Disruptive Compliance: Practical and Ethical Considerations in Advising the Cutting-Edge Healthcare Company

By William W. Horton

I. INTRODUCTION: THE FUTURE IS NOW, BUT THE LAW USUALLY ISN'T

A. Where No Relator Has Gone Before

Out on Rigel IV, a Class M planet in Deep Space Sector X-7, the situation grew increasingly dire. The grim-faced man in the gold velour shirt snapped at the doctor, "Bones! I've told you we only have 36 solar minutes to get this man's leg reattached so we can beam up! Otherwise, the unstable anti-matter core of this planet will blast us all the way from here to the Neutral Zone!"

"Dammit, Jim, I'm a doctor, not a welder!" snarled the blue-shirted medico, his Georgia accent reasserting itself as his tone got angrier. "Anyway, this crewman has the Blue Sword-Red Shirt bronze plan, and that won't cover treatment with the Acme Extremity Resynthesizer. They say it's experimental! Not approved by the Federation Device Authority! I've been on the communicator with some numbskull clerk in the Precertification Department for over a solar hour, and all she'll tell me is that I can appeal to the Galactic Medical Director Review Panel when it meets next month. Dammit, Jim, I'm a doctor, not a bureaucrat!"

The other blue-shirted member of the team, a saturnine figure whose skin-tone suggested a latent liver disorder, spoke for the first time. "Doctor, a question: Would not the bronze plan cover reattaching the crewman's limb using Thanagarian syntho-thread with an exterior coating of Fontana Regenerative Paste? I believe that is the orthodox treatment for a patient presenting with ICD-27 Code 1673876309719, 'Extremity Amputation Resulting from Armed Physical Altercation with Cardassian Warrior of Enlisted Rank, Left Side', is it not?"

"Of course it does!" the irascible doctor snapped, "but that's not the best treatment for this man. He needs the Acme Extremity Resynthesizer, but his insurance won't pay for that! They won't pay for anything unless it's been done for 20 solar years or more!"

The saturnine man responded, "Doctor, under the circumstances it seems that the logical thing to do would be to perform the Extremity Resynthesizer procedure but document and bill it as if it were the syntho-thread procedure.

Perhaps you could throw in charges for some additional medical testing to get the reimbursement back up to an appropriate level."

"Do it, Bones!" the man in the gold shirt snapped. "Maybe it's not strictly by the manual, but these stupid regulations can't keep this man from getting the care he needs! And anyway, how is the Federation ever going to find out you intentionally billed for the wrong thing anyway? You can always say you just hit the wrong buttons on your Tricorder Interstellar Electronic Health Records device! It's not like anyone's around to blow the whistle on you. Now get going! We have to beam up in exactly . . . twenty . . . two . . . point . . . four . . . minutes!"

In the shadow of a conveniently placed space boulder, the young Russian ensign smiled enigmatically to himself as he tapped notes into an encrypted file on his own Tricorder. *Once I talk with that lawyer on Deneb VIII*, he thought, *I'll be rich enough to buy my own starship and fly it straight to Moscow . . . .*

B. Yesterday's Rules, Tomorrow's Technology and Today's Compliance

The healthcare industry in the United States, as advanced and effective as it is in many ways, is criticized for lots of things. It is criticized for purportedly wasteful spending of resources on unnecessary "defensive medicine". It is criticized for an inadequate focus on preventive care and population health. It is criticized for socioeconomic and race-based inequities in access to care. It is criticized for its emphasis on prolonging life over providing for a humane and dignified process of dying. Oh, the criticisms leveled at healthcare in this country are numerous. And almost no one ever mentions one thing the United States healthcare system is really, really good at.

What is that thing? Regulating and paying for what happened yesterday.

Spurred on in part by the changes in delivery and reimbursement models promoted by the Affordable Care Act, there is an enormous focus today on innovation in healthcare products, services and payment systems. Large sums of capital are being poured into healthcare services companies, device and technology companies, and other industry

components, largely in search of the operator that will be able to provide the next big thing, the new breakthrough.[1] Under the ACA, the federal government itself put an initial $10 billion behind the development and testing of "innovative payment and service delivery models to reduce [federal healthcare] program expenditures . . . while preserving or enhancing quality of care".[2]

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[1]*See, e.g.,* Steven Loeb, *What does the future of healthcare look like?*, vator.tv, Nov. 23, 2016, *available at* http://vator.tv/news/2016-11-23-what-does-the-future-of-healthcare-look-like ("In the first quarter of [2016], even as [venture capital] funding sunk to a two-year low, healthcare accounted for nearly a third of all venture capital investments, with $4.1 billion across 191 deals. [¶] As of the beginning of [November 2016], the healthcare space had raised $13.1 billion, . . . which has been spread across . . . 1,287 deals."); Phil Wickham, *Venture Capital Is Facing an Impending Health-Care 'Avalanche'*, fortune.com, May 5, 2016, *available at* http://fortune.com/2016/05/05/venture-capital-health-care/ (interview with venture capital fund partner about investor perspectives on dynamics driving innovation in healthcare); John Sculley & Bruce Broussard, *It's Time To Disrupt the $3 Trillion Healthcare Industry*, forbes.com, Nov. 16, 2016, *available at* http://www.forbes.com/sites/sciencebiz/2016/11/16/its-time-to-disrupt-the-3-trillion-healthcare-industry/#24cfb9272534 ("Numerous major players—from Silicon Valley innovators, to health care professionals, to government leaders—are looking to use technology to transform healthcare. [¶] Silicon Valley is focused on harnessing technology through the power of entrepreneurship to disrupt an industry that's one-sixth of the U.S. economy. According to Dow Jones VentureWire, 'venture-capital funding in U.S. healthcare companies rose to a record $16.10 billion last year, a 34% jump from 2014.' "); Bob Herman, *Why venture capital firms are pouring money into health insurance*, modernhealthcare.com, Mar. 19, 2016, *available at* http://www.modernhealthcare.com/article/20160319/MAGAZINE/303199964 ("Health-insurer and insurance-technology startups raised more than $1.2 billion in venture funding in 2015. That's more than double the $570 million raised in 2014, and 10 times the $123 million raised in 2013, according to CB Insights, a data company that tracks private startups and venture capital."). Even large insurers, the same ones who (as discussed below) are often slow to provide coverage for new healthcare technologies, have gotten into the act. *See* Erin Griffith, *Why Big Health Insurance is pouring money into startups*, fortune.com, Jan. 6, 2015 (updated; originally published Sept. 24, 2014), *available at* http://fortune.com/2014/09/24/health-insurance-invest-startups/ (discussing how the Affordable Care Act's medical loss ratio requirements have spurred health insurers to invest part of their capital in start-up ventures).

[2]Patient Protection and Affordable Care Act, Publ. L. 111-148, 124 Stat. 389, § 3021(a), codified at 42 U.S.C. § 1315a(a)(1) (establishing the Center for Medicare and Medicaid Innovation) (the Patient Protection and Affordable Care Act, as amended by the Health Care and Education

And yet, it may take years for public or private healthcare reimbursement systems to begin paying for new products and innovative treatment methodologies:

> After a spinal stroke in 2007 robbed Rick Batty of his ability to use his arms and legs, the then 54-year-old agricultural salesman wasn't sure he'd ever walk again. Then he found ReWalk, a battery-powered exoskeleton that uses small motors at the knees and hips to help paraplegics stand up and walk.
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> . . . About half the 260 [ReWalk] devices currently in use are located in therapy centers, where the sessions are covered by many insurers as normal rehabilitation or gait training.
>
> But to own a ReWalk for use at home and around town, there's less financial support. Only a handful of insurers cover the take-home version of the device, for which . . . ReWalk charges $77,500.
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> . . .
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> For patients who want to use newer, novel devices beyond clinical trials, affordability is often the central issue blocking access when insurers won't cover their purchase. Manufacturers that can't get widespread coverage for their products face the prospect of limited sales.
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> "Unless we make it practical for people to get this compensated, I don't think we're going to be able to bill the market," said ReWalk CEO Larry Jasinski.[3]

The challenge, of course, is not limited to gaining coverage and appropriate payment for new medical devices. New drugs fall into much the same regime, and new diagnostic and treatment methodologies may find similar resistance

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Reconciliation Act of 2010, Pub. L. 111-152, will be referred to throughout this article as the "Affordable Care Act"). *See generally, e.g.,* Robert A. Berenson & Nicole Cafarella, *The Center for Medicare and Medicaid Innovation: Activity on Many Fronts* (Robert Wood Johnson Foundation, Feb. 2012), *available at* http://www.rwjf.org/content/dam/web-assets/2012/02/the-center-for-medicare-and-medicaid-innovation; Brian Dolan, *The $10 billion CMS Innovation Center and healthcare efficacy's need for speed*, mobihealthnews.com, Feb. 4, 2014, *available at* http://www.mobihealthnews.com/29565/the-10-billion-cms-innovation-center-and-healthcare-efficacys-need-for-speed.

[3]Adam Rubenfire, *Why can't devicemakers and insurers get along?*, Modern Healthcare, Nov. 28, 2016, 8, 8. The article provides a brief but thorough outline of the challenges faced by medical device manufacturers in getting new devices approved for use and marketing by the Food and Drug Administration, covered for payment by Medicare and Medicaid, and covered for payment by private health plans, three distinct processes.

from payors reluctant to pay for services whose efficacy, risks or medical necessity may not be as easy to evaluate as "the way it's always been done".[4] For reasons good or less good, the reimbursement system is often not welcoming to innovation, or at least not quickly so.

Coupled with that challenge is a regulatory system that is, in many ways, rooted in the past and that may impose substantial costs and roadblocks on new ideas. Consider, for example, the Medicare Shared Savings Program ("MSSP") established under the Affordable Care Act[5] and the accountable care organizations ("ACOs") to be formed under that program, described by the Centers for Medicare and Medicaid Services ("CMS") as "a key component of the Medicare delivery system reform initiative designed to reduce fragmented or unnecessary care and excessive costs for health care services furnished to Medicare fee-for-service beneficiaries".[6] The MSSP was designed to encourage the formation of ACOs, joint enterprises among payors, hospitals, other institutional providers and individual healthcare practitioners that would assume responsibility for overseeing and coordinating the care of a large population of Medicare beneficiaries. In order to function without fear of civil or criminal liability, ACOs required regulatory relief in the form of waivers and/or policy statements from CMS (concerning the application of the Stark self-referral law to ACOs), the Office of Inspector General of the Department of Health and Human Services (the "OIG") (application of the federal Anti-Kickback Statute and Civil Monetary Penalties Law), the Federal Trade Commission and the Department of Justice (application of federal antitrust laws), and the Internal Revenue Service (application of laws relating to

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[4]*See, e.g.,* Douglas Moeller, M.D., *How To Develop Coverage Policies for Molecular Diagnostics*, managedcaremag.com, May 2009, available at http://www.managedcaremag.com/archives/2009/5/how-develop-coverage-policies-molecular-diagnostics (the article's tagline offers up a pithy summary of payors' concerns: "These tests can be expensive. Worse, they can pave the way for enormous costs, some unwarranted. And there are more of them every year.").

[5]Affordable Care Act § 3022.

[6]U.S. Dep't of Health & Human Serv., Centers for Medicare & Medicaid Serv., *Final Rule: Medicare Program; Final Waivers in Connection with the Shared Savings Program*, 80 Fed. Reg. 66726, 66726 (Oct. 29, 2015).

tax-exempt status)—that is to say, in order to do something *expressly encouraged and promoted by the law*, ACO participants needed affirmative protection from the enforcement of provisions of at least five other major laws. That does not sound much like a system that innovators would find easy to navigate.

Other examples abound. An entrepreneur who comes up with a new approach to the delivery of medical services may encounter a bewildering patchwork of state-specific laws involving restrictions on the corporate practice of medicine, often derived from high-minded statements in 75-year-old judicial opinions issued in an entirely different world (at least as far as healthcare delivery is concerned).[7] The fraud and abuse laws have been construed in such a constrictive manner as to give severe pause to any innovator whose idea requires any sort of collaborative relationship with providers. The OIG is so fearful that any advantage that might cause a physician to choose one supplier of items or services over another might constitute a kickback that it has even stated that it might constitute illegal remuneration to relieve a physician practice from paying an expense that it no longer needed to incur.[8] These and similar laws may or may not have beneficially, socially useful effects in particular cases.

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[7]While it is not particularly material to the topic at hand, it is irresistible to note that many states that still enforce a prohibition on the corporate practice of medicine have statutory or common-law exceptions for the employment of physicians by nonprofit hospitals. This leads to the somewhat ludicrous conclusion that public policy is concerned with the corruption of medical judgment that might come about from a physician's having his practice managed by Flynn Brothers, Inc. (a layperson-owned practice management company that provided emergency department staffing to one hospital in Texas, apparently through one doctor; *see* Flynn Brothers, Inc. v. First Medical Associates, 715 S.W.2d 782 (Tx. Ct. App. 1986)), but is not concerned about any potential corruption arising from a physician's becoming an employee of a hospital affiliated with, say, the 141-hospital nonprofit system Ascension Health. This paradoxical circumstance illustrates the sort of roadblocks to innovation with which the U.S. healthcare system abounds, and as to which innovators and entrepreneurs tear out their hair.

[8]*See* OIG Advisory Opinion No. 15-04 (Mar. 18, 2015). That advisory opinion involved a proposal by a clinical laboratory to enter into exclusive arrangements with physician practices to provide all lab services for those practices' patients and to waive fees for patients whose insurance covered only lab tests performed by a different laboratory. The physician practices themselves would derive no financial benefit from the waiver arrange-

However, it may safely be said that the convoluted, and often fairly arbitrary, nature of healthcare regulation—which tends to create traps for the unwary (and sometimes even the wary), and which tends to be enforced by people who are trained to look with suspicion on new business methodologies (because they might arise from impure motives and allow the public fisc to be bilked)—are not particularly compatible with the perspectives commonly held by entrepreneurs and innovators.

That mindset, and its relationship to highly regulated industries, was colorfully described a few years ago in an online article by a "new media" pundit:

> . . . I used to host the startup competition at a technology conference called "TechCrunch Disrupt." The original Silicon Valley meaning of a disruptive company was one that used its small size to shake up a bigger industry or bloated competitor. Increasingly, though, the conference stage was filled with brash, Millennial [*sic*] entrepreneurs vowing to "Disrupt" real-world laws and regulations in the same way that me stealing

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ment, since they would not be drawing samples or performing the lab tests and so would bill nothing to any payor for the tests. However, in concluding that the arrangement might still provide impermissible remuneration to the physician practices under the Anti-Kickback Statute, the OIG applied the following rather remarkable analysis:

> [A]lthough the physicians and physician practices would not receive direct payments under the Proposed Arrangement, the Requestor [i.e., the clinical laboratory] certified to other facts that we believe, in combination, would amount to remuneration. First, according to the Requestor, physician practices have expressed a preference to work with a single laboratory because of the convenience of receiving all test results with consistent reference ranges and the efficiency gained from maintaining a single interface with a single laboratory. Second, although the interfaces themselves may be free, the Requestor stated that some electronic medical record system vendors charge physician practices a monthly maintenance fee in connection with the interface. The Proposed Arrangement could relieve physician practices of this expense for any interface that the physician practice no longer would maintain. Thus, under the Proposed Arrangement, by declining to charge certain patients, the Requestor would offer physician practices a means to work solely with the Requestor, reducing administrative and possibly financial burdens associated with using multiple laboratories.

That's right. Providing physician practices with more efficient services, doing work for which neither patients nor payors were charged any money (and which thus resulted in a loss to the clinical laboratory but did not enrich the physician practice), and relieving the practices from the need to pay for interfaces *that they would no longer need to use* could potentially be a criminal kickback. Is it any wonder that the second most common statement made by healthcare clients to healthcare lawyers (after "This bill is too high") is "That can't possibly be the law!"?

> your dog is Disrupting the idea of pet ownership. On more than one occasion a [competition] judge would ask an entrepreneur "Is this legal?" to which the reply would inevitably come: "Not yet." The audience would laugh and applaud. What *chutzpah*! So Disruptive![9]

This is not, one would think, an approach to life that would find all that much favor with the OIG, CMS, the Department of Justice and other key regulatory players in the healthcare universe (although would-be qui tam relators might well endorse it).

This juxtaposition of dynamics—an industry that desperately needs and seeks innovation, but does not particularly have good ways to pay for it; a regulatory structure that encourages conservatism and adherence to established precedent; an economic climate in which the market clamors for "disruptive" companies, companies that will "Uber-ize" traditional industries[10]—has many implications. From one perspective, at least, one of these implications is very clear: more, and more challenging, work for lawyers.

This article focuses on some of those challenges as they apply to lawyers representing both healthcare technology companies and traditional healthcare organizations as they attempt to reconcile the tried-and-true world of compliance with the brave new world of innovation. That process may create both practical and ethical dilemmas for lawyers, especially when their clients seek to boldly go where no one—including the OIG, for example—has gone before. To set the

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[9]Paul Bradley Carr, *Travis Shrugged: The creepy, dangerous ideology behind Silicon Valley's Cult of Disruption*, pando.com, Oct. 24, 2012, *available at* https://pando.com/2012/10/24/travis-shrugged/. For a theoretical discussion of the role of lawyers in the sort of disruption Carr describes, see Jack Wroldsen, *Creative Destructive Legal Conflict: Lawyers as Disruption Framers in Entrepreneurship*, 18 U. Penn. J. Bus. L. 733 (2016).

[10]*See, e.g.,* Geoffrey A. Fowler, *There's an Uber for Everything Now*, wsj.com, May 5, 2015, *available at* http://www.wsj.com/articles/theres-an-uber-for-everything-now-1430845789; Abby Phillip, *'The Uber of' . . . you name it*, washingtonpost.com, May 28, 2014, *available at* https://www.washingtonpost.com/news/post-nation/wp/2014/05/28/the-uber-of-you-name-it/?utm_term=.c3e88ae78310; Laura Entis, *'We're the Uber of X!'*, entrepreneur.com, Aug. 12, 2014, *available at* https://www.entrepreneur.com/article/236456; and, of course, the website The Uber of Everything, www.uberofeverything.com. *Cf.* Dick Metzler, *Why 'Uber of' startups fail*, betanews.com, August 8, 2016, *available at* http://betanews.com/2016/08/08/why-uber-of-startups-fail/.

stage, we will first lay out some of the differing perspectives of the various players that give rise to, and frame, these challenges. Later, we will explore some representative examples of such challenges, and offer practical advice on how to analyze and deal with them.

II. IT'S ALL IN THE WAY YOU LOOK AT IT: THREE VIEWS OF THE WORLD

Joliet Jake Blues:	*Ma'am, would it make you feel any better if you knew that what we're asking Matt here to do is a holy thing?*
Elwood Blues:	*You see, we're on a mission from God.*[11]

In order for a lawyer to be an effective counselor to a client, the lawyer must be a bit of a psychologist. To advise the client on how the other party to a transaction or dispute will respond to a proposal or strategic maneuver, it is necessary for the lawyer to be able to understand the motivations and priorities of that other party, and how that party assesses the strengths and weaknesses of its own position. Similarly, to get the client to take the lawyer's advice, it is also necessary for the lawyer to understand his or her client's personality, its business needs, and often what personally may be driving the thought process of the particular client decisionmaker(s) in the situation. Where the subject at issue raises compliance considerations—and what subject in the healthcare world does not?—it is also critical for the lawyer to understand the attitudes of the client and the counterparty toward compliance matters in general. If the decisionmaker is a compliance officer, for example, or an executive who has been brought in to clean up a situation after a scandal, that decisionmaker's views may skew toward conservatism and avoidance of risk.[12] On the other hand, if the decisionmaker is an entrepreneur, or an executive intent on catching the next big wave, that decisionmaker's views may instead skew

[11]The Blues Brothers (Universal Pictures 1980).

[12]As Mark Twain said, "[The cat that sits down on a hot stove-lid] will never sit down on a hot stove-lid again—and that is well; but also she

toward asking for forgiveness rather than permission,[13] especially a lawyer's permission. The lawyer who cannot differentiate his or her approach based on an understanding of the mindset of the intended audience is likely to be ineffective.

Of course, there is another side to this story as well. Lawyers—trained to worship at the altar of precedent, jealous custodians of form files that can be marked up without the bother of original thinking—often do not find it easy to open up to innovative ideas. Particularly in the healthcare compliance arena, where the nail that sticks up the highest not infrequently ends up as the defendant in a False Claims Act suit, there can be a strong bias in favor of sticking to the status quo and being skeptical of "disruptive" ideas.

And when all these viewpoints and biases have to be reconciled, there is yet another factor that can make that a difficult process: The fact that all of the players tend to believe that they are on a mission from God. The technology entrepreneur—and the healthcare system executive that adopts the entrepreneur's innovation—will revolutionize the way care is delivered to those who need it most (or the way in which health systems can still operate profitably in a time of regulatory overload and declining reimbursement). The compliance officer will ensure that entrepreneurial zeal is duly constrained by prudence and caution, even if that means the sales projections are not met and the big private equity money goes elsewhere. And the lawyer? Why, the lawyer knows more than everyone involved; his or her mission is to ensure that all the other players stay out of the potholes that he or she alone is smart enough to see.

In order, then, to assess the professional and practical challenges to effective representation of clients in the emerging world of healthcare technology innovation, it is vital for

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will never sit down on a cold one any more." Mark Twain, Following the Equator (1898), epigraph to Chapter XI.

[13]The quote "It's easier to ask forgiveness than it is to get permission" is often attributed to Rear Admiral Grace Murray Hopper, a pioneering computer programmer. However, the original source of the phrase is in some question. *See* Fred Hopper, *Quotes Uncovered: Forgiveness, Permission, and Awesomeness*, freakonomics.com, June 24, 2010, *available at* http://freakonomics.com/2010/06/24/quotes-uncovered-forgiveness-permission-and-awesomeness/.

healthcare lawyers to do some psychological exploration, to understand the mindsets and motivations of the other players at the table—the client bent on innovation, the compliance team bent on, well, compliance—and to understand how their own mindsets and motivations affect their approach to the representation. The following subsections attempt to illustrate some of these environmental dynamics.

A. Men and Women of Tomorrow: Entrepreneurial Innovation Meets Time-Honored Regulation

It's easy to shrug off a startup that operates in the gray area of the law when it's just a few people and an idea. We assume they'll figure out the regulations and comply before they get big enough to cause any real problems. But in the so-called Age of Unicorns, startups can go from zero to $1 billion in the blink of any eye. It's become very clear that we can't assume a billion-dollar company is legit just because some venture investors said so.[14]

Go to your favorite online search engine and type "rise and fall of Theranos" into the search bar. Then wait for the results to finish pulling up; you should have time to grab a cup of coffee.

Theranos, of course, was the red-hot laboratory start-up that promised to revolutionize the blood-testing industry with its claim that its proprietary "Edison" device allowed it to run 240 lab tests with a few drops of blood obtained from a finger-prick. Its founder Elizabeth Holmes, a 19-year-old Stanford dropout when the company was formed in 2003, became a celebrity, the admittedly photogenic face of a professedly disruptive technology that, she said "was going to save millions of lives and, in a phrase she often repeated,

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[14]Erin Griffith, *When Software Tries to Eat Regulation*, fortune.com, Feb. 9, 2016, *available at* http://fortune.com/2016/02/09/zenefits-regulation-meltdown/ (hereinafter Griffith, *Eat Regulation*). The term "unicorn", in this context, is Silicon Valley slang for a startup company with an indicated valuation of at least $1 billion, based on the value attributed to the company in prior rounds of equity investment. *See* Ben Zimmer, *How 'Unicorns' Became Silicon Valley Companies*, wsj.com, Mar. 20, 2015, *available at* http://www.wsj.com/articles/how-unicorns-became-silicon-valley-companies-1426861606.

'change the world.' "[15] The company entered into a groundbreaking deal with Walgreens, establishing 40 in-store labs that accounted for the majority of its business.[16] Although Theranos was privately held, prevailing estimates put its value at $9 billion, giving Ms. Holmes a paper net worth of a cool $4.5 billion, give or take.[17]

However, the wheels began to come off in October 2015, when *Wall Street Journal* reporter John Carreyrou published the first of what became a series of damning articles about Theranos. According to Carreyrou, not only had Theranos been performing the vast majority of its tests using conventional equipment rather than its proprietary Edison device, but it had also been running tests on blood obtained through more conventional phlebotomy techniques rather than the "finger prick" method touted by the company. Further, the article reported, some Theranos employees—as well as referring physicians—had become concerned with the accuracy of results obtained through use of the Edison system, and the article suggested that Theranos had potentially failed to comply with CMS "proficiency testing" requirements, reporting only results obtained on other manufacturers' equip-

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[15]Nick Bilton, *Exclusive: How Elizabeth Holmes's House of Cards Came Tumbling Down*, vanityfair.com, Sept. 16, 2016, available at http://www.vanityfair.com/news/2016/09/elizabeth-holmes-theranos-exclusive (hereinafter Bilton, *House of Cards*). In a decision that looks unfortunate in hindsight, Ms. Holmes once made the observation "I think that the minute that you have a backup plan, you've admitted that you're not going to succeed," which continued to be a widely circulated Internet meme even after the company's troubles became widely reported. *See* Deborah Petersen, *Theranos CEO Elizabeth Holmes: 'Avoid Backup Plans'*, inc.com, Feb. 10, 2015, *available at* http://www.inc.com/deborah-petersen/elizabeth-holmes-avoid-backup-plans.html; an example of the meme, which for months seemed to turn up daily on the LinkedIn social media site, is at https://onsizzle.com/i/the-minute-you-have-a-back-up-plan-youve-admitted-youre-836013.

[16]Reed Abelson & Andrew Pollock, *Walgreens Cuts Ties to Blood-Testing Company Theranos*, nytimes.com, June 12, 2016, *available at* http://www.nytimes.com/2016/06/13/business/walgreens-cuts-ties-to-blood-testing-company-theranos.html?_r=0.

[17]*See, e.g.,* Roger Parloff, *This CEO is out for blood*, fortune.com, June 12, 2016, available at http://fortune.com/2014/06/12/theranos-blood-holmes/.

ment, despite the fact that it routinely continued to perform tests using the Edison.[18]

After Carreyrou, the deluge, at least as far as Holmes and Theranos were concerned:

> Walgreens severed its relationship with Holmes, shuttering all of its Wellness Centers [the in-store labs established with Theranos]. The [Food and Drug Administration] banned the company from using its Edison device. In July [2016], the Centers for Medicare and Medicaid Services banned Holmes from owning or running a medical laboratory for two years. (This decision is currently under appeal.) Then came the civil and criminal investigations by the U.S. Securities and Exchange Commission and the U.S. Attorney's Office for the Northern District of California and two class-action fraud lawsuits.[19]

The implications of Theranos's alleged compliance failures were enormous. Nine billion dollars in estimated stock value disappeared without a trace, and an estimated $900 million in actual capital invested was put in severe jeopardy.[20] Because of the nature of the company's business, there were, of course, other more personal costs as well. Reports have arisen of patients who discontinued necessary medication,

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[18]John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, wsj.com, Oct. 16, 2015, *available at* http://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901. For a somewhat more technical discussion of the scientific issues with Theranos's testing methodology, see Norman A. Paradis, *The Rise and Fall of Theranos*, scientificamerican.com, Apr. 22, 2016, *available at* https://www.scientificamerican.com/article/the-rise-and-fall-of-theranos/.

[19]Bilton, *House of Cards.* Theranos also discarded all test results obtained through the Edison device in 2014 and 2015 and issued "tens of thousands" of corrected test results obtained through the use of other equipment. *See* John Carreyrou, *Theranos Voids Two Years of Edison Blood-Test Results*, wsj.com, May 18, 2016, *available at* http://www.wsj.com/articles/theranos-voids-two-years-of-edison-blood-test-results-1463616976.

[20]*See* Christopher Weaver, John Carreyrou & Michael Siconolfi, *Big Names Take Hit on Theranos*, wsj.com, Nov. 28, 2016, *available at* http://www.wsj.com/articles/big-names-take-hit-on-theranos-1480379536.

took unnecessary medication, and even received erroneous diagnoses of cancer as a result of relying on the faulty tests.[21]

But there is a bright side to everything: after the government imposed severe sanctions on the company and its founder, Theranos got around to taking care of some unfinished business. In July 2016, the company hired a new regulatory and quality vice president and a chief compliance officer.[22]

Theranos has not been alone in seeing a sky-high valuation put at risk by an apparently cavalier attitude toward legal compliance. Consider, for example, the story of Zenefits, a company that set out on a self-professed mission to "disrupt" the human resources function by providing employers with free software that would, allegedly, automate human resources administration—and particularly the selection and purchase of insurance plans for employees.[23] Its founder and chief executive officer, Parker Conrad, "compared Zenefits' mission of fixing employee benefits administration to the rebel alliance in Star Wars", according to one report.[24] As for traditional insurance brokers, Conrad told the 2013 TechCrunch Disrupt conference, "If you're an insurance broker, we're going to drink your milkshake."[25] By 2015,

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[21]*See* Christopher Weaver, *Agony, Alarm and Anger for People Hurt by Theranos's Botched Blood Tests*, wsj.com, Oct. 20, 2016, *available at* http://www.wsj.com/articles/the-patients-hurt-by-theranos-1476973026.

[22]Marisa Kendall, *After sanctions drop, Theranos hires compliance execs*, mercurynews.com, July 21, 2016, *available at* http://www.mercurynews.com/2016/07/21/after-sanctions-drop-theranos-hires-compliance-execs/.

[23]*See, e.g.,* Liz Welch, *How Zenefits Disrupted Human Resources*, inc.com, Mar. 2015, available at http://www.inc.com/magazine/201503/liz-welch/hr-technology-with-benefits.html. "Zenefits", officially "Zenefits FTW Insurance Services", is a trade name for the company legally known as YourPeople, Inc.

[24]Griffith, *Eat Regulation.*

[25]*See* Claire Suddath & Eric Newcomer, *Zenefits Was the Perfect Startup. Then It Self-Disrupted*, bloomberg.com, May 9, 2016, *available at* https://www.bloomberg.com/features/2016-zenefits/ (hereinafter Suddath & Newcomer, *Perfect Startup*).

the private company had raised nearly $600 million from investors and had an estimated valuation of $4.5 billion.[26]

But then shoes began to drop—first one by one, and then at rates reminiscent of Old Testament plagues. Early on, the state of Utah temporarily halted Zenefits from operating in the state because it considered the company's provision of free software to customers to be a violation of state law prohibiting the offering of rebates in connection with sales of insurance.[27] Although that ban was ultimately rescinded, other compliance issues soon followed. A series of *BuzzFeed News* articles beginning in late 2015 revealed that Zenefits had allegedly routinely used unlicensed salespeople to engage in insurance brokerage activities in multiple states.[28] According to the online news service, in Washington State alone, public records revealed that 83% of the insurance policies sold or serviced by Zenefits in that state through August 2015 had been sold by unlicensed employees; *Buzzfeed News* suggested that the practice extended through at least seven states.[29]

Zenefits apparently took that concern seriously, taking steps to ensure, for example, that its employees who would be selling insurance in California could report compliance with the state's strict requirement that applicants for licensure as a health insurance broker spend 52 hours on a training course. The course was an online course, and persons taking the course had to remain logged in and periodically "click" to show that they were in fact devoting the full 52 hours to the course. Unfortunately, what enabled

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[26]*See* Suddath & Newcomer, *Perfect Startup*. *See also* Kia Kokalitcheva, *VCs gave Zenefits $66.5M—because even they don't want to deal with HR paperwork*, venturebeat.com, June 3, 2014, *available at* http://venturebeat.com/2014/06/03/vcs-gave-zenefits-66-5m-because-even-they-dont-want-to-deal-with-hr-paperwork/.

[27]*See* Suddath & Newcomer, *Perfect Startup*.

[28]*See* William Alden, *Startup Zenefits Under Scrutiny For Flouting Insurance Laws*, buzzfeed.com, Nov. 25, 2015, *available at* https://www.buzzfeed.com/williamalden/zenefits-under-scrutiny-for-flouting-insurance-laws?utm_term=.ogJdeMOre#.ygYyQP2pQ.

[29]*See* William Alden, *80% Of Zenefits Deals In Washington State Done By Unlicensed Brokers*, buzzfeed.com, Feb. 5, 2016, *available at* https://www.buzzfeed.com/williamalden/80-of-zenefits-deals-in-washington-state-done-by-unlicensed?utm_term=.cq5mELdAE#.nrYDl2eQl.

at least some of the Zenefits employees to report compliance was not actual compliance, but rather a Chrome browser extension developed by someone at the company—allegedly, Conrad—and referred to internally as "the Macro". The Macro made it appear that an employee was logged in and taking the course for 52 hours, even if the employee were somewhere else entirely doing something else entirely. The Macro apparently also directed employees to sign a certification, under penalty of perjury, that they had in fact spent the mandatory 52 hours on the training.[30]

Ultimately, Conrad was forced out, and Zenefits began what has been a protracted and expensive process of settling with various states over claims that it used unlicensed persons to make sales, violated state anti-rebate requirements through the provision of free software to its customers, or otherwise violated state law.[31] Even so, the company's attitude has not entirely been conciliatory. After reaching a settlement with Washington over the state's claim that Zenefits' provision of free software to its customers violated the state's anti-inducement law, designed to protect insur-

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[30]*See* William Alden, *Zenefits Software Helped Brokers Cheat On Licensing Process*, buzzfeed.com, Feb. 5, 2016, *available at* https://www.buzzfeed.com/williamalden/zenefits-program-let-insurance-brokers-fake-training?utm_term=.ehyXxoNqx#.uq7j74rp7; Suddath & Newcomer, *Perfect Startup*; Julie Bort, *Lies, Booze, and Billions: How one of the fastest-growing startups in Silicon Valley history raised $580 million then spiraled out of control*, businessinsider.com, Mar. 11, 2016, *available at* http://www.businessinsider.com/the-inside-story-of-zenefits-2016-3.

[31]*See, e.g.,* Joseph Conn, *Zenefits will pay $3.7 million settlement over licensing issues*, modernhealthcare.com, Dec. 3, 2016, *available at* http://www.modernhealthcare.com/article/20161203/MAGAZINE/312039951 (California); David Etherington, *Zenefits ordered to stop offering free insurance software in Washington state*, techcrunch.com, Dec. 1, 2016, *available at* https://techcrunch.com/2016/12/01/zenefits-ordered-to-stop-offering-free-insurance-software-in-washington-state/ (Washington); *Missouri Insurance Department Fines Zenefits $62K for Unlicensed Activity*, insurancejournal.com, Dec. 8, 2016, *available at* http://www.insurancejournal.com/news/midwest/2016/12/08/434686.htm (Missouri); Heather Clancy, *Zenefits Settles Compliance Issues with 3 More States*, fortune.com, Sept. 13, 2016, available at http://fortune.com/2016/09/13/zenefits-settles-new-jersey-arizona-minnesota/ (New Jersey, Arizona and Minnesota). According to one report, the California settlement marked Zenefits' 17th state settlement. *See Zenefits has settled with another state, businessinsider.com*, Nov. 30, 2016, *available at* http://www.businessinsider.com/zenefits-legal-problems-2016-11.

ance brokers from anti-competitive activity by other brokers, the company's general counsel published a blog post in which he called the state's position "counter-intuitive" and a "decidedly minority view"—not precisely the sort of penitential attitude that government regulators tend to favor.[32]

And, in the aftermath—or at least the intermission—of all of this regulatory activity, Zenefits took one other major step. It named a chief compliance officer, established a 9-person compliance team ("up from zero under [Conrad]", the announcement noted) and declared that it would become "the Compliance Company". (Oh, and it also declared that it was adopting "new company values", of which the first one would be "Operate with integrity", identified as a change from the "old value" of "Ready, Fire, Aim".)[33]

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[32]Josh Stein, *Zenefits and Washington State Reach Agreement on Pricing*, Zenefits Blog, Dec. 1, 2016, *available at* https://www.zenefits.com/blog/zenefits-washington-state-reach-agreement-pricing/.

[33]David Sacks, *The New Zenefits—Becoming the Compliance Company*, Zenefits Blog, May 9, 2016, *available at* https://www.zenefits.com/blog/new-zenefits-becoming-compliance-company/.

As a side note, the company's approach to the chief compliance officer position has been interesting to observe. In a February 2016 announcement, the company noted that Joshua Stein, who had been serving as the company's Vice President of Litigation, Regulatory Affairs and Public Policy, had been named as its Chief Compliance Officer. See David Sacks, *Announcing the New Zenefits Executive Team*, Zenefits Blog, February 18, 2016, *available at* https://www.zenefits.com/blog/new-zenefits-executive-team/. Thereafter, in November 2016, Mr. Stein was named as the company's General Counsel (after the incumbent in that role had left for another job), a position he had also apparently held for a short period in 2015. *See* Chris Rauber, *In midst of big legal battle with ADP, Zenefits snags new top attorney*, San Francisco Business Times, July 13, 2015, *available at* http://www.bizjournals.com/sanfrancisco/blog/2015/07/adp-zenefits-general-counsel-legal-battles.html; *Zenefits Promotes Compliance Chief to Vacant GC Spot*, corpcounsel.com, Nov. 7, 2016, *available at* http://www.corpcounsel.com/id=1202771736695/Zenefits-Promotes-Compliance-Chief-to-Vacant-GC-Spot?slreturn=20161118175843#. At the time of this writing in December 2016, it does not appear that a new Chief Compliance Officer has been named, and Mr. Stein's biography on the Zenefits website says that "he leads the company's compliance, regulatory affairs, and government relations efforts across the enterprise." *See* https://www.zenefits.com/about/ (Joshua Stein bio). For a discussion of considerations involved in combining the general counsel and chief compliance officer roles (or having them in a direct reporting relationship), especially in the healthcare industry, *see generally* William W. Horton, *When Two Worlds*

Theranos and Zenefits provide two of the more dramatic cases, but similar illustrations abound in the world of technology start-ups, including those in the healthcare industry. These cases reflect a fundamental tension between the entrepreneurial mindset[34] and the strictures of a regulated industry. As one commentator has described it,

> Silicon Valley [by which we may understand, the business of technology innovation in general] has its own value system, and its most successful companies have been rewarded for their ability to operate outside the confines of the status quo. With all the money and accolades raining down on them, it must be hard to determine how much disruption is too much, or why breaking down the system is laudatory, but breaking what they see as archaic regulatory roadblocks begets, at best, a slap on the wrist. Regulators do not care how swooned-over a [chief executive officer] is. To them, a law is a law, no matter how shiny the unicorn.[35]

And yet, innovation in healthcare—and these days, much of that innovation is technology-driven—is undeniably vital. A healthcare lawyer who steers his or her client away from the new frontiers may indeed protect that client from regulatory scrutiny and onerous penalties, but that can have a cost: lost opportunities for patient care, lost opportunities for efficiency, even lost opportunities to remain in business. How does the lawyer help his or her client keep on the right side of that fine line? To explore that, it is necessary for us first to consider the nature of the healthcare compliance function as it applies in this setting.

Collide: Legal Ethics, OIG Policy and the General Counsel-Compliance Officer Relationship, *in* Health Law Handbook (Alice Gosfield, ed., 2016).

[34]*See, e.g.,* Robert J. Kriegel & Louis Palter, If It Ain't Broke . . . Break It! And Other Unconventional Wisdom for a Changing Business World (1991), a title which seems to be a condensed manifesto for today's technology entrepreneurs.

[35]Emily Jane Fox, *Zenefits Under Investigation as Regulators Clamp Down-on Start-Ups*, vanityfair.com, Feb. 12, 2016, *available at* http://www.vanityfair.com/news/2016/02/zenefits-investigation-regulators.

B. "Don't Give Him Anything Good to Hit, but Don't Walk Him": Traditional Healthcare Compliance in the World of Tomorrow[36]

Compliance is a little like the black swan. If you're not compliant, then it's possible that no one will ever find out or care. But if something bad happens, you better have been compliant from the beginning.[37]

Within traditional healthcare organizations, the compliance function has become pretty well institutionalized over the past 20 years or so. At any given time, the OIG has in effect several hundred Corporate Integrity Agreements with healthcare organizations, substantially all of which either require the organization to establish a corporate compliance function or impose additional specific requirements on an existing compliance structure.[38] Further, the OIG has published a number of "compliance guidance" documents setting forth what it views as key considerations in establishing effective compliance programs.[39] Organizations such as the Health Care Compliance Association provide a variety of educational programs, publications and training resources

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[36]The reference is to the accurate, but unhelpful, advice anecdotally given to a baseball pitcher facing a formidable hitter when the game hangs in the balance. *See, e.g.,* Carl Erskine, Carl Erskine's Tales from the Dodger Dugout: Extra Innings (2004) 61 ("[D]uring a mound conference, the pitcher might hear this kind of instruction from his manager: 'Now look, the tying run is on third base and the winning run is at the plate. He's the league-leading hitter. Don't give him anything good to hit, but don't walk him.' ").

[37]Lauren Fifield, Head of Health Benefits at ZenPayroll, Inc. d/b/a Gusto, as quoted in Christina Farr, *Dear Silicon Valley: There Are No Shortcuts In Health Care*, fastcompany.com, Feburary 12, 2016, *available at* https://www.fastcompany.com/3056658/startup-report/dear-silicon-valley-there-are-no-shortcuts-in-health-care/ (hereinafter Farr, *No Shortcuts*).

[38]*See* https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp; U.S. Dep't of Health & Human Serv. Off. of Inspector Gen'l, "Focus on Compliance: The Next Generation of Corporate Integrity Agreements", Aug. 7, 2012, at 4-5, *available at* https://oig.hhs.gov/compliance/compliance-guidance/docs/Focus_on_Compliance.pdf.

[39]These are collected at https://oig.hhs.gov/compliance/compliance-guidance/index.asp.

for healthcare organization compliance officers.[40] And the seminal case regarded as imposing on a corporate board a duty to ensure that the organization had an adequately designed system to detect and remediate violations of law by corporate agents—a compliance program—arose in a case involving alleged healthcare fraud.[41]

This is not particularly surprising. As already alluded to, healthcare is one of the most heavily regulated industries in the United States, both in terms of the sheer volume of laws and regulations and the multiple jurisdictions from which they arise. A compendium of the major federal laws and regulations affecting the industry now encompasses three volumes plus a one-volume supplement, each of which volumes is approximately the size of a standard King James Bible (with paper of similar thickness and a typeface as frustratingly small).[42] Each of the states and the District of Columbia have their own laws and regulations, and various private accreditation bodies such as The Joint Commission have their own requirements, which do not have the force of law but which may, as a practical matter, be almost as important to the continuing viability of an organization. Practices that are permissible under state law may be prohibited by federal law, or vice versa, and arrangements that are legal when private insurance (or cash-paying patients) are involved may be criminal if the relevant items or services will be paid for by a governmental reimbursement program like Medicare.

And the sheer volume of regulation is really just the tip of the compliance iceberg for healthcare organizations. Probably as much as or more than in any other industry, the ability to advise a healthcare organization on compliance issues requires a detailed knowledge of subregulatory guidance such as rulemaking preambles and advisory opinions, and sometimes of informal guidance as well. Remarks made by

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[40]HCCA's flagship Annual Compliance Institute typically features well over 100 speakers covering a broad scope of compliance issues. *See, e.g.,* http://www.hcca-info.org/portals/3/PDFs/hcca-2017-ci-brochure.pdf (brochure for 2017 conference).

[41]*See* In re Caremark International, Inc. Derivative Litig., 698 A.2d 959 (Del. Ch. 1996).

[42]*See* Am. Health Law. Ass'n, AHLA's Federal Healthcare Laws & Regulations (William W. Horton, ed., 2015 and Supp. 2016).

government officials at industry conferences and seminars, positions taken in inter-agency communications and educational materials, views expressed in journal articles—all of these have become part of the "common law" of healthcare compliance.[43] In other words, understanding the law (so that it may be complied with) in the healthcare industry is a process that may start with pulling a volume of the Code of Federal Regulations off the shelf, but it does not come close to ending there.

Beyond that, of course, is the highly, shall we say, *nuanced* nature of much of healthcare compliance. There is, of course, the *Greber* "one-purpose" test for violations of the Anti-Kickback Statute, an interpretation of the law that makes almost any arrangement between referral sources and those to whom they refer illegal—heck, a felony—in the absence of a safe harbor.[44] There is the Stark Law, under which millions of dollars can turn on such minutiae as whether a contract renews automatically unless terminated or terminates automatically unless renewed. There is the fact that exactly the same procedure can be reimbursed at dramatically different amounts depending on where it is performed. And, as noted above, there is the fact that even creating efficiencies and cost savings (at no cost to the government) might be deemed to violate the law.[45]

Those who have worked in healthcare compliance in traditional organizations are accustomed to such arcane

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[43]For example, the conventional wisdom that a hospital may violate the Anti-Kickback Statue by paying any amount attributable to goodwill in acquiring a physician practice is derived from correspondence between the then-Chief Counsel to the OIG to a lawyer in the office of the Associate Chief Counsel (Employee Benefits and Exempt Organizations) of the Internal Revenue Service, correspondence that provided little actual definitive legal support for the positions taken therein. *See* Letter from D. McCarty Thornton to T.J. Sullivan (Dec. 22, 1992), *available at* http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm.

[44]United States v. Greber, 760 F.2d 68,69 (3d Cir. 1985). For a discussion of *Greber* and why the Third Circuit never actually needed to announce, essentially in dicta, the one-purpose test, *see* William W. Horton, *The Past, Present, and Future of the Anti-Kickback Statute: A Practical History*, *in* Health Care Fraud and Abuse: Practical Perspectives (Linda A. Baumann, ed., 2013 and Supp. 2016), Ch. 9, § II.C.

[45]*See* OIG Advisory Opinion No. 15-04 (Mar. 18, 2015), discussed at n.8, above.

analyses, such recondite nuances. Their antennae are trained to quiver when an executive says, "I've got a great idea about how we can increase our volumes," or when a physician says, "I'd really like to get behind this idea, but it's going to take a lot of my time. If only there were some way you could incentivize me . . . ." They know the importance of assiduously training staff in how to avoid the grey areas and of taking every call to the hotline seriously. They understand the desirability of building positive relationships with regulators In short, they are cautious, deliberate people who view protecting the organization from straying off the straight and narrow path as a high calling. They recognize the delicate balance between helping an organization achieve its business goals and keeping the organization from running afoul of the complex regulatory requirements that enmesh it.

In short, you might think, they are just the sort of folks a brash young technology organization needs to keep it from getting into expensive trouble. But if that is, in fact, what you think, you might not be a technology CEO.

Historically, technology start-ups have been rather famously reluctant to elevate compliance officers and adopt what might be viewed as a compliance mindset. Some of the reasons for that may be philosophical or cultural:

> Many Silicon Valley companies view federal regulators as the big bad wolf that is out to get them. Countless articles position the [Food and Drug Adminisration ("FDA")] as "killing" or "stifling" innovation.
>
> As a result, startups will act in defiance [of] or indifferently to regulators. In 2013, 23andMe[46] famously blew through

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[46]23andMe, Inc. marketed a direct-to-consumer genomic testing service until the FDA ordered it to discontinue doing so in November 2013, based on the company's failure to obtain required marketing clearance or approval from the FDA despite what the FDA asserted were lengthy efforts to work with the company to help it come into compliance with FDA requirements. *See* Letter from Alberto Gutierrez, Director, Office of In vitro Diagnostics and Radiological Health, to Ann Wojcicki, CEO, 23andMe, Inc., Nov. 22, 2013, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm. After nearly two years, the company was able to re-enter the market on a more limited basis, with FDA approval, allowing radio listeners the chance to resume listening to its somewhat overwrought commercials. *See* Jennifer Ouellette, *23andMe Is Back in the Genetic Testing Business With FDA Approval*,

> deadlines and effectively cut off communication with the FDA for a matter of months. That prompted regulators to take action.
>
> "Behaving in an antagonistic way with regulators is surprisingly common, in many different types of companies, large and small, startup or established," says Arien Malec, a vice president at RelayHealth [a McKesson-affiliated healthcare information technology company] and a former government employee.[47]

This attitude is reinforced by what has been characterized as "the 'move fast, break things' mentality that is fundamental to the success of consumer-tech companies,"[48] the standard by which successful early-stage investing in technology companies has come to be evaluated.

Beyond that attitude/philosophy/culture may also lie an even more fundamental issue: money. Typically, technology start-ups are relatively leanly staffed, and their resources are focused on two primary goals: product development and customer acquisition. The idea of spending scarce resources on a compliance department, or even a single compliance officer, who will (it may be perceived) be focused on slowing down progress on both of those goals, is not immediately appealing. Indeed, the view of company management and investors may be expressed even more simply: "If we run out of money before we have sales volume, then compliance won't matter because we'll be out of business."

This, then, is the challenge presented by the dueling mindsets of the start-up entrepreneur and the traditional healthcare compliance function. The priority of the entrepreneur is often "Get the product to market and deal with the problems later"—indeed, where "disruption" is regarded as a driver of value, a rather cavalier attitude toward mossbacked regulations may be part of the sales pitch. The priority of the compliance officer is, ideally, on helping the company avoid such problems, and to remediate them when they do occur. Reconciling those two priorities in the start-up phase of a cash-burning technology company can be a challenge. How can the compliance officer position the compliance func-

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gizmodo.com, Oct. 23, 2015, *available at* http://gizmodo.com/23andme-is-back-in-the-genetic-testing-business-with-fd-1737917276.

[47]Farr, *No Shortcuts*.

[48]Farr, *No Shortcuts.*

tion in such a way as to complement strategic disruption without letting it run wild? Is that, perhaps, something that can be accomplished by adding yet a third mindset to the mix, that of the experienced healthcare lawyer?

C. The Lawyer: The Smartest Guy (or Gal) in the Room, or At Least the Only One with a Suit On

What did I tell you the first time you walked into this office? I told you two things. I told you, "Irene, I'm not gonna be your friend. I'm gonna be your lawyer. But I'm gonna do more for you than your friends." And I said, "Irene, you know why I do this? I do it for money.[49]

The role of the healthcare transactional lawyer is, in some respects, a curious thing. A conventional transactional lawyer spends most of his or her time helping clients do things that they want to do. A healthcare transactional lawyer spends a lot of his or her professional life telling clients that they cannot do things, at least the way it first occurs to them to do them, because of concerns like the Stark Law and the Anti-Kickback Statute and non-intuitive reimbursement methodologies. Then, of course, the healthcare transactional lawyer, at least with any luck, tells the client how to do something that is permissible and that at least closely approximates the client's original goals. That first part of the process, however, does tend to slow things down a bit, and can also create the perception of the lawyer as a naysayer.

(In fact, one of the recurring frustrations of being a healthcare lawyer, whether transactional or compliance-focused, is the need to beat down the impulse for "You can't do that" to be the first words out of one's mouth when a client proposes a course of action that makes commercial and economic sense. Over nearly three decades of Anti-Kickback Status jurisprudence and more than two decades of Stark Law jurisprudence, it has become almost a reflex for a healthcare lawyer's first approach to a proposed transaction or arrangement to be skeptical—if it makes sense, there must be something wrong with it. Sometimes, though, there

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[49]Tom Wolfe, The Bonfire of the Vanities (1987) 366-367 (the speaker is the nattily dressed criminal lawyer Tommy Killian).

really is not anything wrong with it, and it requires self-discipline, at least at times, to go through the details and figure that out.)

On the other hand, this deliberate, and deliberative, process has its advantages. Healthcare is a complex industry, as pointed out above, and the lawyer's skill in seeing how the disparate pieces of a business arrangement fit together and in figuring out how to reconcile them all with the applicable regulatory requirements and compliance risks can be a hugely important part of ensuring that the client's goals are achieved and the risks associated therewith are managed. Some clients understand and appreciate that; others, not so much.

In some ways, the role of the lawyer in advising an early-stage technology client in a highly regulated industry is even more curious. In part, this arises from the love-hate-distrust-ignore relationship that innovative technology companies tend to have with their counsel, which in turn arises from a series of phenomena.

First, of course, there is the harsh reality of money:

> Many entrepreneurs start their companies on a shoestring budget. The corporate work lawyers typically perform is often too intangible for entrepreneurs to understand and, therefore, justify the expense. For example, an entrepreneur with partners clearly should invest in drafting a good agreement among them. Although most entrepreneurs already know this, they have a choice as to where they can obtain the contract. They can either pay $3,500 for you to draft it, or they can buy one for $99 off "www.GreatestLegalFormsWebsite.com" or some other forms factory and hope for the best.
>
> As lawyers, you and I know the value in paying the extra money to have a lawyer draft a high-quality agreement. In the eyes of the entrepreneur, however, that $3,500 could easily buy something more tangible, such as a good-looking website that could help them find paying clients. When you compare playing with a cool website to thumbing through a 45-page operating agreement that, to them, is about as fun to read as watching paint dry, it's no wonder that legal services can be a tough sell.[50]

That is to say, much as is the case with the compliance func-

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[50]Stephen T. Furnari, *Start-Ups: Providing Value with Non-Legal Advice*, GPSolo, Jan.-Feb. 2008, *available at* http://www.americanbar.org/content/newsletter/publications/gp_solo_magazine_home/gp_solo_magazin

tion, an early-stage technology company may simply not view spending money on lawyering, especially compliance-oriented lawyering, as a good use of scarce resources.

Likewise, there is the harsh reality that providing competent advice and competent legal work, especially in a highly regulated industry, inherently takes some time. Time is another scarce resource for many start-ups, both because of the need to get a product to market before funding runs out and/or better-funded competition emerges and because speed is simply part of the culture of start-up technology companies—the need to keep up the "buzz" around innovative and disruptive technology before venture capital/private equity investors become dazzled by the next shiny object. This in turn may make the start-up entrepreneur fearful of giving the lawyer too much information or too much time to digest and analyze it, lest the legal analysis derail or delay the deal.[51]

On the other hand, even the most lawyer-averse start-up CEO would likely acknowledge some of the benefits of a strong attorney-client relationship. Particularly in the technology world, it has long been argued that lawyers—at least those within the "club" of counsel actively and repeatedly working with start-up clients and venture capitalists—act as "reputational brokers" for start-ups. The thought is that by working with start-up management teams in the course of organizing and launching their businesses, lawyers can assess the abilities, skills and general credibility of their clients and, in effect, vouch for those clients with funding sources with whom the lawyer has already established his or her own credibility.[52]

Beyond that, many technology start-ups are built around

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e_index/startups.html (hereinafter Furnari, *Non-Legal Advice*). *See also* Alison R. Weinberg & Jamie A. Heine, *Counseling the Startup: How Attorneys Can Add Value to Startup Clients' Businesses*, 15 J. Bus. & Sec. L. 39, 46 (Fall 2014) (hereinafter Weinberg & Heine, *Counseling the Startup*) ("Further, a startup's limited financial resources are devoted to immediate growth, not to paying attorneys for long term protections. Without short-term success, there is no long term; and it is difficult to convince an entrepreneur to spend money on protecting themselves [*sic*] from future issues when the short term is life or death.").

[51] *See, e.g.,* Weinberg & Heine, *Counseling the Startup,* at 48-49.

[52] *See, e.g*., Abraham J.B. Cable, *Startup Lawyers at the Outskirts*, 50 Willamette L. Rev. 163, 169-171 (2014) (hereinafter Cable, *Outskirts*);

an innovator, or a small group of innovators, with experience on the research-and-development side or the sales side, but with little or no grounding in the basic dynamics of business organization, capital-raising and regulatory compliance. There, experienced business lawyers can provide valuable practical advice about the non-technology issues the start-up will face, from basic supply contracts to employment agreements to strategic analysis, including advice that may fall outside of traditional concepts of "legal advice".[53]

Thus, the classic dilemma of start-up clients and their lawyers is encapsulated: those clients need good lawyers, but often are unwilling or unable to pay for effective legal work, at least under traditional hourly-rate models. One compromise approach that some clients try is simply to minimize the costs by bringing the lawyers into the game late and then seeking to limit both the time spent on the work and the scope of it, an approach that raises its own set of problems:

> [E]ntrepreneurs may compartmentalize their legal issues and, in doing so, fail to communicate the necessary business context to their attorneys.
>
> [One of the outside counsel responding to a survey by the authors] stated:
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> Many times, with a newer client, they will just send over contracts and say to us—review it. Reviewing a document is meaningless without a business context. We then need to lay out for our client, here is what we expect of our clients and in exchange here is what you can expect us to do.[54]

This sort of compartmentalization is understandably

John F. Coyle & Joseph Green, *Startup Lawyering 2.0* (Oct. 17, 2016), N.C. L. Rev., forthcoming (UNC Legal Studies Research Paper No. 2853445, *available at* SSRN: https://ssrn.com/abstract=2853445), at 12-15 (hereinafter Coyle & Green, *Startup Lawyering*). *Cf.* Jose Ancer, *Why Founders Don't Trust Startup Lawyers*, siliconhillslawyer.com, Mar. 8, 2015, available at http://siliconhillslawyer.com/2015/03/08/founders-dont-trust-startup-lawyers/ (arguing that startup representation by counsel that has ongoing relationships with venture capital funding sources may present irreconcilable conflicts) (hereinafter Ancer, *Why Founders*).

[53] *See, e.g.,* Coyle & Green, *Startup Lawyering*, at 10-11; Furnari, *Non-Legal Advice.*

[54] Weinberg & Heine, *Counseling the Startup,* at 44. An in-house lawyer responding to the same survey observed that "Business people tend to view the legal affairs department as dry cleaning . . . . [The business people] want to just be able to hand [work] to [the attorneys] and

frustrating to lawyers, especially when the client may lack the legal subject-matter expertise to understand the difference that fine factual distinctions may make in legal analysis. On the other hand, because it is in the nature of lawyers to assume (a) that they can see how the pieces fit together better than anyone else, (b) that the client is, knowingly or not, always hiding the most important piece necessary for the analysis, and (c) that more analysis and identification of potential risks is better than less, clients likewise become frustrated that their quest for advice and answers tends to lead to more questions and expanded uncertainty, all while little dollar bills with wings on them metaphorically fly out the window.

In order then, to ensure that the lawyer may work effectively with the client both in accomplishing the client's business goals and in assuring that those goals are accomplished in compliance with applicable legal and regulatory requirements, the lawyer must find a way to reconcile these various dynamics. And to do that, the lawyer must be cognizant of his or her obligations under applicable rules of professional responsibility. The following section discusses both the backdrop of such rules as they apply to counseling start-ups and other early-stage technology clients and some illustrative scenarios where professional responsibility issues come into play.

III. THE INTERSECTION OF DISRUPTION AND LEGAL ETHICS: OLD ETHICS WINE IN NEW TECHNOLOGY BOTTLES

Lawyers must, of course, fulfill their duties in compliance with the requirements of the rules of professional responsibility in effect in the jurisdictions(s) where they are licensed. For the most part, those rules are derived from the American Bar Association's Model Rules of Professional Conduct.[55] The Model Rules, adopted by the ABA House of Delegates,

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when they come back everything is going to be fine." *Counseling the Startup,* at 51.

[55]Am. Bar Ass'n, Model Rules of Professional Conduct (2016) (hereinafter "Model Rules"). The Model Rules form the basis for the professional conduct rules in each state except California. However, there are significant state-to-state variations. This article will refer the text of the Model Rules and the associated official commentary, but readers should consult

are periodically updated, but as a practical matter they start from the underlying construct that the practice of law consists of a single client asking a single lawyer to perform a rather clearly defined task. This is not the way in which most healthcare lawyers experience the practice of law, nor is it the environment in which lawyers representing technology start-ups of any kind tend to work. Instead, lawyers advising early-stage healthcare technology companies often must grapple with ethics questions of unusual complexity, ranging from client identification issues to financial conflicts to scope-of-representation questions.[56] It is important for lawyers to be sensitive to these issues and understand how they may play out in this sort of representation.

A. The Duty of Competence and the Scope of Representation

As a threshold matter, lawyers representing healthcare technology clients, particularly in the start-up/early-stage mode, must consider the first requirement of legal ethics: the requirement of Model Rule 1.1 that the lawyer be—or be able to become, in a timely manner—competent to provide the legal services required.[57] The comments to the rule make it clear that, taking into account the relevant circumstances, a lawyer who lacks established competence in a particular area may still meet the rule's standard if the lawyer can obtain the competence through "necessary study" or "through the association of a lawyer of established competence in the field in question".[58] In 2012, the ABA added language to the commentary specifically noting that the duty of competence

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the actual text of the professional conduct rules in the state(s) where they are licensed for defintive guidance.

[56]The discussion of ethics rules and their application to start-up representation in this article is necessarily limited. For a more scholarly, and within the scope of its coverage, comprehensive discussion, *see generally* Therese Maynard, *Ethics for Business Lawyers Representing Start-Up Companies*, 11 Wake Forest J. Bus. & Intell. Prop. L. 401 (2011) (hereinafter Maynard, *Ethics for Business Lawyers*).

[57]Model Rules R. 1.1 ("A lawyer shall provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation.").

[58]Model Rules R. 1.1, cmt. [2].

requires a lawyer to "keep abreast of changes in the law and its practice, including the benefits and risks associated with relevant technology".[59] While that change, in context, is focused primarily on the "risks and benefits" of technology relating to the practice of law itself—security of client communications, proficiency in e-discovery, etc.—it also suggests, at least by implication, that a lawyer undertaking to represent a technology client must obtain at least a working knowledge of how that client's products and processes affect the legal environment in which the client operates. For a healthcare technology company, the duty of competence also implies a need for the lawyer—even if his or her focus is primarily on general business representation of the company or other issues the company faces—to have enough knowledge of the healthcare industry and its associated compliance requirements at least to recognize potential issues when they arise.

Suppose the lawyer lacks the requisite competence in a particular area, or simply does not want to provide this particular client with advice except in a very narrow field. Alternatively, suppose that the client, for whatever reason, wants to limit the size of the sandbox in which the lawyer is allowed to play—for example, by engaging the lawyer to provide advice on corporate organization but not on healthcare regulatory compliance. May the client and the lawyer agree to limit the lawyer's role, and thus the scope of the lawyer's professional responsibility obligations to the client? This may be particularly appropriate in some aspects of the representation of a technology start-up—the client's perfectly competent healthcare lawyer may not know anything about intellectual property protection or private equity transactions, or the client may simply want clear demarcations between lawyers with different tasks. Model Rule 1.2(c) allows a lawyer to limit the scope of his or her representation of a client, "if the limitation is reasonable under the circumstances and the client gives informed consent."[60] Within those boundaries, the client and the lawyer may agree to limit even the work that will be done within a specific area: for example, "the terms upon which representation is under-

[59]Model Rules R. 1.1, cmt. [8].

[60]Model Rules R. 1.2.

taken may exclude specific means that might otherwise be used to accomplish the client's objectives. Such limitations may exclude actions that the client thinks are too costly or that the lawyer regards as repugnant or imprudent."[61] However, a limitation will not be reasonable, and thus permissible under the rules, if it so restricts the lawyer's activities so that he or she cannot provide adequate and reliable representation.[62]

Model Rules 1.1 and 1.2, and their juxtaposition, may arise with some frequently in advising healthcare technology start-ups. For example, suppose a start-up client manufactures a new, highly advanced surgical implant of some sort. Faced with the challenge of seeking market adoption of this new product, the client's CEO hits upon an extraordinary idea: Since surgeons typically have great influence over the selection of implants they use, why not recruit a bunch of surgeons in the relevant specialty, have them set up shell corporations to serve as distributors of the implants, sell the implants to those shell corporations at a discount, and then let the surgeons keep the profit when those implants are sold to the hospitals or surgical centers where the surgeons will be doing cases? To make it even more attractive, the CEO proposes, the implants could be shipped from the start-up company's manufacturing facility straight to the end-user healthcare facility on a just-in-time basis, relieving the surgeons' shell distributor companies from the costs and risks associated with maintaining inventory.

Now, this is an idea that, from a business standpoint, seems to be almost a guaranteed moneymaker for both the start-up manufacturer and the surgeons, right? It offers a secure and reliable customer base with little or no economic risk, and it aligns the interests of the start-up with those of the purchasing decisionmakers—in this case, the surgeons, who tend to effectively control the decisions of the end-user

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[61]Model Rules R. 1.2, cmt. [6].

[62]See Model Rules R. 1.2, cmt. [7] ("If, for example, a client's objective is limited to securing general information about the law the client needs in order to handle a common and typically uncomplicated legal problem, the lawyer and client may agree that the lawyer's services will be limited to a brief telephone consultation. Such a limitation, however, would not be reasonable if the time allotted was not sufficient to yield advice upon which the client could rely.").

institutional purchasers. So, what happens when the CEO asks the start-up's lawyer to draft up some contracts to make this happen?

Well, if the lawyer is reasonably knowledgeable about healthcare law, the lawyer will say, "You know, this sounds a little like one of those suspect physician-owned distributorships the OIG talked about in a Special Fraud Alert,[63] and maybe we ought to think about this a little before we roll it out." On the other hand, if the lawyer has not worked in the healthcare area, the lawyer may say, "Great idea! I'll get right on it!" Ideally, though, that non-healthcare lawyer will say, "Gee, I'm not a healthcare compliance lawyer myself, but I've studied the area a bit and know that there are all kinds of issues that come up when you have financial transactions with doctors. Let me look into this a bit." Competence, under Model Rule 1.1, does not mean that the lawyer must necessarily know all there is to know to represent the client, but it does mean that the lawyer must at least be a bit sensitive as to what might cause bells and whistles to go off, and when to get help.

Could the lawyer avoid this by entering into an appropriately documented limited-scope engagement? Perhaps, but arguably not. As one professional liability expert has said, "[E]ven in a limited-scope representation, the attorney has a duty to advise the client of reasonably apparent legal problems, even if outside the narrow scope of the services the lawyer has agreed to provide."[64] In our hypothetical, the question would then become whether the risk that the client's proposed business strategy might be construed to violate the Anti-Kickback Statute was so "reasonably apparent" that a non-healthcare lawyer should have been on notice of it (or on notice that there was an Anti-Kickback Stat-

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[63]U.S. Dep't of Health & Human Serv., Off. of Inspector Gen., "Special Fraud Alert: Physician-Owned Entities" (Mar. 26, 2013).

[64]Merri A. Baldwin, *Lawyers representing startups: Managing ethical obligations and risks*, Cal. Bar J., Dec. 2013, *available at* http://apps.calbar.ca.gov/mcleselfstudy/mcle_home.aspx?testID=80 (citing Nichols v. Keller, 15 Cal. App. 4th 1672, 1684 (1993) ("However, even when a retention is expressly limited, the attorney may still have a duty to alert the client to legal problems which are reasonably apparent, even though they fall outside the scope of the retention. The rationale is that, as between the lay client and the attorney, the latter is more qualified to recognize and analyze the client's legal needs.")).

ute, for that matter). Perhaps the answer to that is "no"; as we have said above, healthcare regulation is a complex and arcane thing. However, a lawyer who undertakes to represent a healthcare client without at least a high-level awareness that the words "physician", "orders" and "get rich", appearing together in a sentence, signal a need for further investigation is playing with fire.[65]

In any event, though, when a lawyer agrees to take on a limited-scope representation with a technology start-up—with any client, really, but particularly with a technology start-up, for some of the reasons discussed in earlier sections—it behooves the lawyer to do at least three things: (a) obtain at least some basic familiarity with the client's general legal needs and risks outside the scope of the limited engagement, so as to be able to identify issues and make sure the client is aware of them; (b) carefully document the agreement with the client on the limited scope; and (c) develop at least a preliminary strategy for other resources to contact if and when help is necessary, and ideally at least discuss that with the client before the need arises.

B. The Duty of Loyalty: Clients, Quasi-Clients and Conflicts of Interest

The duty of competence is owed to the lawyer's client. That raises yet another issue that runs throughout representation of start-up technology companies: identifying who the client is. Where the client is the technology company itself, Model Rule 1.13 gives us fundamental guidance: "A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents," but does not by representing the organization become the lawyer for those constituents—officers, directors, shareholders, etc.—themselves, at least where their interests may diverge from those of the organization itself; the lawyer's profes-

[65]Similarly, one might argue, if our hypothetical technology client had entrusted its work to someone who was primarily a healthcare compliance lawyer, that lawyer would at least need some awareness of what constitutes a red flag in other relevant areas of the law, such as securities law and intellectual property law.

sional duties are owed to the organization as an entity.[66] That can be complex enough in ordinary circumstances, but it can be particularly complex with start-up/early stage companies, for a variety of reasons.

First among those is the uniquely personal nature of start-up representation. Unlike in the representation of an established institutional client, the lawyer representing a start-up will ordinarily be dealing with a founder or a small group of founders who are personally invested—in both the emotional and financial senses—in the success of the Company. Technology start-ups need money, so when those founders come to you, the lawyer, they are likely either looking for assistance in raising capital from venture investors (whether "angels" or established venture funds) or they have those investors already and are now trying to keep them happy with progress. Although the founders and the venture investors will both be owners in the client organization—your client, remember?—the founders may regard themselves as "us" and the outside investors as "them", and as far as they are concerned, your client is "us".

On the one hand, this can be a satisfying aspect of representing the early-stage client. Realistically speaking, the day-to-day representation of large health systems or global pharmaceutical companies may well be lucrative and professionally challenging, but it does not usually offer the same level of personal connection as being the lawyer for a start-up, knowing that you may be a major part of the difference between success and failure for individuals who have put essentially their whole lives at risk on a new venture.

On the other hand, the same personal aspect of start-up representation may raise conflicts. For example, assume the client's CEO comes to you and says, "I've just had an offer to buy the company at a favorable valuation, but the buyer has its own management team and will get rid of my partners and me. We never got around to doing employment agreements with change-in-control protection, and by the time the venture investors get their preferred returns, all we'll get is peanuts. I need you to draw up some guaranteed long-term contracts for us with big buy-out provisions, and for you to tell the Board of Directors that these are 'market standard'

[66] Model Rules R. 1.13(a) and 1.13(g) and cmt. [10].

employment arrangements for founding executives in a company like ours. And do it quickly—I don't know how long I can stall before I have to tell the Board and the VCs[67] about this deal. Remember, you're my lawyer and I'm counting on you."

Now, as the lawyer, your natural impulse is to think, okay, this is the CEO, the one who tells me what legal work they need and approves my bills, so of course I have to follow his direction. But then, you remember Model Rule 1.13, and recognize that your duties are owed to the client organization, not to the CEO. So perhaps you should talk with the investors? After all, they own the largest part of the company. But they're not really the client either, are they? Who really is your client here, and what do you do with all these other people?

Of course, the real answer is that you have to advise the CEO that, at least assuming that this is a credible, bona fide offer, all of this has to be put before the Board of Directors, including the proposed employment agreements. That is a hard answer, but it really is the answer, and the lawyer undertaking to represent a start-up needs to have given some thought to how that situation will be addressed at the beginning of the relationship—and ideally to have a clear statement in the engagement letter that the attorney-client relationship runs to the organization and not to its constituents.

That scenario raises, however, a less dramatic but perhaps more common question in start-up representation. Often, start-up founders who have not been directly involved as entrepreneurs in the past will not know appropriate lawyers or have any particular idea how to engage and utilize them. For that reason, it is not uncommon for founders to seek advice from their investors as to what lawyers to hire, or simply to seek out lawyers who are active in the venture capital/private equity arena and who work both sides of the table.

That, in turn, can give rise to professional liability issues, at least theoretically. One start-up lawyer, in explaining his own firm's decision not to represent venture investors but to focus only on entrepreneurs, summarized the concern in a pithy fashion:

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[67]The common acronym for venture capital investors.

> How can you [i.e., the start-up founder] trust my opinion about whether an acquisition offer is fair to the Company if the investors pushing you to sell have me on speed dial, and just sent me an invitation to their pool party? How can you trust me to give an honest assessment of a term sheet, or even a comparison of one term sheet v. another, if I've closed 20 deals for the VCs who submitted one of those term sheets, and have 3 more in the works? You are one deal. They are 25. Lawyers aren't that bad at math.[68]

A more scholarly commentary identified much the same phenomenon:

> According to [another academic study,] Silicon Valley lawyers "foster and reinforce community norms by promoting certain types of financing transactions over others" and "define and communicate the socially constructed range of 'reasonable behavior' " to their clients. For example, lawyers help entrepreneurs prepare business plans that conform to the expectations of venture capital funds, and school clients in the unique terminology of startup company finance. In the words of one observer, Silicon Valley lawyers do not just represent their clients to the Valley, "they represent the Valley to their clients."
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> According to some, the attitude of Silicon Valley lawyers towards their clients is so distinctive that it "treads near the boundaries of conventional legal ethics." If they take the right steps, Silicon Valley lawyers do not violate black-letter rules of professional conduct. But, at a high level, it can appear that an individual startup client takes a back seat to the lawyer's relationship with financing sources, reputation within the community, and fidelity to the Silicon Valley system of entrepreneurship.[69]

Model Rule 1.7(a) provides that, subject to certain exceptions,

> . . . a lawyer shall not represent a client if the representation involves a concurrent conflict of interest. A concurrent conflict of interest exists if:
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> . . .
>
> (2) there is a significant risk that the representation of one or more clients will be materially limited by the lawyer's re-

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[68]Ancer, *Why Founders.*

[69]Cable, *Outskirts*, at 171.

> sponsibilities to another client, a former client or a third person or by a personal interest of the lawyer.[70]

This rule is written in terms of the lawyer's "responsibilities" to another client, etc. That is a fairly narrow term, and thus the fact that a lawyer may have an existing client relationship with venture investors involved with the start-up company client or may regularly get referrals from those investors[71] does not necessarily present a conflict under the rule; a lawyer does not generally have "responsibilities" to a referral source, even a frequent referral source. However, the lawyer should consider the possibility of a "personal interest" conflict. If the lawyer is engaged by a start-up to negotiate with investors whom the lawyer represents in other matters or from whom the lawyer derives referrals, that fact should be disclosed in writing to the start-up and informed consent should be obtained. More substantively, though, the lawyer should be honest with himself or herself about whether his or her representation of the start-up is likely to be less effective because of the third-party relationship. If the lawyer cannot honestly say "no", then perhaps it is wiser to decline the engagement.

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[70]Model Rules R. 1.7(a). Subsection (b) provides that, with the informed consent (confirmed in writing) of each affected client and subject to certain other requirements, "notwithstanding the existence of a concurrent conflict of interest . . ., a lawyer may [nonetheless] represent a client if . . . the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client." This exception would come into play if the lawyer were, say, representing both the company and the venture investors in the investment transaction itself, which is not particularly the situation we are concerned with here. However, that sort of joint representation creates its own set of problems. *See generally* William W. Horton & Lisa A. Taylor, *"Counsel to the Deal": Lawyers, Clients, and Conflicts in Complex Healthcare Transactions*, *in* Health Law Handbook (Alice Gosfield, ed., 2015), Ch. 13.

[71]It is not especially uncommon for a venture capital firm to suggest to a start-up that is one of the firm's potential portfolio companies that it engage a law firm known to the venture capital firm, on the basis that the deal will be more likely to succeed if the start-up has knowledgeable and experienced counsel. Suspicious minds have, however, been known to suggest that another motivation behind such a referral is to ensure that the start-up is represented by counsel who will be less inclined to negotiate aggressively with the venture capital firm that referred the business. *See, e.g.*, Ancer, *Why Founders*.

C. Money Talks: Another Aspect of the Duty of Loyalty

One thing that is common to most technology start-ups is that cash is scarce and precious. This can be particularly true with healthcare technology start-ups, since regulatory reviews can mean that it may take months or years to get an otherwise completed product to market, during which time the start-up is consuming cash at a prodigious rate and generating little or none of it from operations. This can be a particularly acute problem if the start-up produces a drug or device that requires clinical trials for approval, but it is common for virtually all start-ups, especially in the technology sector.

One time-honored way of addressing this challenge is for the start-up to offer its outside counsel equity in the company in lieu of some or all of the legal fees. Law firms may be interested in working on that basis as a marketing strategy, a way to get start-up companies to sign on as clients and to show that the firm's interests are aligned with the interests of the client. They may also like it for pragmatic reasons, because some law firms active in the technology start-up area have made quite a bit of money through equity-for-fees arrangements.[72]

There is a general consensus that taking equity in a client in lieu of a cash fee (in whole or in part) is ethically permissible, so long as the fee is reasonable, as required by Model Rule 1.5(a), and the arrangement meets the relevant standards of Model Rule 18(a) for engaging in a business transaction with a client (essentially that the terms are fair and reasonable to the client and have been disclosed to the client in writing, that the client has a reasonable opportunity to consult with independent counsel, and that the client gives written informed consent).[73] In 2000, the ABA's Standing Committee on Ethics and Professional Responsibility issued a formal opinion indicating that there was no per se ethical prohibition on a lawyer's acquiring equity interests in a cli-

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[72]*See, e.g.,* Maynard, *Ethics for Business Lawyers*, at 403 n. 1 (discussing the financial results of the Wilson Sonsini law firm's equity-for-fees strategy).

[73]*See* Model Rules R. 1.5(a) and 1.8(a).

ent, either in lieu of (or as part of) a fee or as a stand-alone investment.[74]

However, Formal Opinion 00-418 made it clear that the general propriety of taking equity in lieu of fees, subject to certain safeguards, did not end the inquiry. The question of whether such ownership did in fact, under particular circumstances, create a "personal interest" conflict under Model Rule 1.7(b) would still have to be addressed as applicable circumstances arose. The opinion offered up several examples:

- The situation where the lawyer represented the client in a transaction and had to call upon the client to disclose negative information that might kill the deal and thus impair the value of the company (and the lawyer's stake therein).
- The situation where the lawyer's equity interest in the company was his or her major asset, so that the failure of the company could be devastating to the lawyer.
- The situation where the company had determined to discharge the lawyer and the lawyer challenged that decision.[75]

Thus, lawyers who elect to take equity in a client in satisfaction of all or part of a fee must be hyper-sensitive to ensure that such equity interest does not, under the particular facts at hand, create a conflict that, under Model Rule 1.7(b), would require the lawyer to withdraw from representation.

Formal Opinion 00-418, and much other commentary on the matter, has focused on the situation where the lawyer with the equity interest was outside counsel. Much the same considerations apply where an inside lawyer receives equity (whether "real" or in the form of stock options or other equity derivatives) as part of his or her compensation. The same rules of professional responsibility apply to an inside lawyer functioning as a lawyer (and some of them apply even when the lawyer is not expressly functioning as a lawyer, although

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[74]Am. Bar Ass'n Standing Comm. on Ethics & Prof. Responsibility, Formal Opinion 00-418, July 7, 2000. Note that equity-for-fees arrangements may take many forms, from ownership of equity by an individual lawyer to ownership by a law firm to ownership by an investment vehicle owned by lawyers in the firm. In particular cases, those distinctions might have significance, but they are ignored for purposes of this discussion.

[75]Formal Opinion 00-418 at 10-11.

that is beyond the scope of this discussion). Where inside counsel determines that his or her advice might be (or might reasonably be perceived to be) inappropriately tainted by an equity stake in the client-employer, he or she must be prepared to take steps to bring in outside counsel (or delegate authority to "untainted" inside counsel, if available). Conflict-of-interest violations are not pretty, whether they involve inside counsel or outside counsel, and the lawyer who owns equity in a client must always be aware of the risks.

IV. CONCLUSION: WHAT COULD POSSIBLY GO WRONG (AND HOW CAN WE MAKE IT BETTER)?

Ethics and professional responsibility issues can be notoriously abstract. In closing, let us consider some of the issues discussed above in the context of a brief hypothetical scenario.

Suppose, for example, that you are an outside lawyer serving in the dual roles of general counsel and (outsourced) chief compliance officer for a healthcare technology start-up. In consideration to your agreeing to provide both legal and compliance services at a fixed monthly fee (that reflects a substantial discount from your hourly rates, in a typical month), you have been given 25,000 shares of the company's stock valued at the "friends and family" price of $0.25 per share.[76] The company, with your help, is in the process of completing a second venture-capital investment round in which it expects to sell 100,000 shares of its stock at $5.00 per share.

As you are reviewing the recently received stock subscriptions, you idly punch up the voicemail on the company's compliance hotline. Slowly, you put down your pen as you listen to the muffled voice of someone who claims to work in the company's clinical trials operation. The anonymous message goes into some detail about how the clinical trial data used to support the company's application for FDA approval

[76]"Friends and family" investors are very-early-stage investors who typically have some existing relationship with the founders of a start-up and who buy in at a low price, with the expectation that the value of their equity, at least on paper, will rise substantially when "real" venture capital investors buy in.

was meticulously faked. If you do not take action as compliance officer, the caller says, her next call will be to the United States Attorney's Office.

With your scribbled notes in hand (this is not something you want on your computer network, after all), you head over to the company's headquarters to alert the CEO to the voicemail. Closing his door, the CEO tells you not to pay attention to some disgruntled employee was probably upset because he or she had been made to do some work for a change. Anyway, the CEO says, sure, there were some innocent mistakes in the clinical trial data, but the company has figured that out and will amend its application with the FDA just as soon as the dust settles from closing the venture capital deal. Just a routine amendment, the CEO says; people do it all the time. If you cause a big stir about it now, the Board won't understand and will get all agitated, and the second-round venture investors will kill the deal and put the company out of business, and that's not something you want on your conscience over a little paperwork snafu, right? Just think, says the CEO, all that stock you've earned that will get flushed down the tubes . . . .

> *Okay*, you say to yourself, *I don't know much about the FDA process, but the CEO sounds like he does and anyway, that seems pretty reasonable. If there's any problem with the FDA, there should be plenty of time to sort it out after the financing is done. Anyway, this sounds more like an issue for our FDA lawyers, and I'm sure someone has already talked with them about it . . . .*

This little scenario contains, in four short paragraphs, the material for FDA sanctions, a securities fraud claim, and potential violations of Model Rules 1.1, 1.2(d), 1.7(b), and at least arguably 1.13(a) and (b), among other things. You, our hypothetical lawyer, seem to have failed to represent your client—the company—competently as required by Model Rule 1.1, since you neither had nor obtained (via research or by engaging someone else) the specialized knowledge concerning FDA processes necessary to evaluate the company's true legal position or the significance of the compliance problem. Model Rule 1.2(d) was not specifically discussed above, but it provides, among other things, that "[a] lawyer shall not counsel a client to engage, or assist a client, in

conduct that the lawyer knows is criminal or fraudulent".[77] By remaining silent about an allegation that would, in all likelihood, be regarded by the venture capital investors as material to their investment decision, you have set yourself up for a claim that you assisted the company, or at least the CEO, in securities fraud. If that allegation is made against you, it will almost certainly be accompanied by an allegation that the reason that you did not take appropriate action was that you had a conflict under Model Rule 1.7(b) due to your "personal interest" in ensuring that the value of your stock in the company was not destroyed, as would likely have been the case if the venture investors had walked away from the second-round financing. Finally, the fact that you followed the CEO's instructions to sit tight and say nothing strongly suggests a violation of Model Rule 1.13(b), which generally requires that a lawyer representing an organization who knows that an officer or other agent of the organization "is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization", then that lawyer must report that violation up the ladder within the organization, if necessary to the highest authority that can act on behalf of the organization (in this case, the company's board of directors).[78] That in turn suggests a violation of Model Rule 1.13(a), since it appears that you acted not in the best interests of your actual client, the organization, but instead furthered the interests of the CEO in ensuring that the malfeasance on his watch was not exposed.

One hopes that in real life most lawyers would not be as willfully obtuse as our hypothetical lawyer was here. However, this scenario does demonstrate, with modest exaggeration, how easy it is for clients in the high-pressure, high-speed, high-dollar world of healthcare technology innovation—and the lawyers for such clients, if they are insufficiently attentive—to make mistakes from which recovery can be long and painful, if it is achievable at all.

As much as one might wish it were otherwise, it seems

[77]Model Rules R. 1.2(d).

[78]Model Rules R. 1.13(b).

unlikely that our healthcare regulatory and reimbursement systems are going to change radically, at least not in ways that make them less complex and self-contradictory. Accordingly, it remains necessary for lawyers and their clients to find ways to work together so that the pressure to obtain financing for innovative healthcare technology and to get that technology to market is tempered by appropriate compliance structures as well. The point is not for compliance to be a roadblock, or even a speed bump, for useful "disruption". Instead, the point is that technology innovators, compliance professionals and lawyers must constantly strive to understand each other's mindsets and develop paths of communication that enable timely innovation and effective regulatory compliance to work together, side by side. Lawyers, with their training in assimilating information, organizing it and communicating it to others, are in a great position to help make that process work, but in doing so must remain mindful of their obligations to their clients—and themselves—under the rules of professional responsibility and remain sensitive to how those obligations evolve with the healthcare technology business models of today . . . and the future.