

MAURICE D. HINCHEY
22ND DISTRICT, NEW YORK

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FOOD AND DRUG ADMINISTRATION,
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INTERIOR

Congress of the United States
House of Representatives
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July 21, 2004

Dr. Lester Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Crawford:

As you know, I am looking into the activities of Daniel E. Troy, Chief Counsel of the Food and Drug Administration. The information I have uncovered is very troubling in that it displays a radical departure from FDA's previous policies and practices. Mr. Troy's actions raise serious questions of ethics and conflicts of interest, suggesting collaboration between a federal agency and parties to private lawsuits. These actions and the circumstances surrounding them have been misrepresented to Congress. Most troubling, they undermine FDA's fundamental mission: the protection of the public's health.

FDA's responses to inquiries on this matter continue to raise more questions. Therefore I request that you provide the following items to my office:

1. All documents, briefs, memoranda, letters, phone logs, emails and meeting materials related to FDA's involvement in Murphree v. Pacesetter (Civil No. CT-005429), Motus v. Pfizer (358 F. 3d 659), Dowhal v. SmithKline Beecham Consumer Healthcare (No. S109306), and In re Paxil (2002 U.S. Dist. LEXIS 16221);
2. A list of cases in which FDA, through the Department of Justice, filed briefs or Statements of Interest to support the argument of any company regulated by the FDA that claims brought against such a company in litigation are expressly or impliedly preempted;
3. A list of all litigation to which FDA has been a party since August 20, 2001;
4. A list of all Mr. Troy's official speaking engagements since his date of appointment - the list contained on FDA's public calendar website is incomplete - and a copy of Mr. Troy's December 15, 2003 speech at the 8th Annual Conference for In-House Counsel and Trial Attorneys: "Drug and Medical Device Litigation;"

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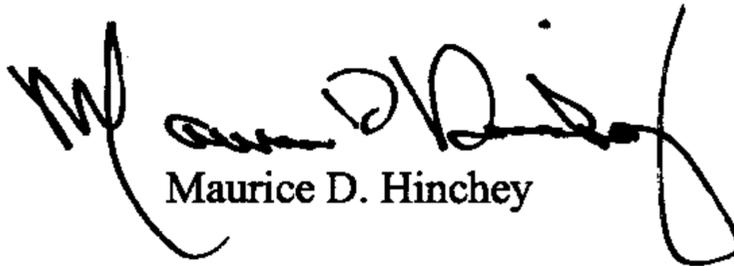
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5. The ethics reviews FDA referred to in response to my question concerning the "specific details" of Mr. Troy's relationship with Pfizer;¹
6. The exact date of the July 2002 phone call from Mr. Malcolm Wheeler of Wheeler, Trigg, Kennedy, LLP to Mr. Troy regarding Motus v. Pfizer;²
7. All communications concerning Motus v. Pfizer between Mr. Troy's office and the law firm of Wheeler, Trigg, Kennedy;
8. All notes, meeting materials, messages, emails and documents relating to Mr. Troy's July 18, 2002 meeting with Michele Corash of Morrison and Foerster regarding "Prop 65 issues;"³
9. All communications concerning Dowhal v. SmithKline Beecham Consumer Healthcare between Mr. Troy's office and the law firm of Morrison and Foerster;
10. All communications concerning Murphree v. Pacesetter between Mr. Troy's office and the law firm of Feldman, Gale & Webber, P.A.

The House Appropriations Committee has expressed concern about FDA's responses to questions on this matter and its intention to look further into this matter.⁴ Additionally the House of Representatives, on a bipartisan basis, recently passed an amendment that cut funds from your office⁵. I offered this amendment to express my concern with Mr. Troy's activities. Given these rebukes, it is critical that you fully cooperate with congressional efforts to seek more information about the actions of Mr. Troy. Please provide this information no later than July 30, 2004.

Sincerely,



Maurice D. Hinchey

¹ See page 89 of Part 3 of Hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, One Hundred Eight Congress, Second Session, on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2005.

² See "FDA Counsel's Rise Embodies US Shift," *Boston Globe*, December 22, 2002.

³ See FDA Public Calendar <http://www.fda.gov/bbs/topics/calendar/2002/calendar184.html>

⁴ See "Concerns about FDA Response" page 89 of House Report 108-584.

⁵ See adoption of Amendment (A018) offered by Mr. Hinchey to H.R. 4766, Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for the fiscal year ending September 30, 2005, and for other purposes, page H5599 Congressional Record Vol. 150, No. 96.