

MAURICE D. HINCHEY
22ND DISTRICT, NEW YORK

COMMITTEE ON APPROPRIATIONS

SUBCOMMITTEES:
AGRICULTURE, RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION,
AND RELATED AGENCIES
INTERIOR

Congress of the United States
House of Representatives
Washington, DC 20515-3222

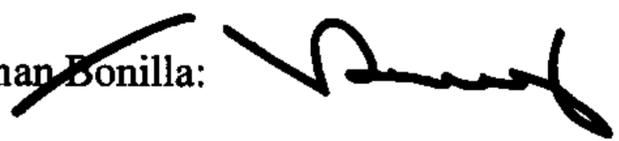
WASHINGTON OFFICE:
2431 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3222
(202) 225-6335

www.house.gov/hincey

August 5, 2004

The Honorable Henry Bonilla
Chairman
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Appropriations Committee
House of Representatives
Room 2362A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Bonilla:


On July 15, 2004 five former Food and Drug Administration chief counsels sent you a letter¹ regarding an amendment I offered to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2005. My amendment cut \$500,000 from the office of the FDA's Chief Counsel and added \$500,000 to FDA's Division of Drug Marketing, Advertising, and Communications.

The letter seeks to rebut my argument that unsolicited FDA involvement in certain private, state-law tort suits on behalf of corporations represents a "radical new direction."

I have great respect for the former chief counsels and for their years of public service. Their letter, however, mischaracterizes my floor statement and contains numerous factual errors, which combine to undermine their basic argument against my amendment.

Mischaracterization

According to the letter, I stated "that Mr. Troy 'has taken the agency in a radical new direction' by submitting amicus curiae briefs in cases in which courts have been asked to require labeling for pharmaceutical products that conflicts with FDA decisions about appropriate labeling for those products." That is not what I argued. As my floor statement clearly indicates, the phrase "radical new direction" refers to Mr. Troy's practice of soliciting lawyers for drug companies and medical device companies to come to him with cases in which to intervene; and submitting briefs in private civil cases in which FDA has not been asked for its opinion.

Legal experts agree with me on this point. Law professor James O'Reilly, a former medical device industry lawyer recognized by the U.S. Supreme Court as an expert on FDA and

¹ See letter dated July 15, 2004 from Peter Barton Hutt, Richard A. Merrill, Richard M. Cooper, Nancy L. Buc, and Thomas Scarlett.

BINGHAMTON OFFICE:
100A FEDERAL BUILDING
BINGHAMTON, NY 13901
(607) 773-2768

ITHACA OFFICE:
123 SOUTH CAYUGA STREET
SUITE 201
ITHACA, NY 14850
(607) 273-1388

KINGSTON OFFICE:
291 WALL STREET
KINGSTON, NY 12401
(845) 331-4466

MIDDLETOWN OFFICE:
CITY HALL, THIRD FLOOR
16 JAMES STREET
MIDDLETOWN, NY 10940
(845) 344-3211

MONTICELLO OFFICE:
18 ANAWANA LAKE ROAD
MONTICELLO, NY 12701
(845) 791-7116

preemption, has stated Mr. Troy's "solicitation of private lawsuit defendants for cases, into which the federal agency could intervene, is unprecedented in [my] thirty years of administrative law teaching, writing and practice with FDA and other administrative bodies."²

Factual Errors

The letter cites four cases as "ample precedent" for FDA's unsolicited involvement in private, state-law tort suits on behalf of corporations. It states, "In none of these cases did any court request FDA's opinion." These assertions are simply not true.

- In Bernhardt v. Pfizer, Inc., 2000 U.S. Dist. Lexis 16963 (November 16, 2000), the court *requested* that FDA file a brief. This is clearly indicated in the court's ruling. It is surprising that the letter claimed otherwise.
- In Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973), FDA was the defendant. It goes without saying that that FDA participated without being asked by the court to do so. The cases I cited were ones in which FDA was an intervener, not a defendant.
- In Eli Lilly & Co. v. Marshall, 850 S.W. 2d 164 (Texas 1993), there is no mention of any FDA involvement in the case in the court's ruling.
- Jones v. Rath Packing Co., 425 U.S. 933 (1977) was not a private tort suit between an injured party and a corporate entity. It was a dispute between a county agency in California and a private party concerning labeling requirements for flour. FDA's involvement was not at the district court or appellate level, but only at the U.S. Supreme Court, as an amicus. This hardly stands as a precedent for FDA's participation at the lower federal and state court levels.

Previous FDA Preemption Policy

In addition to the FDA's new policy of soliciting cases, the substance of FDA's legal arguments concerning prescription drug and medical device preemption is also a radical departure from past policies. To begin with, there is no statutory authority to preempt state tort claims with respect to prescription drugs. Furthermore, Judge Mariana Pfaelzer pointed out, in one of the prescription drug cases in which FDA filed an unsolicited brief, that FDA provided "no case holding that the FDCA (Food, Drug, and Cosmetic Act) preempts state law either expressly or impliedly. If anything FDA's ... arguments run contrary to the grain of other decisions."³ Judge Pfaelzer went on to say that "FDA's ... position vitiates, rather than advances, the FDCA's purpose of protecting the public health," and "contravenes common sense."⁴

² O'Reilly, James; Amicus Curiae Brief filed in Murphree v. Pacesetter Inc., Civil No. CT-005429, (Tenn. Cir. Ct., 13th Judicial District, Memphis).

³ In re Paxil, United States District Court, C.D. California, Case No. CV 01-07937 MRP, October 18, 2002.

⁴ *Ibid.*

With respect to medical devices, in 1997, then FDA Chief Counsel Margaret Jane Porter wrote, "Since the passage of the Medical Device Amendments of 1976 (MDA), it has been the agency's position that the scope of preemption under section 521 should be interpreted narrowly, with a presumption against preemption. This is true particularly when the effect of preemption would be to override a state scheme offering greater consumer protection than that currently afforded under the FDCA."⁵

The consequences of this new policy are alarming. As Ms. Porter points out, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."⁶ By attempting to shut down private suits against manufacturers of FDA-approved products, FDA is removing an important layer of consumer protection: the courts. This is a position that even the most ardent advocates of tort reform have stopped short of. The end result of FDA's efforts would be blanket immunity for companies with FDA-approved products, even if that product causes death. This is a completely new policy.

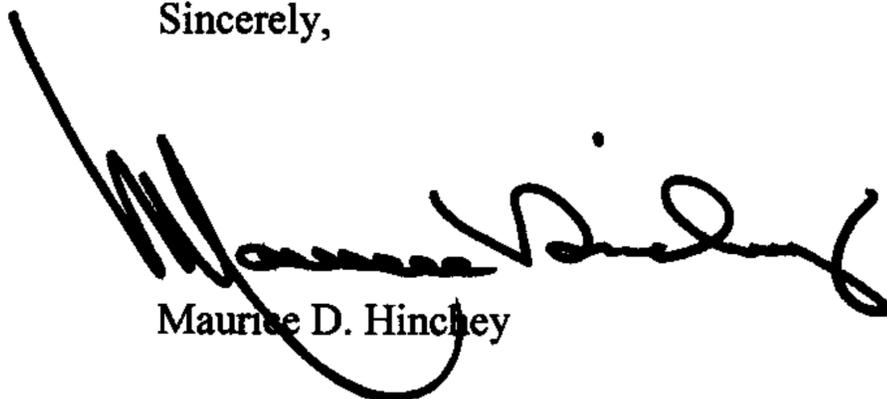
I hope you will take this information into account as you consider the letter sent by the former FDA chief counsels. I am at a loss to explain why their letter contains so many errors.

As you know, this is a matter I have been following for some time. My most recent efforts resulted from the misleading answers I received in response to questions I asked during the FY 2005 FDA budget hearing. It is clear to me that FDA has not been fully forthcoming in this matter. I have requested additional materials concerning this matter from the agency but, to date, have not received any response.

I look forward to working with you as this bill moves to conference. If you have any questions please do not hesitate to contact me, or Mike Iger of my staff, at 5-6335.

Best regards.

Sincerely,



Maurice D. Hinchey

MDH:mi

⁵ Porter, Margaret Jane; "The Lohr Decision: FDA Perspective and Position," *Food and Drug Law Journal*, Vol. 52 (1997).

⁶ *Id.*