

February 25, 2008

The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

The Honorable Henry A. Waxman, Chairman
Committee on Oversight and Government Reform

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health, Committee on Energy and Commerce

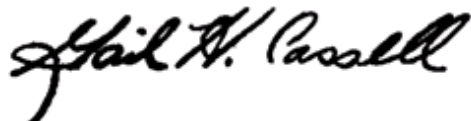
Dear Representatives Dingell, Waxman, Stupak and Pallone:

On behalf of the former members of the Subcommittee on Science and Technology of the FDA Science Advisory Board, thank you for your interest in our report: "FDA Science and Mission at Risk." Our conclusions were serious and troubling, so we are grateful that Members of Congress see the need to address the concerns we raised.

Pursuant to your request of February 4, 2008, I have attached our estimate of the resources required to implement the Subcommittee's recommendations with regard to FDA resources. The years of neglect cannot be wiped away instantly, so we have provided 5-year estimates for the amounts required. The Subcommittee did not do a program by program analysis, with specific needs down to the lowest operational levels. However, the Subcommittee did conduct a thorough review of the Agency's major programs and capabilities, and has concluded that most of the programs are massively underfunded if they are to carry out the public and Congressional expectations presented to them. Thus, whether the Subcommittee has reached a proposed number that is accurate to the dollar is not the issue; it is that FDA needs a very substantial increase in resources if it is to protect us as the public expects and Congress demands. We believe the resources proposed can be highly justified as a proper fit compared with the long list of deficiencies we identified. We are confident that other studies of FDA's needs that might be conducted would fall within the same order of magnitude.

I appreciate your sensitivity to the fact that the Subcommittee completed its work and was thus disbanded by the FDA Science Board. However, I can report that all of the Subcommittee members contributed to our evaluation of resource needs throughout our work and all but four members (two were unavailable and two were government employees) had a chance to review and sign off on the attached document. On behalf of this group, I emphasize that we remain available to each of you in our common pursuit of a stronger FDA that has the resources it needs.

Sincerely,



Gail H. Cassell, Ph.D., D.Sc.(hon)
Vice President, Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases
Eli Lilly and Company

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Tom Davis, Ranking Member
The Committee on Oversight and Government Reform

The Honorable John Shimkus, Ranking Member
The Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health, Committee on Energy and Commerce

Barbara J. McNeil, M.D.
Ridley Watts Professor and Head
Department of Health Care Policy
Professor of Radiology
Harvard Medical School



D. Bruce Burlington, M.D.
Executive Vice President for Business
Practices and Compliance
Wyeth Pharmaceuticals (retired 7/07)



Allen D. Roses, M.D.
Jefferson-Pilot Professor of Neurobiology and
Genetics
Director, Deane Translational Drug Discovery
Institute
Senior Scholar, Fuqua School of Business
Duke University Medical Center



Robert Califf, M.D.
Vice Chancellor for Clinical Research,
Director of the Duke Translational
Medicine Institute (DTMI), and Professor
of Medicine in the Division of Cardiology
at the Duke University Medical Center



David Altshuler, M.D., Ph.D.
Founding Member and Director, Program
in Medical and Population Genetics
Broad Institute of Harvard and MIT
Associate Professor of Genetics and
Medicine
Harvard Medical School and
Massachusetts General Hospital



C. Thomas Caskey, M.D.
Chief Operating Officer and CEO-
Director-Elect
The Brown Foundation Institute of
Molecular Medicine
Executive Vice President of Molecular
Medicine and Genetics
The University of Texas Health Science
Center at Houston



Leslie Z. Benet, Ph.D.
Professor, Department of
Biopharmaceutical Sciences
University of California, San Francisco

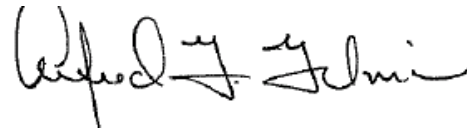


P. Joan Chesney, M.D.
Professor of Pediatrics at the University
of Tennessee Health Science Center
Associate Dean for St. Jude Academic
Affairs at the University of Tennessee
College of Medicine
Director of the Academic Programs
Office at St. Jude

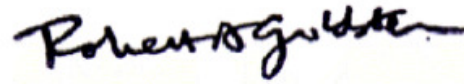




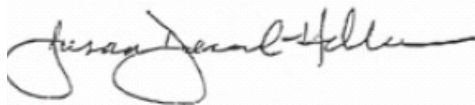
David L. DeMets, Ph.D.
Professor and Chair
Department of Biostatistics
University of Wisconsin



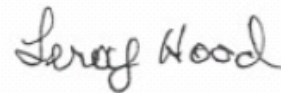
Robert Goldstein, M.D., Ph. D.
Chief Scientific officer
Juvenile Diabetes Research Foundation
International



Susan Desmond-Hellmann, M.D., M.P.H.
President, Product Development
Genentech, Inc.



Leroy E. Hood, M.D., Ph.D.
President
Institute for Systems Biology



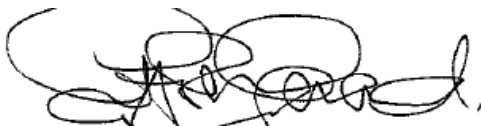
Susan Ellenberg, Ph.D.
Professor of Biostatistics
Associate Dean for Clinical Research
University of Pennsylvania School of
Medicine



Peter Barton Hutt
Former Chief Counsel FDA
Covington & Burling LLP



Garret A. FitzGerald, M.D.
Professor of Medicine
Professor and Chair of Pharmacology
Department of Pharmacology
University of Pennsylvania School of
Medicine



Sangtae Kim, Ph.D.
Donald W. Feddersen Distinguished
Professor
Purdue University



Alfred Gilman, M.D., Ph.D.
Nobel Laureate
Dean, Southwestern Medical School and
Regental Professor
Department of Pharmacology
The University of Texas Southwestern
Medical Center at Dallas


Cato T. Laurencin, M.D., Ph.D.
Lillian T. Pratt Distinguished Professor of
Orthopedic Surgery
Professor of Biomedical and Chemical
Engineering
The University of Virginia Health System



Jeffrey M. Leiden, M.D., Ph.D.
President & Chief Operating Officer
Pharmaceutical Products Group
Abbott Laboratories (retired 6/07)



J. Glenn Morris, M.D., M.P.H., T.M.
Director, Emerging Pathogens Institute
University of Florida, Gainesville



Robert M. Nerem, Ph.D.
Parker H. Petit Professor and Director
Institute for Bioengineering and
Bioscience
Georgia Institute of Technology



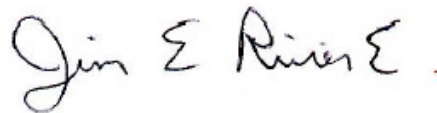
Dale Nordenberg, M.D.
Managing Director, Healthcare Industry
Advisory
PriceWaterhouse Coopers
Former Associate Director for
Informatics
And Chief Information Officer
National Center for Infectious Diseases
Centers for Disease Control and
Prevention



J. Marc Overhage, M.D., Ph.D.
President and CEO of the Indiana Health
Information Exchange
Director of Medical informatics at the
Regenstrief Institute, Inc.
Professor of Medicine at the Indiana
University School of Medicine



Jim E. Riviere, D.V.M., Ph.D.
Burroughs Wellcome Fund Distinguished
Professor
Director, Center for Chemical Toxicology
Research
Pharmacokinetics, and Biomathematics
Program
College of Veterinary Medicine
North Carolina State University



Eve Slater, M.D., F.A.C.C.
Former Assistant Secretary for Health,
US Department of Health and Human
Services
Former Sr. Vice President of Merck
Research Labs for Clinical and
Regulatory Development
Senior Vice President-Worldwide Policy
Pfizer, Inc.



John A. Thomas, Ph.D.
Vice President
University of Texas Health Science Center
at San Antonio (retired 1998)

John A. Thomas

P. Roy Vagelos, M.D.
Retired Chairman and CEO
Merck & Co., Inc.

P. Roy Vagelos

Catherine E. Woteki, Ph.D.
Former Undersecretary for Food Safety
in the U.S. Department of Agriculture
Former Dean, Iowa State University
College of Agriculture
Global Director of Scientific Affairs
Mars, Inc.

Catherine E. Woteki
