

Identifying **11** Leading Food and Drug Lawyers

They're the cure for what ails the drug manufacturers, the food producers, their trade associations, and their public interest watchdogs. In the D.C. metropolitan area, no one else in private practice knows the law on food and drugs better than these 11 attorneys.

Feeling queasy over some new regulation out of the Food and Drug Administration? They know the agency (at least seven of them did time inside). Getting heartburn from the esteemed senator's latest proposal? They know the Hill. Temperature spiking due to a competitor's newest foray into the market? They know the case law.

How did *Legal Times* pick them? We solicited suggestions from our readers and our reporters. Then, freelance journalist Jenna Greene (formerly an editor at *Legal Times*) called experts in practice and in business to ask for further suggestions, to learn more about who does what for whom in corporate America, and to narrow down the list to Washington's top attorneys.



To learn more about the Leading Lawyers series, including how to nominate attorneys for next year's reports, visit www.legaltimes.com.

Leading LAWYERS

Eleven of the D.C. Area's Top Food and Drug Attorneys

Peter Safir

Covington & Burling

Peter Safir's client list is a veritable who's who of pharmaceutical companies. During the past year alone he has advised more than half of the world's top 15 drug-makers, including Pfizer Inc., Sanofi Aventis Pharmaceuticals Inc., Johnson & Johnson, Merck & Co. Inc., Astra Zeneca PLC, Hoffmann-LaRoche Inc., Eli Lilly & Co., and the Schering-Plough Corp.

A partner at Covington & Burling, Safir is best known for his work involving issues pertaining to drug advertising, intellectual property and marketing exclusivity, and manufacturing quality and product safety.

Sanofi General Counsel Joe Haggerty relies on Safir for his experience and expertise. "I know when I call Peter, I'll get someone who probably knows the answer already," says Haggerty.

Safir has advised Sanofi on regulatory and marketing matters related to Allegra, Arava, and Lovenox. "He is not hesitant to help you make very difficult decisions," Haggerty says. "He has incredible judgment in terms of helping us navigate through legal issues in ways that are most successful for the company."

Linda Friedman, general counsel at Astellas Pharma Inc., shares this view. "Not only is [Safir] a terrific attorney, with a wealth of experience behind him, but he understands the business," she writes in an e-mail. "As a result, his advice is practical and on point."

As the co-head of Covington's food and drug practice, Safir, 60, works with a cast of all-star attorneys, including senior counsel Peter Barton Hutt (*see Page 35*). Other notable colleagues include Ellen Flannery, Richard Kingham, Eugene Lambert, and Richard Merrill.

Much of Safir's work relates to the Hatch-Waxman Act of 1984, which addresses the interplay between drug patent rights and Food and Drug Administration rules and establishes a system to encourage the marketing of generic drugs.

For example, Safir recently represented Johnson & Johnson before the FDA and in federal court to extend its exclusive right to market the pain reliever Duragesic for children. Mylan Laboratories had challenged Johnson & Johnson's right to pediatric exclusivity, which is granted by the FDA as a reward

for conducting drug studies in the pediatric population. In December 2004, the U.S. Court of Appeals for the D.C. Circuit ruled for Safir's client, extending Johnson & Johnson's patent for six months.

In 2003-04, Safir successfully represented Pfizer in similar litigation over pediatric exclusivity, this time for the anti-fungal drug Diflucan.

Safir enjoys handling such cases. "They involve fascinating legal issues," he says, "but are rapidly resolved by the courts"—typically in about six months, with virtually no discovery.

He also provides clients with more general advice on drug life-cycle management—that is, "what strategies are available during the life of the patent to protect from premature generic competition."

One of the industry's biggest ongoing debates, in which Safir has a hand, is whether there should be a legal mechanism to allow for generic versions of patented biologic drugs, such as gene-based and cellular medicines. These drugs are unusually complicated to make, Safir notes, and one concern of his clients is that their manufacturing data covered by trade secrets might be revealed by the FDA to competing generic-drug makers.

Product safety is another Safir specialty. Last month he was retained as counsel to the Guidant Corp.'s independent panel investigating the company's defective heart defibrillator devices.

His work in the area of drug marketing is largely confidential, Safir says. Generally, it includes reviewing advertising campaigns and promotional materials and conducting internal investigations of marketing practices.

In 2002, Safir advised the Pharmaceutical Research and Manufacturers of America in drafting an industry-wide marketing code. "It sets out the appropriate relationship between pharmaceutical companies and physicians regarding gifts, grants, the overall relationship," he explains.

Safir earned his law degree from Yale Law School in 1972 and then took a job on Wall Street with the law firm of Breed, Abbott & Morgan. He moved to Washington, D.C., in 1975 to work for food-and-drug boutique Kleinfeld, Kaplan & Becker. Safir joined Covington in 2002.

His enthusiasm for his work is clear. "People care about what they eat, drink, and put in their bodies. It's important," he says. "You read about what you're working on every day in the paper."



PETER SAFIR
COVINGTON & BURLING

ROBERTO WESTBROOK