

File Henney

STATEMENT OF

DR. JANE E. HENNEY

NOMINEE FOR
COMMISSIONER OF FOOD AND DRUGS
U.S. FOOD AND DRUG ADMINISTRATION
THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

SEPTEMBER 2, 1998

Mr. Chairman, Senator Kennedy, distinguished members of the Committee, I thank each of you for the invitation to be here today and for the courtesies you have already extended to me in the confirmation process. I also want to express my gratitude to Senators Domenici and Bingaman for their friendship and support for my nomination.

It is an honor to appear before the Committee that has shown so much leadership on health care issues, particularly through the enactment of the Food and Drug Administration Modernization Act of 1997. I appreciate this opportunity to discuss my qualifications and commitment to lead the Agency's effort to implement the Act, and to promote the public's access to safe and effective medical products.

I am also grateful to President Clinton for nominating me and for his continued confidence in my abilities to serve as the next Commissioner of Food and Drugs. I have been fortunate to serve in the Administrations of Presidents Ford, Carter, Reagan, Bush and Clinton. My goal has always been to promote the public health, and I am here again because of this opportunity to serve the public.

As a medical oncologist with two decades of experience managing change in public health care institutions, I am eager to meet the challenges that lie ahead for one of our nation's pre-eminent public health agencies. The Food and Drug Administration touches each American's life every day. And industries that the Agency regulates -- food, cosmetic, pharmaceutical, biotechnology, blood, medical device, and veterinary medicine -- are respected worldwide for their ingenuity, success, and, perhaps most importantly, for the quality of their products.

American industries produce the finest medical therapies because of this nation's substantial investment in basic research and because FDA ensures that new medical products meet the American public's expectation that the treatments they use will be safe and effective. By ensuring the high quality of the products it regulates, FDA plays a critical role in promoting and protecting the public health.

Mr. Chairman, if I am confirmed, my priorities will be very clear. First and foremost will be implementing the FDA Modernization Act, both the letter and the spirit of the law. My desire to return to federal service is in large part driven by the content and substance of the Act and the new philosophy that it embodies. I intend to build on this collaborative, constructive model by working closely with Congress, the regulated industries, patients, consumers, and health care professionals. I am deeply committed to building bridges of communication and breaking down the barriers that have kept the

Agency from being as effective and productive as it should be.

One key element of the new collaborative spirit embodied in the FDA Modernization Act is the reauthorization of the Prescription Drug User Fee Act. This Act was the prototype legislation that I am proud to have helped develop during my previous tenure at FDA. It increased the Agency's resources and dramatically improved the Agency's performance, speeding safe, effective drugs and biologics to those in need. This Act also demonstrated the benefits that come when the Congress, FDA, industry and consumers work together to achieve a common goal that benefits the public health. The FDA Modernization Act takes this philosophy further through innovative procedures, such as third-party reviews for devices that will expedite review times without compromising the public's health. In addition, the Act will provide companies an expedited process for making certain health claims.

I also intend to focus on other key responsibilities of FDA. In particular, I share the commitment of members of this Committee to make our nation's food supply as safe as it can be. The safety of our blood supply and preventing the harm that can come to our country's youth from tobacco use also are of great concern. I know that we can, and must, work together to assure the American public that we, as a government, are doing all we can, and should do, in these critical areas.

Finally, if I am confirmed as Commissioner, it will be a high priority of mine to strengthen the science base of the Agency. Recruiting and retaining the best scientists is key to FDA's success. A firm scientific foundation is critical to assure the accuracy and timeliness of our regulatory activities. It should concern us all that, at the very time the public and private research enterprise in this country is flourishing, one of our essential regulatory agencies may have difficulty recruiting and retaining strong scientists. Certainly not all scientists need to be engaged in active bench research, and there may be many opportunities to develop alliances with other public agencies, but together we must find ways and means to keep the science base of the Agency from eroding.

I am confident that these difficult and often complex issues can be managed efficiently and effectively. But you also need to know why I am confident, and why I am qualified to lead this important public agency.

I am a physician and cancer specialist who has demonstrated strong management and leadership skills in a variety of large and complex health organizations.

FDA is an agency that I know well. For two years, I managed its daily activities and recruited most of the extremely capable center directors who now lead the Agency. I know its strengths; I know its limitations.

Leading a science-based organization is not a new experience for me. The first nine years of my career were spent in federal service at the National Cancer Institute, where from 1980 to 1985 I served as Deputy Director. I have been privileged to hold leadership positions in large academic health centers, first at the University of Kansas and now as Vice President for Health Sciences of the University of New Mexico. As Vice President, I have led the organization by implementing significant change, both in the way health care is delivered and in how the next generation of health care professionals learn. One of the keys to success in our work has been the meaningful involvement of legislators, other policy makers, health care providers and payers, professionals, and patients. These voices from the community have been critical in assuring that we are meeting our state's needs.

In carrying out my responsibilities at both the University of Kansas and the University of New Mexico, I have fostered an environment and recruited leaders that resulted in tremendous growth in our research efforts.

In addition to my responsibilities in an academic health science center, my current service on the Director's Advisory Committee of the National Institutes of Health and as President of the United States Pharmacopeia continues to give me an appreciation and perspective of the strengths and needs of science -- and of the patients who benefit from its results.

I also have had "hands-on" participation in the scientific enterprise. During my early years at the National Cancer Institute, I was responsible for drug development activities as a drug monitor for investigational drug studies. Later, at the University of Kansas, I became a principal investigator on investigational studies for the treatment of breast cancer.

As you know, I now live and work in New Mexico, but much of what has shaped my career is rooted in the small community of Woodburn, Indiana, a town of just 512 people when I was a child. A woman who I admired in Woodburn was stricken with breast cancer, a disease that was only mentioned in a hushed voice in those days. She shared some of her struggle with me. As her cancer advanced, she opened herself to the possibility -- and risk-- of what research could offer. It was her belief that if the experimental therapy did not benefit her, then her experience would at least help

others. This experience and her altruism influenced my choice of a career in medicine at a time when women often were not welcomed.

There were many other lessons to be learned in Woodburn. In our small community, resources were finite in terms of people and finances. Both were valued and used wisely.

Some of you know first-hand the privilege of learning to live in a community where everyone – *literally* – knows your name and almost everything about you. In small towns, there are few places to hide; responsibility and accountability become second nature. Consequently, I have never shied away from tough or uncomfortable decisions. I also learned first-hand that if decisions are to last, they need to be reached by consensus and collaboration. This is not to say everyone in our town thought alike, for as Walter Lippman once said, "if we all think alike, someone's not thinking." Expressing oneself clearly, and, more importantly, listening were placed at a high premium in our community.

In Woodburn, people who knew and respected one another were able to build strength out of differing points of view and make wise and long-lasting decisions. It was in this community that I learned many fundamental lessons of leadership and management, lessons that I have applied over and over again in even the most complex organizations. The result is, I believe, an approach of being open, fair, forthright, and honest. It is my intention to bring this same discipline and integrity to the role I would assume as Commissioner.

I have been fortunate to enjoy a challenging career that, I believe, well prepares me for the task at hand. I look forward to our discussion today and to our working together in the future. Thank you.

Genentech, Inc.
Genentech, Inc.
Genentech, Inc.
Genentech, Inc.
Genentech, Inc.

808 17th Street, N.W.
Suite 250
Washington, D.C. 20006
(202) 296-7272
FAX: (202) 296-7290

FAX COVER SHEET

TO: Chris Jennings

FROM: Walter Moore

DATE: 10/8/98

NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 3

COMMENTS: _____

IF YOU HAVE ANY PROBLEMS RECEIVING THIS FAX, PLEASE CONTACT

Sheila AT (202) 296-7272.



GENZYME CORPORATION
ONE KENDALL SQUARE
CAMBRIDGE, MA 02139-1562
617-252-7573
FAX 617-374-7423

HENRI A. TERMEER

CHAIRMAN AND
CHIEF EXECUTIVE OFFICER

October 5, 1998

*Memo
Trent
2/19
8271*

The Honorable Trent Lott
Senate Majority Leader
S-230 Capitol Building
Washington, DC 20510-7010

Dear Mr. Leader:

I am writing to urge you to schedule a floor vote to confirm Jane Henney, M.D. as FDA Commissioner prior to your adjournment of the Senate at the end of this week.

Genzyme is a U.S. biotechnology company that develops breakthrough treatments for patients with serious and life-threatening diseases whose medical needs are unmet by existing therapies. I believe that our industry and our Nation would be best served by an FDA that is fully committed to achieving early patient access to treatments that may save their lives and improve their health.

The biotechnology industry's highest legislative priority, during my tenure as chairman of the Biotechnology Industry Organization, was translating these principles into meaningful FDA reforms. Our industry has always been deeply grateful for your personal commitment and leadership in enacting the FDA Modernization Act of 1997 (FDAMA) and know you share our eagerness for effective and expeditious implementation.

In my personal opinion, the timely appointment of a permanent Commissioner who is clearly empowered to implement the new law is necessary to ensure that full implementation is achieved before the momentum that led to FDAMA's enactment dissipates. I believe that, by confirming a new Commissioner who is committed to greater collaboration and cooperation with regulated industries, we will succeed in demonstrating that this new law should be recognized as one of the 105th Congress' major achievements, one that will benefit millions of American patients and their families.

I believe that Dr. Henney has demonstrated that she is absolutely committed to both the letter and the spirit of the FDA Modernization Act. This belief appears to be shared by the Labor Committee, which voted to support her confirmation to be Commissioner of Food and Drugs.

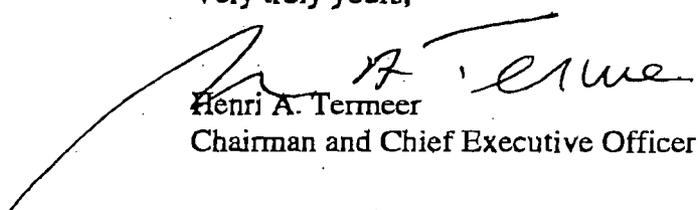
The Honorable Trent Lott
October 5, 1998
page 2

We recognize that the Senate has many urgent matters to take up in the very short time that remains until adjournment. We respectfully request that you consider that it is also critical, for the 25% of the U.S. economy that is regulated by the FDA, that the Senate confirm a Commissioner who respects Congress' intent in implementing a new law that has profound consequences for companies and consumers alike.

I believe that the appointment of a permanent Commissioner is so critical that, if the Senate does not find time to consider confirming Dr. Henney prior to adjournment, my company and others may consider encouraging the President to make a recess appointment. While regulated industry has long respected the leadership's request that we defer to your political judgment on whether and how to proceed on this nominee, we are quickly reaching the point at which our industry's ability to market new products in a timely and appropriate fashion may become an even more compelling consideration.

Thank for you considering Genzyme's views of this matter. Please call me at 617/252-7573 if I can provide further information.

Very truly yours,



Henri A. Termeer
Chairman and Chief Executive Officer

POSSIBLE NEXT STEPS FOR HENNEY NOMINATION

1. Leadership Contact:

A. Senators (contact):

- Domenici (Lott, Nickles)
- Frist (Lott, Nickles)
- Coats (Lott, Nickles)?
- Collins (Lott, Nickles)
- Gregg (Lott, Nickles)?
- Mack (Lott, Nickles - Post agreement on off-label)

Dodd, Mikulski, Bingaman. Murray letter to Lott and Nickles

B. Potential Industry Supporters:

- PHARMA
- BIO
- PFIZER
- UPJOHN
- MERCK
- NOVARTIS
- MEDTRONICS
- GLAXO
- GENENTECH
- GENZYME

C. Administration (contact):

- VP (Mack Post agreement on off label)?
- Bowles (Lott)?
- Shalala (Lott, Nickles, Domenici, Frist, Coats)
- Stein (Hoppe)?
- Thornton (Nickles staff)
- Childress (Mack and Staff)
- Tarplin (Lott and Nickles staff)

2. Groups/Press Activity

- Sullivan, Bowen calls to Lott, Nickles?
- Letters from endorsing organizations to Lott, Nickles
- Mississippi and Oklahoma affiliates contact Lott, Nickles
- Cancer groups contact Mack
- Press conference with supporting organizations (with Domenici)?
- Renew push for editorials and op-eds in Mississippi, Oklahoma, Florida

3. Miscellaneous Activity

- Henney meeting with women senators
- Henney meeting with House Women's caucus
- Dodd/Domenici meeting with select industry representatives?

Jane Henney FDA File

BIO

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

October 14, 1998

BOARD OF DIRECTORS

EXECUTIVE COMMITTEE

CHAIRMAN

Gordon M. Binder
Amgen

VICE CHAIRMAN

FOOD AND AGRICULTURE

Carrol D. Bolen
Pioneer Hi-Bred International, Inc.

VICE CHAIRMAN

HEALTH CARE

Mark Skaletsky
GenTex Pharmaceuticals, Inc.

SECRETARY

Vaughn M. Kailian
COR Therapeutics, Inc.

TREASURER

Mitchel Sayare
ImmunoGen, Inc.

EX-OFFICIO

Henri A. Termeer
Genzyme Corporation

MEMBERS AT LARGE

Paul Abrams

NeoRx Corporation

David W. Anstice

Merck & Co., Inc.

Richard F. Pops

Alkermes, Inc.

J. Leighton Read

Aviron

David E. Robinson

Ligand Pharmaceuticals, Inc.

EMERGING COMPANIES

SECTION

CHAIRMAN

Thomas G. Wiggins
Connetics Corporation

VICE CHAIR

H. Stewart Parker
Targeted Genetics Corporation

**The Honorable Trent Lott
Majority Leader
United States Senate
Washington, D.C. 20510**

Dear Senator Lott,

The Biotechnology Industry Organization (BIO), representing more than 800 companies, academic institutions and affiliated organizations in the U.S., urges the Senate to bring the nomination of Dr. Jane Henney to the floor, and to confirm her as Commissioner of the Food and Drug Administration (FDA). Her credentials as an oncologist and her previous experience as a key member of the FDA leadership, give Dr. Henney a perspective of the FDA's needs and processes that will help her lead this critical federal agency into the 21st century.

Dr. Henney has indicated throughout the confirmation process that she will adhere to both the letter and spirit of the recently enacted FDA Modernization Act (FDAMA), and continue to streamline and improve FDA operations. Dr. Henney has testified that she is committed to an FDA which reviews biologics and drugs expeditiously without compromising patient or consumer safety.

We also commend Dr. Michael Friedman, the current Acting Commissioner of the FDA for the superb job he has done in the interim. However, we believe the agency will benefit from having the leadership of a permanent Commissioner confirmed by the Senate.

1625 K STREET, N.W., SUITE 1100
WASHINGTON, D.C. 20006-1604

202-857-0244
FAX 202-857-0237
<http://www.bio.org>

The Honorable Trent Lott
Page 2

The FDA Commissioner is the appointed federal official with the greatest impact on the biotechnology industry. More than 250 biotech drugs and vaccines are under FDA review and millions of people are in need of the potential benefits of these new therapies. The FDA is also a key regulatory agency overseeing development of biotech food and agriculture products. BIO believes that Dr. Jane Henney offers great promise to provide strong leadership to the FDA, and we respectfully urge the Senate to confirm her nomination.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl B. Feldbaum". The signature is written in a cursive style with a long horizontal line extending to the right.

Carl B. Feldbaum
President

Henney File
FDA ~~File~~

October 9, 1998

The Honorable Don Nickles
Assistant Majority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Nickles:

As you know, I have been nominated by President Clinton to serve as Commissioner of the Food and Drug Administration (FDA). I appreciate the consideration that you and your colleagues in the Senate have given to my nomination.

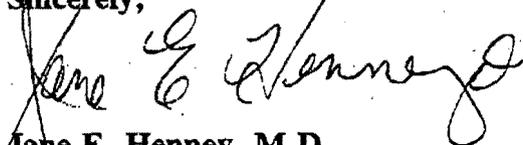
I wanted to take this opportunity to clarify what I believe is a misconception about my views concerning FDA's regulatory authority. First, let me say that I respect the role of Congress in defining the parameters of FDA's authority and the goals and mission of the Agency. During my service at both the National Cancer Institute and the FDA, I worked hard to maintain collaborative relationships with our committees of jurisdiction, and to ensure that our activities were in full compliance with the law and congressional intent. Indeed, in the context of my current nomination, I have pledged that my top priority will be timely implementation of the FDA Modernization Act of 1997 based on the letter and spirit of the law.

I also want to clarify any misconceptions about my service at the agency from 1992-1994 with respect to the FDA tobacco rule and the Agency's review of RU-486. As I stated in response to questions submitted by the Committee on Labor and Human Resources, I did not participate in the FDA's consideration of whether the Agency has authority under existing law to assert jurisdiction over tobacco products. If confirmed as Commissioner, I would obviously abide by any final congressional or judicial action on this matter.

With respect to RU-486, I stated during my confirmation hearing and in response to the Committee's written questions that I was not involved either in the solicitation or the review of the RU-486 application.

I appreciate your willingness to consider my nomination. I would be pleased to meet with you to discuss these or any other issues at your convenience.

Sincerely,



Jane E. Henney, M.D.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

OCT 12 1998

The Honorable Don Nickles
Assistant Majority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Nickles:

Thank you for the letter from you and Chairman Hyde concerning the Department's interpretation of the Hyde amendment as it affects federally funded abortions. As you know, I take very seriously the Department's obligation to fully implement the law as enacted by the Congress. Nancy Ann DeParle, the Administrator of the Health Care Financing Administration (HCFA), shares this commitment.

Let me assure you that in order for federal funds to be used to cover abortion, a physician must certify that a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused or arising from the pregnancy itself, that would place the woman in danger of death unless an abortion is performed.

We have no intention to instruct states on this issue other than to reiterate the statutory obligation that must be met to utilize federal funds for legally permissible abortions.

I trust this addresses your concerns. Please let me know if I can be of further assistance in this matter. An identical letter has been sent to Chairman Hyde.

Sincerely,

A handwritten signature in cursive script that reads "Donna E. Shalala".

Donna E. Shalala



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

The Honorable Don Nickles
Assistant Majority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Nickles:

Thank you for the letter from you and Chairman Bliley concerning abortion coverage under the Title XXI State Children's Health Insurance Program (S-CHIP). As explained in greater detail below, states do have the discretion to determine whether to provide coverage for permissible abortion services in their S-CHIP programs.

First, let me say that we have gone to great lengths to ensure that the Department's implementation of the S-CHIP program is consistent with congressional intent and flexible to meet the needs and circumstances of individual states. We have consulted frequently with Members of Congress and staff on a bipartisan basis, and have worked with state officials to facilitate the implementation of their programs. To date, we have approved 42 state plans under the Title XXI program.

In addition to the Title XXI Medicaid expansion option, states have three options for insurance coverage under the S-CHIP program: Benchmark, Benchmark-Equivalent, or Secretary-Approved Coverage. States are free to exclude coverage for permissible abortion services in their Benchmark (provided a state's Benchmark plan does not cover abortions) or Benchmark-Equivalent options.

To ensure as much consistency as possible in our approval process, we have limited the exercise of our discretion under the third option, Secretary-Approved Coverage, to cases in which the benefits offered under a state's S-CHIP program are the same as under its Medicaid plan. This provides states with the flexibility to use their existing Medicaid programs and structures without having to extend an entitlement to new S-CHIP enrollees. Given the substantial flexibility in designing their benefit packages that states enjoy under the Benchmark and Benchmark-Equivalent options, this limited approach to Secretary-Approved Coverage does not unduly constrain the benefit options available to states.

Please let me know if I can be of further assistance on these issues. An identical letter has been sent to Chairman Bliley.

Sincerely,

A handwritten signature in black ink that reads "Donna E. Shalala".

Donna E. Shalala

FAX

Date: October 13, 1998

Number of pages including cover sheet: 9

To: Chris Jennings

TEL: 202-456-5560

FAX: 202-456-5557

CC:

From:

XXXX ALAN F. HOLMER

MARY BETH SEELY

SHARON M. MARSHALL

TEL: 202-835-3420

FAX: 202-835-3429

Urgent As Discussed For your review Reply ASAP Please comment

Chris,

You may already have these, but enclosed are letters from six PhRMA member companies supporting Dr. Henney's confirmation. (Bayer co-signed the Pharmacia & Upjohn letter.)

Alan Holmer



98 Corporate Drive
P.O. Box 8808
Kridgeman, NJ 06807-0808
(202) 328-4401
Fax (202) 328-1850

FRED HASSAN
Chief Executive Officer

October 2, 1998

The Honorable Trent Lott
Senate Majority Leader
S-230 Capitol Building
Washington, D.C. 20510

Dear Mr. Leader:

I am writing this letter to urge you to schedule a floor vote to confirm Jane Henney, M.D., as Commissioner of the Food and Drug Administration prior to adjournment. As you are well aware, this position has been vacant for over one year. It is essential that a permanent, accountable Commissioner provide over the implementation of the FDA Modernization Act and I can think of few who would be more qualified or able to lead this Agency than Dr. Henney.

I support Dr. Henney's commitment to run the FDA with open lines of communication between the Agency, the Congress and the regulated industries within its jurisdiction. She is a highly regarded manager who has successfully lead complex and important governmental and academic organizations throughout her career. I feel she would become a most successful Commissioner.

I recognize that there are many competing priorities in these remaining days of the Congress. I hope you can agree that it is critical for the Senate to confirm a Commissioner who respects Congressional intent in implementing the FDA Modernization Act and that you and your colleagues will support, with all due swiftness, Dr. Henney's nomination.

Thank you for your serious consideration of this most important request.

Sincerely,

Fred Hassan

October 7, 1998

The Honorable Trent Lott
Majority Leader
United States Senate
9-250 Capitol Building
Washington, DC 20510

Dear Majority Leader Lott:

We the undersigned organizations urge the Senate to confirm this year Jane Henney, MD to be the Commissioner for the Food and Drug Administration (FDA) at the Department of Health and Human Services.

The Senate Labor and Human Resources Committee voted overwhelmingly to report her nomination to the full Senate on September 23, 1998. This position has been vacant for over a year. Return this Congress adjourns, it is essential to put in place a permanent Commissioner to implement the FDA Modernization Act that Congress enacted last year.

Dr. Henney is well regarded in the health care industry and has superb qualifications that will provide critical leadership to the FDA. She has served four Administrations, and has earned the respect and trust of her colleagues. In her previous position at the FDA as the Deputy Commissioner for Operations, Dr. Henney proved her ability to make wise fundamental decisions on issues of importance. We have no doubt that she will enable the FDA to adhere to high standards while protecting the well-being of the nation.

We highly recommend Dr. Henney and feel that her outstanding medical and academic reputation makes her the ideal candidate for this position and urge you and the Members of the Senate to confirm Dr. Henney before Congress adjourns this year.

Sincerely,

AIDS Action
American Academy of Physician Assistants
American Association of Colleges of Pharmacy
American Cancer Society
American College of Obstetricians and Gynecologists
American College of Physicians-American Society of Internal Medicine
American College of Surgeons
American Dental Association
American Heart Association
American Medical Association
American Medical Women's Association

**American Nurses Association
American Society for Reproductive Medicine
Association of Academic Health Centers
Association of American Medical Colleges
Bayer Corporation
National Association of County & City Health Officials
National Coalition of Hispanic Health & Human Services Organization
National Community Pharmacists Association
National Partnership for Women and Families
Nonprescription Drug Manufacturers Association
Older Women's League
Partnership for Prevention
Pharmacia & Upjohn
Research! America
Society for the Advancement of Women's Health Research**

Genentech, Inc.

1 DNA Way
South San Francisco, CA 94080-1990
(650) 225 1102
FAX: (650) 225 2929

Arthur D. Levinson, Ph.D.
President and
Chief Executive Officer

October 8, 1998

The Honorable Trent Lott
Majority Leader
United States Senate
Washington, D.C. 20510

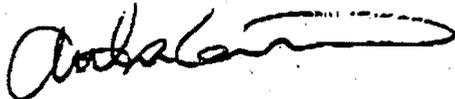
Dear Mr. President:

I am writing to inform you that Genentech, Inc., a leading biotechnology company based in South San Francisco, supports the confirmation of Jane Henney, M.D., as Commissioner of the Food and Drug Administration (FDA).

As the FDA moves forward with implementation of the historic Food and Drug Administration Modernization Act (FDAMA), it is critical that the Agency have in place a dedicated, able Commissioner who is committed to fulfilling the spirit and intent of FDAMA. As illustrated at her confirmation hearing, Dr. Henney is well-qualified to lead the FDA and will pursue modernization of the Agency with tremendous energy and integrity.

Clearly, a well-functioning FDA is critical to the ongoing development and availability of new life-saving drugs and technologies. Dr. Henney's confirmation will help ensure that patients continue to have access to the latest medical advances.

Sincerely,



ADL:rp

Genentech, Inc.

1 DNA Way
South San Francisco, CA 94080-1990
(650) 225 1107
FAX: (650) 225 2979

Arthur D. Levinson, Ph.D.
President and
Chief Executive Officer

October 8, 1998

The Honorable
William J. Clinton
The White House
Washington, D.C. 20510

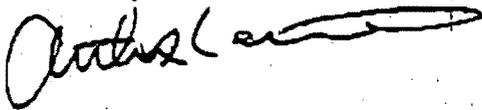
Dear Mr. President:

I am writing to inform you that Genentech, Inc., a leading biotechnology company based in South San Francisco, supports the confirmation of Jane Henney, M.D., as Commissioner of the Food and Drug Administration (FDA).

As the FDA moves forward with implementation of the historic Food and Drug Administration Modernization Act (FDAMA), it is critical that the Agency have in place a dedicated, able Commissioner who is committed to fulfilling the spirit and intent of FDAMA. As illustrated at her confirmation hearing, Dr. Henney is well-qualified to lead the FDA and will pursue modernization of the Agency with tremendous energy and integrity.

Clearly, a well-functioning FDA is critical to the ongoing development and availability of new life-saving drugs and technologies. Dr. Henney's confirmation will help ensure that patients continue to have access to the latest medical advances.

Sincerely,



ADL:rp

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 873 3116



William C. Steere, Jr.
Chairman of the Board and
Chief Executive Officer

June 23, 1998

The Honorable James M. Jeffords
Senate Committee on Labor and Human Resources
728 Senate Hart Office Building
Washington, D.C. 20510-4503

Dear Chairman Jeffords:

We are writing to express our support for the nomination of Dr. Jane E. Henney for the position of Commissioner of the Food and Drug Administration (FDA). We are pleased that the Senate will be considering such a qualified candidate to fill this important position.

Dr. Henney's leadership qualifications, management skills and science background combine to make the right mix to ensure that the FDA operates efficiently, protects the public health, and patients have timely access to health care treatments. The challenging health care issues we will face in the coming years will be shaped, in part, by the next FDA Commissioner. We have confidence that Dr. Henney is an individual who can successfully meet these challenges.

We appreciate the opportunity to share Pfizer's views about a person as qualified as Dr. Henney, and we hope you will act swiftly to approve her appointment as FDA Commissioner.

Sincerely,

A handwritten signature in black ink, appearing to read "William C. Steere, Jr.", written in a cursive style.

William C. Steere, Jr.



GENZYME CORPORATION
ONE KENDALL SQUARE
CAMBRIDGE, MA 02139-1562
617-282-7673
FAX 617-376-7428

HENRI A. TERMEER

CHAIRMAN AND
CHIEF EXECUTIVE OFFICER

October 5, 1998

The Honorable Trent Lott
Senate Majority Leader
S-230 Capitol Building
Washington, DC 20510-7010

Dear Mr. Leader:

I am writing to urge you to schedule a floor vote to confirm Jane Henney, M.D. as FDA Commissioner prior to your adjournment of the Senate at the end of this week.

Genzyme is a U.S. biotechnology company that develops breakthrough treatments for patients with serious and life-threatening diseases whose medical needs are unmet by existing therapies. I believe that our industry and our Nation would be best served by an FDA that is fully committed to achieving early patient access to treatments that may save their lives and improve their health.

The biotechnology industry's highest legislative priority, during my tenure as chairman of the Biotechnology Industry Organization, was translating these principles into meaningful FDA reforms. Our industry has always been deeply grateful for your personal commitment and leadership in enacting the FDA Modernization Act of 1997 (FDAMA) and know you share our eagerness for effective and expeditious implementation.

In my personal opinion, the timely appointment of a permanent Commissioner who is clearly empowered to implement the new law is necessary to ensure that full implementation is achieved before the momentum that led to FDAMA's enactment dissipates. I believe that, by confirming a new Commissioner who is committed to greater collaboration and cooperation with regulated industries, we will succeed in demonstrating that this new law should be recognized as one of the 105th Congress' major achievements, one that will benefit millions of American patients and their families.

I believe that Dr. Henney has demonstrated that she is absolutely committed to both the letter and the spirit of the FDA Modernization Act. This belief appears to be shared by the Labor Committee, which voted to support her confirmation to be Commissioner of Food and Drugs.

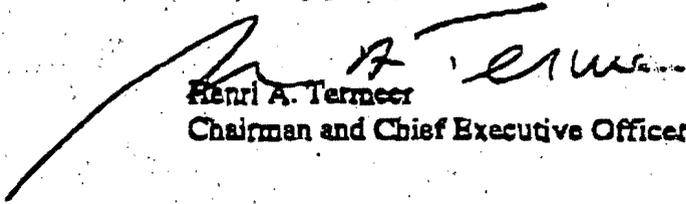
The Honorable Trent Lott
October 5, 1998
page 2

We recognize that the Senate has many urgent matters to take up in the very short time that remains until adjournment. We respectfully request that you consider that it is also critical, for the 25% of the U.S. economy that is regulated by the FDA, that the Senate confirm a Commissioner who respects Congress' intent in implementing a new law that has profound consequences for companies and consumers alike.

I believe that the appointment of a permanent Commissioner is so critical that, if the Senate does not find time to consider confirming Dr. Henney prior to adjournment, my company and others may consider encouraging the President to make a recess appointment. While regulated industry has long respected the leadership's request that we defer to your political judgment on whether and how to proceed on this nominee, we are quickly reaching the point at which our industry's ability to market new products in a timely and appropriate fashion may become an even more compelling consideration.

Thank for you considering Genzyme's views of this matter. Please call me at 617/252-7573 if I can provide further information.

Very truly yours,



Henri A. Termeer

Chairman and Chief Executive Officer

TOTAL P.02

10/05/98 MON 14:28 [TX/RX NO 9885] 002

SB
SmithKline Beecham

Jan Leschly
Chief Executive

September 25, 1998

The Honorable Jim Jeffords
Chairman
Committee on Labor and Human Resources
428 Dirksen Senate Building
Washington, DC 20510

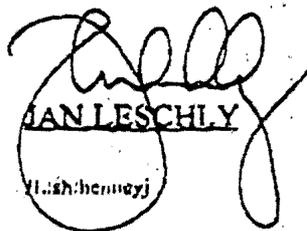
Dear Senator Jeffords:

We write in support of the nomination of Dr. Jane Henney as Commissioner of the Food and Drug Administration, and we urge the Senate's expeditious confirmation of this nomination. Based upon Dr. Henney's background and experience, as well as the record of your Committee's confirmation hearings, we are satisfied that she is immanently qualified and prepared for the position.

While we think that Dr. Friedman has served very professionally and responsibly during his tenure as Acting Commissioner, we also believe that the agency is at a critical time and the demands on it such that it deserves a permanent and politically accountable Commissioner. Timely and faithful implementation of the recently enacted Food and Drug Administration Modernization Act is a priority to us all. We believe that with the support of the Administration and the Congress, Dr. Henney as a confirmed Commissioner, represents the best opportunity to achieve this goal.

We greatly appreciate your consideration of our views.

With best regards,


JAN LESCHLY
j.lesch:henneyj

Genentech, Inc.

1 DNA Way
South San Francisco, CA 94080-4970
(650) 225-1102
FAX: (650) 225-2929

Arthur D. Levinson, Ph.D.
President and
Chief Executive Officer

October 8, 1998

The Honorable
William J. Clinton
The White House
Washington, D.C. 20510

Dear Mr. President:

I am writing to inform you that Genentech, Inc., a leading biotechnology company based in South San Francisco, supports the confirmation of Jane Henney, M.D., as Commissioner of the Food and Drug Administration (FDA).

As the FDA moves forward with implementation of the historic Food and Drug Administration Modernization Act (FDAMA), it is critical that the Agency have in place a dedicated, able Commissioner who is committed to fulfilling the spirit and intent of FDAMA. As illustrated at her confirmation hearing, Dr. Henney is well-qualified to lead the FDA and will pursue modernization of the Agency with tremendous energy and integrity.

Clearly, a well-functioning FDA is critical to the ongoing development and availability of new life-saving drugs and technologies. Dr. Henney's confirmation will help ensure that patients continue to have access to the latest medical advances.

Sincerely,



ADL:rp