San Diego Union-Tribune, The (CA)

January 14, 2003

Michael A. Swit
PENNI CRABTREE

Age: 46

Title: Special counsel, Food and Drug Administration Regulatory Law Practice Group

Firm: Heller Ehrman White & McAuliffe

As one of the few attorneys in Southern California to specialize in FDA law, **Michael Swit** is positioned to help guide biotechnology companies through the regulatory maze required to get a new drug or product approved.
Swit also brings to his job a corporate perspective: In the early 1990s, he was general counsel of Pharmaceutical Resources, a generic drug company, where he spearheaded the company's defense of grand jury investigations, enforcement actions and securities litigation stemming from alleged FDA violations by previous management. While there, **Swit** wrote the firm's first code of business conduct and oversaw the ethics program, crucial aspects of the company's program to restore FDA confidence.

Why does your law practice exist? The FDA is the "gatekeeper" to the marketplace. Most products need FDA review and approval, so we help with all phases of the approval process. And the FDA is the "cop on the beat"; it exists to protect the public health from those that violate FDA law. So if a violation is alleged, you definitely need a lawyer at that stage to guide you and to whom you can speak confidentially.

What about your job keeps you up at night? The thing that would keep me up is if -- which fortunately has not happened recently -- I had a client involved in a drug recall or other major incident involving a significant risk to the public health. In those situations, business is tested to do the right thing morally and make the hard decisions on when profit must yield to protecting the public. As more local companies emerge into maturity with marketed products, it is bound to happen somewhere along the line.

What aspects of your job do you brag about? When I get ahold of an issue where the government has taken a position that I think is just wrong or poorly thought out. While this does not happen often, when it does, the challenge is to raise the matter to FDA's attention in a way that resolves the issue effectively and diplomatically for the client, while still making clear that the issue never should have arisen in the first place. Those are fun.

How do you see the FDA regulatory climate shaping up in 2003, now that there is a new commissioner and the agency has been reorganized? While I am optimistic that Mark McClellan has the skills and insights to tackle as tough a job as FDA commissioner, the Bush administration has saddled him with at least one huge problem that will impact drug, device and biologics firms -- the proposed transfer of virtually all therapeutic biotech products from FDA's Center for Biologics to the FDA Center for Drugs.

It has already triggered the departure of several key biotech regulators from the senior ranks at FDA and reportedly demoralized many in the agency. Thus, I think the "reorganization" is likely to even further lengthen review cycles and other key agency actions.

Tell us something interesting about yourself. My wife, Vera, gave birth on Leap Day 1996 (yes, Feb. 29, 1996) to triplet boys -- Anthony, Joseph and Rafael. Since then, things have been truly unique.
