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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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June 3, 2004

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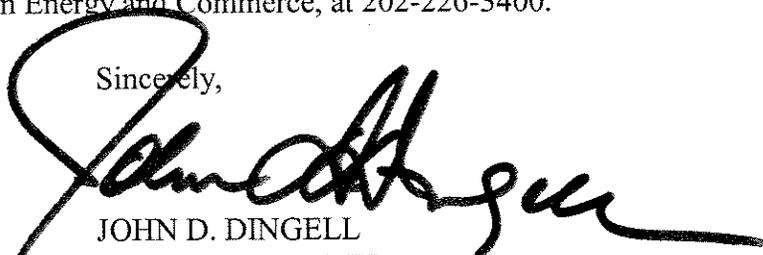
Dear Mr. Swindell:

On May 18, 2004, you testified before the Subcommittee on Oversight and Investigations in a hearing entitled "NIH Ethics Concerns: Consulting Arrangements and Outside Awards." We now ask for your help on several additional questions (attached).

Because we wish to include the questions and responses in the printed record of this hearing, please respond no later than Friday, June 18, 2004. Please fax and e-mail the response. The faxed response should be directed to Billy Harvard, Committee on Energy and Commerce, Majority staff, at 202-226-2447, and Voncille Hines, Committee on Energy and Commerce, Minority staff, at 202-225-5288. The e-mail copy of the response should be directed to (Billy.Harvard@mail.house.gov) and Voncille Hines (Voncille.Hines@mail.house.gov). Due to the uncertainties of postal deliveries on Capitol Hill, we ask that your response not be sent through the postal service.

If you have any questions, please have your staff contact David Nelson, Minority Investigator/Economist, Committee on Energy and Commerce, at 202-226-3400.

Sincerely,


JOHN D. DINGELL
RANKING MEMBER

Attachment

Mr. Edgar M. Swindell
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cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

**Questions for Mr. Edgar M. Swindell, Associate General Counsel
Department of Health and Human Services
from the Honorable John D. Dingell
regarding the May 18, 2004, hearing entitled
“NIH Ethics Concerns: Consulting Arrangements and Outside Awards”**

1. As you are no doubt aware, 5 C.F.R. 5501 contains supplemental restrictions on Food and Drug Administration (FDA) employees. Could you explain the additional restrictions on outside activities and financial interest applicable to FDA employees’ dealings with firms regulated or likely to be regulated by that Agency (e.g., start up biopharmaceutical firms)?
2. If an FDA ethics official approved an activity, such as a paid speech that included travel expenses, to address a drug or biotech or medical device firm’s “scientific conference,” as an “outside activity,” would that official be approving a violative activity?

Would any consulting arrangement between a regulated firm and an FDA employee for professional services be violative on its face?

What is the legal liability, including criminal liability, for FDA employees who violate these restrictions?

What is the legal liability, including criminal liability, of firms that pay the funds?

What sanctions might apply to ethics officials who approve such activities, when it is clear that payments from that entity are violative?

3. Do you agree with Dr. Zerhouni, who testified on Wednesday, May 12, 2004, that the agency’s conflict of interest policies have “failed”?

If you agree with Dr. Zerhouni, please expand upon what policies have proven ineffective and how they might be rectified.

If you disagree with Dr. Zerhouni, please explain why you think the agency’s conflict of interest policies have not “failed.”