An Overview of Food and Drug Law Practices

By Stuart TenHoor

The U.S. has several thousand food and drug lawyers in the private bar and a high percentage of them practice law in Washington, D.C. Upon analysis of these lawyers and their firms through the use of firm websites, lawyer rating entities, FDA documents, www.fdli.org and the author's professional knowledge, it seems that firm practices fall loosely into five categories. Before outlining the elements of each category, defining the type of food and drug law attorney we discuss here helps guide the analysis.

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Generally, a private practitioner might label him or herself a "food and drug lawyer" for handling food and drug related regulatory issues. A broader definition would include practitioners in a food and drug context dealing with any or all of the following: advertising and promotion, antitrust, bio-similar developments, consumer protection, corporate transactions, dietary supplements, enforcement or "white collar" crime issues, "food" issues, related health care issues, legislative or lobbying, litigation (administrative, intellectual property or products liability), medical devices and now also the regulation of tobacco. While this list is not exhaustive, it sets forth the FDA practice area subsets in which most food and drug lawyers practice. And firms with varying levels of the talent necessary to handle these issues are categorized in the analysis below.

Category 1 firms typically provide services in most of the areas listed above. Although they may lack depth in, for example, "food law" or bio-similars, they generally possess skilled practitioners in most or all of these subsets. These larger general prac-

tice firms (750+ lawyers), with multi-national offices, have been successful in part due to their ability to provide "one stop shopping" for the most complex FDA legal issues. They are able to accomplish this because of the ability of their lawyers from each of the required subsets, on any given matter, to work as a team.

While these standout firms have very successful practices, one drawback they face, given the large number of matters they handle, is that business or ethical conflicts can hamper client representation opportunities. The firms in this category also often lack expertise in the "agricultural/food' area, something the category II firms generally possess in depth.

Category II firms are food and drug regulatory boutiques. These firms usually have five or more (if not many more) regulatory practitioners and focus all but exclusively on food and drug law. They frequently employ in house scientific personnel, often with highly advanced educational degrees and years of experience in regulatory experience in government to provide additional expertise and more fully serve the client on the often very technical regulatory issues handled by the FDA, USDA, FTC or other relevant federal agencies. They also tend to handle a higher percentage of food related work involving the USDA.

These boutiques frequently obtain referrals of FDA work from a number of general practice firms when such firms have client conflict situations. These referral networks can be long-lasting provided original client loyalties are not threatened.

Category III firms are far more numerous than those in Category I. These are general practice firms almost always with 200 or more lawyers; a few even have up to 10 times that number.

Such firms typically have five or so regulatory practitioners that might handle, for example, FDA administrative litigation, advertising and promotion or medical device work, yet have no white collar or advertising and promotion capabilities. In many general practice firms, FDA related intellectual property (IP) litigation has become more important to their evolving client bases. The rise of such issues have enabled those firms specializing in IP matters to begin highlighting their "FDA practices" despite the lack of most of the other food and drug practice sub-sets previously listed.

Category IV covers many other large general practice firms (200+ lawyers), but their FDA lawyer numbers are small and they tend to handle a more episodic stream of work. Further, lawyers in this group often are not full time food and drug practitioners. They frequently work on other non-FDA regulatory legal issues or, for example, might handle antitrust or transactional matters of which only 10-20 per cent relate to food and drug matters.

Category V firms comprise a large, but not the largest, category. While it can be hard to precisely identify such firms, most of them either have no or just several food and drug law practitioners. Those without a currently competitive practice see advantages in having food and drug law expertise within the firm due to firm clients they know have food and drug legal issues. While a small number of these firms may have been able to handle some type of food and drug related matters for their clients, most recognize the need for a deeper talent base to nurture this type of work from their existing clients.

Lateral Hiring Issues:

Category I firms can have a recruiting advantage since they already perform a sizeable amount of FDA work. This enables them to hire attorneys from the government (most often from the FDA itself), trade associations or corporations even though such lawyers do not join the firm with clients. Those attorneys hired hope to utilize their new firm's position to quickly make an impact on current client legal issues or positively affect potential future client's analysis of the firm's FDA capabilities.

Category 1 firms also attract talented laterals from other firms who often lack sufficient critical mass of FDA talent to maintain existing clients or develop new ones. Firms in categories III and IV have had some success finding "pioneers" — those confident of their abilities to jump-start a practice — by demonstrating their firm's current ability to offer opportunities for new client work to these prospective laterals. They can often do this by showing the firm's consistent representation on perhaps tangential FDA issues such as products liability matters for pharmaceutical companies. Although most sizeable clients needing FDA expertise already have outside counsel supplying this, firms from all categories hope to show prospective laterals how their firm is well positioned through existing client relationships to obtain future FDA regulatory work for laterals to handle.

Conclusion

Since the number of food and drug attorneys capable of creating or expanding law firm FDA practices is relatively small, the demand for those available remains strong and has continued to increase. Further, since approximately 25% of every consumer dollar spent in the U.S. is for products regulated by the FDA, it is certain that demand will remain strong for top food and drug legal talent.