Methods for determining how a patient will respond to a medicine. New drugs for age-old illnesses. DNA. These are just a few of the pieces of intellectual property biotechnology companies are trying to protect in the marketplace. But first, they have to find a way to get that intellectual property to the market. Some of the leading life science innovators are managing to do just that, finding partners who will pony up cash despite the shaky economy and cumbersome regulatory approval process. Behind the scenes, of course, are lawyers. To honor their work, the Daily Journal decided to put together its first-ever list of 25 leading biotech attorneys. Take a look at the work they’re doing to finance and protect their clients’ cutting-edge projects.

David M. Hoffmeister
Wilson Sonsini Goodrich & Rosati
Palo Alto
Specialty: Food and drug, health care

The potential loss of lives, along with jobs, has Hoffmeister concerned about the U.S. Food and Drug Administration’s increasingly hard-line approach to moving new products through the pipeline.

“The FDA has certainly tightened up the screws on small medical device companies and pharmaceuticals in what it takes to get products on the market,” he said.

Time being money, this is costing companies megamillions, Hoffmeister said.

“Many of our clients are going to Europe first, because the regulatory requirements are much more predictable and transparent,” he said.

Meanwhile, he added, “people are dying and they need treatment, and they’re not getting access in the U.S. as quickly.”

Hoffmeister said he’s trying to stay optimistic.

“We’ve done work with trade associations to tell the stories of young medical device companies, and how the landscape has changed, and how the lack of transparency and predictability has hurt — losing jobs to Europe.”

Hoffmeister and his team provide regulatory support and counsel to every life sciences deal that’s handled by his firm.

Among them: the sales of Acclarent Inc. to Ethicon Inc., a subsidiary of Johnson & Johnson, for about $785 million; SenoRx Inc. to CR Bard Inc. for $213 million; Calistoga Pharmaceuticals to Gilead Sciences Inc. for $375 million; and Ardian Inc. to Medtronic for $800 million in cash.

Hoffmeister also devotes part of his practice to counseling clients on what he calls “ethical interactions with health-care providers,” in light of the government’s crackdown on company kickbacks paid to doctors as incentives to buy their products.

“The whole industry used to wine and dine physicians,” he said.

But those days are long gone, Hoffmeister said.

“It’s getting that message out to young clients that’s been difficult,” he said. “They are new to the industry, and the medical profession doesn’t know about their products, so there is no incentive for them to try their products, and the young companies don’t think that the government will focus on their conduct.”

But, Hoffmeister added, “With the government being the biggest purchaser of drugs and devices, they want to know that a doctor’s decision is based on their medical opinion and not what the company is doing in providing remuneration.”

That’s fine with him.

“Once the competitive landscape is level, everyone is going to be acting the same way,” Hoffmeister said, “and that’s a good thing.”

— Pat Broderick