FDA's counsel accused of being too close to drug industry

Jeanne Lenzer *New York*

Daniel Troy, chief counsel to the US Food and Drug Administration, is under fire for inviting drug companies to inform him of lawsuits against them so the FDA could help in their defence. "We can't afford to get involved in every case—we have to pick our shots," he said, advising them therefore to "make it sound like a Hollywood pitch."

Congressman Maurice Hinchey of New York charges Mr Troy with a "pattern of collusion" with drug and medical device manufacturers. Mr Hinchey told the *BMJ* that the FDA had "corrupted its mission to protect the public health" and that Mr Troy "is aggressively intervening against the public on behalf of drug companies and medical device manufacturers."

Mr Troy's supporters insist that it has been necessary for him to involve himself in court cases to protect the interests of the FDA. The agency says that court plaintiffs are intruding more heavily on the FDA's primary jurisdiction than ever before and it wants to ensure that it maintains its right to determine the labelling requirements for drugs and medical devices.

Mr Troy is one of over 100 industry advocates who have become regulators under President George W Bush's administration. Although recent counsels for the FDA were civil servants, President Bush made a political appointment by naming Mr Troy as chief counsel on 21 August 2001. President Bush has received substantial funding from drug companies (19 June, p 1458).

Before coming to the FDA, Mr Troy was with the law firm Wiley Rein & Fielding in Washington, DC, where he advanced the interests of drug and tobacco companies against the FDA. In 1993, he was successful in a suit that forced the FDA to relax its rules prohibiting drug companies from promoting off-label prescribing.

Since coming to the FDA, Mr Troy has filed briefs defending four companies, including Pfizer, SmithKline Beecham Consumer Products, and GlaxoSmithKline, arguing the side of the defendant corporation against people who were suing for damages after using that corporation's product.

Pfizer had been one of Mr Troy's clients, and Mr Hinchey charges that Mr Troy hid and minimised his ties to Pfizer by failing to report to Congress that he had been paid $358 000 (£192 000; €290 000) by Pfizer in 2001—the same year he was appointed to the FDA. Mr Hinchey said that Mr Troy then minimised his role, saying he only worked some 80 hours for Pfizer annually. "That's $4475 per hour," said Mr Hinchey, who said that Mr Troy was either very well paid or obfuscating his involvement with the company.

Mr Troy and the FDA have declined to respond to media inquiries, but the acting commissioner of the FDA, Lester Crawford, issued a news release saying that Mr Troy is a "talented public servant who has provided excellent legal advice to FDA since his appointment."

An FDA official told the *BMJ* that the reason for Mr Troy's interest on behalf of drug and medical device manufacturers is justified because of the right to "pre-emption" in which federal law pre-empts local and state laws. "FDA [must have] primacy over the package insert. The package insert is the primary way the FDA informs doctors about what is safe and effective." She added: "If you over-warn, you scare people away; if you under-warn, you expose people to risk."

Five former chief counsels to the FDA signed a letter to Congress in support of Mr Troy and pre-emption, saying that if "every state judge and jury could fashion their own labeling requirements for drugs and medical devices, there would be regulatory chaos for those two industries that are so vital to the public health."

But Mr Hinchey disagrees, saying that drug companies "compile the data given to the FDA, and sometimes, when adverse consequences happen, they keep that information to themselves." That, says Mr Hinchey, makes it necessary to protect the right of injured citizens to seek compensation for their care.

Dr Sidney Wolfe of Public Citizen told the *BMJ* that the FDA now views industry, instead of just the public, as its client—a problem, he says, that is exacerbated by political appointments and by the Prescription Drug User Fee Act, which uses industry fees to pay for the review of their products.

JIM McKNIGHT/PA

Maurice Hinchey (above) accused Daniel Troy of collusion

Mr Hinchey introduced an amendment to take $500 000 away from Mr Troy's office and add it to the Drug Evaluation Research budget to counteract false and misleading advertising. The US House passed the amendment unanimously.

A spokesman for the FDA said that it was not the FDA that filed briefs that have been described as defending Pfizer; it was the Department of Justice that did. Moreover, the briefs defended the government's own interests, not Pfizer.

In addition, the payment of $358 000 by Pfizer was not to Mr Troy himself but to his firm. □

Drug companies frame rules to work with NHS

Madeleine Brettingham *London*

The NHS needs to overcome reservations to work in greater partnership with drug companies, a document launched by the Association of the British Pharmaceutical Industry (ABPI) last week says. The guidelines aim to provide a framework for future joint working initiatives between drug companies and primary care organisations.

The Framework for Joint Working is the result of a collaboration between ABPI and the NHS Alliance, which represents primary care trusts. Several hundred senior staff at primary care organisations across the United Kingdom were interviewed, and the findings paint a complex picture of the current state of relations between the industry and the NHS.

"Some PCOs [primary care organisations] are very sceptical about the role and motives of the pharmaceutical industry," admits Kevin Jones, managing director of Wyeth Pharmaceuticals and chair of the working group responsible for the document. "Some PCOs have strong positive experiences of working with the industry, but some have not. Through talking to staff we have been able to understand their reservations and concerns more deeply and to spread examples of best practice."

The document cites the government's NHS Plan of 2000, which argued for greater collaboration with the private sector, and includes a written endorsement by the primary care tsar, Dr David Colin-Thome.

"Some people do have philosophical problems with the idea of joint working," says Mr Michael Sobanja, chief executive of the NHS Alliance. But he argues that the key to effective cooperation between the public and private sector lies in well managed projects with clear aims. "Often people simply do not know the best way to go about joint working. It has had a chequered history because in the past both parties have entered into initiatives without a clear idea of what they wanted to get out of them."

In particular, the ABPI document argues that the industry's expertise and resources can enhance education and training, and provide support in prescribing and conducting medication reviews. □

The framework is accessible at www.abpi.org.uk