THE WHITE HOUSE

WASHINGTON

June 13, 1996

MEMORANDUM TO HAROLD ICKES
DOUG SOSNIK

FROM: Jennifer Klein J.K.

SUBJECT: Letter from Dr. William Haseltine

Dr. William Haseltine raised four issues in the attached letter to the President: Federal support for biomedical research; technology transfer; FDA reform; and prevention based medicine. I asked for comments on these issues from the Office of the Assistant Secretary for Policy and Evaluation at the Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and the Office of Science and Technology Policy (OSTP).

On Federal support for biomedical research, Dr. Haseltine's letter is not very specific. Generally, everyone I consulted agreed with his ideas. Public sponsorship of biomedical research is an example of "good government," and our strong support for NIH in all of the President's budget requests indicates that the Administration has made biomedical research a high priority.

On FDA reform, Dr. Haseltine says only that the current efforts are a good first step, but that more is needed. FDA has proposed to review certain biotechnology products as "drugs" rather than "biologics," thereby subjecting them to less cumbersome review. FDA is working on additional steps in this area.

On "technology transfer"-- the transfer of information gained in government sponsored research to the private sector -- Haseltine is critical of NIH's track record and suggests that a commission be created. NIH believes that this view is not widely shared and that, on the contrary, NIH has been heralded for its leadership in this area. This leadership is evidenced by the significant number of Cooperative Research and Development Agreements signed by NIH with commercial organizations, the large number of licenses that have been executed for use of its inventions, and the substantial royalties NIH has received from licensed inventions. NIH does not believe that a commission is necessary.

Finally, on prevention based medicine, Dr. Haseltine recommends the creation of a commission to address the shift from treatment based to prevention based medicine. By prevention based medicine he seems to mean only gene testing and therapy, rather than the normal understanding of prevention as a whole range of ways to reduce the risks of disease and improve health. HHS and NIH do not believe a new commission is necessary. Gene therapy was recently analyzed by an NIH advisory group. The issues surrounding genetic testing are the primary focus of the Task Force on Genetic Testing, established jointly by the NIH and the Department of Energy.

In addition, NIH shares Dr. Haseltine's view that the study of molecular genetics can lead to improvements in prevention based medicine. An interagency committee -- chaired by Dr. Ernest Moniz, Associate Director for Science at OSTP and Dr. Philip Lee, Assistant Secretary for Health at HHS -- is currently addressing this issue. A recent report of the committee called for expanded efforts on those diseases for which molecular genetics might provide valuable insights about both predisposition and disease mechanisms. During the coming year, the committee will explore how molecular genetics might improve clinical preventive services and promote their use among health care providers.

Please feel free to let me know if you need additional information on any of these issues.

cc: Karen Hancox
Debbie Fine

WIN IN '96 DEMOCRATIC NATIONAL COMMITTEE
Donald L. Fowler, *National Chair* • Christopher J. Dodd, *General Chair*

# MEMO

**To:** Doug Sosnik
**From:** Don Fowler dlf
**Subject:** Health Care Presentation for POTUS
**Date:** May 16, 1996

Several weeks ago, I proposed that Jan Leschly, CEO of SmithKline Beecham, and Bill Haseltine, CEO of Human Genome Sciences, brief the President on their mutual activities and the future of health care research and development. Specifically, they propose to discuss research in biotechnology, shifting the paradigm in health care from treatment to prevention, and related matters.

I spoke to the President on Tuesday (14 May 96) about this proposed meeting. He expressed an eagerness to have it set up. It is my understanding that this meeting is now being staffed in the White House, although it is not clear to me by whom.

Messrs. Leschly and Haseltine are currently working on their presentation. I hope you will do what is necessary to expedite preparations for their visit and provide us with a contact person on this matter.

Please find relevant documentation attached.

DLF/psw

cc: Alexis Herman
Marcia Hale

**MEMORANDUM**

**TO:** ✓Doug Sosnik
Don Baer
Secretary Donna Shalala

**FROM:** Donald L. Fowler DLF

**DATE:** April 1, 1996

**RE:** Proposal to the President

---

Please review the attached. Bill Haseltine of HGS has proposed to the President an exciting effort in hi-tech biomedicine. This seems to have substantive value as well as considerable political appeal.

Because it is complicated - politically and substantively - I am sending each of you a copy in hope that some effective follow-up can be achieved. If I can be helpful in this, please let me know. Thanks.

cc: Bill Haseltine

DLF/jeh

**Human Genome Sciences, Inc.**
9410 Key West Avenue
Rockville, MD 20850
(301) 251-6300 Fax (301) 309-8512
Internet E-mail:
William_Haseltine@hgsi.com

February 14, 1996

*via facsimile # 202/863-8174*
Mr. Donald L. Fowler
National Chair
Democratic National Committee
430 South Capitol Street, S.E.
Washington, DC 20003

Dear Don:

It was a pleasure to talk to you this morning. Enclosed please find a facsimile copy of the materials we discussed. An entire packet will also be forwarded to you by federal express.

I do hope the President can visit Human Genome Sciences and SmithKline Beecham. The field of genomics is central to the transition from treatment based to prevention based medicine. The genomics story highlights the productive relationship amongst federally supported research institutions (NIH), biotechnology companies (Human Genome Sciences), and large pharmaceutical companies (SmithKline Beecham).

Thank you for your interest in this area and Human Genome Sciences.

Sincerely yours,

William A. Haseltine, Ph.D.
Chairman of the Board and
Chief Executive Officer

P.S. I am pleased to confirm that HGS and I have renewed our membership in the Democratic Business Council

WH/csh

Attachments

— Lili Engstrom
690-8252

Faxed to Jack Ebeler

Memo to Harold
cc Doug

April 2, 1996

William A. Haseltine, Ph.D.
Chairman of the Board and
Chief Executive Officer
Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, Maryland 20850

Dear Bill:

Thank you for sharing your priorities regarding federal medical and technological expenditures. I enjoyed discussing these subjects with you, and I'm glad you took the time to follow up with me.

I particularly appreciate your suggestion for the creation of a Presidential commission to study a shift from treatment-based to prevention-based medicine, and I have circulated your letter for comment within my Administration. As you know, I remain committed to facilitating a more prevention-based health care system, which would both reduce skyrocketing costs and help to create a healthier population.

As we work to advance the health and well-being of our citizens while preparing our nation for the challenges of the next century, I will certainly keep your words in mind. You have my best wishes.

Sincerely, BILL CLINTON

BC/SEM/JFB/JRS/lynn-ckb (Corres. #2776347)
(3.haseltine.wa)

cc: w/copy of incoming to Jennifer Klein, West Wing
cc: w/copy of incoming to Chris Jennings, ODP
cc: w/copy of incoming to Marilyn Yager, OPL

E X E C U T I V E  O F F I C E  O F  T H E  P R E S I D E N T

24-Mar-1996 06:05pm

TO: Seth E. Masket

FROM: Christopher C. Jennings
Domestic Policy Council

SUBJECT: RE: Haseltine letter

Seth, I would suggest that you do a general acknowledgment letter (as you proposed) with an emphasis on the importance of health care moving from a treatment to a preventive focus.

Re his proposal for a Presidential Commission, I think we should get the comments of (and hopefully investment in) of HHS -- NIH, HCFA, ASPE, ACHPR, PHS in particular about the idea. We could say in the POTUS response that the President is circulating his idea for comment within the Administration.

I want to go this route b/c I think we should first learn what we have done, are doing, and are planning before pushing too quickly on a new Prez Commission. However, I bet we could get some strong interest in it if nothing else is going on. We should also enlist the Vice President's office as well as OSTP. (They love this stuff, and particularly the people suggesting it.)

If Jen is interested in following through with this, I think it would be great. (She knows this stuff well and is well connected to make something happen.) If you need my help, call or write me back...

cj

E X E C U T I V E  O F F I C E  O F  T H E  P R E S I D E N T

25-Mar-1996 11:14am

TO: Jennifer L. Klein

FROM: Seth E. Masket
Presidential Correspondence

SUBJECT: Chris' response

Jen, as you can see, Chris wants us to do some serious circulation of Haseltine's proposal. I can get a response out pretty quickly. Do you want to start forwarding this idea around, or do you want to wait until the response letter has been signed?

-Seth

HGS

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9410 Key West Avenue
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(301) 251-6000 Fax (301) 309-8513
Internet E-mail:
William_Haseltine@hgsi.com

# *Burden Center for the Aging*

## *Remarks*

***William A. Haseltine, Ph.D.***
***Chairman and CEO***
***Human Genome Sciences***

***November 27, 1995***

# The White House
## Office of Presidential Letters and Messages


Facsimile from Seth Masket
Voice: (202) 456-5514; FAX: (202) 456-2806

No. of Pages (including cover): 8 Date: 3/21/96

To: JEN KLEIN

Voice: 6-2599 Fax: 6-2878

Comments: HERE'S THE HASELTINE LETTER + MY PROPOSED RESPONSE. PLEASE LET ME KNOW IF IT'S OKAY & IF ANYTHING MORE CAN BE SAID TO DON FOWLER.

HGS

#155213

**Human Genome Sciences, Inc.**
9410 Key West Avenue
Rockville, MD 20850
(301) 251-6000 Fax (301) 309-8513
Internet E mail:
William_Haseltine@hgsi.com

January 29, 1996

Received in
ORM from
Arnie Lois
3/4/96

President William J. Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President:

It was a very special privilege to meet with you over breakfast to discuss a broad range of economic and political issues with other business leaders.

To follow-up our discussion:

## FEDERAL SUPPORT FOR BIOMEDICAL RESEARCH

Federal support of medical research - now $2 billion directly to NIH, and approximately $10 billion to universities via NIH- has strong public and bipartisan support. It is a prototypical example of "good government".

Federal support biomedical research ought to be highlighted as an example of what good government should do.

## BIOTECHNOLOGY: TECHNOLOGY TRANSFER

The U.S. is the world's leader in biotechnology, the seed bed of future medical advances - so much so that last week 350 European business and pharmaceutical executives met to discuss how they might overcome what they view as the insurmountable lead the U.S. is building. Federal funding of medical research creates knowledge useful for the development of new drugs. **However, new knowledge does not automatically translate to new products.** New products are created by the private sector, both biotechnology and pharmaceutical companies. Despite the by Dole-Bush Act and other laws and directives intended to facilitate the transfer of government sponsored research to the private sector, serious problems remain. In fact, my own experience is that NIH officials often seem to impede deliberately such transfer. **A commission to examine biotechnology transfer issues would be useful.**



**FDA REFORM**

Continued FDA reform - the latest FDA revision on biologicals is a good first step - is needed.

**PREVENTION BASED MEDICINE**

A shift from treatment based to prevention based medicine is possible based on advances in understanding of human genes. I believe that such a shift will dramatically reduce health care costs. Prevention based medicine is the foundation to a solution to the healthcare dilemma. Unfortunately, we do not have the institutional structures that are needed to facilitate such a shift. Indeed, our institutions are now structured so as to inhibit the introduction of preventive medicine. For example, costs of diagnostic tests and treatments that prevent serious diseases from occurring 10 to 20 years out, are not reimbursed. Current reimbursements limit treatments that demonstrate efficacy within a three year horizon, at most.

The U.S. does not have strong protection for genetic information. Such protection of genetic privacy is necessary before gene based predictive medicines are widely adapted. Our hospitals are largely treatment and not prevention oriented. A Presidential commission to study changes in our institutions necessary to facilitate the shift from treatment based to prevention based medicine would be welcome.

Once again thank you very much for the opportunity to share ideas with you.

I am enclosing a speech I gave on the occasion of receiving an award for Contributions to the Aging by the Burden Center for the Aging. The speech highlights my view of the impact of the understanding human genes on the future of medicine.

Sincerely yours,

William A. Haseltine, Ph.D.
Chairman of the Board and
Chief Executive Officer

WH/csh

Enclosures

cc: Secretary Donna Shalala - DHHS
Susan M. Charlton - DNC
Don Fowler - DNC


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# *Burden Center for the Aging*

## *Remarks*

*William A. Haseltine, Ph.D.*
*Chairman and CEO*
*Human Genome Sciences*

*November 27, 1995*

Good Evening. I would like to thank the Burden Center for the Aging for their recognition. I am pleased to accept this honor on behalf of my colleagues at Human Genome Sciences who have worked so hard with me to make our dream a reality. It is also a great honor to share your recognition with former First Lady Nancy Reagan for her outstanding contributions to our understanding of the problem of Alzheimer's disease.

I'd also like to take this opportunity to survey briefly what I foresee as the future of medicine -- a future that is fast approaching -- a future based on a deep understanding of our genes.

Let me begin by summarizing our recent progress in learning about our genes, the inherited instructions that make us what we are.

**FIRST** -- Using arrays of laboratory robots and sophisticated computers, we have identified virtually all the human genes.

**SECOND** -- We have determined which of those genes are used to build and maintain the normal functions for our normal organs, tissues, and cells.

**THIRD** -- We have begun a systematic study of changes that occur in gene usage in disease. Modern science has taught us that the root cause of disease is a change in our genes.

**FINALLY** -- We have begun to determine how our genes are used to construct our bodies, from a single fertilized egg to a mature adult. The information in our genes is used to build our bodies, and it is my belief that this information can be used to rebuild damaged and aging tissues.

The impact of this change will be far more profound than substitution of one type of medication for another. Genetic medicine will alter our individual experience with health care.

Today, in most cases, disease is diagnosed after illness has occurred. Too often today, the symptoms but not the underlying cause of the disease are treated.

Gene-based medicine will change this picture. The text of our genes will be read and used to predict inherited diseases before they occur. Such predictions will be followed by our ability to prevent the serious consequences of the disease. For example, last year we at Human Genome Sciences discovered three genes that predict, with 90% certitude, the onset of colon, ovarian, and endometrial cancer in people over 50. This problem affects 1 in 200 Americans. Early detection of these cancers, followed by surgery, is life saving.

Diseases will be detected early on before symptoms appear. Predictable changes in the pattern of genes in a tissue can predict disease. Such changes can be detected in time to avoid the disease altogether.

Knowledge of our genes is speeding the development of new treatments. The entire encyclopedia of life can now be read.

At Human Genome Sciences, we together with our partners, have initiated over 400 new studies directed to creating treatments for hitherto intractable diseases. Some of these will result in new drugs, such as the one described in the Friday, November 24th issue The Wall Street Journal for the treatment of osteoporosis and atherosclerosis.

For others, the gene itself and its natural products will be the drugs themselves. Use of such medication offers the hope of eliminating the root cause of many diseases.

And finally medicine will, at last, provide true cures. Damage to our tissues will be repaired by regeneration and regrowth. The same genes used to create our tissues will be used to regrow and repair damaged organs and tissues.

Let me end on a note of caution. All that I describe is possible. It can happen. But such progress is not inevitable. Each of us must work, as best we can, to make sure that the research environment and the health care system is receptive to these changes that promise so much.

I'd like to close by thanking my wife, Gale Hayman, for her support and cheerful good will over the past several years as I moved from the comfortable life of a Harvard professor to the much more demanding role of scientist-businessman, and for her help in organizing this splendid evening.

Thank you.

DRAFT OF BC LETTER

INITIALS: BC / sem / DOCUMENT TITLE: /slr/p/haseltine.wa.sem

DRAFT DATE / LETTER DATE: Mar 12 1996 / CORRESPONDENCE #: 2776347

CLEAR WITH: WHCC: CC: FWD.W/COPY OF INC.TO: Jennifer Klein, WW
FWD.W/COPY OF INC.TO: OSTP
FWD.W/COPY OF INC.TO: Marilyn Yager, OPL

CORRESPONDENCE ADDRESSED TO: APPROVAL/ENCLOSURES/SPECIAL INSTR:
William A. Haseltine, Ph.D.
Chairman of the Board and Chief Executive Officer
Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, Maryland 20850

---

Dear Bill:

Thank you for writing to express your priorities regarding federal medical and technological expenditures. I enjoyed discussing these subjects with you recently, and I'm glad you took the time to follow up with me. As we work to advance the health and well-being of our citizens while preparing our nation for the challenges of the next century, I will certainly keep your perspective in mind.

Thank you for taking the time to write.

# COVER SHEET FAX

**To:** Jennifer Klein
**Fax #:** (202) 456-2878
**Subject:** Attached letters
**Date:** May 9, 1996
**Pages:** 3, including this cover sheet.

COMMENTS:

Call

From the desk of...

**Diane Jones**
Secretary to Dr. William F. Raub
Office of Science Policy, OSASPE, DHHS
200 Independence Avenue, S.W.
Washington, D.C.

(202) 690-5874
Fax: (202) 401-7321

HGS

**Human Genome Sciences, Inc.**
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William_Haseltine@hgsi.com

April 5, 1996

Mr. Donald L. Fowler
National Chair
Democratic National Committee
430 South Capitol Street, S.E.
Washington, D.C. 20003

Dear Don:

Thanks once again for your follow-up on the proposed presidential commission. Enclosed please find a copy of the President's letter to me on this subject.

Sincerely yours,

William A. Haseltine, Ph.D.
Chairman of the Board and
Chief Executive Officer

WH/csh

cc: Secretary D. Shalala

THE WHITE HOUSE

WASHINGTON

April 2, 1996

William A. Haseltine, Ph.D.
Chairman of the Board and
Chief Executive Officer
Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, Maryland 20850

Dear Bill:

Thank you for sharing your priorities regarding federal medical and technological expenditures. I enjoyed discussing these subjects with you, and I'm glad you took the time to follow up with me.

I particularly appreciate your suggestion for the creation of a Presidential commission to study a shift from treatment-based to prevention-based medicine, and I have circulated your letter for comment within my Administration. As you know, I remain committed to facilitating a more prevention-based health care system, which would both reduce skyrocketing costs and help to create a healthier population.

As we work to advance the health and well-being of our citizens while preparing our nation for the challenges of the next century, I will certainly keep your words in mind. You have my best wishes.

Sincerely,

Bill Clinton

# FAX TRANSMITTAL SHEET

**DATE:** 12 JUNE 1996

**TO:** JENNIFER KLEIN

**ORGANIZATION:** EOP

**VOICE:** 202/456-2599

**FAX:** 202/456-2878

**FROM:** BILL RAUB

**ORGANIZATION:** DEPARTMENT OF HEALTH
AND HUMAN SERVICES

**VOICE:** 202/690-5874

**FAX:** 202/401-7321

**EMAIL:** wraub@osaspe.dhhs.gov

**NUMBER OF PAGES FOLLOWING:** 4

**MESSAGE:** PER CONVERSATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

June 12, 1996

NOTE TO JENNIFER KLEIN
SPECIAL ASSISTANT TO THE PRESIDENT, EOP

FROM BILL RAUB, SCIENCE ADVISOR, OASPE

SUBJECT: LETTER FROM DR. WILLIAM HAZELTINE

In response to your request, I am pleased to provide comments related to the issues raised by William A. Hazeltine, Ph.D. of Human Genome Sciences, Inc. in his January 29, 1996 letter to President Clinton. The comments below are a distillate of the views of pertinent senior staff of the DHHS.

1. Federal Support for Biomedical Research

Dr. Hazeltine cites public sponsorship of biomedical research as an example of "good government". We agree. More important, the President consistently has accorded high priority to biomedical research -- e.g., through a succession of very favorable budget requests for the National Institutes of Health (NIH).

2. Biotechnology: Technology Transfer

Dr. Hazeltine is correct about the social and economic importance of biotechnology and the need for continuing attention to technology transfer. Again, it already is a high priority for the Administration. Dr. Hazeltine's apparently critical view of the NIH track record in regard to technology transfer is not widely shared. On the contrary, NIH almost invariably is heralded not only for the seminal research it funds but also for its leadership in technology transfer. One cannot overstate the role of NIH in creating and expanding the knowledge base that fuels the biotechnology industry.

3. FDA reform

Dr. Hazeltine supports current efforts as "a good first step".

4. Prevention-based medicine

Dr. Hazeltine's comments focus on only a small part of what normally is included under the rubric "disease prevention". He is referring specifically to broader use of genetic testing and gene therapy for what, strictly speaking, is called "secondary prevention" (i.e., intervening to slow or arrest the course of a disease once it has been discovered) rather than "primary prevention" (i.e., reducing or eliminating the risks of the disease arising in the first place). He also refers appropriately to the critically important social issue regarding the privacy of genetic information.

I have discussed the notion of creating a Presidential commission to focus on this area with other pertinent senior officials of DHHS, including the Director of the NIH and the Assistant Secretary for Health. None of us believe that such a commission either is necessary or desirable. The issues associated with gene therapy recently were examined thoroughly by an NIH advisory group. The issues associated with genetic testing currently are the primary focus of a broadly representative Task Force on Genetic Testing, established jointly by the NIH and the Department of Energy.

Looking to the longer term, my colleagues and I share Dr. Hazeltine's view that molecular genetics has much to offer prevention-based medicine. This prospect already is being addressed by an interagency Committee under the auspices of the National Science and Technology Council. Further emphasis through the Council and its participating agencies seems the most appropriate course. The accompanying draft letter to Dr. Hazeltine develops this point in more detail.

I hope this information is helpful to you. If I can be of further assistance, please call (202/690-5874).

Draft letter to Bill Hazeltine from EOP

This is in follow up to your correspondence with President Clinton earlier this year regarding prevention-based medicine.

Preventing disease and disability is a high priority for the Administration. All of the health-oriented agencies of the Executive Branch are making major contributions toward this end -- e.g., by promoting healthy life-styles, by reducing risks to public health, and by developing diagnostic techniques and therapeutic interventions to help health-care providers arrest or retard the progression of illness. Initiatives now include such wide-ranging activities as those related to tobacco and children, immunization, dietary guidelines, the Surgeon General's Report on Physical Activity and Health, and prevention of infection with human immunodeficiency virus. Moreover, thanks in large part to the Human Genome Project of the National Institutes of Health and the Department of Energy, the concepts and methods of molecular genetics are attracting ever-increasing interest because of their potential to make virtually every one of these approaches more effective.

My colleagues and I share your enthusiasm about the prospects and challenges of prevention-based medicine and believe they are being addressed effectively through existing mechanisms. The principal interagency forum for fostering both prevention-related research and practical applications of its results is the Committee on Health, Safety, and Food (CHSF) of the National Science and Technology Council. The CHSF co-chairs are Dr. Ernest Moniz, Associate Director for Science within the Office of Science and Technology Policy, Executive Office of the President, and Dr. Philip Lee, Assistant Secretary for Health within the Department of Health and Human Services.

Earlier this year, in its report "Meeting the Challenge: A Research Agenda for America's Health, Safety, and Food", the CHSF explicitly identified the promise of molecular genetics. For example, the report called for expanded efforts with respect to those diseases for which molecular genetics might provide invaluable insights about both predisposition and disease mechanisms and thereby open new opportunities for the development of dietary regimens that reduce risk. During the coming year, the CHSF and its member agencies undoubtedly will go further -- e.g., exploring with the relevant scientific and clinical

communities how molecular genetics might improve clinical preventive services and promote their wider adoption across the national health-care community.

Thank you for highlighting this important area of biotechnology research and applications. We look forward to your continued counsel and contributions to the national effort.

WFRaub, DHHS 06VI96

# FAX TRANSMITTAL SHEET

**DATE:** 13 JUNE 1996

**TO:** JENNIFER KLEIN

**ORGANIZATION:** EOP

**VOICE:** 202/456-2599

**FAX:** 202/456-2878

**FROM:** BILL RAUB

**ORGANIZATION:** DEPARTMENT OF HEALTH
AND HUMAN SERVICES

**VOICE:** 202/690-5874

**FAX:** 202/401-7321

**EMAIL:** wraub@osaspe.dhhs.gov

**NUMBER OF PAGES FOLLOWING:** 4

**MESSAGE:** SUPPLEMENTAL INFORMATION AS REQUESTED

June 13, 1996

NOTE TO JENNIFER KLEIN
SPECIAL ASSISTANT TO THE PRESIDENT, EOP

FROM BILL RAUB
SCIENCE ADVISOR, OASPE, DHHS

SUBJECT: SUPPLEMENTAL MATERIAL RE DR. HAZELTINE'S LETTER

As requested, I am providing the following additional details:

FDA Reform

As part of Administration-wide efforts to "reinvent government", FDA has taken the initiative to streamline the premarket-review procedures affecting therapeutic biotechnology products -- i.e., drugs produced with the use of genetically engineered microorganisms. In particular, earlier this year, FDA sought public comment on a regulatory proposal that would enable its staff to review "well-characterized" therapeutic products of biotechnology as "drugs" rather than "biologics" (e.g., vaccines), which necessarily require more complex assessment procedures both before and after the agent is approved for market. Biotechnology has advanced to a point where many products are as well characterized chemically and physically as those produced by synthetic chemists. By recognizing this, FDA is moving to spare the industry and itself unnecessary premarket- and postmarket-review steps without compromising its judgements about safety and efficacy of new therapeutic products of biotechnology.

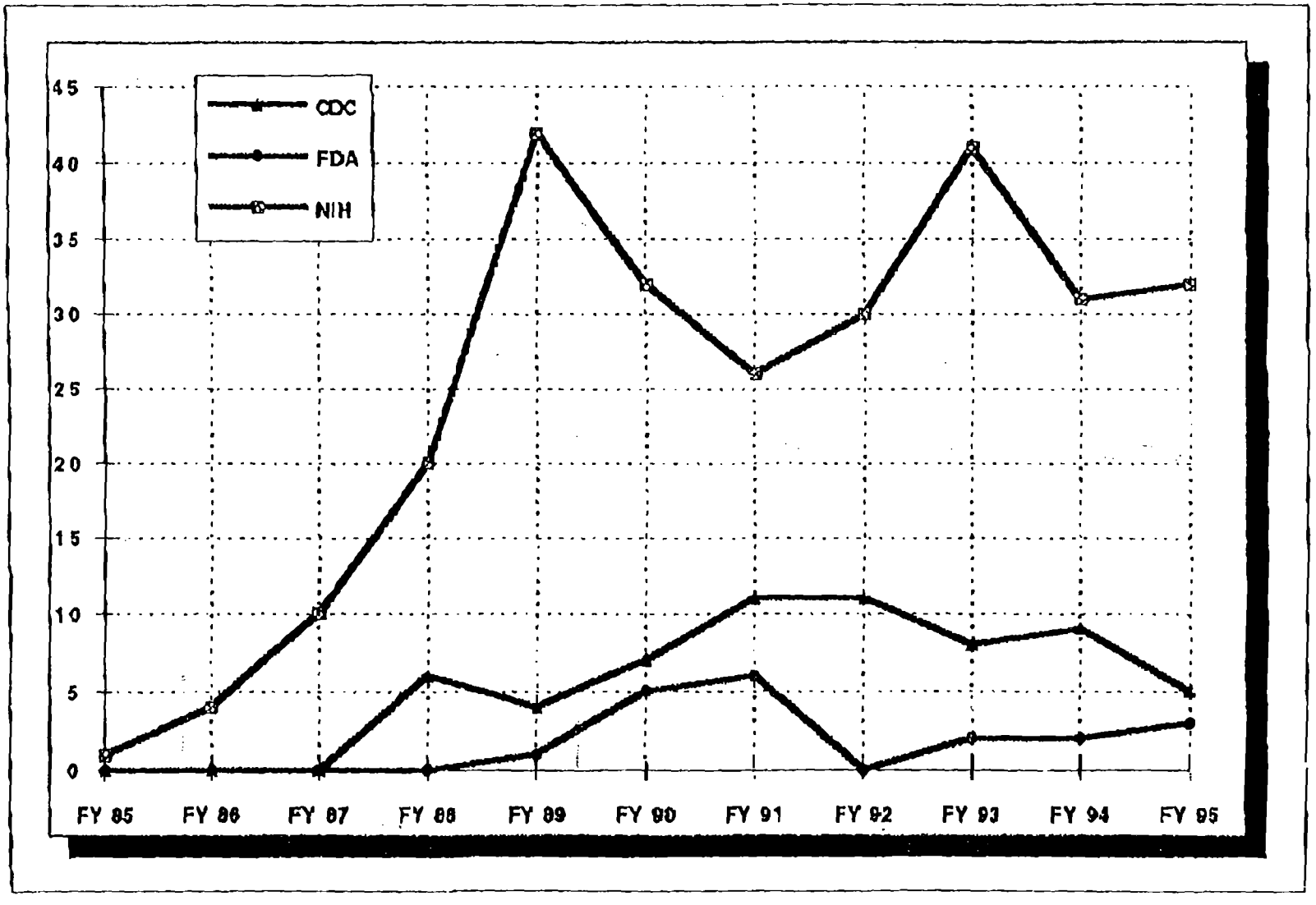
Technology Transfer

Three measures of the effectiveness of the NIH in this area are (1) the number of Cooperative Research and Development Agreements (CRADAs) with commercial organizations, (2) the number of licenses on its inventions -- thereby enabling commercialization, and (3) the royalties received from licensed inventions -- an indicator of the degree of success in commercialization. As indicated by the first two accompanying graphs, NIH has executed 269 CRADAs and 713 licenses, respectively, since 1985. Moreover, as indicated by the third accompanying graph, the royalties received from HHS inventions (mostly NIH) account for 75% of the royalties received by all other USG agencies combined.

# HHS Technology Transfer Activities

| HHS Executed* CRADAs | FY 85 | FY 86 | FY 87 | FY 88 | FY 89 | FY 90 | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CDC | 0 | 0 | 0 | 6 | 4 | 7 | 11 | 11 | 6 | 9 | 5 | 61 |
| FDA | 0 | 0 | 0 | 0 | 1 | 5 | 6 | 0 | 2 | 2 | 3 | 19 |
| NIH | 1 | 4 | 10 | 20 | 42 | 32 | 26 | 30 | 41 | 31 | 32 | 269 |
| TOTAL HHS Executed CRADAs | 1 | 4 | 10 | 26 | 47 | 44 | 43 | 41 | 51 | 42 | 40 | 349 |

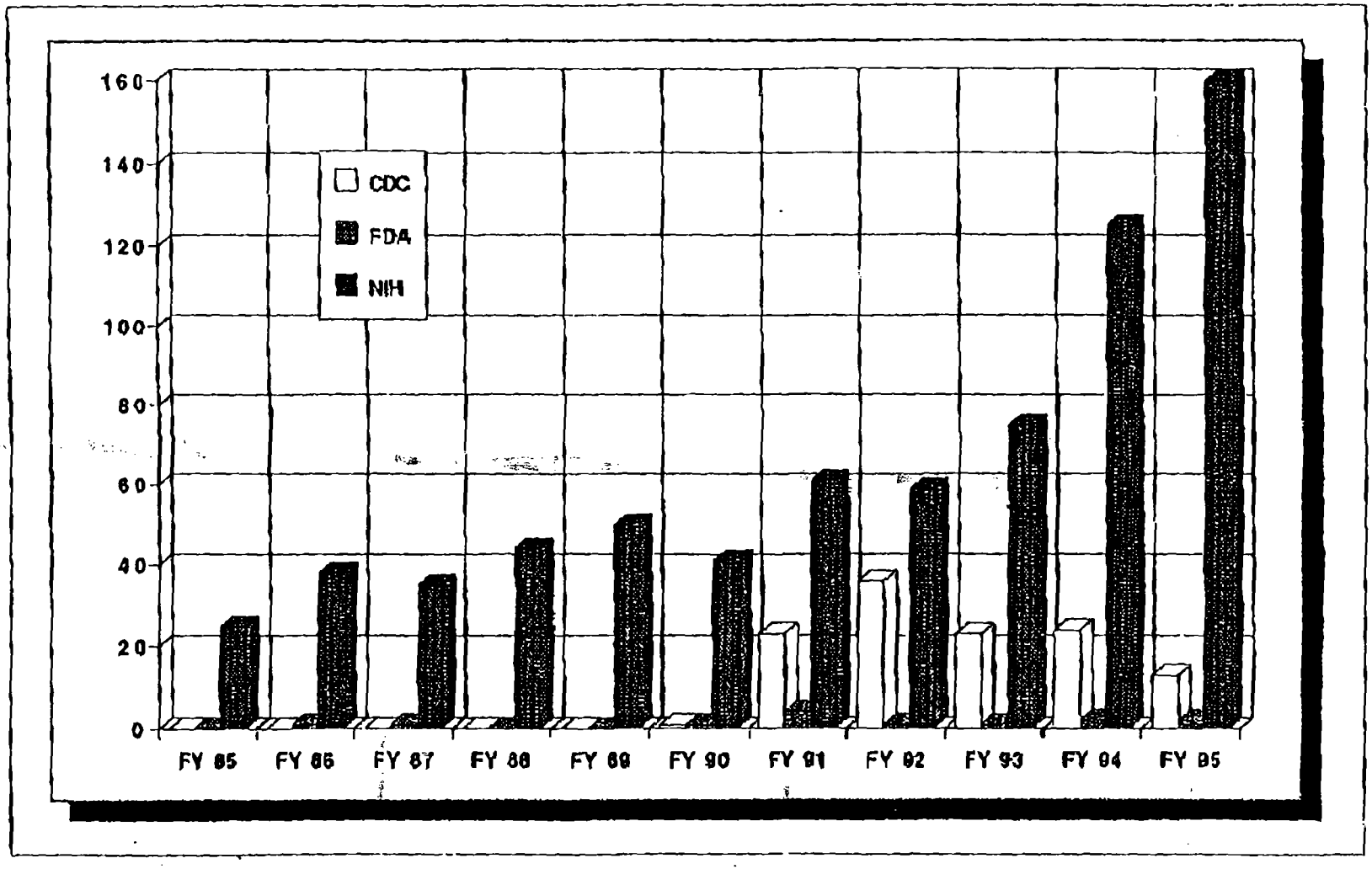
*Executed means CRADAs actually signed by both NIH and the collaborator. The execution date is the date of the last signature.



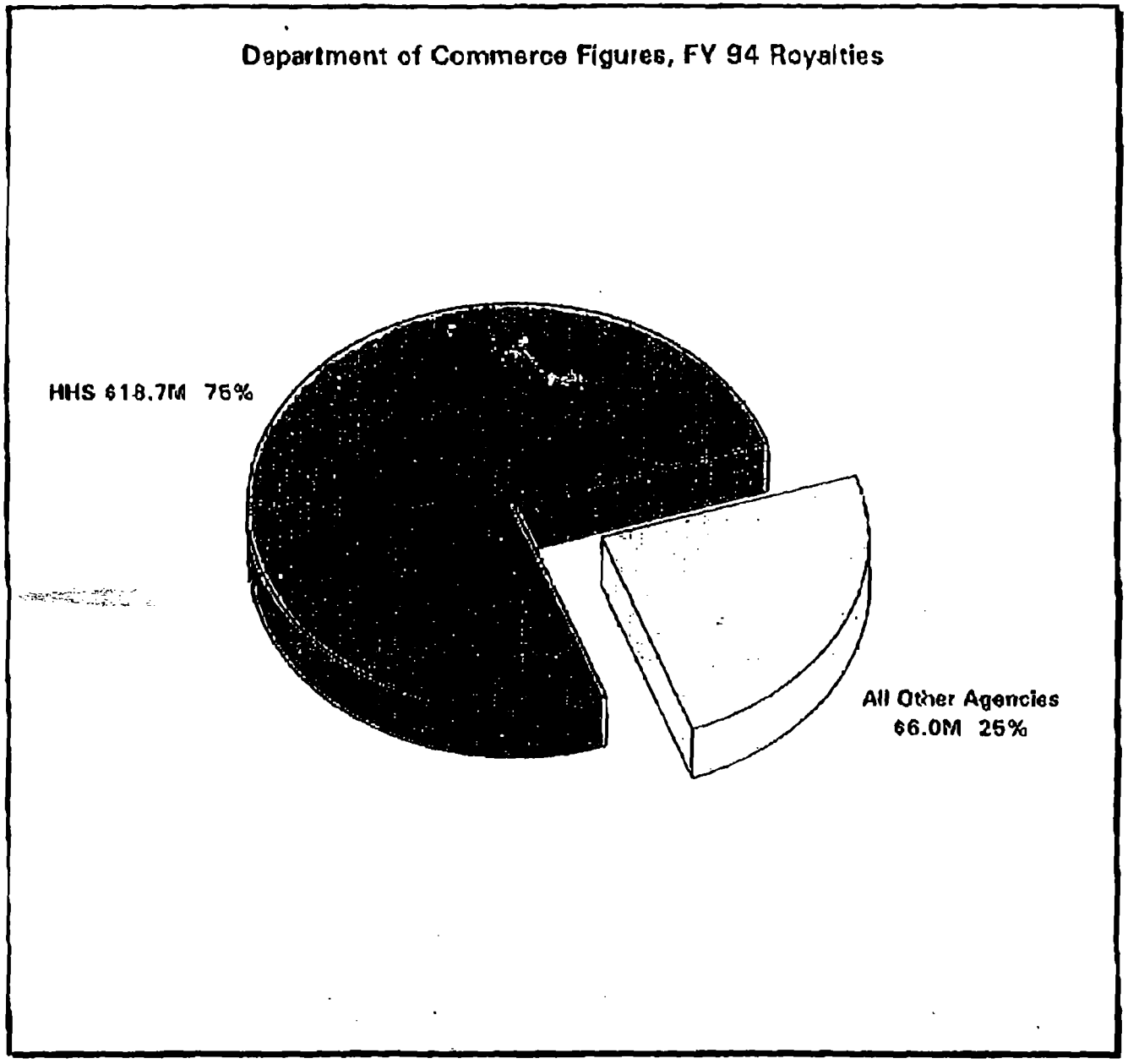

Prepared by NIH Office of Technology Transfer 6/13/96

# HHS Technology Transfer Activities

| HHS EXECUTED LICENSES | FY 85 | FY 86 | FY 87 | FY 88 | FY 89 | FY 90 | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CDC | 0 | 0 | 0 | 0 | 0 | 1 | 23 | 36 | 23 | 24 | 13 | 120 |
| FDA | 0 | 1 | 1 | 0 | 0 | 1 | 4 | 1 | 1 | 2 | 2 | 13 |
| NIH | 25 | 38 | 35 | 44 | 50 | 41 | 81 | 59 | 75 | 125 | 160 | 713 |
| Total HHS Executed Licenses | 25 | 39 | 36 | 44 | 50 | 43 | 88 | 96 | 99 | 151 | 175 | 846 |



# HHS FY 94 Royalties




Prepared by NIH Office of Technology Transfer 6/13/96