YOUR HEALTHCARE COMPANY'S EXCELLENT LEGAL ADVENTURE

KEY LEGAL STRATEGIES & SOLUTIONS THAT HEALTH & WELLNESS VENTURES CAN PROFITABLY DEPLOY

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Your Healthcare Company's Excellent Legal Adventure:

Legal Strategies & Solutions Health and Wellness Ventures Can Profitably Deploy

The case studies are a work of fiction. Names and identifying details have been changed to protect the privacy of individuals. Names, characters, businesses, places, events, locales, and incidents are either the products of the author's imagination or used in a fictitious manner.

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"We provide legal strategies and solutions to businesses that accelerate health and wellness."

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For Alexander

With Love

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Introduction

Why Healthcare: Of Service and Purpose

A Crystal-Clear Day

It was a crystal clear, brilliantly sunny day in August, last century. My century to be precise.

The century in which I was born.

I was 35 years old.

I felt that I'd accomplished everything that I wanted to achieve by this age. I had graduated law school with a very fine record, securing a job at one of the three top-tier and most prestigious law firms in New York City. On **Wall Street**, to be exact. I was a corporate lawyer, rotating through the departments of banking, securities, and mergers and acquisitions. I had also received my MBA from University of California, Berkeley.

Besides the professional prestige that was so important to me throughout my early adult life, I had also managed to win acceptance to a program in creative writing at the famous Iowa Writer's Workshop. This meant that I had the opportunity to study with poets and fiction writers from among the very best in the country. My mentors were published authors who were celebrated in the literary and commercial communities, and crowned with commercial success.

I was an unshakeable rock of confidence, purpose, and commitment to a wonderful life that seemed to unfold by itself.

The Endless Country Road

I was spending my summer at a spiritual retreat center under the loving gaze of a spiritual teacher from India who I understood to have blessed my path.

We were driving down this endlessly green, country lane on our way from one building at the spiritual center to another. My driving companion, a beautiful long-haired and long-limbed woman with a difficult to pronounce Indian spiritual name that translated into something like the most brilliant manifestation of the goddess you could ever imagine, was in the driver's seat.

We had just finished a healing session in our bungalow, where she had performed a healing on me, aligning my spiritual centers to the highest vibration. Life couldn't be better. To top it off, happily relaxing in the passenger seat to the sound of Sanskrit chants, I was drinking this exquisite coffee specially made by the spiritual center, which had in it cardamom, cinnamon, nutmeg, and a variety of exoteric spices guaranteed to induce good feelings and good vibrations.

Everything seemed to be perfect.

A Moment of Revelation

There was a saying at the ashram which comes from the Hindu tradition. Om, *this is perfect, that is perfect*. When the perfect is taken away, only the perfect remains.

At that very moment, while listening to this transcendental chant emanating from the car's music player, something flashed. Out of the corner of my eye, I noticed an oncoming car speeding into our lane.

Within moments, the perfect was taken away. I only had a fraction of a second, in which I ducked to the left and downward. I uttered the mantra given to me by my spiritual teacher, in which I affirmed the unity of all consciousness, in fact, that we're all spirit embodied flesh. Then there was a collision and I blanked out.

The next thing I knew, we were on the side of the road and I was shouting to my companion, *"Get out of the car! Get out of the car!"*

I had seen a lot of movies where the car explodes, and this was my fear. Somehow, I don't remember how, magically, the scene changed: we were both lying down on the side of the road on the gravel. Someone was leaning over me, whispering. *"An angel must have saved your life. Don't move*," she said quietly.

My heart felt full of compassion. I didn't know whether I was alive or dead. For all I knew, these were my final moments. I uttered prayers for everyone in the universe, including my dear companion, healer-driver and now fellow passenger to the Other Side; who I could not see, except it occurred to me that we were laying side by side on the gravel. I also blessed the driver of the oncoming vehicle, because all I wanted to do at that moment was bless everyone. I felt incredible love for each person that came by my side and assisted us as we were hoisted into the ambulance.

Then we were in the hospital, warding off the harsh voices of the emergency room staff who seemed oblivious to that tenuous state of consciousness I was experiencing between worlds; who seemed to me in those moments to live in the world of paperwork and questions about insurance that I could not answer. And after that, a whole of meetings at work that my mind could not comprehend. I had the ability to read the energy in the room, and where it was dark, it was dark – I was privy to all the political machinations and infighting and intrigue at a whole new level of awareness. I experienced angels, as well as demons. One of my legs kept tingling, as if partly left in the other world.

For months after the car accident, I was having exquisite visions of alternate realities. I saw myself go up and meet various divine figures. I received a personal affirmation or set of words, a mantra for my life. It seemed that my life had been spared, and from now on, my governing phrase would be service to God, service to the planet. That was the only reason I'd been kept alive. **I was given a new lease on life at age 35, and from now on it was all gratitude.**

A Change in Perspective

There's a reason that each one of us does what we do.

For me, what I do is **healthcare law**. My firm's "magic statement" is, *we provide legal strategies and solutions to businesses that accelerate health and wellness.*

For many years I had resisted being a lawyer. I held a vibrant spiritual identity and *I found the law in some respects dry, in many respects arcane, and from an emotional perspective, largely disconnected from people's experience*. Kafka had said as much—he compared law to sawdust, which had already been chewed for him in other people's mouths.

There's a lot to be said for this perspective. Read a 100-page asset acquisition agreement and you'll agree.

There's also a lot to be said for honoring and also reclaiming law as a noble profession.

We have a sacred relationship between attorney and client. **The attorney is in a position of trust, and under our ethical rules must zealously advocate for the client**. The attorney is entrusted with giving the client good advice, so that the client can then do good things and build their dream.

It's all about protection. It's all about growth. It's all about transformation.

In the end, law is ministry for me. Whether I am working as an attorney or as a priest, healer, or shaman, to me the function is the same. We're here to do good and to spread the good in the world through our professional powers and practices. This is why I am a healthcare and FDA lawyer.

So many times I tried to escape this path, but I was like Noah in the belly of the whale. My spirit called and here I am today, still moving along this path. Every day, my work as a healthcare and FDA lawyer, as founding attorney of Cohen Healthcare Law Group, I am summoned to continue the ministry, if you will, that was given to me around the time of my near-death experience. **Service to God, service to the planet.**

That service is by giving advice and counsel to businesses and practices that accelerate health and wellness.

Bring Your Gift to the World

Your dream may be to have a medical practice that combines functional medicine or integrative medicine in a holistic approach that addresses the whole patient, the whole person, the whole being. You might be a healthcare startup yearning to bring a new product to the health and wellness market. You might have a medical device, a dietary supplement that will improve health, a cosmetic product that will improve beauty, or some other design of your own imagination which will bring a better and more glorious future to the health and wholeness of humanity.

In that dream I believe. To that dream I dedicate my professional work.

This book is about the legal challenges and obstacles that lay along the path to achieving the healthcare practice or venturous dream.

We provide legal strategies and solutions to businesses and practices that accelerate health and wellness.

We chose this tagline deliberately after much thought. It is not simply a marketing statement or an advertising slogan. It is what we believe in practice every day.

My intent in this book is to lay out some of the key legal strategies and solutions and how we use them every day in our law firm to help our clients penetrate the legal and regulatory work and find their way into the light where they can fulfill their professional practice and business dreams.

Chapter 1

Corporate Practice of Medicine

A Tale of Epic Proportions

***Case Study*: "Doctors, Make Money While You Golf!"**

Seymour Heart, MD gave his golfing companion a high-five, as the golfing ball happily rolled down the putting green and into the hole. Just then his phone buzzed, signaling that another patient had signed up with the Beauty Spa, where he served as Medical Director – and there was more money in his account, and shown on the dashboard on his phone's home screen.

Life was good.

Meanwhile, Rodney, his cousin, was receiving the same message on his dashboard, inside the Beauty Spa. Rodney escorted the new patient from the Finance Office down the hall to a special room where an RN was smiling and waiting to flip the switch on the laser.

Just then, the new patient flashed his badge at Rodney and the RN. "Dick Jones," he said, "State Police, Special Unit for Investigating Medical Spas. Where is Dr. Heart?"

"P-p-playing golf," the RN blurted out, overcoming a loud and simultaneous "shhhh!" from Rodney.

"You're under arrest for unlicensed practice of medicine," Jones said. He looked at the name on the door. "Come to think of it, so is Beauty Spa, for Corporate Practice of Medicine."

"What the heck is that?" the RN asked, as she watched the SWAT team charge into the office and begin hauling away all the computers and records.

A Variation on Unlicensed Practice

When you launch any virtual, electronic, online, mobile, or other non-physical telemedicine or telehealth venture, you have to navigate several interlocking, overlapping legal issues, from licensure to Corporate Practice of Medicine and fee-splitting, to basic state law rules that govern any medical endeavor.

Unlicensed practice of "medicine" is a crime.

Non-medical doctors who are healthcare licensees have a defined scope of practice. However, if they practice *beyond* their scope of practice, then they are considered to be engaged in unlicensed *medical* practice. Companies that hire and direct such persons can be *aiding and abetting* unlicensed medical practice.

This leads to the evil twin of unlicensed practice of medicine, the infamous Corporate Practice of Medicine.

Corporate Practice of Medicine

Many healthcare ventures seek to avoid Corporate Practice of Medicine (or psychology) and fee-splitting violations, but they need to first understand how deeply down the rabbit hole these prohibitions go.

Corporate Practice of Medicine (Corporate Practice of Medicine or sometimes "CPOM") is a variation of the statutory prohibition against unlicensed practice of medicine. In some states, the prohibition against Corporate Practice of Medicine is created by statute; in other states, the prohibition is established through common law, or derives from the state's medical practice act, or is suggested by an Attorney General ("Attorney General") opinion.

California law provides that an individual engages in the practice of "medicine," when he or she:

> *practices or attempts to practice, or … advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or … diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person.*

The California Medical Board has a webpage on Corporate Practice of Medicine, and aggressively enforces Corporate Practice of Medicine violations. California Medical Board cites the statute above regarding unlicensed practice, as well as the prohibition against corporations having professional rights, privileges, or powers.

In California, the prohibition against Corporate Practice of Medicine, imposes strict rules on contractual arrangements between physicians and non-physicians.

One of the purposes of the Corporate Practice of Medicine doctrine is to separate medical from business decision-making. Under this doctrine, neither non-physicians nor lay corporations (corporations that are not medical professional corporations) nor limited liability companies (LLC) may contract to provide medical services. Nor may they contract with a physician to have the physician provide medical services, either as an employee or an independent contractor.

In addition, California law places limits on the activities of non-medical corporations and LLCs managing health care practices, so as to ensure that such companies do not engage in clinical decision-making.

For example, the California Medical Board states that the following health care decisions should be made by a California-licensed physician and would constitute the unlicensed practice of medicine if performed by an unlicensed person:

- Determining what diagnostic tests are appropriate for a particular condition.
- Determining the need for referrals to, or consultation with, another physician/specialist.
- Responsibility for the ultimate overall care of the patient, including treatment options available to the patient.
- Determining how many patients a physician must see in a given period of time or how many hours a physician must work.

The California Medical Board has been paying particular attention to medical spas and other ventures that can raise unlicensed practice and Corporate Practice of Medicine issues.

For example, in The Accusation against Joseph F. Basile, M.D., California Medical Board found that the licensed physician had aided and abetted unlicensed medical practice, when he permitted his wife (a non-licensee) to provide laser services to patients in a vein and cosmetic enhancement center that she owned, where the physician acted as "Medical Director."

Among other things, California Medical Board rejected the contention that the physician's wife was acting as a "medical assistant," since the physician was not always physically presented when his wife administered intense pulse light (IPL) and laser treatments to patients; further, although it was the physician who "obtained patient histories, performed physical examinations, determined whether patients were appropriate candidates for treatment and who determined appropriate machine settings," the wife solely owned "The Vein & Cosmetic Enhancement Center."

The California Medical Board had this to say about the wife's defense:

> *It was her business. Importantly, the treatment was not ancillary to respondent's [i.e., the physician's] workup or diagnosis of a patient's condition. Instead, it was the primary treatment mode sought by patients seeking removal of unsightly varicose veins or other cosmetic blemishes….. When … [the wife] provided IPL/laser treatment to patients, particularly when respondent was absent from the facility, she was not performing adjunctive services for respond. She was engaged in the unlicensed practice of medicine.*

The California Medical Board went on to differentiate the wife's legally impermissible activities, from those "technical supportive services" legally permissible to medical assistants.

Although medical spas have been the particular targets of enforcement by California Medical Board of late, due to rampant abuses with regard to unlicensed practice and lack of medical supervision, the California Medical Board does scrutinize arrangements more generally between LLCs and physicians as they raise similar issues.

For example, the California Medical Board also notes in *The Bottom Line: The Business of Medicine—Medical Spas*, that California Business & Professions Code, Section 2272 requires advertising for an enterprise such as a medical spa, which offers medical services, to include the physician's name or the name for which the physician has a fictitious name permit.

The Board notes that California law prohibits many advertising practices currently being used (including "discount or 'bait and switch' promotions").

Further, the California Medical Board cautions that the "clients" are the physician's patients, and must be treated as such—not as those of the non-physician entity.

The MSO Model

We advise our non-physician clients in California that because of the Corporate Practice of Medicine doctrine, and anti-kickback/fee-splitting rules, they cannot own a medical clinic or hire physicians.

However, they can own a management entity which can serve as an administrative and non-medical, management services organization ("MSO") for the clinic or medical practice, which is frequently organized as a professional medical corporation.

In this model, the MSO contracts with the Professional Medical Corporation so that the Professional Medical Corporation agrees to provide professional services, and the MSO agrees to provide administrative and management services, such as:

- front desk, receptionist, and scheduling
- advertising and marketing
- sublease space and/or provide equipment (each under a written lease or management agreement with the Professional Medical Corporation)
- book-keeping
- billing and collecting on behalf of the Professional Medical Corporation.

All of these services are subject to applicable legal requirements (including more specific Corporate Practice of Medicine prohibitions), and rules relevant to billing and collecting, and would require specific contractual provisions between the Professional Medical Corporation and the MSO.

With respect to the MSO, the California Medical Board still imposes constraints through its interpretation of California law and strong enforcement posture.

The California Medical Board on its webpage on Corporate Practice of Medicine has noted that, the following "business" or "management" decisions and activities, resulting in control over the physician's practice of medicine, should be made by a licensed California physician and not by an unlicensed person or entity:

- Ownership is an indicator of control of a patient's medical records, including determining the contents thereof, and should be retained by a California-licensed physician.
- Selection, hiring/firing (as it relates to clinical competency or proficiency) of physicians, allied health staff and medical assistants.
- Setting the parameters under which the physician will enter into contractual relationships with third-party payers.
- Decisions regarding coding and billing procedures for patient care services.
- Approving of the selection of medical equipment and medical supplies for the medical practice.

The California Medical Board further states:

The types of decisions and activities described above cannot be delegated to an unlicensed person, including (for example) management service organizations. While a physician may consult with unlicensed persons in making the "business" or "management" decisions described above, the physician must retain the ultimate responsibility for, or approval of, those decisions.

According to California Medical Board, the following types of medical practice ownership and operating structures also are prohibited:

- Non-physicians owning or operating a business that offers patient evaluation, diagnosis, care and/or treatment.

- Physician(s) operating a medical practice as a limited liability company, a limited liability partnership, or a general corporation.

- Management service organizations arranging for, advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice (non-physician exercising controls over a physician's medical practice, even where physicians own and operate the business).

- A physician acting as "medical director" when the physician does not own the practice. For example, a business offering spa treatments that include medical procedures such as Botox injections, laser hair removal, and medical microdermabrasion, that contracts with or hires a physician as its "medical director."

In 2000, the California Attorney General issued an opinion that a proposed agreement where the MSO would charge a management fee to a labor union, in exchange for the MSO arranging to "select, schedule, secure, and pay for radiology services ordered by the union's physician for union members," would violate Corporate Practice of Medicine.

The Attorney General stated:

The activities to be performed by the MSO would include selecting a radiology site with the appropriate imaging equipment and qualified operators of the equipment, as well as selecting a qualified and duly licensed radiologist to view the films and prepare an interpretive report…

We believe that the selection of a radiology site with appropriate equipment and operational personnel best suited for the performance of a diagnostic radiology study of a patient's particular disorder, as well as the selection of a qualified radiologist to view and interpret the films, would involve the exercise of professional judgment and evaluation as part of the practice of medicine.

Corporate Practice of Medicine issues frequently overlap with kickback and fee-splitting concerns. As the California Attorney General noted in the above opinion:

In addition to the selection, scheduling, and securing of the technical and professional aspects of the radiology services to be rendered, the MSO would pay for the radiology services and profit by adding a fee for its own management services. This financial aspect of the arrangement would be a further intrusion into the relationship between the physician and the patient.

We will talk about the kickback and fee-splitting issue in a later chapter.

How the MSO Gets Paid

The MSO gets paid by the Professional Medical Corporation for the services the MSO renders, at fair market value.

This is the single most important limitation on the MSO's fee. By law, compensation must be for fair market value. Otherwise, the arrangements could conceivably be seen as creating an unlawful inducement to refer patients (i.e., a kickback or fee-splitting).

For this reason, with the MSO model, our law firm typically advises that the MSO keep a backup spreadsheet that justifies Fair Market Value for each management service rendered. Additionally, it is a good idea to get a formal, professional valuation done of the Professional Medical Corporation and the actual value of the MSO services. This can help put the MSO fee "beyond reproach," so to speak—at least, it sets the bar very high.

Typically, the management fee must be:

- For services other than the referral of patients—i.e., not an inducement to refer patients to those physicians or the Professional Medical Corporation;
- Based on a percentage of gross revenue or similar type of contractual arrangement; and
- Commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

As well, MSOs often reduce legal risk by complying with the federal safe harbor for the "personal service arrangement or management contract." This safe harbor requires the following:

- the management agreement covers all the services the manager provides for the term of the agreement and specifies those services;
- the agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
- the term of the agreement is for at least one year;
- the aggregate compensation paid to the manager over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties;
- the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Even if the safe harbor does not apply because no Medicare/Medicaid services are being provided, compliance with the safe harbor can help bolster the argument that the arrangement is defensible.

"No" or "Weak" Corporate Practice of Medicine States

Not all states are as tough on Corporate Practice of Medicine as California.

Sometimes healthcare companies will seek to actually hire the physicians, in states that have a "weak" Corporate Practice of Medicine doctrine in place. One can go online and find charts showing states that have a "weak" or "no" Corporate Practice of Medicine rule.

The reality is that corporations (unless they are a Professional Medical Corporation) cannot practice medicine, and must take care to not intrude on medical decision-making. Given the blurred lines between the clinical and the business side in a world where services are provided online, do not believe there is an absolute green light in any given state.

Of course, a state by state analysis is recommended particularly where the venture is online and will deliver services across states. Corporate Practice of Medicine is in many senses an archaic rule, heavily enforced, and one whose pillars are being eroded daily by digital and mobile healthcare.

How Widespread are Corporate Practice of Medicine Enforcement Fears?

Healthcare ventures desiring to create MSOs or operate them in legally compliant ways often worry about enforcement efforts under the Corporate Practice of Medicine and anti-kickback rules, and related legal rules that can create traps for the unwary. This is a very broad rule and it creeps into many different kinds of healthcare arrangements.

The kinds of healthcare business seeking healthcare legal advice and MSO compliance that we have advised, include:

- A high-profile, plastic surgeon in charge of a highly profitable cosmetic and aesthetic medicine.

  The physician decided that he would like to open a new revenue stream, by creating an MSO, alongside his lucrative practice. However, the physician was unsure about how to create value in the MSO, so it could later be sold for a high multiple.

  Unlike the medical practice, which could only sold to another physician (or MD majority owner in a professional medical corporation), the MSO could be sold to anyone, including a layperson.

  Unlike the plastic surgery practice, the MSO would attract investors.

  And, the physician hoped to build value in the MSO and have the branding successes and marketing dollars go to benefit the MSO.

- More typically, non-physician investors and entrepreneurs seeking to create a branding and marketing success. The venture folks behind the idea have access to capital, and an intelligent way to capture and bring potential patients to the medical practice.

- Chiropractors or acupuncturists wanting to create a multidisciplinary healthcare care, such as a holistic health care or center for integrative medicine, or simply a collaboration with practicing physicians.
- RNs, NPs, or PAs seeking to create a medical spa or model of care that integrates esthetic treatments with aesthetic medicine treatments.

  Sometimes, it seems that Corporate Practice of Medicine fears are everywhere.

  The penalties for violations can be serious.

It is also important to note that enforcement priorities vary. Sometimes there can be "technical" violations of the statutes yet enforcement will be light, or the arrangement might be regarded as creating a

low risk of fraud and abuse. One can find this attitude expressed in many federal advisory opinions regarding the anti-kickback laws, which, as mentioned often dovetail with Corporate Practice of Medicine concerns.

A "Perfect Storm" for Enforcement

Often, investigation, enforcement and penalties arise from a "perfect storm" of negative facts and circumstances.

In a state enforcement action by the New York Attorney General against an MSO, the enforcement triggers were numerous. They included:

- **Extensive Consumer Complaints:** There were over 300 consumer complaints to the Attorney General about consumer experiences, including: "quality of care, billing practices, misleading advertising, upselling of medical services and products the consumers felt were unnecessary, and unclear or incomplete terms for the financing of dental care."

- **Extensive MSO Control:** The MSO "did not merely provide arms-length, back-end business and administrative support to independent dental practices," but rather "developed what amounts to a chain of dental practices technically owned by individual dentists but which, in violation of New York law, were subject to **extensive control** by the MSO. "
- **Profit-Sharing; a Shared Trade Name**: The control "included sharing individual clinic profits with the management company and the marketing by the management company under" a shared trade name.

- **Control over Care via Banking Arrangements:** The MSO "exercised undue control over the clinic's finances by controlling substantially all of the dental practices' bank accounts through a single consolidated account to which the clinic owners themselves did not have access."

- **MSO Revenue Based on Percentage Gross Profit:** The MSO took a percentage of each dental office's monthly gross profit -- "a*n arrangement prohibited under New York law*."

- **Over-broad non-compete and non-solicitation:** The MSO "also subjected the dental practices to non-competition and non-solicitation agreements that effectively prevent the practices from competing with any other dental practice affiliated with" the MSO, regardless of location.

One can look at this enforcement scenario two ways: first, enforcement citing Corporate Practice of Medicine violations is alive and well; second, it took a lot, including an egregious number of consumer complaints, for enforcement to get involved.

And that brings us to *Epic Medical Management v. Paquette*, a recent California appellate court decision.

An Epic MSO Enforcement Case

In *Epic*, there was a dispute between an MD and a medical management company, Epic Medical Management, LLC, with which the physician had contracted to supply non-medical management services to his practice. According to the Court:

The doctor and the management company had a falling out and agreed to terminate their contract. The management company believed it was due additional fees under the agreement; the doctor believed the Management company had under-performed its duties under the contract and owed him money.

Here are some of the key elements of the Management Services Agreement in dispute in the case:

- Under the agreement, the doctor engaged the management company "to provide management services as are reasonably necessary and appropriate for the management of the non-medical aspects of [the doctor's] medical practice."

- Among other things, the management company was required to lease office space to the doctor, lease to him all equipment he deemed reasonably necessary and appropriate, provide support services, provide non-physician personnel, establish and implement a marketing plan, conduct billing and collections, and perform accounting services. The doctor was responsible for providing medical services.

- The management company was required to provide non-physician personnel, including nursing staff, but the physician was responsible for training and supervising the nurses.

Significantly, as to compensation, the contract stated the parties agreed that:

it will be impracticable to ascertain and segregate all of the exact costs and expenses that will be incurred by [the management company] in performance of the [management services]. However, it is the intent of the parties that the compensation paid to [the management company] provides a reasonable return, considering the investment and risk taken by [the management company] and the value of the … [management services provided by the management company].

The agreement then provided that the doctor would pay a management fee of 120% of the aggregate costs incurred by the management company in providing the management services, but no more than 50% of professional medical fees collected.

The contract also included an arbitration clause and a prevailing party attorney's fee clause.

According to the complaint, this 120% was never charged; instead, the doctor paid a different fee. With these unusual facts, the arbitrator decided that it was the doctor, not the management company that had breached the contract.

The physician tried to get out of the contract, by arguing that it was "an illegal kickback scheme." The physician's argument included that one cannot pay a percentage for marketing fees as that itself can be considered a kickback.

Interestingly, the arbitrator did not buy the argument, but rather, dismissed it as "technical."

The physician also argued that the contract violated the Corporate Practice of Medicine, by referring patients to the physician, and by using the 50-25-75 method of calculating fees.

Without getting deep into the weeds on the procedural aspects, we can simply note that the arbitrator's decision then went to a judge, and that the appellate court took the opportunity to review the sweep and scope California's prohibition against the Corporate Practice of Medicine, as well as the twin of this rule, the anti-kickback rule as embodied in Section 650 of the California Business & Professions Code.

The appellate Court stated:

Referral patients were a small percentage of the patients seen while the doctor and management company were operating pursuant to the agreement. The agreement was not a referral agreement, but one for management services, of which referrals played only an incidental part.

The news here is that the Court takes a very light enforcement stance, and simply looks to see whether the management fee was fair market value for the management services. As well, the Court also found no Corporate Practice of Medicine violation, since according to the judge, the Management Services Agreement showed "a strict delineation between the medical elements of the practice which the doctor controls, and the non-medical elements which the doctor has retained the management company to handle."

In that sense, *Epic* changes the landscape. It is not from the highest court in California, nor is the decision binding on other states – nor does the decision express views of anti-kickback rules based on federal law. Nonetheless, as an expression of a more liberal view of management service organizations and other healthcare ventures that create business their arrangements with physician and medical groups.

As such, *Epic* is a sea change in regulatory policy.

Lessons Learned

Here are some key lessons around Corporate Practice of Medicine:

- The Corporate Practice of Medicine prohibition lurks behind almost every arrangement in the healthcare industry that involves a medical doctor and an entrepreneur or business who is a layperson.
- This means telemedicine ventures, many mobile medical apps, medical spas, and a million variations on these themes.
- Corporate practice of medicine is a crime.
- One of the purposes of the Corporate Practice of Medicine doctrine is to separate medical from business decision-making. Typically (but not always), it means the non-physicians cannot own a medical clinic or hire physicians.
- The workaround is the management services organization (MSO), a business that contracts with the physician or professional Medical Corporation or clinical entity to manage and market the clinicians.
- California is particularly strong in its enforcement with respect to perceived Corporate Practice of Medicine violations.
- The MSO must get compensated at fair market value for its management and marketing services.
- States with "no" or "weak" Corporate Practice of Medicine rules or enforcement can still present legal traps.

- Often, investigation, enforcement and penalties arise from a "perfect storm" of negative facts and circumstances.

- There are some countertrends toward more liberal and lighter enforcement of Corporate Practice of Medicine prohibitions.

While healthcare ventures can find charts an online that claim to tell people whether a given state "does" or "does not" have a strong prohibition against Corporate Practice of Medicine, this is a tricky area that requires careful legal navigation. The rules here are not always what they seem, and because the penalties can be criminal, it pays to get good advice—and not have an epic adventure go south.

Chapter 2

Telehealth

From Medicine Anywhere to Medicine Everywhere

***Case Study*: Noah's Tele-Chiro Adventure**

Noah, the Montana chiropractor, has a gift for giving functional medicine advice to help obese patients gain a healthy permanent weight. Noah has become known across several states through his perky and uplifting podcast.

Noah decides he will offer functional medicine services via telehealth in several nearby states that he has heard are "friendly" to telemedicine.

Noah's chiropractic partner is puzzled, since "chiropractic" comes from the Greek word *Chiropraktikos*, meaning "effective treatment by hand;" and Noah's telemedicine patients will not receive any manual treatment.

Noah consults a law firm that understands telemedicine medicine, to test whether his "telemedicine friendly" theory—which he got from another senior chiropractor, who heard it from a lawyer—is correct.

The Rapidly Growing World of Telehealth

Noah is not the only one puzzled by the growing world of telehealth, and all the conflicting definitions of telemedicine and telehealth.

Healthcare providers who move beyond a brick-and-mortar physical practice often find themselves in a legal gray zone, wondering whether they are compliant, or even what rules might apply.

This confusion is understandable. The laws governing medicine were first framed in the late 19th century and were slowly adapted to advancing medicine and treatments; technological progress has always moved faster than laws can evolve.

The result is a patchwork of laws. Some states have statutes regulating telemedicine but only apply them to the practice of medicine (at a distance). They do not address, for example, telepsychology or chiropractic or any other profession does online, or via mobile means, or by other means than physical.

Other states include in their legal definition of telehealth any clinical practice online. But these legal rules are ambiguous as to who can practice and under what circumstances or constraints.

In states where no statutes exist, medical or other regulatory boards have issued regulations. These have to be carefully consulted; one board's policies may differ from another's. Further, there are states where there is no explicit regulation, which means one has to apply existing laws which preceded the development of the Internet.

The upshot is that before embarking on any telemedicine venture, Noah and his attorney should review the laws and legal rules in your state that apply to your clinical practice as well as to the business

model you intend. This will be a matter of interpretation and analysis; the trail of legal breadcrumbs must be traced as clearly as possible.

An additional complication that Noah has is that, as his partner has pointed out, chiropractic may have a broad scope of practice, but that scope may be more limited in some states than others. And the fact that Noah is not engaging in any chiropractic manipulation—and in fact, is branding his offering as tele-*medicine*, including *functional medicine*, puts him at risk for exceeding the scope of practice of chiropractic, and engaging in unlicensed practice of medicine.

For now, focusing on the telemedicine rules themselves, legal definitions also in terms of what aspects of practice they cover; and there are also federal and state differences. As examples:

- The Centers for Medicare Services (CMS) defines telemedicine as the provision of clinical services to patients by practitioners from a distance via electronic communications.

- The Joint Commission on the Accreditation of Hospital Organizations (JCAHO) defines telehealth as the use of electronic information and telecommunication technologies to support long-distance clinical healthcare, patient and professional health-related education, public health, and health administration.

- JCAHO defines telemedicine as the use of medical information from one site to another via electronic communications to improve patients' health status. JCAHO thus considers telemedicine a subset of telehealth.

- Videoconferencing is telemedicine. But in many states, electronic communications that do not involve video are not considered telemedicine. For example, in California, information consultations between practitioners, telephone conversation, email, instant messaging (IM), or fax are not considered "telemedicine" and therefore not subject to the telemedicine laws. Similarly, in Virginia, "telemedicine services" do not include an audio-only telephone, electronic mail message, facsimile transmission, or online questionnaire. Likewise, Florida provides, "Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof." These are examples of state regulation can differ—and why someone in Noah's position requires a state-by-state review.

- Adding to the epistemological chaos, telemedicine can be: (1) non-simultaneous— such as radiology services, which are read later, after the patient undergoes the imaging ("asynchronous"), or (2) simultaneous ("real-time" or "synchronous").

The telemedicine rules have many twists and turns—and, the map is being updated all the time.

Telemedicine vs. Online Education or Health Coaching: The Puzzle Deepens

Just as there are many legal and regulatory definitions of telemedicine, there are also many meanings to "telemedicine" in the world of the healthcare provider.

Some healthcare providers simply want to expand their offerings beyond the brick-and-mortar. For example, a physician working in one state may want to determine whether they can follow up with their patients when the patient goes out of state—say, for vacation. Others want to offer a particular kind of service—like Noah's functional medicine for weight loss service—beyond their physical office, and in fact beyond the state.

Still others want to stop clinical practice altogether. They might try to style what they do as educational; or, they might use the term "health coaching."

Telemedicine law is layered, as is any practice involving practice beyond the brick-and-mortar. As with Noah, there might be one set of questions as to whether the provider is still offering services within their legally authorized scope of practice. Then there is a separate question as to whether the provider has to do an in-person, "good faith exam" with the patient.

A whole separate question is whether the provider is engaging in clinical practice online (or through mobile/digital), or, can call what they do, information, education, or even "health coaching." These questions do not have simple or authoritative answers.

A starting point—at least with respect to concerns about unlicensed practice of "medicine"—is the usual statutory definition of practice of medicine. This typically involves diagnosis and treatment of disease.

The problem here is what does or does not constitute a "diagnosis" or "treatment." The medical licensing statutes are exceedingly broad. If a blog post encourages readers to eat a paleo diet, and the author responds to individual comments—or gets paid for mobile consults with clients—is this the practice of medicine? What if the client comes for advice to ameliorate a specific condition that is amenable to nutritional intervention? What if the client seeks advice to reduce their obesity? What if they ask whether they should keep taking their prescription appetite suppressants?

Clearly there is a slippery slope here, between educational advice on one hand, and clinical advice on the other.

The cases we read about, where there are actual judges' opinions, are few and far between. These cases often arise when there is egregious conduct by the provider, or, harm to the client. The case draws a boundary, a line in the legal sand, and stands as a warning to future practitioners not to tread the same path.

Because there are few cases, and, prosecutors and judges typically interpret words such as "diagnosis" and "treatment" very broadly, there is always a risk when a practitioner decides to style their practice as education or health coaching.

Again, these rules—and their application—are morphing all the time. At least one state, Arkansas, has made it easier for physicians in the second and third category. The new telemedicine statute in Arkansas says that simply providing information of a generic nature, not meant to be specific to an individual patient,

and does not require a professional relationship. This definition contains considerable ambiguity, and practitioners are still at risk.

Practicing telehealth and telemedicine requires a nuanced look at the exact nature of the practitioner's plans, and the applicable law. One thing we can count on is an ever-changing legal landscape. As practices evolve, so do legal rules and enforcement priorities.

The Home State and the Remote State

In telemedicine law, there are two different states: the state where the provider is located when the provider gives an online/mobile/digital session (the "Home State") and the state where the patient is located (the "Remote State"). *Both* states' laws can apply.

To understand how the patchwork of state laws came to be, we go back to the original design, in which the Tenth Amendment to the U.S. Constitution gave the states the power to regulate healthcare. While the federal government still has enormous power in all aspects of our lives—including healthcare—the question of who can be licensed and under what criteria, is up to the states. This is the reason we have a Home State and a Remote State.

The Federation of State Medical Boards, which provides policy guidance to state medical boards, has weighed in with a Model Policy for Appropriate Use of Telemedicine Technologies in the Practice of Medicine. This is not law, and does not have the force of law, unless adopted by the individual state. However, the guidelines provide a set of rules to keep in mind as these influence ongoing legal and regulatory developments. Many states have adopted some, or all, of the Federation's Model Policy as part of their own telemedicine law.

Among other things, the Federation's Model Telemedicine Policy requires that before practicing telemedicine, the physician establish a physician-patient relationship. This means the doctor undertakes to diagnose and treat the patient, and the patient agrees, whether or not this initial encounter has been in person. The Federation's requirements include that the physician:

1. Fully verify and authenticate the location and identity of the requesting patient.

2. Disclose and validate the identity of the Remote provider, if there is one. For example: the case of a medical doctor in the Home State, working with a nurse practitioner in the Remote State.

3. Obtain appropriate consents from requesting patients, after giving disclosures about the benefits and limitations of a telemedicine consult

4. Ensure the physician's identity is known to the patient

Also, the physician must also practice informed consent and use the same standard of care as in an in-person visit. Physicians must maintain accurate medical records, respect the privacy of patient records, exercise necessary confidentiality around exchange of information, and otherwise abide by all laws and ethical standards.

On another front, the Federation has been responsible for developing an Interstate Medical Licensure Compact. This offers a streamlined licensing process for physicians interested in practicing medicine in multiple states. States vary as to whether they have adopted the rules from the Compact.

Prescription, Matters

While laws governing telemedicine are generally loosening across states, the rules governing prescribing online can be stricter. This is in part because of the abuses associated with Internet pharmacies, especially during the early days of the Internet.

As one response to those abuses, the federal government passed the Ryan-Haight Online Pharmacy Consumer Protection Act. Among other things, the Act:

- Toughened restrictions and reporting requirements on Internet pharmacies.
- Prohibited the sale of controlled substances on the Internet without a valid prescription.
- Required an in-person medical evaluation of the patient as part of the definition of "Valid Prescription."
- Provided for federal enforcement authority with respect to violations.

States regulate what physicians must have in place before providing a prescription related to an online physician-patient encounter.

The big question is whether a physician has to see a patient in person, before prescribing a medication, or when a physician should see a patient before prescribing medication. States differ as to their answers and some are more liberal while others have more restrictive rules. Rules are more restrictive with controlled substances.

As an example of a more liberal toward online prescribing generally, the Virginia Board of Medicine's statement on Telemedicine gives physicians a lot of latitude to make judgment calls on the appropriateness of prescriptions via telemedicine.

Virginia says: "Prescribing medications, in-person or via telemedicine services, is at the professional discretion of the prescribing practitioner."

This is a very broad, permissive opening statement. The Virginia Board goes on to say:

> *The indication, appropriateness, and safety considerations for each prescription provided via telemedicine services must be evaluated by the practitioner in accordance with applicable law and current standards of practice and consequently carries the same professional accountability as prescriptions delivered during an in-person encounter. Where such measures are upheld, and the appropriate clinical consideration is carried out and documented, the practitioner may exercise their judgment and prescribe medications as part of telemedicine encounters in accordance with applicable state and federal law.*

Note that the Virginia Board emphasizes the practitioner's judgment. Of course, the Board's statement also clarifies that the physician must do more than have the patient fill out an online questionnaire.

Contrast this with Florida's telemedicine rules, which not only prohibit prescribing based on an electronic questionnaire, but also require, among other things, a "documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed."

Delaware legislation takes a middle ground. Firstly, Delaware law mirrors the prohibition against basing a prescription only on the patient's response to a questionnaire sent by email or filled out online: "A physician may not prescribe solely in response to an Internet questionnaire, an Internet consult, or a telephone consult."

With this language, Delaware, also in addition to other states, warns against basing a prescription-only on an Internet or phone consult. Having given the above prohibition, Delaware law then goes on to say that a physician can prescribe via telemedicine (i.e., outside an in-person encounter) so long as the physician has first "established" the physician-patient relationship.

Delaware law uses some of the Federation concepts, and provides that a physician "establishes" the physician-patient relationship either by seeing the patient in person, or by means of including these seven points:

- Fully verifying and authenticating the location and, to the extent possible, identifying the requesting patient;
- Disclosing and validating the provider's identity and applicable credential(s);
- Obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including informed consents regarding the use of telemedicine technologies as indicated in subsection (5) below;
- Establishing a diagnosis through the use of acceptable medical practices, such as patient history, mental status examination, physical examination (unless not warranted by the patient's mental condition), and appropriate;
- Diagnostic and laboratory testing to establish diagnoses, as well as identify underlying conditions or contra- indications, or both, to treatment recommended or provided;
- Discussing with the patient the diagnosis and the evidence for it, the risks and benefits of various treatment options; and
- Ensuring the availability of the distant site provider or coverage of the patient for appropriate follow-up care; and
- Providing a written visit summary to the patient.

While many of these are already standard obligations of the physician, Delaware law focuses some of these on telemedicine. For example, if the physician is out-of-state but the patient is in Delaware and the physician is working with a Delaware nurse, then (2) requires the physician to validate the nurse's credentials.

Like other states, North Carolina provides that prescribing online based solely on the use of Internet questionnaires is inappropriate and unprofessional. However, North Carolina provides that in certain

situations, a physician may prescribe for a patient even when the physician has not personally examined the patient."

These situations include:

- Admission orders for a newly hospitalized patient;

- Medication orders or prescriptions, including pain management, from a hospice physician for a patient admitted to a certified hospice program, prescribing for a patient of another licensee for whom the prescriber is taking call;

- Continuing medication on a short-term basis for a new patient prior to the patient's first appointment;

- An appropriate prescription in a telemedicine encounter where the threshold information to make an accurate diagnosis has been obtained;

- Prescribing an opiate antagonist to someone in a position to assist a person at risk of an opiate-related overdose.

In addition, the North Carolina Board notes several other instances in which the good faith exam for prescribing can be online:

- Established patients may not require a new history and physical examination for each new prescription, depending on good medical practice;

- Prescribing for an individual whom the licensee has not met or personally examined may also be suitable when that individual is the partner of a patient whom the licensee is treating for gonorrhea or chlamydia.

These selected rules show how much the laws can vary from state to state.

Standard of Care Issues

When it comes to standard of care in telemedicine, state laws often emphasize that the standard of care in telemedicine is identical to the standard of care in an in-person office visit. For example, the Virginia Board of Medicine, in its policy statement on telemedicine, states:

> *These guidelines should not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not authorized by law. In fact, these guidelines support a consistent standard of care and scope of practice notwithstanding the delivery tool or business method used to enable practitioner-to- patient communications.*

The Virginia Board of Medicine emphasizes that practicing medicine by telemedicine imposes the same general obligations on the physician as practicing in person: Toughened restrictions and reporting requirements on Internet pharmacies. The Board states:

It is the expectation of the Board that practitioners who provide medical care, electronically or otherwise, maintain the highest degree of professionalism and should:

- *Place the welfare of patients first;*
- *Maintain acceptable and appropriate standards of practice;*
- *Adhere to recognized ethical codes governing the applicable profession;*
- *Adhere to applicable laws and regulations;*
- *In the case of physicians, properly supervise non-physician clinicians when required to do so by statute; and*
- *Protect patient confidentiality.*

No differentiation is made between an in person and a tele-visit.

Similarly, Florida's Telemedicine Practice Standards state that "the standard of care remains the same regardless of whether a Florida licensed physician or physician assistant provides health care services in person or by telemedicine."

Virginia, like some other states, emphasizes the need to adhere to the standard of care when discussing evaluation and treatment of the patient through telemedicine:

A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided must be obtained prior to providing treatment, which treatment includes the issuance of prescriptions, electronically or otherwise. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional, in-person encounters. Treatment, including issuing a prescription based solely on an online questionnaire, does not constitute an acceptable standard of care.

Not only must standard of care be equally met, whether the care is provided in person or remotely, but the Board warns against telemedicine 'shortcuts' such as basing a prescription solely on an online questionnaire.

Informed Consent

One aspect of ensuring that the standard of care has been met is to make sure the patient receives proper informed consent. Informed consent means communication to the patient as to the risks and benefits of a recommended course of treatment and all reasonable and feasible material alternatives. Once again, referring to Virginia's statement on telemedicine, appropriate informed consent should include such items as:

- Fully verifying and authenticating the location and, to the extent possible, identifying the requesting patient;

- Identification of the patient, the practitioner, and the practitioner's credentials;

- Types of activities permitted using telemedicine services (e.g., prescription refills, appointment scheduling, patient education, etc.);

- Agreement by the patient that it is the role of the practitioner to determine whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;

- Details on security measures taken with the use of telemedicine services, such as encrypting date of service, password protected screen savers, encrypting data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;

- Hold harmless clause for information lost due to technical failures; and

- Requirement for express patient consent to forward patient-identifiable information to a third party.

The Virginia Board mirrors many other states in simply applying medical-legal standards in their entirety, whether the encounter is in person or through an online or mobile platform.

Medical Record-Keeping

The medical record-keeping requirements do not vanish or change simply because the physician patient encounter occurs through telemedicine. As Virginia puts it:

> *The medical record should include, if applicable, copies of all patient-related electronic communications, including patient- practitioner communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telemedicine services. Informed consents obtained in connection with an encounter involving telemedicine services should also be filed in the medical record.*

Informed consent should be documented in the medical record for telemedicine visits, just as it should be for in-person patient visits.

Increasingly, telemedicine is seen as an integral part of medicine with a seamless physician patient relationship more virtual than physical. To ensure patients receive high quality treatment, state laws and medical board regulations require the standard of care in telemedicine reflect that of an in-person physician-patient encounter.

Last, privacy, confidentiality, and security issues arise when practicing telehealth or telemedicine just as they do in a brick-and-mortar practice. It is especially important to understand these issues, since many clinicians advertise on their website that they are "HIPAA compliant."

Lessons Learned

In the world of telehealth:

- There are many legal definitions, often under the big umbrella of "telemedicine," that the savvy healthcare venture or practice has to navigate.

- Telemedicine law is layered, as is any practice involving practice beyond the brick-and-mortar.

- A starting point—at least with respect to concerns about unlicensed practice of "medicine"—is the usual statutory definition of practice of medicine. This typically involves diagnosis and treatment of disease.

- Practicing telehealth and telemedicine requires a nuanced look at the exact nature of the practitioner's plans, and the applicable law. One thing we can count on is an ever-changing legal landscape. As practices evolve, so do legal rules and enforcement priorities.

- In telemedicine law, there are two different states: the state where the provider is located when the provider gives an online/mobile/digital session (the "Home State") and the state where the patient is located (the "Remote State"). *Both* states' laws can apply.

- In telemedicine, the usual rules regarding standard of care, informed consent, and medical record-keeping, also apply.

- The rules governing telemedicine prescription are usually somewhat tougher.

Once again, healthcare practitioners and companies should beware of easy-to-find, Internet charts, graphs and summaries that seem to provide handy answers. As they say in NLP, "the map is not the territory."

Many healthcare practitioners are expanding and freeing themselves from the brick-and-mortar; many healthcare companies are pioneering new models of care that take advantage of digital and mobile delivery strategies. To do so on a sound legal footing, mindful of enforcement hazards while creatively adaptive to modern tools, is a great and sublime, and monetarily rewarding challenge.

Chapter 3

Fee-Splitting, Anti-Kickback & "Stark"

Flea-Splitting Prohibited

Case Study: John's Wellness Venture

John has started a wellness venture. He is not a physician, but his cousin Ned is a licensed medical doctor.

John decides to offer Ned's services under a branded name in two physical locations as well as online.

John wants to charge patients $100 per visit and he cuts a check to Ned for $10 per patient Ned sees. Most of the work is done by a nurse, or by some algorithms John has developed part-time. Ned likes the arrangement, but his wife has read about a federal uncover investigation of nursing home kickbacks and wonders whether Ned is at risk.

Stark-Raving Self-Referral

When thinking about kickbacks and "Stark" violations, here are a few fundamentals:

- There are two different issues here. One is known as *self-referral*. Self-referral means that the physician refers the patient to a person or entity in which the physician (or an immediate family member) has a financial interest.

  For example, the physician refers the patient for physical therapy or imaging (like a CT scan) but the physician is a shareholder in the physical therapy practice or imaging center.

  The other issue is the prohibition against *kickbacks* and *fee-splitting*. As in self-referral, the physician has a financial interest; only here, it comes in the form of a "kickback" or payment, typically to the physician that "induces" the referral.

  Both situations present a conflict of interest in that the physician has a financial interest in the transaction or arrangement, and the public policy concern here is that the physician's financial interest may trump their interest in providing good patient care.

- Both federal and state law have prohibitions against self-referral as well as kickbacks.

  On the federal side, the prohibition is embodied in the "Stark" law and regulations.

  Federal law only applies if the healthcare service is reimbursable (covered by) a health care program that federally funded such as Medicare/Medicaid.

  However, healthcare professionals also have to think about the state law prohibitions.

Typically, the self-referral prohibition only applies if "designated health services" (DHS) are involved. On the federal side, DHS includes:

- clinical laboratory services;
- physical therapy services;
- occupational therapy services;
- radiology services (including MRI, CT scans, ultrasound services, and nuclear medicine);
- radiation therapy services and supplies; durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies; home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospitalization services.

The list is often roughly similar on the state side; and if no DHS are involved, then state law normally requires disclosure to the patient and to the medical board.

The self-referral law, both on the federal and state side, usually contains a list of exceptions, such as (for example) a passive investment by the physician. These exceptions can get very complicated. For instance, there is a long and convoluted exception involving a "group practice," and another complex exception involving "in-office ancillary services."

On the kickback side, we have "safe harbors," instead of exceptions. This creates much more enforcement discretion, on either side of the equation (to enforce or not). If a healthcare practitioner or entity meets the safe harbor, this does not mean that they are safe from enforcement, but rather that the enforcement criteria are probably (but not definitely) lined up in their favor. On the other hand, the fact that the safe harbor is not meant, does not mean there is no possibility of enforcement. (Warning, triple negative in that sentence!) A savvy healthcare practitioner or business will consult a healthcare attorney for nuanced healthcare law advice in the anti-kickback arena, and look to build in "safeguards" that make enforcement less likely.

Variations on a Kickback Theme

The federal anti-kickback law states that *whoever* knowingly and willfully receives or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be held accountable for a felony.

Stark/self-referral and anti-kickback concerns potentially overlap whenever compensation arrangements involve a physician interest in the entity receiving or giving referrals. However, federal anti-kickback is broader than Stark in two respects:

- The term “whoever” means that unlike Stark, the anti-kickback statute applies to all practitioners, not just “physicians” (so long as the referral is regarding health care services that involve reimbursement under a federal insurance program, such as Medicare, CHAMPUS, or federal employee benefits).

- While Stark only applies to DHS, the anti-kickback law applies to health services beyond those designated in Stark.

The kickback scenario plays out in many different variations on a theme.

Like John, let’s say that you are an entrepreneur, seasoned in healthcare ventures, and you would like form a company that brings in healthcare practitioners (such as: medical doctors, chiropractors, psychologists, health coaches, wellness coaches, massage therapists, Reiki practitioners, nurses) and/or healthcare services (Botox, fillers, injectables, body sculpting, lasers, telemedicine and telehealth services, online healthcare subscriptions, concierge medical services, anti-aging, homeopathy, naturopathic medicine, energy healing, stem cell therapies, hydration therapy, integrative medicine …. the list goes on).

Some of the common safe harbors to anti-kickback law include:

- investments in large publicly held health care companies;

- investments in small health care joint ventures;

- space rental;

- equipment rental;

- personal services and management contracts;

- sales of retiring physicians' practices to other physicians;

- referral services;

- warranties;

- discounts;

- employee compensation;

- group purchasing organizations;

- waivers of Medicare Part A inpatient cost-sharing amounts;

- certain practices in managed care settings.

States have their own laws that mirror many aspects of federal anti-kickback law. Typically, the anti-kickback and fee-splitting prohibitions are contained in the state licensing law. In some states, practitioners such as massage therapists are not licensed. They may be subject to a certification process through a professional organization, or regulated by county, or there may be establishment registration in a

given county or municipality or city. It can take careful legal spade-work to determine whether practitioners such as massage therapists are subject to the fee-splitting prohibitions.

Aggressive enforcement authorities can move in if the scenario presented involved paying for leads in a way that varies based on patient value or volume. Sometimes it seems that the more legally safe and plain vanilla the arrangement is, the less likely it will make money; and the more aggressive or proactive the business strategy, the more it can tread on compliance hot buttons. A lot of judgment and experience is required to titrate the difference. Ned has been careless, but his wife is on the right track.

Kickbacks v. Fee-Splitting

Kickbacks and fee-splitting are related, in that a "kickback" involves the payment to or from a physician (or, depending on the state, chiropractor, acupuncturist, nurse, and other licensed healthcare practitioner) in exchange for a referral, while fee-splitting involves splitting the physician's fee to the patient between the physician and a third-party.

Suppose you charge the patient $100 for one chiropractic session, and pay the independent contractor chiropractor $40 for the session, this could appear to regulators as though you are splitting your fee of $100 with, and receiving a $40 kickback from, the independent contractor chiropractor as a reward for referring the patient to the chiropractor.

This may violate California Business & Professions Code 650, and possibly other statues as well such as California Business & Professions Code 2273(a) (prohibition on steering patients).

What may start out as an economically advantageous situation becomes a potentially illegal fee-splitting or kickback arrangement.

The California Attorney General opinions are uniformly negative on arrangements that potentially constitute fee-splitting. This includes:

- No. 00-1002 (prohibiting chiropractors from promoting online naturopathic products in exchange for a fee);
- No. 99-11 (prohibiting retention of a fee, from a workers' compensation payment, in exchange for referring patients to clinicians);
- No. 93-807 (prohibiting a podiatry referral service for profit); and
- No. 90-304 (prohibiting payment of fees for referral for imaging services).

Anti-kickback and fee-splitting issues can arise with many different types of healthcare ventures, including such diverse enterprises as medical spas and integrative or functional medicine centers. Put very simply, regulators do not like arrangements that appear to be volume-based or per-patient based.

Your Typical Anti-Kickback and Fee-Splitting Prohibition

While state laws have nuances in the way they define (or prohibit) kickbacks and fee-splitting, the typical provision references some of kind of payment made as an "inducement" for a referral—i.e., as a reward to refer patients.

The language of California Business & Professions Code 650 showcases the thinking behind this kind of statute. Subsection (a) says:

> *The offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.*

When we break this down, it has several elements:

1. The offer, delivery, receipt, or acceptance

2. By a healthcare licensee

3. Of a payment (in the language of statute, "any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise")

4. As "compensation or inducement"

5. For referring patients, clients, or customers.

The end of the statute simply says, "is unlawful."

California law contains some other anti-kickback and fee-splitting laws. For example:

- California Welfare and Institutions Code Section 14107.2 prohibits kickbacks in the context of public health services such as Medicaid and Medi-Cal.

- California Business & Professions Code, Section 2273(a) states: "Except as otherwise allowed by law, the employment of runners, cappers, steerers, or other persons to procure patients constitutes unprofessional conduct."

- California Health & Safety Code ("H&S") Section 445 ("Medical Referral Services"), states: "No person, firm, partnership, association or corporation, or agent or employee thereof, shall for profit refer or recommend a person to a physician, hospital, health-related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition."

- There are additional prohibitions in the Knox-Keene Act applicable to health plans.

- With respect to professional corporations, California Corporations Code, section 13408.5 provides: "No professional corporation may be formed so as to cause any violation of law, or any applicable rules and regulations, relating to fee splitting, kickbacks, or other similar practices by physicians and surgeons or psychologists, including, but not limited to, Section 650 or subdivision (e) of Section 2960 of the Business and Professions Code. A violation of any such provisions shall be grounds for the suspension or revocation of the certificate of registration of the professional corporation. The Commissioner of Corporations or the Director of the Department of Managed Health Care may refer any suspected violation of such

provisions to the governmental agency regulating the profession in which the corporation is, or proposes to be engaged."

The bottom line is that referrals must not "be induced … by considerations other than the best interests of the patients" (i.e., by promise of financial remuneration). Care must be taken in structuring the arrangement that it does not trigger enforcement red flags for either corporate practice of medicine, or self-referral and anti-kickback violations.

That Safe, Hopefully Safe, Harbor under State Law

Let's look at a key safe harbor under California law as an example of how the anti-kickback and fee-splitting prohibition affects many healthcare practices and ventures.

We talked about the basic prohibition in Section 650(a) of California's Business & Professions Code. Section 650(b) is the safe harbor. It states:

> *The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer*.

California's anti-kickback law does not require intent to refer patients. No showing of increased patient costs is required, regardless of how fees are characterized, nor is it necessary to find a physician-patient relationship in order for there to be a violation.

California anti-kickback law is broader than the federal prohibitions (i.e., under federal anti-kickback law), as California law includes not only goods and services billed under Medicare and Medicaid, but also those billed under private insurance payer services and workers compensation.

Section 650(b) is often used to justify payment of the management fee based on a percentage of gross revenues at fair market value—*i.e.*, the management services organization (MSO) model. In fact, 650(b) is the basis for many creative ways to structure an arrangement.

Taking advantage of these structural possibilities requires some creative, adroit thinking and a written strategy that provides an analytical framework to help justify any such arrangements. Sophisticated legal counsel is advisable, particularly as enforcement authorities draw the net ever tighter around arrangements that raise fee-splitting red flags.

"Mall Model" vs. "Center Model"

During the early days of integrative medicine, we borrowed the concept of a "mall model" vs. a "center model" to describe the different situations in which an integrative medicine center had more or less integration of conventional medicine and the complementary medicine practitioners.

The idea was that an integrative medicine clinic could function like a shopping "mall," in the sense that practitioners were independent, each with their own "shop" within the medical "mall;" or it could function more like a "true center," in which the practitioners were tightly woven within the organizational structure.

From a legal perspective, the key to the choice is how successfully the clinic can manage Corporate Practice of Medicine and kickback/fee-splitting issues.

In a state with strong Corporate Practice of Medicine and anti-kickback prohibitions (such as California and New York), the "mall" model is almost mandated by the fact that there has to be strict separation between the business entity (or MSO) on one hand, and the clinicians on the other. A true "center" model is very difficult, although some lawyers feel comfortable setting up a business model in "weak" Corporate Practice of Medicine states in which they believe that enforcement will be light to non-existent, so long as there is no overt control by the employer over the physicians.

Put another way, the most conservative model is a "mall" in which practitioners are loosely organized as tenants in a space that is branded by the MSO and co-branded by featuring the practitioners are independent and responsible for their own clinical decision-making. Still, the conservative model is not always best.

Every situation has to be analyzed separately to see how it meets the symphony of legal rules about self-referral, kickbacks and fee-splitting, Percentage-based, revenue arrangements in the healthcare environment often require a detailed written analysis; and one must be sensitive to states in which this is outright prohibited.

In the medical mall model, the practitioners (or their unifying professional corporation) is a tenant and subleases space from the MSO.

There are also issues with the flow of payments.

The most conservative model here is to have payments flow from the patient, to the physician/clinician or Professional Corporation, and from there to the MSO for the management and marketing fees. This is because a payment from the MSO to the clinician can be considered a kickback or fee-splitting.

Increasingly, as payment models get more sophisticated (for example, there are online companies that separate streams of payments between the various players), these flow-of-payment distinctions become increasingly archaic, anachronistic, and operationally unwieldy. Thus, while the flow of payments between the patients, the practitioners, and the MSO or business side can create kickback and fee-splitting challenges; evolving digital payment models might provide a solution.

It takes creativity and legal acumen to review and/or design models that work adaptively with these evolving models of payment and care. It is not wise to have a lawyer that is a "yes man" (or yes woman!); nor one whose favorite words are "no," "it depends," or "this is a grey area." (Yes, most business judgments based on legal advice are in a gray area.)

There is nothing cookie-cutter here; only 99% perspiration, and the 1% inspiration that makes it work.

Lessons Learned

- Self-referral means that the physician refers the patient to a person or entity in which the physician (or an immediate family member) has a financial interest. On the federal side, this is called "Stark."

- Both federal and state law have prohibitions against self-referral as well as kickbacks.

- Typically, the self-referral prohibition only applies if "designated health services" (DHS) are involved.

- Stark/self-referral and anti-kickback concerns potentially overlap whenever compensation arrangements involve a physician interest in the entity receiving or giving referrals. However, federal anti-kickback is broader than Stark.
- States have their own laws that mirror many aspects of federal anti-kickback law.

- Aggressive enforcement authorities can move in if the scenario presented involved paying for leads in a way that varies based on patient value or volume.

- Kickbacks and fee-splitting are related, in that a "kickback" involves the payment to or from a physician (or, depending on the state, chiropractor, acupuncturist, nurse, and other licensed healthcare practitioner) in exchange for a referral, while fee-splitting involves splitting the physician's fee to the patient between the physician and a third-party.

- Some states have a broader anti-kickback law than the federal prohibition and state law is often the legal stumbling block for healthcare practices and businesses.

- The most conservative model is a "mall" in which practitioners are loosely organized as tenants in a space that is branded by the MSO and co-branded by featuring the practitioners are independent and responsible for their own clinical decision-making. Still, the conservative model is not always best. The flow of payments between the patients, the practitioners, and the MSO or business side can create kickback and fee-splitting challenges; here, though, evolving digital payment models might provide a solution.

Taking advantage of these structural possibilities requires some creative, adroit thinking and a written strategy that provides an analytical framework to help justify any such arrangements. Sophisticated legal counsel is advisable, particularly as enforcement authorities draw the net ever tighter around arrangements that raise fee-splitting red flags.

Chapter 4

HIPAA

Caution: Do Not Use Against Mothers-in-Law

Case Study: Your Mother Violated HIPAA!

Martha was furious.

On a recent visit to her local pharmacy, she found out that Sheila, her mother-in-law, had taken her prescription slip to the pharmacist, picked dup Martha's prescription anti-anxiety medication, and chatted up the pharmacist about Martha's nervous habits.

"Your mother!!!" she shouted, as her husband Jim prepared himself for the worst. "She's a … she's a …." Martha began.

Martha took a deep breath. She reminded herself of her recent lesson from the mindfulness class, took a huge gulp of air, and began trying to slow her breathing by a simple counting technique. Mentally she considered a bunch of expletives, but then seeing Jim's face, and remembering her training, she held herself back from articulating any of them. Yet Martha's lips were moving—and something was about to explore.

"She violated HIPAA!" Martha yelled.

Jim looked horrified. Exactly eight minutes later, he called our law firm.

At that very moment, Jim received a call from his supervisor at the downtown IT firm where Jim worked. Jim picked up his second phone and listened.

"We've been hacked," the supervisor said. "The subcontractor that holds all our data installed something malicious in our system and now they've accessed patient files and have released protected health information on the Internet. We need to get a HIPAA lawyer right away."

Jim also took a deep breath. "Consider it done!" he said, and hung up his second line.

"Are you talking to the lawyers about your mother violating HIPAA?" Martha asked.

Jim nodded his head, pulled over his laptop, and began to type, as his HIPAA lawyer asked a number of questions about his company's existing privacy and securities practice.

"Jim, does your company have a formally named Privacy Official and Security Official?"

"Uh, no."

"Do you have current HIPAA compliance? Do have HIPAA Policies & Procedures, forms, and workforce training?"

"I think I watched an online video when I joined the company."

"Let's talk about your internal processes when there is a security incident or breach. What kind of investigation is your CEO planning?"

"Not sure."

"Ok, let's talk about mitigating the breach."

"Huh?"

"All right, let's take a step back. Who is your internal regulatory affairs person?"

"That would be me. I talk to our company's business lawyer once a quarter – he's the one who got us the incorporation papers. I think he also does trademarks."

"OK, Jim, the clock is ticking with respect to breach notification. Let's set up a meeting right away so we can dig in to what have and don't have internally already, and what needs to be done…. Oh, about your Mom talking to the pharmacist … let's talk about strategies for having a conversation with your Mom about this, and your wife."

Jim picked up the mindfulness course meditation manual, while he fidgeted with the phone.

HIPAA: The Government's Fire-Breathing Regulatory Dragon

The good news about HIPAA is that it provides a lot of protection for your privacy rights as a patient.

The bad news about HIPAA (for Martha) … Martha cannot use it against her mother-in-law. HIPAA does not provide a private right of action.

Violations of HIPAA are punishable, mostly by hefty fines by the state government, and sometimes by a fines and other enforcement tools by the state government.

Martha might be able to find some alternate grounds for a claim—and then, like so many plaintiffs, she might lump in a HIPAA argument in kitchen-sink mode. However, Martha and Jim would need marital counseling, and the better thing is probably to have a sit-down with Sheila and talk about boundaries.

We are not trying to minimize the suffering that can ensure when family members violate privacy boundaries; simply to say that HIPAA, while onerous and stringent, typically is not a plaintiff's field of dreams, nor meant to be wielded as a sword by patients. It is more a layer of government oversight, a fire-breathing regulatory dragon that every healthcare business or practice must face in one form or another.

At the same time, there are lots and lots of vendors and Internet sites (and even lawyers) promising "HIPAA compliance."

For the science and math geeks out there, we like to say that HIPAA compliance is "asymptotic." For the Zen or yogi in you, let's say it's a "practice" or "process"—an ideal that one approaches, never quite reaching perfection.

This does not mean that one should not "try" to improve their level of HIPAA compliance (sorry, Yoda: there *is* "try" here—it may not lift a spaceship, but it might stop an investigation). HIPAA compliance can always be improved; and in fact, HIPAA law itself says that HIPAA compliance is *scalable*, depending on the size, complexity, resources, and other attributes of the organization.

But When Am I Under HIPAA?

Whether and when someone is "under" HIPAA is a trick question. HIPAA's reach is broad and extensive, and even if HIPAA does not "technically" apply, it is still the gold standard, and more and more, state authorities look to HIPAA for rules and guidance.

"Under" is a good metaphor. Think back to a scene in the movie, *The Last of the Mohicans*.

Daniel-Day Lewis is asked by a British officer who is dragooning farmers into the army:

British Officer: *You* call yourself a patriot, and loyal *subject to* the *Crown*?

Hawkeye: I do *not* call myself *subject to* much at all.

Ah, if only. We have moved from the Age of Agriculture to the Age of Regulation. Big Brother is watching, to make sure *you* don't violate anyone's healthcare privacy and security rights. Never mind Big Brother—he can watch, as all animals are creating equally but some more equal than others. We digress.

What HIPAA in fact regulates in the electronic data exchange of health care information. Put in simple terms, if a healthcare practitioner or entity bills insurance, this comes under HIPAA.

Ironically, the relevant provisions of HIPAA are known as the "Administrative Simplification" provisions, which essentially amend the federal Social Security Act's Medicare and Medicaid provisions.

HIPAA is intended to protect the privacy of patients' protected health information ("PHI").

PHI, a term you will frequently see in connection with HIPAA, means *individually identifiable health information* that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium (whether electronic or hardcopy). PHI is a subset of the individual's health information; identifiable health information means health information (including demographic information) that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

A key term in HIPAA is "Covered Entity;" this includes healthcare practitioners such as physician. HIPAA requires Covered Entities to:

- Provide information, in writing, to patients about their privacy rights and how their information will be used.
- Develop policies, procedures, and systems to protect patient privacy and patients' ability to access, addend and amend their records.
- Train staff on these procedures.

- Appoint a "privacy officer" to ensure privacy procedures are developed, adopted, and followed.
- Appoint a "security officer" to ensure that security procedures are developed, adopted, and followed.
- Secure patient records that contain PHI from individuals who should not see them.
- Account for specified disclosures of PHI.
- Establish a complaint mechanism for privacy concerns.
- Establish and enforce a system of sanctions for employees who violate privacy policies and procedures.
- Notify patients and government agencies in the event of a breach, where required.

To accomplish all this, typically the Covered Entity will have or develop a compliance manual with a full set of policies, procedures and forms that respond to all the many requirements of HIPAA.

"Required" vs. "Addressable"

We mentioned that HIPAA compliance is scalable.

HIPAA requires that practices and business subject to HIPAA evaluate the risks to electronic PHI, taking into account these factors:

- The company's size, complexity, and capabilities;
- The company's technical infrastructure, hardware, and software security capabilities;
- The costs of security measures; and
- The probability and criticality of potential risks to ePHI. Security controls are proportionate to risk.

When developing HIPAA in a way that is scalable to the organization, the attorneys, company management, and IT specialists involved should consider which HIPAA requirements are "required" by HIPAA, and which are "addressable." When a standard is "addressable," the healthcare organization must determine how (or whether) it is reasonable and appropriate to create a policy and procedure to meet the implementation specification set by HIPAA.

Since much of HIPAA security compliance is **scalable**, we can work with smaller offices to reduce the burden.

Once More, Unto the Breach!

In a famous Shakespearean speech, King Henry V urges his army forward, shouting: "Once more unto the breach, dear friends, once more!"

In HIPAA, "unto the breach" is something we want to *avoid*.

A breach essentially means that the privacy or security of PHI has been compromised. Someone has hacked into the data, or the data has been stolen, lost, copied, and diverted. When this happens, HIPAA has a set of rules governing "breach notification"—the process by which patients (and the State) get notified that the breach has occurred, and are informed what the healthcare organization is doing to "remediate" or help fix the breach.

Some of the breaches our law firm has handled include facts like these:

- A nurse at a home healthcare agency left a set of patient papers in the passenger of her car, during a visit to a friend's house. The papers were stolen, and the home healthcare agency had to file a HIPAA breach notification report with the California Department of Public Healthy and the federal Department of Health & Human Services, and to notify the affected patients.

- A caseworker at an alcohol and drug abuse outpatient facility thought she had forwarded a patient's file to the insurance company. The insurance company never received the file, and the caseworker reported to her superiors that the file was lost. The alcohol and drug abuse outpatient treatment facility had to go through HIPAA breach notification.

- A healthcare facility performed an in-home intake of a potential patient. It was a windy day, the caretaker dropped the files, and the front sheet, containing critical patient information, blew away. Once again, HIPAA breach notification was required.

Here are some of the things the healthcare organization did to remediate the breach:

- The healthcare organization conducted an internal investigation.

- The healthcare organization disciplined, and in some cases, terminate the responsible worker.

- The healthcare organization contacted HIPAA counsel to review, revise, and update internal HIPAA policies and procedures to ensure that similar HIPAA breaches would not recur.

- The healthcare facility was exposed to federal and state HIPAA penalties and paid the price.

The cost of HIPAA breaches can be steep, as regulators showcase the consequences by imposing Draconian penalties, sometimes in the millions.

State Law Privacy & Security Rules

If HIPAA itself is arduous and daunting, and a gold standard to boot, there are also state laws governing the privacy and security of PHI, that can apply even if HIPAA does not.

For example, California has the Confidentiality of Medical Information Act (CMIA). This statute imposes certain obligations with respect to disclosure of patient medical information, and governs patient access to medical records.

State laws, including, those of California, typically require that healthcare providers make reasonable efforts to maintain the privacy and security of medical information. In addition, these state laws usually entail consent/authorization from the patient for disclosure of information regarding genetics, HIV treatment, and other specialized medical documentation.

Other sections of state law govern such matters as retention of medical records, as well as responsibility regarding reporting communicable diseases.

Where HIPAA applies, it supersedes relevant state law standards, unless state law is found to be more stringent. HIPAA does not preempt state requirements related to reporting of disease, child abuse, birth and death, nor does it preempt state requirements that authorize public health surveillance, public health investigation, or intervention. In addition, state and federal law, as well as hospital policies, may establish stricter standards than HIPAA.

Increasingly, states also regulate privacy breaches.

For example, the California Department of Health Care Services has a webpage describing procedures that should be followed in the case of a privacy breach or unauthorized disclosure of personal confidential information that violates state or federal privacy laws. The Department also has a Privacy Office which conducts incident investigation, privacy training, and compliance audits.

The Office describes examples of privacy breaches, including:

- Loss or theft of documents containing PHI.
- Mailings to incorrect providers or beneficiaries.
- Stolen, unencrypted laptops, hard drives, thumb drives, or PCs with PHI.

The bottom line is that healthcare practices and businesses need to demonstrate efforts regarding privacy and security compliance, regardless of whether HIPAA applies.

Healthcare business also should understand that even if HIPAA does not apply, anyone who claims they are HIPAA compliant now has obligations under HIPAA. Many healthcare businesses claim that they are HIPAA compliant, as a marketing tool. The flip side is that now they actually have to do all that HIPAA requires.

Are You a Business Associate?

Importantly, HIPAA requires that business associates of a covered entity also comply with HIPAA.

Essentially, the **healthcare provider** is the covered entity; the **business associate** is anyone who *creates*, *maintains*, *receives*, or *transmits* PHI.

This could be, for example, the billing company which a healthcare practice employs; or the telemedicine company that engages the physicians.

These Business Associates must also put compliance measures into place, and the covered entity should ensure that the business associates are doing so.

Failure to have written arrangements in place for Business Associate compliance can result in liability to the Covered Entity as well as the Business Associate.

Even if not technically under HIPAA, the organization should cover its liability exposure by having an agreement in place that obligates the business associate to reasonable compliance. This is known as the Business Associate Agreement (BAA). Even though many provisions of the BAA are fairly standard, and required by HIPAA, still, many kinds of liabilities and obligations can lurk inside these agreements. BAAs should be carefully reviewed by legal counsel.

Also, many cloud vendors require users to sign Business Associate Agreements (BAAs) if the user's business involves healthcare; often these agreements are electronically accepted merely by purchasing the cloud vendor's services. Thus, companies can be Business Associates without realizing it. And if they do not at least "try" to work on HIPAA compliance, they can face even stiffer penalties in case of a PHI breach.

Cybersecurity is more and more a corporate concern. Data breaches affecting millions of patients are in the news all the time. These reflect concerted attacks on data security, not a lone incident such as a stolen laptop or thumb drive. Breaches can involve not only paper documents, but also network servers, portable devices, phones, emails, and electronic health records.

Lessons Learned

- HIPAA provides a lot of protection for your privacy rights as a patient.
- HIPAA does not provide a private right of action.
- HIPAA compliance is a practice or process. Compliance is *scalable*, depending on the size, complexity, resources, and other attributes of the organization.
- Whether and when someone is "under" HIPAA is a trick question. HIPAA's reach is broad and extensive, and even if HIPAA does not "technically" apply, it is still the gold standard, and more and more, state authorities look to HIPAA for rules and guidance.
- HIPAA aims to protect the privacy and security of patients' "protected health information" or PHI.
- Some HIPAA standards are required; others are "addressable," depending on the organization's situation.
- A breach essentially means that the privacy or security of PHI has been compromised. Someone has hacked into the data, or the data has been stolen, lost, copied, and diverted. When this happens, HIPAA has a set of rules governing "breach notification"—the process by which patients (and the State) get notified that the breach has occurred, and are informed what the healthcare organization is doing to "remediate" or help fix the breach.
- The cost of HIPAA breaches can be steep, as regulators showcase the consequences by imposing Draconian penalties, sometimes in the millions.

- If HIPAA itself is arduous and daunting, and a gold standard to boot, there are also state laws governing the privacy and security of PHI, that can apply even if HIPAA does not. The bottom line is that healthcare practices and businesses need to demonstrate efforts regarding privacy and security compliance, regardless of whether HIPAA applies.

- Importantly, HIPAA requires that business associates of a covered entity also comply with HIPAA. Essentially, the healthcare provider is the covered entity; the business associate is anyone who *creates*, *maintains*, *receives*, or *transmits* PHI. This could be, for example, the billing company which a healthcare practice employs; or the telemedicine company that engages the physicians. These Business Associates must also put compliance measures into place, and the covered entity should ensure that the business associates are doing so.

HIPAA came along in the early days of the Internet, and was supposed to prevent the evils of public disclosure of private, sensitive information.

Arguably (and actually!) the world has changed, with exponential technological accelerating outstripping regulatory capacity to adapt. Lots and lots of data is in fact no longer private like it was in the early days of HIPAA. Nonetheless, regulators take HIPAA very seriously; and with Business Associates now carrying the weight of HIPAA too, and the fact the current environment makes almost anyone in the health and wellness industry a possible Covered Entity *or* Business Associate, it is increasingly mission-critical to have a HIPAA compliance plan in position.

Chapter 5

FDA Exposure

Throwing Down the Regulatory Gauntlet

Case Study: Janet Enters the Dietary Supplement Business

Growing up as an only child, Janet had everything. Her parents doted on her and bought her every conceivable toy. She spent many fun hours in their huge backyard, playing with her school friends who invariably came to the family mansion for play dates.

Janet's uncle was mayor of her town, a huge man with enormous popularity and influence. Toward the end of his political career, he developed inflammatory bowel syndrome (IBS). He went to a functional medicine doctor and completely healed himself with dietary and lifestyle changes. Never one to miss an evangelical opportunity—be it in politics or business—Janet's uncle launched a holistic health consulting business, and an affiliated company that distributed dietary supplements. Eventually he sold the consulting business and focused on growing the dietary supplement business into a multi-million-dollar enterprise.

When Janet's uncle was in his seventies, his company received an FDA warning letter, targeting three claims that FDA turned his gut health dietary supplement line into "drugs." This made no sense to Janet's uncle. After all, these supplements had helped him tamper down the "inflammation" in his system, and that inflammation had been the root cause of his ailments so many years ago—and thousands of consumers had benefits. Heck, FDA's position was "inflammatory!"

Janet's uncle asked the CEO of the dietary supplement company to hire an FDA attorney, who advised that FDA had the upper hand here, given its enforcement discretion and broad rules prohibiting "disease claims" in dietary supplement marketing. The FDA attorney wrote to FDA, toned down the marketing claims, and implemented a compliance plan limited to the three claims identified in the FDA warning letter. The company then prospered for many years.

Janet's uncle handed the reins to her shortly before he moved to Florida for a happy retirement.

Janet had a marketing background, and she decided to push the envelope a bit further. After all, the company only had received one FDA warning letter in all its years, and that was a long time ago, and under her uncle's tenure.

One day, Janet's executive assistant opened the mail and found simultaneous envelopes from FDA, FTC, the District Attorney, and some law firm she had never heard of with a lot of lawyer names, from somewhere in the Midwest.

Meanwhile, similar letters reached the desk of Brett Spine, a chiropractor practicing hundreds of miles away. Brett was a distributor for the dietary supplements manufactured by Janet's company.

When Brett opened the letters, he was very angry. He immediately dialed his business lawyer. "What's this about!" he demanded.

Brett's business lawyer didn't know anything about FDA law. "The … incorporation papers are valid," he said defensively.

"How dare they?" Brett responded. "All I did was copy the exact claims the manufacturer has on *its* website. And what about free speech?"

"I guess we better get a specialist," said the business lawyer, somewhat nervously.

Marketing Dietary Supplements: The Costliest Mistake

The costliest mistake when marketing dietary supplements is underestimating the serious enforcement powers of FDA, as well as other federal and state agencies—and, as well, underestimating the zeal and speed with which class-action plaintiffs' attorneys can move to shred an established company.

Janet was resting comfortably on the legacy of light-touch enforcement, and the years of apparent regulatory safety during which FDA and other enforcement authorities had left her company alone.

The fact remained, though, that Janet had ample warning that her company was in the enforcement sights of FDA. And Janet did not even realize that FDA is under no obligation to give such a warning. Its powers include seizing the goods, stopping sales, and even criminal penalties if it believes the violations were willful or represent a grave danger to public safety.

As for Brett, he did not hire an FDA lawyer, and instead relied on his general business lawyer. Brett did not have his claims reviewed. Instead, he simply relied on the claims Janet's company had made. That was another mis-step.

Why the Healthcare Products Legal Game Is Different

Fundamentally, if you are manufacturing or distributing a healthcare *product*—such as a dietary supplement, cosmetic, or medical device—you are in a different regulatory enforcement environment than when offering healthcare *services*.

For the most part (with exceptions such as federal law with respect to HIPAA, and Stark and anti-kickback), healthcare services are regulated under state law. States control who can be licensed, what are the criteria for licensure and discipline for professional misconduct, what constitutes malpractice and what is required for informed consent.

Healthcare products, on the other hand, typically travel in interstate commerce (which is broadly defined) and are regulated primarily by FDA in terms of consumer safety issues, and by FTC to ensure the advertising is truthful and non-misleading.

Manufacturers of health products can get in legal trouble, if claims do not meet all the specified criteria for a specific product or from either agency.

The legal risks come not only from because FDA, FTC but also from other government agencies (such as the state attorney general) can take enforcement action. Or the National Advertising Division ("NAD") of the Better Business Bureau or private plaintiffs can sue.

Dr. Brett Faces an Uphill Legal Battle

Dr. Brett was shocked because his main adversary in the legal battle he face was an ambitious deputy district attorney. The state chiropractic board left him alone and took no part in the enforcement action.

Dr. Brett had to hire a lawyer to fight the charge of false advertising. The prosecutor did not care that Dr. Brett had simply copied Janet's ad. The prosecutor was uninterested in Janet or her company, as these were housed in a different state. The prosecutor did not like chiropractors and especially Dr. Brett.

It so happened that the prosecutor was best friends with the Governor, who was a former neurosurgeon and did not like it at all that some of his patients were going to get the backs "cracked" instead of going into surgery.

The ensuing battle took months to resolve, and many pages in which Dr. Brett the chiropractor cited the scientific evidence supporting her claims, and the assistant DA disputed all the conclusions.

Finally, Dr. Brett the chiropractor withdrew the ad. There was no further legal fallout; but the cost of prevention--having the ad reviewed before publishing it--would have been far less.

What are Dietary Supplements, Anyway?

The regulation of dietary supplements emerged out of decades of FDA enforcement against vitamin, mineral, and herbal products. Historically, FDA tended to regard these as drugs.

Consumers rebelled. Considerable political leverage was exerted on Congress to ensure that FDA would no longer regulate these products as "drugs" (unless "drug" or "disease claims") were made, but instead would regulate them as "foods." The key regulatory distinction is that Rx drugs must be demonstrated "safe and effective" for their intended use, to FDA; whereas the burden is on the Government to show that dietary supplements are unsafe.

Thus, dietary supplements are "food" as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and specifically, as amended by passage of the Dietary Supplement Health Education Act of 1994 (the "DSHEA"),

In simple terms, dietary supplements are defined, in part, as products (other than tobacco) intended to supplement the diet that bear or contain one or more of the following dietary ingredients:

- A vitamin;
- A mineral;
- An herb or other botanical;
- An amino acid;
- A dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

- A concentrate, metabolite, constituent, extract, or a combination of any ingredient mentioned above.

Furthermore, dietary supplements are products intended for ingestion, are not represented for use as a conventional food or as a sole item of a meal or the diet, and are labelled as dietary supplements.

Importantly, FDA does not "approve" dietary supplements; in fact, the key point that we have just articulated above, is that there is no FDA premarket approval of a dietary supplement.

This does not mean, however, that dietary supplements are "unregulated."

As noted, if a distributor or manufacturer makes disease claims for their dietary supplement, then FDA can classify the product as a new drug. Disease claims are prohibited for dietary supplements.

Another regulatory requirement is registration.

In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States has to register with FDA under section 415 of the FD&C Act and is subject to the requirements related to preventive controls of the Current Good Manufacturing Practice.

Hazard Analysis Critical Control Point (HACCP) is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product, and Risk-Based Preventive Controls for Human Food rule.

Dietary Supplement Labeling

Now that we have briefly explained the meaning of a dietary supplement, let's move on to explore the main labeling requirements to insert on your product.

This topic is a bit arcane, so skip ahead to the next section if it gives you a yawn. On the other hand, if you are a manufacturer or distributor—or simply a consumer who goes into the nutrition store and looks at labels—these definitions will come to life for you.

Also, a bottom line takeaway here is that we will be delving into the rules governing what goes on the dietary supplement *label* itself. Remember, though, that FDA also regulates claims on the *labeling*, and that FDA defines "labeling" as all of the content—including the website and statements on social media—that are part of the dietary supplement company's marketing machine.

Why is labeling important and what information is needed on the Principal Display Panel (PDP)?

Proper labeling is an important aspect of putting the dietary supplement on the market. Moreover, labeling gives the consumer the correct information to make an informed decision of whether or not to purchase that particular dietary supplement.

The following are five main labeling statements required to be displayed on the PDP:

- the statement of identity (name of the dietary supplement);

- the net quantity of contents statement (amount of the dietary supplement);
- the nutrition labeling;
- the ingredient list; and
- the name and place of business of the manufacturer, packer, or distributor.

The above statements must be placed either on the principal display panel or on the information panel.

Note that the PDP is that part of the package that the consumer is most likely to see, and you'll find the above information there.

The statement of identity and the net quantity of contents statement, discussed further below, must also be placed on the PDP.

A product cannot include any other information, therefore only the essential information is presented on the PDP and can then be directly communicated to consumers. When creating a PDP label, the type style is as important as the information included so the label is easily readable.

What is the Statement of Identity?

A statement of identity is used to recognize a common name which describes a single item, and this must be placed on the PDP.

Within the statement of identity, there are multiple requirements for identifying dietary supplements. These include: use of the term "dietary supplement" or, manufacturers can replace the word "dietary" and use an ingredient name in its place. For example, "calcium supplement" or "vitamin B12 supplement" are common supplements seen on the shelves of stores. The statement of identity must be one of the most important features on the PDP and its bold type size must be more prominent than other features on the front panel of the label, located parallel to the base of the package.

What is the Net Quantity of Contents?

The net quantity of contents is defined as the amount of supplement in the container or package and can be expressed either in weight, measure, numerical or in both. If a net quantity is being defined in weight, it must be expressed in the metric or the US customary system. The weight is defined as the weight of the supplement itself. The weight of the container isn't included in this measurement, except in cases where the supplement is designed to deliver results under pressure.

The net quantity of contents must be located on the product label as a distinct item on the PDP, parallel with the base of the container.

What is the Supplement Facts Panel?

The "Supplement Facts" panel, the ingredient list, and the name and place of business of the manufacturer, packer, or distributor must be placed on the information panel.

The required information on a Supplement Facts label includes:

- Serving size information
- Names and quantities of each ingredient
- Total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron
- Dietary ingredients with no daily value must be listed by common name
- Amount per serving (this can be worded as: amount per capsule, packet, per 2 tablets, etc.)
- Percent daily value must be declared on all dietary ingredients

This information panel is located immediately to the right of the principal display panel as the product is displayed to the consumer. The information panel may be any adjacent panel when the top of a container is the PDP.

What to put in the ingredient list?

Any compound used in the manufacture of a dietary supplement is considered an ingredient. An ingredient statement is needed unless the product ingredients are listed under the supplement facts label. Ingredients are required to be listed in descending order of prominence by weight. Ingredient listings should also include the use of spices, natural and artificial flavors.

What other information is required?

The street address must be listed if it is not listed in a current city directory or telephone book, the city or town, the state, and zip code. The address of the principal place of business in lieu of the actual address must be listed accordingly.

What is the required format on a Dietary Supplement Label?

It is a requirement to use a print or type size that is prominent, conspicuous and easy to read. The letters must be at least one-sixteenth (1/16) inch in height based on the lower-case letter "o," and not be more than three times as high as they are wide. The lettering must contrast sufficiently (it does not need to be black and white) with the background so as to be easy to read.16

Unless excepted by law, the Tariff Act requires that every article of foreign origin (or its container) imported into the United States conspicuously indicate the English name of the country of origin of the article.

Do I need to put Warning Statements as well?

Dietary supplements must also include a warning statement on their packaging. This statement must be placed prominently on the information panel located on the product's immediate container. By way of example: "WARNING: accidental overdose of iron-containing products is a leading cause of fatal

poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately."

FDA labeling requirements may be difficult to decipher.

But if you keep these five labeling statements in mind, this could help you avoid the numerous FDA hurdles:

1. The statement of identity (name of the dietary supplement);
2. The net quantity of contents statement (amount of the dietary supplement);
3. The nutrition labeling;
4. The ingredient list, and
5. The name and place of business of the manufacturer, packer, or distributor.

What Goes into Legal Review of a Dietary Supplement Product?

Dietary supplement legal review focuses on analyzing dietary supplement claims, labeling, and substantiation (the evidence required to make a health claim).

These tasks can vary in scope and cost, depending on many factors, including:

- the number of dietary supplements involved
- the type of dietary supplement product
- the number and nature of claims being made for each supplement
- the dietary supplement ingredients (and whether any are active ingredients in OTC drugs, for example; or, on the other side of the spectrum, new dietary ingredients (NDIs) that require a new dietary ingredient notification to FDA
- the labels on the dietary supplement bottles and packages
- the amount of marketing content requiring review (online or in print)

Here are some basic rules to keep in mind.

Misbranding: Under the DSHEA, a dietary supplement product is illegally "misbranded" if, among other things: its labeling is false or misleading in any particular; the container or packaging is misleading or fails to contain the information required by federal law; or it makes inappropriate claims.

Labeling: As we have noted, the term "labeling" means all "labels" and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. The term "label" is further defined to mean "a display of written, printed, or graphic matter upon the immediate container of any article."

Disease claims v. structure/function claims: Disease claims are impermissible under the DSHEA; structure/function claims are allowed.

A disease claim is a claim to diagnose, cure, mitigate, treat, or prevent disease. Disease claims (also known as "drug claims") require prior approval by FDA and may be made only for products that are approved drug products. "Disease" is defined as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition."

Examples of disease claims include: "shrinks tumors."

FDA warns in its Overview of Dietary Supplements: "a product sold as a dietary supplement and promoted on its label or in labeling as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved—and thus illegal—drug. To maintain the product's status as a dietary supplement, the label and labeling must be consistent with the provisions in the Dietary Supplement Health and Education Act (DSHEA) of 1994."

A structure/function claim describes the role of a substance intended to maintain the structure or function of the body, or general well-being from consumption of a nutrient or dietary ingredient. Unlike disease claims that cause products to be regulated as drugs, structure/function claims do not require pre-approval by FDA.

Structure/function claims can include a statement that describes the "general well-being" a consumer can attain from the consumption of a nutrient or dietary ingredient. An example of a structure-function claim is: "Calcium builds strong bones."

In essence, the goal of Marketing—with input from the FDA Attorney—is to craft a claim that falls within the structure/function category, does not fall into the disease claim category, yet provides a competitive marketing advantage.

Ten ways a statement can be a disease claim: To expand on what makes a statement an impermissible disease claim (i.e., a claim that the product will diagnose, mitigate, treat, cure, or prevent disease), FDA clarifies such a statement, explicitly or implicitly, claims that the product does one of the following 10 things:

1. Has an effect on a specific disease or class of diseases;

2. Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

3. Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

4. Has an effect on a disease or diseases through one or more of the following factors:

    a) The name of the product;

    b) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the

definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

c) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

d) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

e) Use of pictures, vignettes, symbols, or other means;

5. Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

6. Is a substitute for a product that is a therapy for a disease;

7. Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

8. Has a role in the body's response to a disease or to a vector of disease;

9. Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

10. Otherwise suggests an effect on a disease or diseases.

FDA further clarified these categories, with examples, in *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure of Function of the Body* (Jan. 6, 2000). FDA stated that claims can be "easily understood by consumers" to refer to a disease even if the statement does not in fact mention the disease. For example, the statement, "controls blood sugar in persons with insufficient insulin" would be considered an impermissible disease claim as it could easily be understood to refer to treatment of diabetes.

FDA also noted: "For example, depending on how it was used in a product's labeling, a scientific reference entitled 'Using Ingredient X For Diabetes' could constitute a claim that the product can diagnose, mitigate, treat, cure, or prevent diabetes, without using any of these specific terms."

In these regulations, the FDA also discussed the extent to which referring to scientific information could create an impermissible disease claim:

> *[T]he use in labeling of a publication title that refers to a disease will be considered a disease claim only if, in context, it implies that the product may be used to diagnose, treat, mitigate, cure, or prevent disease. Highlighting, bolding, using large type size, or prominent placement of a citation that refers to a disease use in the title could suggest that the product has an effect on disease. Placing a citation to a scientific reference that refers to a disease in the title on the*

immediate product label or packaging will be considered a disease claim for that product. The agency will also consider whether the cited article provides legitimate support for the express structure/function statement made for that dietary supplement. Enhancing the bibliography with citations to scientific references that refer to a disease in the title and that have no reasonable relation to the statement made will be considered a disease claim. Similarly, the agency will consider whether citations are to bona fide research.

FDA labeling is one of the most important regulatory requirements for dietary supplements in that it provides the consumer the necessary information on the product. Indeed, ensuring that all information concerning that particular dietary supplement is in compliance with FDA labeling requirements, may be difficult and often very onerous. As a matter of fact, labeling errors may result in FDA enforcement action which could tarnish a company's reputation and business.

Cosmetics Products Are Under Similar "Disease Claim" Prohibitions

Cosmetics are similar to dietary supplements in that FDA prohibits manufacturers and distributors of cosmetics from making "disease claims" for cosmetics products.

One major difference is that with dietary supplements, one can make structure/function claims. The claims a cosmetics company can make are much more limited; and a major mistake cosmetics companies make is thinking they can make structure/function claims for cosmetics products.

We'll cover this more in a bit.

First, it is important to understand that cosmetic products do not require FDA approval unless they have color additives or unless they qualify as a drug, medical device, or dietary supplements.

There are two laws, however, that regulate the entry of cosmetic products into interstate commerce. Since most cosmetic companies sell their products through the Internet and through regional, national, or international distributors; companies that make, pack, distribute or market cosmetic commodities need to understand these laws and how to comply with them.

The cosmetic product laws apply to manufacturers, packers, distributors, importers, advertisers, resellers, and others in the supply chain. Experienced cosmetic lawyers can help guide you through the maze of cosmetic laws and regulations.

The Key Cosmetics Industry Laws

The Food, Drug, and Cosmetic Act (FD&C Act) enacted in 1938 gives the FDA the authority to regulate the safety of food, drugs, and cosmetics. The law provides for civil and criminal remedies for violations of the Act. We have mentioned the possibility of criminal penalties earlier.

The Fair Packaging and Labeling Act (FPLA) which became law in 1967, authorizes the FDA and the Federal Trade Commission (FTC) to issues regulations covering consumer products.

The FDA and FTC require that the cosmetic labels properly disclose the identity and contents of the package; the quantity of the products (how much the consumer is getting); and the identity of the makers, packers, and distributors of the cosmetic products. Labeling cannot be deceptive and should promote value comparisons.

Cosmetics companies must comply with these laws and any relevant regulations passed so these laws can be detailed and enforced. The Center for Food Safety and Applied Nutrition (CFSAN) is the cosmetic product agency, within the FDA, that monitors cosmetic safety and cosmetic labeling.

What products qualify as "cosmetic products?"

Common cosmetics include eye and face makeup, perfumes, shampoos, deodorants, lipsticks, skin moisturizers, hair colors and any product that is intended:

To be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

Cosmetics are also intended to "exert a physical as well as a physiological effect."

Soap is generally not considered a cosmetic if the labeling refers to ability to cleanse. When the labeling includes references to moisturizing, skin softening, and other comparable claims; the soap may be considered a cosmetic.

Cosmetic products that are intended for any therapeutic use, including helping to remedy diseases or to affect the body's structure or function. This is where many cosmetics companies get in trouble. The doctrine of intended use allows FDA to review all of the company's marketing material in order to assess what the company's "intended use" is. If FDA concludes that the intended use is therapeutic, FDA can classify the cosmetic as a drug, or possibly even a medical device.

Some individual care products may even qualify as dietary supplements.

Examples of cosmetics that can qualify as drugs are fluoride toothpastes and anti-dandruff shampoos.

Many cosmetics that are drugs are sold over the counter (OTC).

If you are in the cosmetics business, again this is a totally different regulatory environment then when providing healthcare services. For example, the dermatologist or plastic surgeon who develops a line of skin care products has to understand the sliding line between cosmetics and drugs, and when the product will likely be classified as a drug and consequently must either fit an OTC monograph, or be submitted for New Drug Approval.

Typical Legal Trap Doors in the Cosmetics Industry

We already talked about the doctrine of intended use and how FDA often uses this doctrine to determine that a product is *not* a dietary supplement or cosmetic, but rather, a drug or medical device.

Often, FDA's determination that the product constitutes a "drug" or "medical device" spells the regulatory death-knell of the company; although savvy companies can re-brand and amend or re-invent their marketing—with the help of FDA legal counsel—reconstitute their strategy so as to survive FDA scrutiny.

Additional trap doors that cosmetics manufacturers and distributors should anticipate include these:

1. Understand what the FDA can do if a cosmetic commodity fails to comply with the federal laws or regulations.

   The term "cosmetics" is a legal term of art. They are specifically defined in the FD&C Act and interpreted by the courts.

   FDA has extensive enforcement authority, including the authority to:

   - Conduct and inspect sample products and inspect the places where the products are made.
   - Work with the U.S. Customs and Border Protection agency to refuse to allow the products to enter the United States.
   - Have the products taken off the market by requesting, with the help of the U.S. Department of Justice, that a federal district court enjoin the further manufacture or distribution of the product.
   - Begin criminal proceedings against violators.
   - Request a product recall if the manufacturer or other cosmetic commodity doesn't conduct a voluntary recall - though the FDA can't order a product recall

2. Understand what FDA means by "adulteration" and "misbranding" and why FDA takes this seriously.

   The FD&C Act regulates cosmetics sold through interstate commerce in two fundamental areas:

   Adulterated cosmetics. Cosmetics cannot be adulterated (tainted) in any way including the ingredients themselves or through the packaging, shipping, or handling of the products, or how the cosmetic product is handled. A cosmetic is adulterated if:

   - It includes a poisonous or dangerous substance which can cause injury through standard use or the use detailed in the label.
   - It has any putrid, filthy, or decomposed substance.
   - It was made or packaged under insanitary conditions
   - Its container has a toxic of deleterious substance which can cause harm.

   Misbranded cosmetics. Even if the product is valid, the FD&C Act, considers that cosmetic misbranding has occurred if:

   - The labeling is untrue or misleading in any way
   - The labeling omits required information such as warning statements or instructions on safe usage.

- The requisite information is not "prominent and conspicuous."

- The container is itself misleading such as suggesting that there is more content than there really is

- The label or package violates the Poison Prevention Packaging Act of 1970.

- The FPLA requires that the cosmetic ingredients be listed in a precise order.

3. Understand the steps required to comply with product safety requirements.

   The cosmetic products must be safe. The safety of cosmetic products is largely up to the individual manufacturer.

   FDA does not require that specific tests be taken or met. Companies should, however, create established procedures to test and verify the safety of their ingredients and products – to ensure that the products are indeed safe and to prove, if violations are asserted, that proper precautions were taken.

   Cosmetic product safety factors include:

   - Reviewing existing toxicological test data on similar products

   - Conducting independent toxicology tests
   - Not using prohibiting ingredients such as mercury compounds, methylene chloride and other chemicals listed in the Code of Federal Regulations 21 CFR 700 and other sections.

   - Providing warning statements for ingredients with known concerns - in conformity with the Code of Federal Regulations.

   - Complying with any safety laws if color additives are being used

4. Comply with the cosmetic labeling requirements and ingredient listing requirements.

   Labels must meet strict cosmetic labeling requirements. FDA lawyers understand the Code of Federal Regulation (CFR) rules that dictate the precise label and ingredient requirements.

   Labels include graphic images as well as text and information on both the inside and outside of the packing wrapper.

   The part of the label that consumers normally read is called the *principal display panel*. It should have the product name; usually has a descriptive name or picture; and lists the product's quantity such as its weight, a number, or some other calculable figure. The display panel or other information panel should include the name and address of the marketing company, maker, packer, and/or distributor. also require that the information be easy to read and understand.

   Labels should be in English, be conspicuous, and prominent.

With some exceptions (such as, products meant to be sold to professionals and not consumers), the ingredient list (in addition to the label) must also be conspicuous and likely to be read by the consumer.

The list can appear on the outer container or on a tag or item securely attached to the product. There are strict size (height) requirements that must be met. The ingredient list should include the most predominant ingredient first and the least used ingredient last – in descending order. Ingredients that compose less than one percent can be at the end. Ingredients that are also drugs should be listed first.
Other key cosmetic labeling requirements that must meet CFR standards include the need to have proper statements about hazardous products such as aerosol products and that some products must be secured in tamper-resistant packaging.

5. Implement practical strategies for complying with the FD&C Act and the FPLA.

Some of the most important recommendations for cosmetic makers, packers, distributors, marketers, importers, resellers, and other cosmetic commodities, in addition to a complete understanding of the federal laws and regulations, are:

Safe facilities. The facilities and equipment should be in great working order to reduce or eliminate the risk of contamination, charges of unsanitary conditions, or other safety violations. The building, walls, and ceilings should be easy to clean. The ability of ducts and pipes to cause leaks or condensation should be minimized. The plumbing and electrical utilities should comply with federal and local health and safety laws.

Proper equipment. The equipment and tools to make the cosmetic products should be designed and maintained with product safety and quality as a top priority. These items should be regularly sanitized.

Proper handling of raw materials. The ingredients and packing materials should be stored and used so that they cannot be contaminated or allowed to decompose due to exposure to the elements or other conditions. The materials and packaging should be properly labeled and controlled. Products should be tested properly before they are used.

Use experienced and educated personnel. The team of people managing the design and manufacture of the product should be properly trained and educated and have proven experience in the cosmetic industry. Staff should be educated as to the proper gloves and garments to wear and the hazards to avoid while making the products.

Utilize a controlled production process. The manufacturer of the cosmetic products should use approved materials, should regularly test samples, and have multiple checks by different people. Cosmetics that are returned should be properly discarded or inspected for contamination. Water supplies and other resources should also be routinely inspected. Proper records should be kept verifying the production process, testing process, and all phases of production.

Proper concern for customers. There should be a system in place to handle all customer complaints about injuries and medical treatment including the identity of the local poison control center.

Voluntary FDA registration. Another suggestion is to participate in the FDA's Voluntary Cosmetic Registration Program (VCRP). While manufacturers do not have to register their company or file formulas with the FDA, voluntary registration can help your company show that it is making the effort to comply with the laws.

An FDA cosmetics product attorney can also explain how the FDA's Cosmetics Labeling Guide helps manufacturers, packers, distributors, marketers, importers, and resellers get answers to questions about labeling requirements. However, experienced FDA cosmetic labeling requirement attorneys do more than just help you understand and comply with the relevant laws and regulations. They help you prepare in advance and help protect you when complaints arise.

Lessons Learned

- The costliest mistake when marketing dietary supplements is underestimating the serious enforcement powers of FDA, as well as other federal and state agencies—and, as well, underestimating the zeal and speed with which class-action plaintiffs' attorneys can move to shred an established company.

- Fundamentally, if you are manufacturing or distributing a healthcare *product*—such as a dietary supplement, cosmetic, or medical device—you are in a different regulatory enforcement environment than when offering healthcare *services*. Healthcare products typically travel in interstate commerce (which is broadly defined) and are regulated primarily by FDA in terms of consumer safety issues, and by FTC to ensure the advertising is truthful and non-misleading. Manufacturers of health products can get in legal trouble, if claims do not meet all the specified criteria for a specific product or from either agency.

- Under the DSHEA, dietary supplements (unlike drugs) do not need premarket FDA approval. However, manufacturers and distributors cannot make "disease claims" for dietary supplements.

- Reviewing the label of a dietary supplement is a very technical task, albeit one subject to extensive regulation. The broader concept is "labeling." FDA looks to anything a dietary supplement company says in its market as part of the labeling. Manufacturers and distributors who are overly aggressive in their claims can find that FDA will regulate their product as a drug, and say that their product makes "disease claims."

- Most enforcement focuses on "misbranding," which involves labeling issues; or "adulteration," which involves hazards in the product itself.

- Cosmetics are similar to dietary supplements in that FDA prohibits manufacturers and distributors of cosmetics from making "disease claims" for cosmetics products.

FDA jurisdiction encompasses the huge arena of healthcare products. We have focused on two key parts of this vast landscape: dietary supplements and cosmetics.

There are other areas, such as medical devices, that also crop up frequently in our law firm practice. These areas are more and more significant as technology moves the delivery of healthcare services to the product arena. For example, consider mobile medical apps. Like telemedicine, they move the focus from the in-person visit to the brick-and-mortar doctor's office, to an online or mobile experience. Increasingly,

healthcare is delivered as a product, instead of a service—and this is where those who neglect FDA's legal and regulatory reach may find that agencies are even less forgiving than aggrieved consumers. Here, a good map with an eye toward prevention is well worth the business effort.

Chapter 6

FTC Liability

Disgorging Profits & Other Unpleasantries

Case Study: From Gorgeous to Disgorging

Tina Gregory, the former high school beauty queen and pageant champion, started an online cosmetics business that quickly accelerated into becoming the state's most prosperous and successful.

Unfortunately, on the advice of her Chief Marketing Officer, she approved newspaper and radio ads which said that her flagship product not only made customers' skin glow, but they also "reversed aging" and were "anti-inflammatory," making the "aches and pains of old age go away."

Following a warning letter from FDA for making "disease claims" for the cosmetics lines, and coordinated efforts among FDA and the Federal Trade Commission ("FTC"), Tina found herself the target of a Civil Investigative Demand (CID) by FTC.

Advised by her FDA attorney, Tina immediately ceased all advertising and sales, and entered into negotiations with FTC. Unfortunately, the very claims Tina's company was making were the enforcement target of the month in inter-agency communication, and Tina's company was a prime violator which had "unjustly enriched" itself to the detriment of consumers, to the tune of millions.

FTC filed a complaint in federal district court, asking the Judge to order Tina's company to disgorge all its unlawful profits. The complaint in fact sought $30 million in restitution; which FTC generously reduced to $3 million, in a written settlement, thus allowing Tina's company to barely survive and reconstitute itself with greatly reduced marketing claims for its products.

FTC officials claimed the victory in a press release, noting that the much-shrunken company (with vastly diminished claims) would not have attained its meteoric revenue growth in the first place, had the company played by the rules.

False Advertising Traps: Spot and Stop

To the trained legal or business eye, FTC false advertising traps are not hard to spot; yet from the perspective of marketing, they may be hard to stop. The reason is that what is good for marketing may be bad for compliance, and the reverse. In getting—and digesting and filtering—legal advice, the healthcare practice or business owner often must titrate between legal risk and monetary reward.

The consequences of a false advertising charge or claim—whether by FTC, a state agency, or a private plaintiff—can be serious. Tangoing with FTC can, among other things, result in an FTC judgment that requires the company to disgorge all profits. This can denude the company of its revenues and consign its dreams to the ash-heap of history. Class action plaintiffs can look for small violations and make class action claims in the millions of dollars.

For legal keys to avoiding FTC false advertising legal traps, let's start with FTC's own advice to small business. FTC stays that all advertising must be:

- truthful and non-deceptive
- backed up (all claims must be substantiated)
- not unfair

Also, keep in mind that FTC looks at these key things:

- How the "reasonable consumer" might interpret the ad in context (words, phrases and pictures).
- Whether there are "implied" as well as "express" claims. For example: "mouthwash kills the germs that cause colds" suggests that mouthwash prevents colds. This is a disease claim.
- What the ad fails to include, where the omission can leave consumers with a mis-impression.
- Whether the claim is "material" (makes a difference to consumers' purchase decision).
- Whether the evidence supports the claim. Consumer anecdotes are not sufficient evidence to support a claim. Money-back guarantees are also insufficient evidence to support a claim.

FTC Standards for Healthcare Claims are High

Under FTC law, before disseminating an ad, advertisers must have a reasonable basis for all express and implied product claims. What constitutes a reasonable basis depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified.

FTC looks to several factors including:

1. Type of product (*e.g.*, products related to consumer health or safety require greater substantiation).
2. Type of claim (claims that are harder for consumers to assess require more substantiation; this includes “health claims that may be subject to a placebo effect or technical claims that consumers cannot readily verify for themselves”).
3. Benefits of a truthful claim.
4. Cost/feasibility of developing substantiation for the claim.
5. Consequences of a false claim (including physical injury if the consumer relies on an unsubstantiated claim of therapeutic benefit).
6. Amount of substantiation that experts in the field believe is reasonable (FTC looks to “accepted norms in the relevant fields of research” including those developed by a government or authoritative body).

FTC standards are particularly stringent and exacting in the health and wellness industry. Unfortunately, many advertisers of healthcare products and services fail to realize that FTC imposes a higher standard for health claims.

While advertisers in general must have a reasonable basis for their claims, generally health claims must be supported by *competent and reliable scientific evidence*. This same, high standard is followed by FDA; however, FTC is the primary enforcement with respect to whether the messaging is false, misleading, or deceptive.

Among others, FTC has taken action against:

- dietary supplement manufacturers
- ad agencies for dietary supplements
- infomercial producers
- catalog companies, and
- distributors and retailers of dietary supplements

A quick glance at the FTC website and judicious use of the search bar will reveal many FTC enforcement actions and hefty penalties assessed in the health and wellness industry.

Red Flag Claims

FTC also has "red flag" areas where it pays particular attention. Among these are products claiming to provide quick and easy weight loss.

On the FDA side, while proper weight loss claims for dietary supplements might be considered structure/function claims, obesity statements are disease claims. These claims also raise substantiation issues, because FTC essentially takes the position that these claims cannot possibly be proven by competent and reliable scientific evidence.

FTC enforcement in this area has included claims:

- About weight loss without proper diet or exercise;
- About fat absorption, fat burning, and fat blocking;
- That a product is "clinically proven."

FTC has identified areas of concern in *Red Flag: Bogus Weight Loss Claims*, cautioning that "misleading weight loss advertising is everywhere, preying on consumers desperate for an easy solution."

Some years ago, FTC hosted a seminar on weight-loss fraud, which included the agency's assessment of weight loss claims associated with dietary supplements. FTC's expert panel, comprised of 10 bariatric physicians, medical doctors, and weight loss experts from across the United States, addressed weight loss claims.

FTC specifically rejected claims that: (1) a product can cause weight loss or fat loss to specific areas of the body; (2) that thermogenic agents, or similar substances, can result in increased metabolism; and (3) that dietary ingredients can block fat or promote weight loss through the blockage of absorption of fat, calories, or other nutrients.

FTC therefore starts with an assumption that consumption of dietary supplements, without substantial changes to diet and exercise, alone is inadequate to cause statistically significant (or material) weight loss. That regulatory history adds to the substantiation burden. If ad copy contains "clinically proven" claims (or "establishment" claims), for example, one must ensure that those studies are of high methodological quality sufficient to meet FTC's rigorous standards.

"University Studies Prove…"

In one of its guidance documents for the dietary supplements industry, FTC flags some of the following claims as potentially problematic, especially if there is no clear and prominent, qualifying language explaining the claim:

- "university studies prove"
- "90% of cardiologists...."
- advertising showing people sneezing and coughing (i.e., advertising cold care)
- before and after pictures (before: using walker; after: dancing)
- a weight loss ad failing to disclose that test subjects engaged in regular exercise and diet restriction during the test period for the product
- failing to mention side effects while referencing "without the side effects of over-the-counter" drugs
- failing to mention the product's effect on increase in blood pressure
- "scientists now agree!" and "studied for years abroad" (require a higher level of evidence since these refer to a specific level of support)
- reliance on animal and in vitro studies
- anecdotal evidence
- "proven"
- "found effective"
- relying on "traditional use" (such as "ancient folklore remedy used for centuries")
- reference to a book ("Miracle Cancer Cure") in promotions for a particular dietary supplement

The problem with these claims is they claim too much. They often lack substantiation, the "competent and reliable evidence" that FTC seeks. They may rely on "proof" that is far less than scientists or physicians would accept. They sometimes make disease claims where the product is only a cosmetic or dietary supplement.

People Can "Puff"

The flip side of the coin is that "puffery" is usually allowed and doesn't necessarily make an ad deceptive or misleading.

Puffery can include "an exaggerated, blustering, and boasting statement" about a product, or a general claim of superiority over comparable products that is so vague it's commonly understood as a mere expression of opinion. The overall context is important, though. While FTC law is broad, the principles are clear. Applying these in practice requires sensitivity to marketing goals.

It is easy for legal counsel to say "no," and more challenging for your FTC attorney to take a balanced approach that weighs risks. Especially since FTC can require a company to disgorge profits and thereby level a company's accumulated earnings, early legal review of all marketing materials for FTC risk can be an invaluable preventative strategy.

The bottom line is that FTC heavily enforces truth in advertising and marketing of health claims.

Lessons Learned

- What is good for marketing may be bad for compliance, and the reverse. In getting—and digesting and filtering—legal advice, the healthcare practice or business owner often must titrate between legal risk and monetary reward.
- The consequences of a false advertising charge or claim—whether by FTC, a state agency, or a private plaintiff—can be serious. Tangoing with FTC can, among other things, result in an FTC judgment that requires the company to disgorge all profits. This can denude the company of its revenues and consign its dreams to the ash-heap of history. Class action plaintiffs can look for small violations and make class action claims in the millions of dollars.

- Under FTC rules, all advertising must be truthful and non-deceptive; backed up; and not unfair.

- FTC standards are particularly stringent and exacting in the health and wellness industry. Unfortunately, many advertisers of healthcare products and services fail to realize that FTC imposes a higher standard for health claims. While advertisers in general must have a reasonable basis for their claims, generally health claims must be supported by *competent and reliable scientific evidence*. This same, high standard is followed by FDA; however, FTC is the primary enforcement with respect to whether the messaging is false, misleading, or deceptive.

- Certain common claims (such as "found effective") are enforcement targets, because FTC regards these claims as lacking in substantiation or incapable of substantiation.

- "Puffery" is usually acceptable, so long as the net impression overall is not misleading or deceptive.

- False advertising legal battles can take months or years to resolve. There is no real win here.

The bottom line is that FTC heavily enforces truth in advertising and marketing of health claims. This is an area that most health and wellness service providers and companies neglect. However, even if FTC does not step in, state authorities have the statutory backing and enforcement authority to stop a healthcare practice or business in its tracking. It is a good idea to have all marketing material reviewed by legal counsel for FTC and false advertising issues, even if all the other areas of legal risk have been carefully reviewed and addressed.

Conclusion

A Beautiful Day in the Health & Wellness Neighborhood

Won't You Be My Neighbor

Recently, I was privileged to see the opening scenes from the film about Fred Rogers, "*Won't You Be My Neighbor?*"

I was a little late for the Mr. Rogers' neighborhood wave, however, I was really pleased to see the movie, and it touched a deep cord in me. The messages that Fred Rogers presented are deceptively simple, and yet those very same messages are at the heart of why I devoted myself to the health and wellness industry.

It's a beautiful day in the neighborhood and you can see the beautiful sun, and the trees, and the light that's shining; the beauty of nature. And the incredible calm with which Mr. Rogers delivered every message, the peace in his heart, the peace and calm in his voice, the cadence, the rich tones, the desire to make a meaningful connection with everyone.

I listened to some of the Q&A and some videos about the movie.

He was asked: "How many children have you influenced over the course of your career?"

And his response was utterly disarming and magnetic and compelling.

He said: "It didn't matter the number of children, if we could make even one connection with a human being, when we're present, especially with a child, how important is that?"

He said that he considered the ground between the person transmitting a message and the person receiving the message—even through a T.V., as holy ground.

And he said that becoming the best possible receiver of messages was an act of holy grace, required grace, summoned the best in him.

Promoting Health & Wellness at Every Level of Being

These plain and yet intricately beautiful statements, from Fred Rogers, inspired me and they remind me to share that this is why I do what I do.

We all do what we do for a reason. The reason that health and wellness is so important is because it focuses on the total human being.

Of course, physical health and vitality are absolutely precious. Everybody wants to be healthy, it's the ultimate gift. And we can all become ever healthier and a lot more fit, and for that, we have exercise, we have water, we have different healing traditions; we have a lot at our command. And we have modern medicine as well.

When you look to the WHO, the World Health Organization definition of health, it includes in addition to physical health; mental health, emotional health, environmental health, spiritual health; all of these aspects of what make us a full human being.

So if I'm going to be a healthcare lawyer, or a healthcare and FDA lawyer, then I'm committed to businesses and practices that promote health and wellness, at every level, every dimension of being.

In my career as an academic and legal scholar, lawyer, law school professor, then a medical school professor, I wrote books, I wrote articles for law journals and medical journals on the ultimate dimensions of health: physical, mental, emotional, environmental and spiritual, one might even say, the moral dimension of health, and how the laws could be improved and transformed to support human transformation.

I wrote about how our preoccupation with healthcare fraud drives us to concern for the darker corners of human nature, and it's entirely appropriate that law regulate the darker corners of human nature. Yet at the same point, we must strive for the light. **We need a legal and regulatory system that also accommodates the highest in human potential.**

Using Law to Support Human Transformation

In my book, *Future Medicine*, I looked at the hierarchy of needs proposed by psychologist Abraham Maslow, as a model for how law could ascend towards the highest, and promoting the highest, in human nature.

That we should seek, not only to prevent and curb fraudulent, dark, deviant and dangerous activity, yet also to promote the same values that Fred Rogers was promoting in all of his programs.

He regarded the T.V. as his ministry and, in the same way, I happen to be, also, an ordained Interfaith Minister.

Being a lawyer has been my ministry. That might sound odd to people who regard law as anything but ministry, as something in fact very far from it, as preoccupied and consumed with rules and regulations and penalties, and all of these dark corners of regulating human behavior.

But law truly is a noble profession, and healthcare and FDA law are noble pursuits.

The Spiritual Dimension of Healthcare Law

Let me draw a couple more parallels.

I want to say, also, that from a spiritual vantage point, I had a dream and it was about Fred Rogers.

In my dream his name wasn't actually Fred.

Fred was a pseudonym: his real name was Reuven.

I thought: "Reuven? Reuven, that's interesting. Okay. Maybe he's Jewish? He's not, he’s Presbyterian or Episcopalian, whatever he was. So why Reuven?”

And it was Reuven, not Reuben. It was the Hebrew pronunciation.

And then, it dawned on me; in Hebrew, Ruven is R-E-U-V-E-N.

The Hebrew meaning of the name is: "See your son!"

Every day that I see my son, I'm reminded of all the things that I cherish, everything that Fred Rogers talked about: seeing clearly, being present, being present in the moment, allowing for transformation, being a humble receiver, being a humble servant. So that was the meaning of the dream.

One of the things that I got out of the movie is that Fred Rogers saw television, modern television, as it was back in the 60s, and even more so today, as an instrument of materialism. He said that T.V. was quick to make children into consumers: “as long as they buy something,” as long as they hurry up and go buy something. Those were the messages from television.

And he also said that T.V. was an emblem of violence, that it promoted violence.

I can see, even with my young son, how cartoons geared to toddlers; they contain so much of the language of violence within them. A lot of it is slapstick, it's getting bashed and getting banged and getting bruised and getting beaten.

He already talks about things that I wish were not in his lexicon.

They are in his lexicon and I can no more shelter him from them than the Buddha’s Father could shelter the Buddha from the four Noble Truths: from the fact that there's suffering, that there's old age, that there's birth and there's death, that people get sick; that this our reality.

At the same time, while mindful of these realities, the Buddha was able to transcend them to be the one who was Awakened.

Again, Rogers used the medium to promote a holy message and similarly I believe that, as a healthcare lawyer, as an FDA lawyer, as a business owner, these are values that I can effectively promote.

All of Humanity as a Neighborhood

Ultimately, the message of Mr. Rogers had to do, in a very playful way, with the evolution of humanity and, clearly, that's a theme that I embrace.

He really was emblematic of the Christ consciousness; you get that from him, you get that from his heart.

I would aspire to be more and more like that, in my own conduct, in the way that I am present with others. The biopic movie is described as a "tearjerker,"

As a role model, he presented the option to have tears of love.

Ultimately his message was that Christ-like and Hillel-like message of "Love your neighbor," "Listen to a child," and "Love yourself." Loving yourself if a huge part of it.

From the perspective of "What is healthcare law ultimately about,” to me, there is that spiritual message of finding that place where we are whole; health is about wholeness; creating structures and systems and rules that can accommodate the highest dimensions of health and happiness, that can lead to that, that can support that.

Again, it's seeing not only the worst features of ourselves but, also, the best features of ourselves.

The Legal Rules at Play

Licensing laws determine who gets licensed and why, and how, and what they can do as license professionals.

Malpractice rules determine when practitioners that are negligent, that injure people, will pay the price.

Healthcare fraud aims are avert, deter, and punish, wrongful behavior that involves takings.

FDA law is there to protect consumers from products that make claims that inconsistent with the product classification and that go way beyond what the product should do, given how it's regulated. There's a whole tier of regulation, from dietary supplements, to medical devices, to cosmetics, to drugs.

FTC law is there to prevent and deter misleading and deceptive advertising.

All of these rules are there, with the 'thou shalt nots' and the 'thou shalts'. It's a complex web and it takes a lot of sophistication to navigate that.

At the heart of it is, you, the practitioner who has worked hard to earn their degree, their credentials, to learn a craft; or the business with the mighty idea to spread a mighty product, a mighty package, a mighty offering. On the other side, there's the patient who's trusting, or the client or customer who needs your help.

Legal Strategies & Solutions: The Shining Path Ahead

That's what we do at the Cohen Healthcare Law Group. We provide legal strategies and solutions to businesses and practices that accelerate health and wellness. Those are our clients.

I hope the stories in this book show you some of the danger zones that health and wellness businesses, and professionals, face every day – and some key legal potholes and swamps to avoid. As well, the idea is to show you some paths we often take to help clients mitigate risk and thrive.

I'm so grateful that I was put on this path. I'm so grateful that we're able to help people just like you, and we look forward to many more years of service.