Legal Times: At FDA, Change In Name Only; Legal Business; New counsel keeps industry-friendly policies put in place by his predecessor

By Lily Henning 19 September 2005-- p. 1

Sheldon Bradshaw arrived at the Food and Drug Administration without the baggage lugged around by his predecessor. The previous chief counsel at the FDA, Daniel Troy, was pilloried by critics who slammed his close ties to the drug industry. Troy made a name for himself suing the agency on behalf of drug and tobacco companies before moving to the government agency early in the Bush administration. Bradshaw, who came to the FDA as chief counsel from the Justice Department in April, has escaped that kind of scrutiny, largely because he hasn't had those corporate relationships. But that doesn't necessarily mean a new day has dawned.

In fact, despite Troy's return to the private sector, his controversial legal policies remain in force at the agency. Like Troy, Bradshaw offers one-on-one meetings with the companies regulated by the agency, has kept low the number of warnings issued to companies violating regulations, and, perhaps most notably, has continued to intervene on behalf of drug companies in private civil lawsuits.

Last week, Bradshaw signed off on a brief agreeing with Pfizer Inc.'s claim that three years ago the FDA would not have allowed the drug company to warn consumers about a link between suicidal behavior and the use of its best-selling antidepressant, Zoloft, by adolescents, an argument Pfizer is using to ward off liability.

That approach and a lighter regulatory hand put the public at risk, consumer and public health advocates complain. And even some in the drug and medical-device industries find the regulatory regime under Troy, and now Bradshaw, discomforting, claiming that without strong FDA oversight, companies are being hauled into court more frequently by state attorneys general and private plaintiffs.

"One of our clients said to me a few months ago, 'I miss the FDA,'" says Arnold & Porter's Donald Beers, a food and drug attorney who served as associate chief counsel for drugs and for enforcement in the FDA's Office of Chief Counsel between 1975 and 1985. "An aggressive FDA that occupies the stage is sometimes better than having lots of different people sniping at you."

STAYING THE COURSE

Before joining the FDA in April, Bradshaw was principal deputy assistant attorney general in the Department of Justice's Civil Rights Division. Bradshaw's move to the FDA -- generally considered a less prestigious agency for government lawyers than the Justice Department -- surprised some of his former colleagues, who describe him as being part of an ideologically conservative group of young leaders in deputy positions at the DOJ. He also worked in the Office of Legal Counsel, made up of an elite group of lawyers at Justice who advise the executive branch. Among the office's alumni is Troy. Both he and Bradshaw were part of the Bush administration's advance legal teams in 2001. Bradshaw says that his lack of experience in the food and drug regulatory arena could be, in the wake of what he says was unfair criticism of Troy, a good thing. "I think it's helped me in my transition that I wasn't seen as already having made up my mind on

certain issues," Bradshaw says. "There isn't a perception that I would have a preference in any given case."

But those looking for changes to policies initiated under Troy will be disappointed. Bradshaw says he has no intention of changing the way the FDA's legal department does business. That continuity was evident last Thursday, when the government filed an amicus brief in Utah reiterating the argument championed by Troy that the FDA's jurisdiction over prescription-drug labeling prevents plaintiffs from suing Pfizer over Zoloft's lack of a warning label. "Wherever I go, people ask me if I am going to continue Troy's policy in pre-emption cases," Bradshaw says, adding that the FDA does not take such action by itself and must have consent from the Department of Justice and the political leadership at the Department of Health and Human Services.

Troy was a pioneer of the government's intervention on behalf of Pfizer in cases related to Zoloft and suicide, contending the FDA would not have permitted Pfizer to warn about the suicide risk because there was not enough scientific support for the warning. The government's involvement began in September 2002, when Justice, joined by the FDA, filed a friend of the court brief in the U.S. Court of Appeals for the 9th Circuit case Motus v. Pfizer. (The 9th Circuit, however, ultimately decided the case on different grounds, never reaching the pre-emption issue.)

The argument was based on the premise that since the FDA has sole jurisdiction over the labeling process of prescription drugs, drug companies like Pfizer should not be held liable for warnings on products if they follow FDA requirements.

The FDA's involvement in the Pfizer case sparked indignation among interest groups, which complained that Troy, who had represented Pfizer in private practice, was leaping to the defense of industry. Plaintiffs advocates complain that if the FDA's legal argument in the Zoloft case is applied broadly, then victims won't be able to sue if they are injured by any FDA-regulated product. Pfizer has used the 2002 brief for the past three years to fend off lawsuits involving Zoloft-related suicides.

In June, Judge Paul Cassell of the U.S. District Court for the District of Utah asked the government to weigh in again, noting that the FDA's opinion was important because the agency had injected itself into the debate with the 2002 brief.

In that case -- the first in which the government has intervened since Bradshaw took over -- the family of 15-year-old Shyra Kallas sued Pfizer, claiming that Zoloft's label at the time their daughter committed suicide in 2002 did not disclose the risks of suicide and suicide-related side effects associated with the use of Zoloft in adolescents. They also claim Pfizer failed to warn Kallas' doctor of that possibility. Kallas, who was prescribed Zoloft by her primary-care doctor, shot and killed herself a month after starting on the drug. Cassell asked the FDA to explain whether the 2002 brief would apply to the Kallas case, noting that the case involves a minor. The drug is not approved for treatment of depression in adolescents. And while Bradshaw calls the circumstances of the Kallas case "tragic," last week's filing didn't alter the position the government held under Troy.

Judges have had mixed responses to the FDA's position on the Zoloft cases, of which there are now more than a dozen nationwide. In a March 2005 decision in a federal

court in Texas, in which Pfizer had filed the 2002 amicus brief, Judge William Steger wrote that Pfizer had relied heavily on the FDA to support its arguments. But the judge ruled that evidence before the agency did suggest that a warning about suicide risks was appropriate and that the FDA's regulations do indeed allow a manufacturer to add to or strengthen a warning without prior agency approval.

Karen Menzies, who represents plaintiffs in cases related to Zoloft, notes that Pfizer never asked the FDA if it could warn consumers about the suicide risk, adding that the FDA had information about the suicide risk associated with antidepressants like Zoloft since the early 1990s but did not analyze it.

The contention that the agency would have prevented Pfizer from issuing the warning is "pure speculation by the FDA's attorneys," says Menzies, a partner with Baum Hedlund in Los Angeles. "But the sheer weight of the FDA intervening is very persuasive." Pfizer has consistently denied any link between suicidal behavior and the use of Zoloft by adolescents. Last fall, after a review of studies on risks of suicidal thoughts and behaviors in children taking antidepressants, the FDA directed manufacturers to add a "black box" warning -- the most severe kind of advisory -- to the medications' labels to emphasize the need for close monitoring of child patients taking those drugs.

THE OLD ORDER

Troy, 45, is, for many critics of the Bush administration's FDA, Exhibit A of the dangers of appointing a regulator who clashed with the very agency in which he would later play a pivotal role. The first appointment to the FDA made by President George W. Bush, Troy says his was a necessarily high-profile role. As chief counsel, he gave nearly 80 speeches and met with dozens of industry groups.

Troy says the meetings sometimes helped to narrow the scope of litigation against the agency and, in some situations, to avoid it. "Sometimes when they heard our side, they said that's a good point -- or we're not going to beat you in court," Troy says. "Sometimes I ended up hearing their tale and decided that we were wrong."

Troy was slammed by a wide range of detractors, from newspaper editorial writers to Capitol Hill legislators, for what they said were brazen actions benefiting the industries he represented in private practice. …xxx cut ..xxx