Becoming a Multitalented Administrative Lawyer

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There has never been a better time to pursue a career in administrative law. If you look closely, each and every minute of your day involves a regulated commodity, service, or enterprise. Like it or not, from that first cup of coffee to the gas you pump into your car to the labor laws at work in your office, you would be hard pressed to circumvent a regulation, law, or policy embodied in the code. As laws today work their way through months of committee hearings, meetings with lobbyists and special interest groups, floor debates, and backroom bargaining sessions, it’s no wonder that so much complexity is routinely added to the simplest pieces of legislation.

For example, in 1956, Congress passed the Federal Aid Highway Act, the largest public works act in American history. The Act, comprised of a total of 28 pages, authorized and funded the interstate highway system. In 1991, the Federal Highway Act was reauthorized by the
Intermodal Surface Transportation Efficiency Act composed in 293 pages. Thirty-five years later, the basic legislative goal remained the same; however, the new legislation required building more highways in ways that would aid mass transit, preserve historical sites, encourage wearing seat belts and motorcycle helmets, control emissions and soil erosion as well as outdoor advertisements, reduce air pollution, require a percentage of asphalt to include recycled rubber and U.S. produced raw materials and so forth.

Fast forward 20 years later, and it’s easy to see how elected officials have codified in their rules, which have grown exponentially. Face it; the world we live in today is heavily regulated, and the number of regulations in effect does not appear to be shrinking.

Businesses operate at their own peril should they choose to function without legal counsel skilled in the understanding and practical application of the applicable industry regulations. Thankfully, there are lawyers like you and me who can support the multitude of companies seeking such regulatory guidance.

So how did I become a regulatory lawyer? I’d like to say that from the age of five, it was nothing that my parents did or didn’t do—I was destined to become a regulatory lawyer. However, that would be far from the truth. I actually “fell” into administrative law through a course of events that, thankfully, caught my innate curiosity. After earning my undergraduate degree in communications from the University of Southern California, stepping back onto a college campus for any reason other than the USC–Notre Dame football game was far from my mind. Corporate America beckoned, along with stock options and the chance to learn hands-on the practical skills of an industry professional. By luck, Amgen, Inc., a biotechnology company in Thousand Oaks, California, hired me to develop course materials for their Regulatory Compliance Education Department. Working for Amgen taught me a very important lesson: never say never.

My first day on the job involved plenty of pleasure reading, commonly known as the Code of Federal Regulations or the CFR. Reading and analyzing how to comply with 21 CFR 200, et seq., the current Good Manufacturing Practices, became part of my daily existence. Whereas the regulations offered a road map, executive leadership supplied the desired destination in the form of business goals and objectives. My job involved strategically mapping the journey from point A to point B in compliance with the code. I was hooked. I discovered how
fun it was to think through the requirements, pull together the various business units, and shepherd the team to compliance.

Working closely with my employer’s law department, the in-house counsel at the time must have recognized how much fun I was having. One day, counsel called and asked if I had ever thought about attending law school. I was in shock. My first thought was how could I leave my compliance responsibilities and go back to being a student living on macaroni and cheese. Thankfully, counsel suggested that I attend Loyola Law School in the evenings on a corporate scholarship. How could I say no? Being the type of person open to life’s many opportunities, I knew such a blessing was a once-in-a-lifetime opportunity that had to be pursued.

Law school, law review, and a full-time professional job left me little time for idle hands. Law school supplied many of the “how to think and approach” tools I needed to become a regulatory attorney. Industry supplied the practical challenges for legal consideration. Looking back, going to law school and studying regulatory law was the best decision I ever made aside from marrying my wonderful husband.

As a law school graduate fresh from the California Bar Exam, I knew I needed to obtain practical training in a law firm setting—but where? California is a long-distance commute from the Beltway where much of the government and regulatory practice groups tended to thrive. Law firms, representing diverse clients with a wide variety of legal challenges, offered the best opportunity for me to develop my skills in representing corporations. Plenty of firms were hiring recent graduates to work on matters that nine times out of ten involved regulated entities, but the job descriptions rarely required a passionate interest in regulatory law. Not to be deterred, it would be up to me to enlighten the firms as to the value of my regulatory insight.

I knew my skills and industry experience would prove invaluable in representing such clients in a wide range of matters from transactions to litigation. I just needed to use those powers of persuasion to help the firm partners see the light. Looking beyond the four corners of law firm job postings (i.e., applications accepted from top 10 percent GPA only) I applied, networked, and suggested my candidacy to large international law firms representing clients from my preferred regulated industry, that of the pharmaceutical and medical device manufacturers. All along, I reminded myself that where there’s a will, there’s always a way.
At first, I started out as a litigator representing manufacturers defending allegations of product liability. The firm initially assigned me to traditional first-year associate activities. However, as I became more involved, partners recognized that I understood how to think through and apply the various regulations to client issues. It didn’t matter if the case involved FDA, EPA, FTC, CPSC, or SEC regulations; understanding the regulatory mind-set allowed me to quickly digest the regulatory framework applicable to the client’s interests. I became the go-to person who could identify compliance issues in underlying merger and acquisition agreements, interpret expert witness depositions discussing the regulatory nuances of a particular activity, and incorporate compliance requirements into commercial agreements involving activities subject to regulatory agency oversight. As much as regulations are a part of our everyday lives, their application from a legal practice perspective is equally pervasive.

Fast forward nine years later, and I am still busy applying regulatory law and assisting companies with their compliance efforts. Even in tight economic times, companies operating in the public sector need lawyers to help them navigate through the complex regulations that affect their daily existence.

Over the past few years, I have applied my regulatory background on a global level by drafting and negotiating contracts for clinical research worldwide. Such agreements involve contract drafting and negotiation experience as well as a solid understanding of the regulatory risks associated with the services being performed.

If you find U.S. regulations to be enjoyable, try drafting a contract for technical research services to be performed in Poland, subject to the regulations of the European Union as well as Poland, to obtain protected health data that ultimately will be sent to the U.S. sponsoring company for inclusion in their upcoming license application to the U.S. FDA. Applying the regulations to such contracts protects many people beyond the companies I directly represent. By ensuring that certain terms are included and understood by the contracting parties, patients participating in the clinical trials for new and novel therapeutic medicines are afforded a level of assurance, as the parties conducting the trial understand they can be civilly held accountable for compliance with the regulations enacted for patient safety.

As you can imagine, I love the work that I do, and I am not alone. Recently, I attended the American Conference Institute conference on
drafting international clinical trial agreements and discovered over 1,000 attorneys who, like me, relished the interface between regulatory law and commercial agreements. Wow, I was shocked to learn that so many other lawyers existed, performing and thriving on the buffet of regulatory intensive contracts that I loved so much.

Recently, my employer began exploring the possibility of being acquired and my role as in-house counsel was destined to transfer to the acquiring company. Although the economy appeared to spiraling down, I decided to hang out my shingle and perform contracts work as a solo practitioner. I prepared my professional networking page on LinkedIn to read like an advertisement for my unique regulatory and contracts services http://www.linkedin.com/in/kamoore and reached out to just about every colleague who has crossed my path over the past 10 years.

I also made a point of joining LinkedIn Groups that matched my industry expertise so as to allow my profile to be visible to professionals outside of my direct network. The first time I received an e-mail from an in-house counsel in Switzerland looking for assistance with a U.S. FDA regulatory term in a contract confirmed the power of professional networking to me.

Then, former clients from my life at the law firm and my former employer began knocking on my door. Each asked, “Can you help me? I’m developing a medical device and have some contracts that I need you to draft . . . for a study in Romania, Italy, Russia, India. . . .”

Looking to further build my business, I started running searches on Simplyhired.com to identify companies that were looking to hire in-house counsel to prepare and negotiate contracts for drug development activities. It didn’t matter that the company was located in Texas and I was living in Southern California. The company had a unique business need that I could fill on a temporary basis while they looked to hire the perfect in-house counsel.

In a majority of the cases, sending a cover letter and resume to the human resources department proved ineffective, as HR would note my zip code and make the executive decision that I was geographically undesirable. Seeking a back door, I utilized LinkedIn’s search feature to find former colleagues working at the company. I found colleagues working in a wide variety of roles both as in-house counsel and in nonlegal professional capacities. As colleagues knew the hiring management as well as the protocol for candidates to be referred internally, I was able to efficiently communicate my availability to work on
a temporary telecommuting basis as well as share my resume with general counsel. After interviewing over the telephone, I obtained clients who could use my contract drafting and regulatory compliance services on an as-needed basis.

I also began contacting my former students, who tended to work in-house as regulatory professionals. Back in 2001, I learned that the University of Southern California planned to start a Regulatory Sciences Masters Program serving pharmaceutical management-level professionals. After reviewing the program curriculum on http://regulatory.usc.edu/, I saw an opportunity for me to share the legal liability and practical business considerations associated with regulatory professional activities. Getting involved with the program, I volunteered to guest lecture on a certain topic. Later on that year, the dean called and requested another lecture. The following year lead to a one-unit course. Today, I teach a three-unit, masters level course, “Medical Products and the Law,” on the USC medical campus. The course is simultaneously broadcast worldwide via the Internet. As the program caters to working professionals, teaching class on Saturdays one semester per year is entirely feasible and does not conflict with normal employment.

Have you ever thought about volunteering to lecture on a topic? Although such a step can appear daunting at first, you’d be surprised to learn how much information and insight you actually have to share, particularly to a nonlegal audience. After I spoke with a colleague about my teaching activities, she contacted the local University of California, at Irvine campus and learned that the local certificate program was in need of a co-instructor for their regulatory program. She, too, volunteered and now runs her own class in addition to her normal full-time professional job. Her network expands on a semester basis.

Continuing my quest for additional clients, I also registered with Adams & Martin Group, a local legal recruiting agency under Robert Half Legal. I made a point of developing a personal, first-name-basis relationship with my agency contact and called her each week to remind her of my availability. I was determined to not be just another file logged into their system.

Although corporations have not necessarily been paying recruiters for expensive full-time permanent placements in light of the current economic climate, an agency can market your legal skills on an hourly or temporary basis. As the agency maintained an extensive network of local contacts in Southern California, it could introduce me to in-house
counsel looking for assistance with their commercial contracts and regulatory matters. As a result, I was introduced to some amazing general counsel who could have possibly remained outside of my reach if it were not for the introduction afforded through the local agency. Temporary work also provided a steady paycheck that supplemented the cyclical nature of work that is sometimes experienced when working as a solo practitioner.

Also, consider joining and participating in the bar associations that support your practice profile. In my case, being an active member of the ABA and more importantly, the Section of Administrative Law & Regulatory Practice, has introduced me to some of the most incredible legal practitioners in our nation. I remember one of my first administrative law fall meetings, where a colleague suggested that I sit with him at the Section’s dinner. I ended up sitting next to Attorney General Janet Reno, and later shook hands with Justice Scalia. I felt as if I were stargazing like a groupie at Nobu’s in Malibu. (If you’re ever in Southern California, let me know and I’d be happy to take you there. Lunch or dinner, there’s bound to be at least one celebrity in the restaurant at any time.)

Wanting to expand my network, I started to think about the other in-house counsel with pharmaceutical practices similar to my own. Searching the local nonlegal, industry-specific websites such as Biospace.com, I made a list of companies that worked on products in my desired area of the regulated pharmaceutical industry. I couldn’t believe the number of companies working in and for the pharmaceutical, medical device, cosmetics, and nutritional supplement industries all located within driving distance of my home. So many in-house counsel, but how to meet them? As a member of the Association of Corporate Counsel, I knew that certain committees actively supported many practice areas, but there was yet to be a Food and Drug Law Committee. I contacted the leadership and asked how to establish a Food and Drug Law Committee to allow for networking among in-house counsel practicing in the highly regulated industry. As a result of surveys and discussion, the local Southern California Chapter received the green light to start a Food and Drug Law Committee, and we are working on the very first event of its type for in-house counsel working in the highly regulated industry.

Looking back, law and regulatory practice have opened doors, as well as my eyes, to a practice that has been an incredible experience.
Essentially, there are no limits. As stated earlier, there are regulations each and every place you turn these days. Someone has to draft them, understand them, apply them, and provide their expertise so their regulatory guidance can be followed in fulfillment of the policy objectives. The options available to you in the field of regulatory practice are as endless as the regulations themselves. Enjoy!