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ED WHITFIELD, KENTUCKY
CHARLIE NORWOOD, GEORGIA
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BUD ALBRIGHT, STAFF DIRECTOR

ONE HUNDRED EIGHTH CONGRESS

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

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CHAIRMAN

June 4, 2004

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The Honorable Elias Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

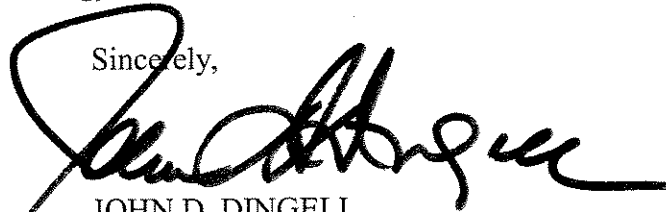
Dear Dr. Zerhouni:

On May 12, 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 Will Carty, 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 (Will.Carty@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

The Honorable Elias Zerhouni, M.D.
Page 2

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 Deusch, Ranking Member
Subcommittee on Oversight and Investigations

**Questions for Dr. Elias Zerhouni, Director
National Institutes of Health (NIH)
from the Honorable John D. Dingell
regarding the May 12, 2004, hearing entitled
“NIH Ethics Concerns: Consulting Arrangements and Outside Awards”**

1. This question relates to some of the more prominent drug and biotech companies that pay NIH employees. I would note that only Abbott Labs and Schering Plough cooperated with Representatives Waxman and Brown, of the ten or so firms asked to provide information. Slide A1 (attached) lists the firms that declined the request to disclose their financial arrangements with the employees that you supervise.

Among the firms that refused to cooperate, there were relatively modest but relatively extensive expenditures for the services of NIH employees, particularly at the National Institute of Mental Health (NIMH). Slide A (attached) gives some information about Pfizer’s dealings with NIH employees. Pfizer makes Zoloft, prescribed for depression, panic and obsessive-compulsive disorders, and at least one other drug for Schizophrenia. It is safe to assume that their research pipeline is full of psychotherapeutic drugs in one stage or another of development. Pfizer has competitors in each of these areas. Why shouldn’t any information available from NIMH be available publicly? Why should companies have to pay NIH researchers to get access to such information?

Another oddity on this slide involves Susan Bates at the National Cancer Institute (NCI). She is apparently being paid to review technology related to drug resistance and give a lecture. Again, a small amount of money, but assuming nothing proprietary is involved, isn’t the dissemination of such information part of her job?

2. This question relates to Slide B (attached) which lists the researchers currently paid by Wyeth Pharmaceuticals. Do you believe that it is possible for Dr. Kitner-Triolo, Dr. Germain, and Dr. Bax to ignore the considerable sums paid to them by Wyeth when determining their research priorities?

Dr. Benjamin Wilfond has a relatively small application pending to provide Wyeth with “advice regarding clinical research consent forms.” Wyeth may need help in this area, but why should they have to pay an NIH employee to deliver it?

3. Slide C (attached) relates to payments made by AstraZeneca. In addition to providing cash and expenses as compensation to Dr. Thomas Chase, Chief of the Experimental Therapeutics Branch of the National Institute of Neurological Disorders and Stroke (NINDS), this company has apparently also paid Dr. Chase with shares of publicly-traded stock for his consulting services. Dr. Chase provides no other details about his outside activities other than “consulting services” and does not disclose the amount of stock he has received, nor its value. Do you approve of this situation? What is the public to make of the potential for conflict of interest in this case? Will the outside consulting activities of branch chiefs be public under your proposal?

4. The new NIH Ethics Advisory Committee (NEAC) in the Office of the Director was apparently created to review those applications for proposed activities with outside organizations that pose the greatest potential for conflict of interest.
 - (A) How often does the Committee meet?
 - (B) Do NEAC members work on outside activity requests individually, or do they jointly reach a consensus on every single outside activity approval or declination?
 - (C) Do NEAC members pursue their own individual research on outside activity requests or do they rely solely on the information provided to them on the application form submitted by the NIH employees and Ethics Officers?
 - (D) What standards will the NEAC use to determine what constitutes a conflict of interest?

5. You have been quoted as saying that NIH outside activity or consulting approval process “focuses on the nature of the activity and the identity of the outside organization.”
 - (A) In our investigation of numerous outside activity requests, we have focused on the so-called “nature of the activity” that NIH employees are participating in. In reviewing many applications, the forms simply list “consulting” as the description of the activity in which the NIH employee wishes to participate. There is no further description about the type of consulting they will be doing. Do you believe that simply listing “consulting” as the description for an outside activity is sufficient to determine the “focus on the nature of the activity” in which NIH employees are engaging?
 - (B) Do you believe that NIH Ethics Officers can make an informed decision as to whether an activity should be approved or not using this very brief and non-descriptive account of the activity which the employee wishes to undertake?
 - (C) Additionally, in reviewing these outside activity requests, we have repeatedly found possible conflicts of interests due to subsidiary companies, companies with overlapping interests, or companies with competing interests. These potential conflicts have gone largely unnoticed by NIH staff because Ethics Officers apparently do not conduct any additional research into the “identities of the outside organization,” aside from the possibility of an initial and superficial background check. Have there been any discussions about requiring companies to submit more detailed information about their relationships with other companies? If not, why not?

6. When you charged the Blue Ribbon Panel with review of existing NIH laws, regulations, policies, and procedures regarding actual and potential financial conflicts of interest, did you recommend that the Panel examine individual NIH employee cases? Did you recommend that the Panel not examine individual employee cases? Please explain your reasoning.

If you did not make such a recommendation either way, do you now believe it would have been beneficial to examine in greater detail how individual NIH employees operated under the current ethics guidelines and restrictions before proposing new recommendations about how NIH should proceed?

7. You say that you will seek to prohibit NIH senior management and NIH extramural employees, who are responsible for program funding decisions and recommendations, from consulting with pharmaceutical or biotechnology companies or from paid consulting for academia.

Since you are seeking to prohibit these practices in the future, do you believe that these practices have posed a conflict of interest in the past?

8. Under "Principle Four" in your testimony, you stated that you are seeking to limit the amount of time that NIH employees spend on consulting.

Do you believe that NIH employees currently spend more than 400 hours a year working on outside consulting activities?

Do you believe that the Blue Ribbon Panel's recommendation to allow up to 400 hours per year in outside consulting activities -- the equivalent of an additional eight-hour workday per week for an entire year -- would actually represent a decrease in the amount of time that NIH employees currently spend on consulting?

SLIDE A1

COMPANIES WHO DECLINED TO PROVIDE INFO IN RESPONSE TO WAXMAN-BROWN LETTER

1. Allergan, Inc.
2. Bristol-Myers Squibb Company
3. Eli Lilly and Company
4. Pfizer Inc.
5. Wyeth Pharmaceuticals
6. Merck & Co. Inc.
7. Johnson & Johnson
8. Amgen

SLIDE A

Pfizer Inc.

- Pfizer Inc develops, manufactures, and markets leading prescription medicines for humans and animals and many consumer brands. The company has three business segments: health care, animal health and consumer health care.
- 1) Adriaan Bax – NIDDK: Senior Investigator – 11/1/2003 - 11/1/2004
 - \$2,000 Fee
- 2) H. Bryan Brewer: NHLBI: Chief, Molecular Disease Branch – 6/29/2002 - 6/28/2006
 - 2001: \$19,000 Fee; \$,2600 Travel
 - 2002: \$16,500 Fee; \$3,400 Travel
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 - Future: \$18,000/year Fee; \$4,000/year Travel
 - “Member: Consulting with Renumeration”
- 3) Wayne Drevets – NIMH: Chief, Neuroimaging in Mood & Anxiety Disorders – 3/28/04 - 3/29/04
 - \$350 Fee plus in-kind expenses (airfare, hotel, meals)
 - Participate in Ziprasidone advisory board meeting (one day)
- 4) Hussein Manji – NIMH: Chief, Lab. of Molecular Pathophysiology – 3/23/2004 - 3/24/2004
 - \$2,000 Fee
- 5) Judith Rapoport – NIMH: Chief, Child Psychiatry Branch – 10/6/2003 - 12/31/2006
 - No consulting assignments to date; Fee is rated at \$450/hr., not to exceed \$3,000.
 - “Consultant: Advise on planning studies for childhood onset conditions; advising on selections of diagnostic and behavioral rating instruments; reviewing preliminary data.”
- 6) Susan Bates – NCI: Lead Clinical Investigator – 3/1/2004 - 2/28/2005
 - \$2,000 honorarium; \$1,429 Expenses
 - “Review a technology related to drug resistance in cancer and to give lecture.”

SLIDE B

Wyeth Pharmaceuticals

- Wyeth has a long history in pharmaceuticals and biotechnology, with products in the areas of women's health care, neuroscience, musculoskeletal disorders, cardiovascular therapy, vaccines and infectious disease, hemophilia, immunology, and oncology. Wyeth is also a leader in the development of nutritionals.
- 1) Melissa Kitner-Triolo – NIA: Research Psychologist – 11/30/2001 - 12/31/2004
 - \$119,322.74 Fee; \$3,297.74 Travel Expenses
 - “Consultant”
 - 2) Ronald Germain – NIAID: Deputy Chief, Lymphoma Bio Section – 1/15/1995 - 11/11/2011
 - Past: \$112,500 Fee; \$4,160 Travel
 - Future: \$25,000/year (contract renewed yearly)
 - “Consultant”
 - 3) Adriaan Bax – NIDDK: Senior Investigator – 10/01/1995 – Cont.
 - 1995 - 2003: \$3,000 Fee Each Year; \$400 Travel Each Year
 - Total Paid Between 1995 – 2003: \$27,000 Fee; \$3,600 Travel
 - 4) Benjamin Wilfond – NHGRI: Staff Clinician – 2002 - 2004 (Awaiting Approval)
 - 2002: \$5,000 Fee
 - 2003: \$2,500 Fee
 - “Provides advice regarding clinical research consent forms.”

SLIDE C

AstraZeneca

- AstraZeneca concentrates on specific areas of medical need - cancer, cardiovascular, central nervous system, gastrointestinal, infection, pain control, and respiratory and inflammation.
- 1) H. Bryan Brewer – NHLBI: Chief, Molecular Disease Branch – 3/14/2002 - 11/11/2011
 - 2001: \$6,000 Fee; \$1,000 Travel
 - 2002: \$10,000 Fee; \$3,000 Travel
 - 2003: \$15,000 Fee; \$2,975 Travel
 - Future: \$8,000/year Fee; \$3,000/year Travel
 - “Member: Service on Advisory Board Committee with remuneration.”
- 2) Neal Young – NHLBI: Chief, Hematology Branch – 9/25/2003 – 11/11/2011
 - \$1,000 Fee/year (final fee not negotiated yet; activity 2-3 hours annually)
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- 3) Thomas N. Chase – NINDS: Chief, Experimental Therapeutics Branch – 5/1/1996 -1/31/2005
 - \$28,000/5 years
 - Stocks: 1999-2003: \$4,000/year in consulting fees
 - “Consulting Services”
- 4) James L. Gulley – NCI: Staff Clinician – 9/23/2002 - 9/30/2010
 - \$1,500/per year; \$3,000 to date
 - “Case discussions, education regarding cancer related topics to health practitioners/support groups.”

SLIDE D

Procter & Gamble

- Pharmaceutical company.
- 1) Pal Pacher – NIAAA: Research Fellow – 1/2/2003 – indefinite
 - 2003: \$7,144
 - 2004: Less than \$10,000
 - “Pharmaceuticals work and Loop model development, data acquisition and analysis consultation and training.”
- 2) Vincent J. Hearing, Jr. – NCI: Research Biologist – 1/1/2003 - 9/30/2004
 - \$2,000 Fee; \$600 Expenses
 - “Lecture and critique research program.”
- 3) Stuart H. Yuspa – NCI: Senior Investigator – 2/1/2002 – ongoing
 - 2002: \$2,830
 - \$2,000/day, not to exceed \$8,000/year
 - “Consulting regarding hair growth control.”

SLIDE E

Abbott Laboratories

- Abbott Laboratories focus on advancing medical science and the practice of health care with expertise in the therapeutic areas of diabetes, pain management, respiratory infections, HIV/AIDS, men and women's health, pediatrics, and animal health.
- 1) Deborah Ader – NIAMS: Program Director, Behavioral and Prevention Research – 9/15/2003 - 12/15/2005
 - \$13,000 Fee; \$3,000 Travel
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- 2) Dennis Charney – NIMH: Chief, Mood and Anxiety Disorders Research Program – 1/2004 – ongoing
 - No fees or expenses received to date.
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- 3) Henry F. McFarland – NINDS: Clinical Director and Chief, Neuroimmunology Branch – 12/10/2002 - 11/19/2005
 - \$250/hour, not to exceed \$20,000 – nothing received to date.
 - “Consulting services.”

SLIDE F

Genecor Intl.

- Genecor International, Inc. is a diversified biotechnology company. Genecor focuses on two markets: bioproducts and health care. For the bioproducts market, Genecor discovers, develops and sells biocatalysts and other biochemicals for the industrial, consumer and agri-processing markets. For the health care market, Genecor has drug development programs in protein therapeutics and immunotherapeutics targeting viral infectious diseases and cancer.
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 - 2) Jonathan Yewdell – NIAID: Section Chief – 4/19/2002 - 11/11/2011
 - Past: \$15,000 Fee; \$3,000 Travel
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Ortho Biotech

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- 1) Luigi Ferrucci – NIA: Chief, Longitudinal Studies Section – 12/6/2002
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