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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 4, 2004

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BUD ALBRIGHT, STAFF DIRECTOR

Dr. Raymond S. Kington  
Deputy Director  
National Institutes of Health  
One Center Drive  
Building 1 - Shannon Building  
Bethesda, Maryland 20814

Dear Dr. Kington:

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](mailto:Billy.Harvard@mail.house.gov)) and Voncille Hines ([Voncille.Hines@mail.house.gov](mailto: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

Dr. Raymond S. Kington

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 Deutch, Ranking Member  
Subcommittee on Oversight and Investigations

The Honorable Ralph M. Hall, Chairman  
Committee on Energy and Air Quality

The Honorable Rick Boucher, Ranking Member  
Subcommittee on Energy and Air Quality

**Questions for Dr. Raynard S. Kington, Deputy Director  
National Institutes of Health (NIH)  
from the Honorable John D. Dingell  
regarding the May 18, 2004, hearing entitled  
“NIH Ethics Concerns: Consulting Arrangements and Outside Awards”**

1. According to the Director of the NIH, Dr. Zerhouni, who testified before the Subcommittee on Health on May 12, 2004, the NIH Ethics Advisory Committee (NEAC) has reviewed every current pharmaceutical or biotechnology consulting agreement involving NIH employees, to ensure that no real or apparent conflict of interest existed. Assuming this is accurate, and every current pharmaceutical or biotechnology consulting agreement has been re-reviewed and approved by the NEAC, please answer the following questions regarding current consulting arrangements between NIH employees and drug and biotech firms.
  - (A) **Slide 1** (attached) shows that Michael Brownstein, Chief of National Institute of Mental Health (NIMH) genetic lab, has received almost \$2 million from four biotech firms. In each case, he serves either as a member of the Board, or on the Scientific Advisory Board, or both. In Dr. Zerhouni’s testimony, he said, “board positions in private entities, I don’t think that should happen for anybody. I mean, we’re prohibiting that for everybody.” Has this prohibition taken effect yet? And if not, when can we expect this ban to be implemented?
  - (B) How can the NEAC know, and how can the public be assured, that nothing Dr. Brownstein knows from his work at NIH, nothing he learns about the projects of competitors of these firms from his work at NIH, or any subject involving his work at NIH will not be brought up at these meetings?
  - (C) Dr. Brownstein has received more than \$1.7 million in the stock of a single company – Neurocrine Biosciences. How can you be sure that his interest in the value of that stock will never conflict with his duty to the public?
2. **Slide 2** (attached) shows that Ronald Germain, Deputy Chief of Lymphoma Bio Section of National Institute of Allergy and Infectious Diseases (NIAID), is receiving \$430,535, as well as stock of an unspecified value, from seven different companies. Apparently all he has stated on his ethics forms is that he is a “consultant” to these firms. How can you be sure he even has the time to do his work and manage his section?

Do you believe that these firms hired Dr. Germain to consult on work that is totally unrelated to his tasks at NIAID? Does the NEAC believe that no real or apparent conflict of interest exists when an NIH Deputy Chief receives almost half a million dollars, as well as stock, to consult with biotechnology companies?

3. (A) **Slide 4** (attached) shows Dr. Elizabeth Nabel receiving \$326,728, as well as stock, from a single firm, Boston Scientific, a large medical device firm. Although Boston Scientific is publicly traded, there is no information about the value of the

stock she has or will receive. Please provide the value of the stock and the terms of its transfer to Dr. Nabel.

- (B) Boston Scientific also makes stents, among other products. Should the chief of the Vascular Biology Section be that closely tied to a single firm that develops and sells products dealing with the circulatory system?
- (C) Dr. Nabel is also Scientific Director for Clinical Research. Do you and the NEAC believe that she has not, and never will, make a decision about that research that would affect Boston Scientific or its competitors?
4. **Slide 8** (attached) shows that Dr. H. Bryan Brewer, Chief of the Molecular Disease Branch of the National Heart Lung and Blood Institute, has five ongoing contracts with major drug companies to either “consult” or serve on their Advisory Boards. He is receiving almost \$200,000, as well as stock. Because these arrangements are not publicly disclosed, it is at least possible that these companies do not realize that he is in an arrangement with their competitors. Each of these firms is a major multinational drug company and all are likely developing new heart drugs. How can the NEAC be sure that Dr. Brewer is keeping his work at NIH, including non-public information learned in his duties as a branch chief, separate from the work he does for these five companies?
5. **Slide 10** (attached) illustrates another potential problem. Kenneth Korach, Chief of the Reproductive and Developmental Toxicity Lab, consults with only one firm, Schering AG, but on the subject of estrogens, a critical topic in his field. Based upon articles in the Los Angeles Times we have learned that the German firm Schering AG has a U.S. subsidiary, Burlex.
- Why should other firms that compete with Schering AG or its subsidiary be unable to get access to Dr. Korach for his expertise on estrogens without paying him?
6. **Slide 12** (attached) shows Richard Rothman, Chief of Clinical Psychopharmacology Section at the National Institute on Drug Abuse (NIDA), selling consulting services to four companies that probably all have an interest in psychotherapeutic drugs. How does the NIH’s Ethics Advisory Committee ensure that this does not pose a real or perceived conflict?
7. **Slide 13** (attached) displays how the National Institute on Aging (NIA) Chief of the Developmental Genomics and Aging Section was collecting thousands of dollars to give advice on genomics and developmental biology for a pharmaceutical company’s drug target discovery program. How could this outside consulting agreement have been approved and how could the NEAC realistically determine that an NIH Chief of Genomics consulting on a pharmaceutical company’s genomics program did not, at the very least, raise the appearance of a conflict of interest?

Furthermore, **Slide 14** (attached) shows the NIA Stem Cells Section Chief accepting thousands of dollars, as well as stock, to consult on cell replacement therapy and to consult on a biotechnology company’s stem cell research program. Please explain how

an NIH Stem Cells Section Chief's acceptance of money and stock to consult on a biotech firm's stem cell research program is not a conflict of interest.

9. There are a number of cases that have allegedly been approved by the NEAC involving either positions on Advisory Boards or positions on the Board of Directors for pharmaceutical and biotechnology firms.

For instance, **Slide 3** (attached) shows William Paul, Laboratory Chief at NIAID, collecting \$426,400 for serving as a member on two pharmaceutical Advisory Boards – for Suntory Pharmaceuticals and for Novartis Pharma AG.

Another example would be **Slide 5** (attached) that shows how Gary Nabel, Director at NIAID, collected tens of thousands of dollars to serve as a member on both a pharmaceutical and a biotechnology Advisory Board – for Celltech R&D and Trivium Capital Management.

In order to serve on either a pharmaceutical and biotechnology firm Advisory Board or Board of Directors, the members would have to sign a letter of confidentiality stating that they would not divulge information regarding what takes place in those meetings, when in fact the full range of a company's activities can, and are, discussed in these meetings.

Why are NIH employees working on federal matters of importance to these firms allowed to serve in these private positions? And even if NIH employees could somehow separate their work from what happens in these meetings, how could you ever implement oversight to assure the public that there is no conflict of interest?

# SLIDE 1

## **Michael Brownstein**

**NIMH – Chief, Lab of Genetics**

- N-Gen Research Laboratories (Biotech) – Member of Board of Directors and Scientific Advisory Board – 9/1/1998 - ongoing
  - Between 1999-2000: \$3,000; Travel: \$400
  - Stock: \$30,000
- Serenix (Biotech) – Scientific Advisory Board Member – 5/1/1997 - ongoing
  - Stock: Owns 7% of company valued at \$100,000
- Neurocrine Biosciences, Inc. (Biotech) – Member of Board of Directors and Scientific Advisory Board Member – 1/1/1992 - ongoing
  - Fee: \$1,500 a day plus expenses – earned \$9,000 in 2003; \$3,000 per year between 1999-2002 + \$3,000 for in-kind tickets, rooms, meals
  - Stock: Approx. 30,000 shares; trading at \$57.64/share -- \$1,729,200 total value
- Thyreos Corporation (Biotech) – Originally Member of Board; Company now dormant and exists only to hold intellectual property – 1/1/1996 - ongoing
  - Invested his own money in company and received equity in return; Owns about 50% of company, valued at approximately \$100,000

**TOTAL MONEY RECEIVED: \$27,400 +**

**STOCK VALUED AT \$1,959,200**

# SLIDE 2

## Ronald Germain

NIAID – Deputy Chief, Lymphoma Bio Section

- Wyeth/Genetics Institute (Biotech) – Consultant – 1/15/1995 - 11/11/2011
  - Fee: \$112,500; Travel: \$4,160
  - Future: \$25,000/year (contract renewed yearly)
- Fish and Neave – Consultant – 3/10/2000 - 11/11/2011
  - Fee: \$57,125
  - Future: \$19,000 - \$36,000
- Perseus LLC – Consultant – 10/30/2000 - 11/11/2011
  - Fee: \$8,000
- Hybridon, Inc. (Biotech) – Consultant – 3/21/2001 - 11/11/2011
  - Fee: \$70,000; Travel: \$500
  - Future: \$24,000/year
- Cell Genesys, Inc. (Biotech) – Consultant – 6/1/2001 - 11/11/2011
  - Fee: \$131,250 + Stock Options; Travel: \$14,900
  - Future: \$25,000 per year + 2,500 Stock Options
- Genecor Intl (Biotech) – Consultant – 4/15/2002 - 11/11/2011
  - Fee: \$22,500; Travel: \$6,600
  - Future: \$7,500/year
- Schroder Ventures Life Sciences – Consultant – 5/9/2003 - 11/11/2011
  - Fee: \$3,000

**TOTAL MONEY RECEIVED: \$430,535 + STOCK OPTIONS**

# SLIDE 3

## **William Paul**

### **NIAID – Laboratory Chief**

- Suntory Pharmaceuticals Res. Lab., LLC (Pharmaceutical) – Member –  
5/1/2000 - 11/11/2011
  - Fee: \$280,000; Travel: \$6,400
  - Future: \$350,000; Travel: \$8,000
- Novartis Pharma AG Science Board (Pharmaceutical) – Member – 2/1/2001 -  
11/11/2011
  - Fee: \$100,000; Travel: \$40,000
  - Future: \$120,000/5 years; Travel/Expenses: \$40,000

**TOTAL MONEY RECEIVED: \$426,400**



# SLIDE 4

## **Elizabeth Nabel**

NHLBI – Scientific Director for Clinical Research;  
Chief, Vascular Biology Section

- Boston Scientific Corp. – Practitioner: Consulting with remuneration –  
9/7/1999 - 11/11/2011
  - 1999: \$23,333 Fee; \$750 Travel expected
  - 2000: \$70,000 Fee
  - 2001: \$70,000 Fee
  - 2002: \$60,000 Fee; \$845 Travel expected
  - 2003: \$50,000 Fee; \$800 Travel expected
  - 2004: Estimated \$50,000 Fee; \$1,000 Travel expected
  - Future: \$50-60,000/year Fee; \$1-4,000/year Travel

**TOTAL MONEY RECEIVED: \$326,728 + STOCK**

# SLIDE 5

## Gary Nabel

NIAID – Director, VRC

- Boston Scientific (Biotech) – Consultant – 8/29/1999 - 11/11/2011
  - Fee: \$275,700; Travel: \$4,000
  - Future: \$50 - 60,000/year; Estimated Travel: \$6,000/year
- Celltech R&D Ltd. (Pharmaceutical) – Member/Consultant – 11/15/2003 - 11/15/2010
  - Fee: \$8,000; Travel: \$11,000
  - Future: \$20,000; Estimated Travel: \$30,000
- Trivium Capital Management (Biotech) – Member – 11/3/2003 – 11/3/2005
  - Fee: \$15,000
  - Future: \$20,000; Estimated Travel: \$2,000

**TOTAL MONEY RECEIVED: \$313,700**

## SLIDE 6

### **Irwin J. Kopin**

**NINDS – Special Volunteer (Scientist Emeritus)**

- National Parkinson Foundation – Member, Medical Advisory Board –  
1/1/1999 - 1/1/2005
  - Fee: \$300/year for 5 years (total: \$1,500)
- Nippon Zoki Pharmaceutical Co., Ltd. (Pharmaceutical) – Consulting  
services – 1/1/2000 - 12/31/2004
  - \$290,000 over 5 years
- Self Employed – Consulting Services – 6/1/2003 - 6/1/2005
  - \$19,000

**TOTAL MONEY RECEIVED: \$310,500**

# SLIDE 7

## Karl Sirotkin

NLM – Staff Scientist

- Avalon Pharmaceuticals (Pharmaceutical) – Consultant – 6/2000 – ongoing
  - 2000: \$24,750 Fee + 6,000 stock options vested
  - 2001: \$76,140.75 Fee + 4,000 shares left to purchase per vesting schedule
  - 2002: \$79,040.50 Fee
  - 2003: \$70,661.40 Fee

**TOTAL MONEY RECEIVED: \$250,592.65 + STOCK**

# SLIDE 8

## H. Bryan Brewer

### NHLBI – Chief, Molecular Disease Branch

- Eli Lilly & Company (Pharmaceutical) – Consulting with remuneration – 3/11/2004 -3/12/2004
  - Fee: \$2,000; Travel: \$500
- Novartis Pharmaceuticals Corporation (Pharmaceutical) – Consulting with remuneration – 11/18/2003 - 11/30/2007
  - 2003: \$2,000 Fee; \$3,000 Travel
  - Future: \$6,000/year Fee; \$2,500/year Travel
- Pfizer (Pharmaceutical) – Member: Consulting with remuneration – 6/29/2002 -6/28/2006
  - 2001: \$19,000 Fee; \$2,600 Travel
  - 2002: \$16,500 Fee; \$3,400 Travel
  - 2003: \$20,000 Fee; \$2,400 Travel
  - Future: \$18,000/year Fee; \$4,000/year Travel
- AstraZeneca (Pharmaceutical) – Member: Service on Advisory Board/Committee with remuneration – 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
- Lipid Sciences (Pharmaceutical) – Consultant: Service on Advisory Board/Committee with remuneration – 4/4/2001 - 11/11/2011
  - 2002: \$5,000 Fee + Stock; \$1,800 Travel
  - 2003: \$78,000 Fee + Stock; \$4,765 Travel
  - Future: \$50,000/year Fee; \$7,500/year Travel

**TOTAL MONEY RECEIVED: \$198,940 + STOCK**

## SLIDE 9

### **Eric Green**

NHGRI – Scientific Director

- Monsanto Company (*Biotech*) – Consultant: Serves as an advisor in the area of plant genetics and genomics – 2000 - ongoing
  - 2000: \$18,500 honoraria; \$7,596.96 expenses
  - 2001: \$36,000 honoraria; \$1,396.25 expenses
  - 2002: \$24,000 honoraria
  - 2003: \$23,000 honoraria; \$1,334.57 expenses
  - 2004: \$5,000 honoraria; \$631 expenses

**TOTAL MONEY RECEIVED: \$117,458.78**

## **SLIDE 10**

### **Kenneth Korach**

**NIEHS – Chief, Lab. Reproductive & Dev. Tox.**

- **Schering AG (*Biotech*) – Consultant: Consults on biochemical and pharmacological actions of estrogens – 1/1/2004 - 12/31/2004**
  - Fee: \$52,580; Travel: \$25,600

**TOTAL MONEY RECEIVED: \$78,180**

# SLIDE 11

## Norman Salem

NIAA – Chief, LMB

- Discovery International (Pharmaceutical) – Panel Member: Answers questions on DHA supplements for infant nutrition – 12/5/2003 - indefinite
  - Fee: \$12,000
  - Future: \$4,000/year
- Hoffman LaRoche (Pharmaceutical) – Editorial Board Member: PUFA newsletter scientific reviewer – 12/1/1997 - indefinite
  - Fee: \$3,000 yearly since 1997
- Martek Corp. (Biotech) – Consultant: Consults on issues regarding essential fatty acids in nutrition including study design – 4/9/2001 -indefinite
  - Fee: \$3,000 yearly since 2001
- Bayer Corp. (Pharmaceutical) – Consultant: Consults on potential vitamin supplements; also serves as member of “Bayer Consumer Care Nutrition Advisory Board” – 3/27/2003 - indefinite
  - Fee: \$16,000
  - Future: \$2,000/year

**TOTAL MONEY RECEIVED: \$58,000**



# SLIDE 12

## **Richard Rothman**

NIDA – Chief, Clinical Psychopharmacology Section

- Sedgwick, Detert, Moran & Arnold (Bristol Myers) (Pharmaceutical) –  
Medical Consultative Services – 1/9/2003 - 11/1/2005
  - Fee: 2003 - \$16,167
  - Future: Estimate for 2004: \$2,500
- McKenna Long & Aldridge LLP (EonLabs) (Pharmaceutical) – Medical  
Consultative Services – 4/4/2003 - 11/1/2005
  - Estimated Fee: \$2,500
- Orrick, Herrington, and Sutcliffe, LLP (Hoffman LaRoche) (Pharmaceutical)  
– Medical Consultative Services – 4/4/2003 - 4/1/2005
  - Fee: \$2,500
- Orrick, Herrington, and Sutcliffe, LLP (Abbott) (Pharmaceutical) – Medical  
Consultative Services – 4/4/2003 -4/1/2005
  - Estimated Fee for 2003: \$27,075

**ESTIMATED TOTAL MONEY RECEIVED: \$48,242**

# **SLIDE 13**

## **Minoru Ko**

**NIA – Chief, Developmental Genomics & Aging Section**

- Daiichi Pharmaceutical Co. (*Pharmaceutical*) –  
Consultant: Advice on genomics and developmental  
biology for drug target discovery program – 4/7/2003 -  
4/6/2005  
– Fee: \$11,200
- Neo-Morgan Lab, Inc. (*Biotech*) – Consultant: Biological  
Research – 1/1/2004 - 12/31/2004  
– Fee: \$1,000

**TOTAL MONEY RECEIVED: \$12,200**

# SLIDE 14

## **Mahendra Rao**

NIA – Section Chief, Stem Cells

- Toucan Capital (Theradigm/Cancer Co.) (Biotech) –  
Consultant: Advice on cell replacement therapy – 9/1/2003  
- indefinite
  - Fee: \$10,000 + Stock Options
- Cue Therapeutics (Biotech) – Consultant: Advice on  
company’s stem cell research – 8/1/2002 - indefinite
  - Fee: Stock Options
  - Travel Expenses: \$2,400
- Amedica, Inc. (Biotech) – Consultant: Advice regarding  
ceramics as a bone substitute – 7/1/2001 - indefinite
  - Fee: Stock Options
  - Travel Expenses: \$50

**TOTAL MONEY RECEIVED: \$12,450 + STOCK**

## SLIDE 15

### Stanley Rapoport

- NIA – Section Chief, Brain Physiology & Metabolism
- Faegre & Benson (*Pharmaceutical*) – Expert witness in litigation involving thimerosal for Aventis Pasteur, Inc. – 11/12/2000 - indefinite
    - Fee: \$17,885
  - Best Practice (*Pharmaceutical*) – Consultant: Advice regarding how to evaluate efficacy of drugs for human brain disorders – 3/1/2003 - indefinite
    - Fee: \$3,750; Travel: \$250

**TOTAL MONEY RECEIVED: \$21,885**

# SLIDE 16

## **Darrell Abernathy**

**NIA – Chief, Laboratory of Clinical Investigation**

- Gray Cary (Pharmaceutical) – Expert witness in litigation in patent dispute involving client Cobalt Pharmaceuticals – 12/10/2003 - 11/30/2006
  - Fee: \$9,375; Travel: \$625
- Centocor (Pharmaceutical) – Consultant – 4/15/2003 - 4/14/2006
  - Fee: \$7,500; Travel: \$2,500
- Penwest Pharmaceuticals Co. (Pharmaceutical) – Scientific Advisory Board Member – 5/1/2003 - 4/30/2008
  - Fee: \$5,000; Travel: \$2,000
- Kirkland and Ellis (Pharmaceutical) – Expert witness for client Boston Scientific and Scimed Life Systems – 6/1/2003 - 5/31/2006
  - Fee: \$10,000; Travel: \$2,000

**TOTAL MONEY RECEIVED: \$39,000**

**U.S. House of Representatives  
Committee on Energy and Commerce, Democratic Staff  
Room 2322 Rayburn House Office Building  
Washington, D.C. 20515-6115**

**FAX COVER SHEET**

**DATE:** June 4, 2004

**TO:** Dr. Raynard Kington - Contact Person: Brenda Monarque, 301-496-7322

**FROM:** Angela E. Davis-West

**FAX:** 301-402-2700

**No. of Pages (including cover):** 6

**COMMENTS:** Please deliver the attachments accordingly. If you have questions  
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Committee on Energy and Commerce, Democratic Staff  
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FAX COVER SHEET

DATE: June 4, 2004  
TO: Dr. Raynard Kington - Contact Person: Brenda Monarque, 301-496-7322  
FROM: Angela E. Davis-West  
FAX: 301-402-2700  
No. of Pages (including cover): 6

COMMENTS: Please deliver the attachments accordingly. If you have questions regarding this transmittal, please contact me at the number listed below. Thanks.

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