Becoming a Food and Drug Lawyer

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Should you consider a career in food, drug, and medical device law?

Only if you want lifelong learning; no two weeks alike; interesting and societally relevant work; fascinating scientists to meet and cutting-edge research to discuss; and a lively and changing field that keeps you interested and stretched as you try to adapt older laws to newer product challenges. Have you moved along the approval of an HIV AIDS drug? Have you kept counterfeit infant formula off retail shelves? Has the vaccine for a virus been moved swiftly because you helped the client overcome barriers? There are psychic rewards galore, and the money’s very good in most of the nongovernmental positions as well.

WHO'S A REAL FOOD AND DRUG LAWYER?

Who are the 600 or so full-time FDA lawyers in this country, and their 1,000 or so extended colleagues, and where are they located? There may be four subsets:
1. The largest number of true “FDA specialists” are in law firms in Washington, D.C.; New York, Atlanta, Indianapolis, and Chicago have a small number each, and southern California is slowly developing a base of private law firms with this specialization. Their practice is largely counseling and advocacy with FDA and related agencies such as the Federal Trade Commission and state attorneys generals’ consumer protection offices.

2. The FDA Office of Chief Counsel employs fewer than a hundred lawyers, all in suburban Washington. FDA also employs dozens more JD holders in the job title “regulatory counsel” or its equivalent, also in suburban Washington. There is a distinction between tradition and internal culture; lawyers who hold the regulatory counsel roles are not regarded with the same deference given to general counsel (GC) attorneys; structurally, GC attorneys are employed by the Department of Health and Human Services (HHS) general counsel, and not by FDA. FDA lawyers responsible for federal litigation are aided by the Office of Consumer Litigation in the Civil Division of the DOJ. Functionally, GC attorneys do all of the external and litigation work; regulatory counsel work on rulemaking and administrative tasks. These lawyers are not any better or worse as individual attorneys, but bureaucracy has its cultural distinctions, and the status differences are subtle but significant.

3. In-house counsel jobs at food, drug, cosmetic, device, biotech, and related companies in the FDA field employ many lawyers, a portion of whose time is spent on FDA issues. No real census of this population is possible since titles vary so greatly in corporate legal departments, and lawyers who have done FDA work well tend to move upward in their respective law departments into management roles.

4. An “all other” category exists, of private lawyers who have had some tangential contact with an FDA problem but have acquired no depth of expertise. Their law firm’s marketing website sometimes calls them FDA practitioners, but it’s a perilous stretch. The FDA field is so sensitive to nuanced errors in dealing with a dominant powerful bureaucracy that the propensity for one’s incorrect legal advice in this category to cause repercussions is very high. Behind many of the larger-firm
criminal convictions and seizures in this field (apart from truly criminal individual cases) is some law firm’s malpractice exposure for having given poor advice. Experienced lawyers from other fields should strive to avoid malpractice and grievance cases, and purported “FDA law specialists” with gaps in their knowledge are at a heightened risk of both of those adverse consequences.

FINDING THE JOBS

How are these jobs to be found? FDA is very selective, and its parent, the HHS Office of General Counsel, posts its entry-level positions on federal job websites discussed elsewhere in this text, and may offer summer intern positions at the FDA Chief Counsel’s office. Talk to your law school’s alumni network in Washington. Former federal appellate clerks or clerks to Washington area federal judges may enter their network of advisors who can recommend them; sometimes lawyers from other administrative agencies move to FDA. Each elective administration change brings a shift in the top two positions within the office, as the HHS general counsel has the nominal power to select these two persons when he is confirmed as head lawyer for the overall Department of HHS. Hiring from a variety of backgrounds and experiences has helped FDA; sometimes politically motivated lawyers have attempted to capture higher policy roles, often meeting with disdain from lifetime FDA managers. Career veteran lawyers do most of the supervisory work and are most knowledgeable about institutional policies.

Sometimes, lawyers come to FDA after service with a congressional committee staff or a nongovernmental advocacy group. During a recent administration, a chief counsel with an aggressive antiregulatory agenda cut back drastically on enforcement; he and his political selectees drew lots of negative feelings before departing for industry. Their zeal was a thankfully rare exception; over the century of FDA’s existence, the great professional work of the FDA chief counsel’s team has required impartiality, writing skill, diplomacy, and sensitivity to science, much more than political attitude. In general, applicants should be exceptionally qualified as administrative law candidates, and leave their political credentials outside. Neutral, science-based regulation demands evenhanded lawyering with a minimum of preconceptions.
How can I start in a food and drug position outside of FDA? Excel in one of the law school courses on FDA law offered at one of about 25 law schools; these tend to be taught pro bono by adjunct professors with many years of successful interaction with FDA. Or win the cash prize in the annual Austern Writing Competition for law student papers on FDA law (http://fdli.org); attend ABA Administrative Law Section meetings to intersect with our very active FDA committee; publish a student paper in the *Food and Drug Law Journal*; or just be the best and brightest candidate for a large Washington firm and then request assignment to FDA projects that can gradually school you for the role of experienced FDA counselor.

**IS SCIENCE A PREREQUISITE?**

Are the lawyers in FDA practice all science-trained? No, a small minority are science-trained, with the majority of FDA practice situations involving close cooperation among the scientific consultants and the attorneys. Liberal arts graduates with excellent listening skills, strong reading comprehension, and polished writing talents will excel in these jobs.

A fine writer with legal and diplomatic savvy will trump a biochem PhD/JD who is full of personal zealotry on issues relating to FDA. The field has more than its share of marginal players known for their particular slant. Success is common for those who have earned peer respect for their good judgment and writing skills; unlike talk radio, your high volume and passion tend to turn off your audience in this sophisticated and high-stakes field. Learn and listen and study about this century-old regime; don’t be afraid to read more than your opponent does, and don’t rush to judgment. The career-making negotiation of my life as an FDA practitioner involved my awareness of an unreported case and a statutory set of preconditions to FDA action; their effective presentation blunted the plans of FDA’s enforcement lawyer and won a favorable settlement that had many millions of dollars in ramifications for the client. My 40 percent pay raise from the client more than offset the grumbling of a competitor’s lawyer who disliked our settlement.

**WHAT IS THE WORK?**

What does the FDA practitioner do? Meetings, e-mails, PowerPoint presentations, phone calls, text messages, policy drafts, and more meetings.
Successful FDA practitioners have these traits: their personality is balanced; they like to understand complex puzzles; they are eager to listen to advice; they talk carefully rather than glibly about the uncertainties of science; they present well at the inevitable meetings; they ask questions of clients; they look for precedents; they write well in papers, advocacy presentation, testimony, and so forth; and they are careful to rebut opposing views with facts. A telephone headset, a travel kit, and a laptop are essential since so much time is spent on informal phone negotiation inside a company, with advisors, and with FDA staff members. Inside FDA, the tasks include rule drafting and dealing with rulemaking comments; advising on penalty or debarment hearings; interpreting FDA norms for field offices; negotiating complex statutory interpretation issues with FDA science managers; and countless meetings with companies and their counsel who seek exceptions or approvals.

Outside FDA, advocacy by the FDA law specialist takes its usual forms, but there is extensive “institutional memory” to be mastered, guiding what steps are acceptable and what steps will hopelessly alienate the regulators. Avoid missteps: if you annoy the district compliance director, maneuver around a key approval official, or put congressional heat on the associate commissioner, then your “fame will precede you” the next time your client needs favors from the FDA. Several of the lawyer tasks are familiar if you have studied administrative practice: comments on FDA proposals, strategy meetings on pending approval applications, due diligence for acquiring a regulated firm, crisis management during recalls, advising on disciplining of potential whistleblower employees, and preparing witnesses for the defense in the exceptional court cases (which are typically settled early, before trial occurs).

**HOW SHOULD YOU PREPARE?**

What should a law student have before entering? Writing skills matter most; at one time a chemistry degree would be a great advantage, but today’s FDA is a crossroads of physics in medical devices, biotechnology in drug and vaccine ingredients, medical epidemiology for adverse event studies, biostatistics in approval decisions, and so forth; thus, the candidate should be prized for his listening and “quick study” capacity rather than for undergrad learnings. Patent law awareness helps in a few cases; history and an awareness of international trade issues is
quite helpful. Integrity is absolutely essential, since the realization that your client is defrauding the FDA should induce immediate withdrawal (after studying your state’s ethical code on lawyer withdrawals). It’s fine to fight hard on a statutory interpretation or factual dispute, but if you plan to be in this field for three or four decades, a “fraud on the FDA” case should be avoided at all costs, as the institution has a long memory for past deceptions. So run, do not walk, away from a scenario that tags you with a “fraud on the FDA” reputation.

**CONCLUSION**

This exciting, dynamic, and highly relevant field has been very good to me and to numerous other lawyers who are available to interact, encourage, and sometimes chastise the younger lawyers. FDA practice has broadened to include many more lawyers, a global set of clients, and a vastly larger financial stake for industry. But it still has many of the pleasant interactions and friendly rivalries that befit a relatively small bar. My 35 years in this field have aided me in bringing along numerous bright younger lawyers to serve the public’s interest, their client’s interest, and their careers. There will always be a need for good lawyers in this important field, commensurate with your skills and preparation. Will you be one of them?