjunctively; in other words, many crimes punish someone who knowingly or intentionally committed an offense.
- **Recklessness:** The defendant knew their action could cause harm (though with less than near certainty) and did it anyway. This involves a conscious disregard of substantial and unjustifiable risk or a gross deviation from the normal standard of conduct that a law-abiding person would observe in the defendant’s situation.
- **Negligence:** The defendant did not know their action would cause harm, but an ordinary person would have been aware of such a fact and taken care to avoid such an action. For particularly tragic examples, think of the number of firearms-related deaths each year from guns that were thought to be unloaded (but weren’t) or firearms left easily accessible to small children.

- **Strict Liability:** Even if the defendant took every precaution possible, they are responsible for the resulting harm. Strict liability offenses are uncommon in criminal law, and they typically result when an individual undertakes a potentially dangerous or hazardous activity. *Device and pharmaceutical manufacturing and distribution offenses are strict liability.* Undisclosed drug or treatment side effects and device malfunction may be classified under strict liability, and medical entrepreneurs may need insurance to avoid litigation and expensive settlements. Strict liability offenses are extremely powerful tools, because mental state is no defense. A defendant may have taken reasonable—even exceptional—care and not wanted the outcome at all but still be guilty of a strict liability offense. These rules vary by state, but courts are often hesitant to impose a strict liability requirement in criminal matters because of the extreme consequences of such liability

Ethics of Entrepreneurship

Moral Shortcuts

Moral shortcuts are procedures that simplify one’s workflow while eschewing conventional moral paradigms (Timmons). For example, ignoring regulatory deadlines or intentionally modifying study incentives to obtain greater participation without obtaining institutional review board approval may be forms of moral shortcuts that may seem to render the work process more efficient. While these shortcuts may work in the short term, they pose a risk to the overall success when exposed.

Rarely do entrepreneurs engage in blatantly unethical behaviors from the initiation of their company. On the contrary, immorality often starts with a moral shortcut. Time, funding, and competitors all weigh on entrepreneurs, who strive to meet the most important deadlines, maintain their company’s cash flows, and outplay the competition. In other words, the environment of the academic entrepreneur inspires the decisions that are classifiable as “unethical.” As a consequence, many ethical people find themselves in situations that could lead to unethical behavior.

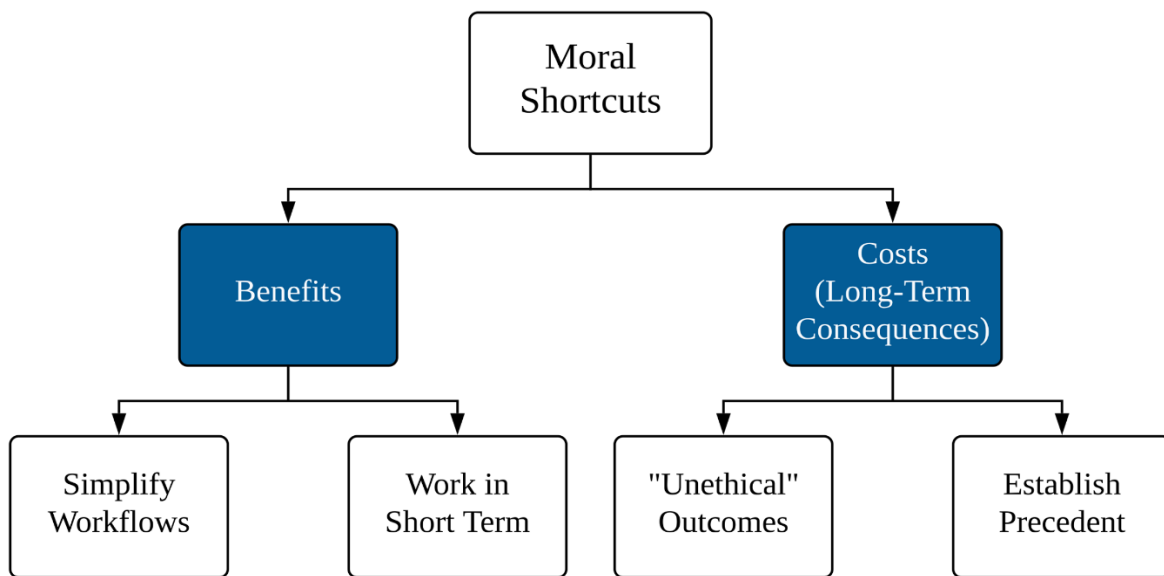
Former federal prosecutor Serina Vash had this to say on the subject: “When I first began prosecuting corruption, I expected to walk into rooms and find the vilest people. I was shocked to find ordinarily good people I could well have had coffee with that morning. And they were *still good people* who’d made terrible choices” (Carucci). These decisions likely seemed not only acceptable but also necessary to these “good people,” given their environment and circumstances. When academic entrepreneurs feel the burden of sustaining a business, moral shortcuts may suit their immediate needs—so they take the shortcuts. Enter precedent.

Precedent is, according to the *Oxford Dictionary*, “[a]n earlier event or action that is regarded as an example or guide to be considered in subsequent similar circumstances” (“Precedent | Meaning

of Precedent by Lexico”). A moral shortcut is most likely and most frequently used when a company is fragile, and generally a company is at its most fragile when it is young. As the company grows, it will continue experiencing obstacles that it is forced to overcome. Executives adapt the company to these obstacles by considering the following question: “How have we handled situations like these before to get us as far along as we are now?”

Companies using conventional morality and companies using moral shortcuts both establish a *precedent* that will be institutionalized in their history. Executives of a conventionally moral company will practice conventional moral behaviors when adapting to their circumstances, whereas the executives of a morally ambiguous company might defend themselves thus: “We did nothing wrong; we simply made a smart decision that kept this company alive.” But now they have fewer reservations because they have already established that the decision that was considered morally unconventional yesterday is considered morally acceptable today. The bar has been lowered, and their perception of ethically acceptable behavior has become more inclusive.

Figure 1. Two Sides Relating Moral Shortcuts.



Elizabeth Holmes and Theranos

Before achieving notoriety for its immense scandal, Theranos was the epitome of MedTech startups. Its founders were innovators who took personal risks (such as dropping out of Stanford) to start a company that would fundamentally shift a healthcare paradigm and disrupt the healthcare industry. One cofounder, Elizabeth Holmes, was frequently compared to another controversial innovator, Steve Jobs. The company promised an incredible product—equipment for laboratory blood testing with minimal sample requirements—and appeared to be delivering both on finances and technological development. When the dream ended and the many faults of Theranos emerged,

the public was left confused. Perhaps a better understanding can be gained by viewing Theranos not as a demonized company but as a startup that had made “questionable business decisions, which in totality create[d] a desperate situation” (Polisi).

When the preliminary results were unsatisfactory, there were two primary choices for Theranos: inform the investors and risk losing funding (thereby risking the company becoming financially insolvent) or withhold the information from investors on the chance that later success would cause “all ... [to] be forgiven” (Polisi). Theranos chose the latter approach. This early decision of omission had a cascading effect.

Eventually, investors will wish to know not only that financial projections are positive but also that the technology works. According to former Theranos employee Doug Matje, when he worked there, Theranos could not complete any test accurately on their devices (O’Donnell). Holmes was ultimately charged with nine counts of wire fraud and two counts of conspiracy to commit wire fraud (Mangan).

From a distance, we can tell that the strategy used by the leaders of Theranos was problematic. But in a high-stakes environment where every weakness can prove fatal, it is not surprising that non-risk-averse entrepreneurs will take those risks. This is why the most crucial lesson is that entrepreneurship relies on careful decision-making and consideration of the associated risks, both in terms of the immediate present and future consequences. Seemingly inconsequential decisions can have cascading effects that can lead to substantial ethical lapses in the future. Seeking counsel from others, relying on objective data, and being aware of innate biases are important ways to mitigate this (see the chapters on “Conducting Insightful Market Research” and “Innate Biases”).

Conclusion

This chapter outlines some of the legal and ethical responsibilities of medical entrepreneurs and needs to be reviewed periodically as laws governing healthcare change. Dramatic moral and ethical situations can arise when one is facing challenging financial situations (e.g., for early startups). These situations are an opportunity for an organization’s leaders to demonstrate the wisdom and judgment they wish to codify in their company culture. In addition, key legal considerations include the Anti-Kickback Statute, the False Claims Act, and the Stark Law.

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