

FOIA MARKER

**This is not a textual record. This is used as an
administrative marker by the William J. Clinton
Presidential Library Staff.**

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: Speechwriting

Series/Staff Member: Terry Edmonds

Subseries:

OA/ID Number: 10988

FolderID:

Folder Title:

Genetic Screening [3]

Stack:

S

Row:

0

Section:

0

Shelf:

0

Position:

0

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	To Michael Waldman & Terry Edmunds [sic] (partial) (1 page)	05/09/97	P6/b(6)

COLLECTION:

Clinton Presidential Records
Speechwriting
Terry Edmunds
OA/Box Number: 10988

FOLDER TITLE:

Genetic Screening [3]

2006-0462-F
ry674

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

05/05/97 MON 11:59 FAX 202 401 5783

cc: Elena
+ return

BR

MEMORANDUM FOR THE PRESIDENT**FROM:** Donna E. Shalala**DRAFT****SUBJECT:** AIDS Vaccine Development

Recent advances in biomedical research supported by the National Institutes of Health (NIH) have created new opportunities and encouragement in our search for an effective vaccine against HIV infection. These advances are a direct result of our sustained investment in both basic scientific research and clinical investigation in the area of HIV/AIDS. This era of important scientific progress and renewed hope for the possibility of an AIDS vaccine provides an unique opportunity for you to consider ways to further this critical scientific endeavor.

To sustain this progress and capitalize on new scientific opportunities, we have increased the NIH budget for AIDS vaccine research by 33.6 percent over the past two years to nearly \$150 million in the fiscal year 1998 proposed budget. Recently, NIH also established a new NIH AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore of MIT, to provide leadership and guidance to an intensified comprehensive search for an AIDS vaccine.

A safe and effective AIDS vaccine is a global public health imperative. More than 29 million men, women, and children around the world have been infected with HIV. More than 3 million of these infections occurred in just the past year, with nearly 95% in the poorest parts of the world. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading infectious cause of death in the world. Even in the U.S., where new and effective anti-HIV therapies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies, and could well become even more dangerous. Only a truly effective preventive anti-HIV vaccine can limit and eventually eliminate the threat of AIDS.

I envision several options for a strong Presidential statement on this priority that will serve to galvanize the worldwide scientific community, renew the commitment of the pharmaceutical industry to AIDS vaccine development, and restate the unwavering commitment of the United States to develop a preventive vaccine:

1. **Presidential Address.** This is an opportune moment for you to deliver a major address on our continuing national commitment to ending the AIDS epidemic with the ultimate goal of developing a preventive vaccine. This could be the focus of one of your upcoming commencement addresses or it could be done in conjunction with the announcement of new initiatives. A good site for such an address could be the National Institutes of Health campus in Bethesda, MD.

DRAFT

2. **White House Meeting to Challenge Industry.** Another option would be to convene a meeting at the White House, to follow-up a meeting held by the Vice President last year, bringing together leading government scientists and CEOs of vaccine manufacturers, to seek solutions to concerns that have deterred the sustained participation of these companies in HIV vaccine development, such as cost of development, potential market, and legal liability issues.
3. **Announcement of New NIH AIDS Vaccine Laboratory.** We are prepared to establish a dedicated intramural HIV vaccine research and development center on the NIH campus, a major new initiative capitalizing on remarkable advances in immunology not previously applied to vaccine development. You could announce this initiative with the leadership of the NIH AIDS vaccine research program in attendance. In addition, you could visit one of several university-based vaccine labs supported by NIH throughout the country, including the University of Alabama, University of Washington, and Vanderbilt.
4. **Announcement of Awards for New NIH AIDS Vaccine Innovation Grants.** NIH has recently established a new funding mechanism to encourage novel research in AIDS vaccines. This new "Innovation Grant Program for Approaches in AIDS Vaccine Research" will award grants totaling \$6 million later this year. You could announce these grants with those scientists on hand.
5. **U.S. Proposal for an International AIDS Vaccine Research Initiative at Denver Summit.** At the Denver Summit in June, the U.S. will propose that the Eight nations make the political commitment to provide, in their own countries, the investments necessary to accelerate research toward the development of an AIDS vaccine as a scientific and public health priority. We will also propose that the U.S. NIH AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore, serve as the convener of vaccine researchers from around the world to discuss progress in research, identify scientific gaps and opportunities, design collaborative programs, and share scientific information. The Director of NIH is already contacting his counterparts in the eight nations to seek their consultation regarding this initiative. This will become part of the Communique of the Summit, and you could highlight this initiative as part of the Summit agreements.
6. **White House Briefing by Key Scientists on Progress towards a Vaccine.** The report of a year-long evaluation by more than 100 eminent scientists, known as the Levine Report, called for a reinvigorated and restructured NIH AIDS vaccine research program. The NIH has taken a number of steps to make AIDS vaccine research a top priority, including the initiation of studies to test a new vaccine strategy. You could invite the key scientists to brief you at the White House or at NIH regarding research progress and prospects for the future. If current research leads to a promising vaccine candidate for large-scale clinical testing, additional resources will be necessary to support clinical trials in the U.S. and at international sites.

In addition to these opportunities for leadership in the area of AIDS vaccine research, this is also an opportune moment to demonstrate our further commitment in the area of AIDS therapies. The HHS, with the advice of non-government clinical scientists and community

05/05/97 MON 11:59 FAX 202 401 5783

DEPUTY SECY

DRAFT

representatives, has prepared a document providing principles, guidelines and recommendations for clinicians and their patients regarding the most effective use of new anti-HIV therapies, including protease inhibitors. This draft is in final review and could be ready for release for public comment shortly. Your participation would highlight not only the importance of these guidelines, but your Administration's commitment to research and treatment. The release of these guidelines will require additional actions to assure access to these critical treatment regimens by those in need. As the Vice President recently announced, HCFA is developing a demonstration program to test the concept of providing Medicaid coverage at an earlier stage of HIV infection. In conjunction with this coverage, you could also announce a request to Congress for additional PY 1998 funds for the AIDS Drug Assistance Programs (ADAP), which helps uninsured and underinsured low-income individuals purchase AIDS drugs.

effects on insurance / liability etc?

Clinton Library Transfer Form

Case #, if applicable	2006-0462-F	Accession #		
Collection/Record Group	Clinton Presidential Records	Series/Staff Name	Terry Edmonds	
Subgroup/Office of Origin	Speechwriting	Subseries		
Folder Title	Genetic Screening	OA Number	10988	Box Number
Description of Item(s)	1 diskette "Sandra Martinez MSU"			

Donor Information

Last Name:		First Name:		Middle Name:		Title:	
Affiliation:		Phone (Wk):		Phone (Hm):			
Street:		City:		State (or Country):		Zip:	

Transferred to:	Audio/Visual Department
Other (Specify):	
Transferred by:	Kara Ellis
Transfer Point	During Processing

Date of Tranfer	9/10/2008
-----------------	-----------



OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Director's Office
Executive Office of the President
436 Old Executive Office Building
Washington, DC 20502

202-456-6047
202-456-6027 (FAX)

FAX TRANSMITTAL SHEET

DATE: May 16, 1997

TO: Terry Edmonds

PHONE NUMBER: 6-2777

FAX NUMBER: 6-5709

FROM: Jeff Smith

NUMBER OF PAGES (INCLUDING COVER SHEET):

Terry -- I know I promised you no more input from Jack Gibbons. But attached are a few comments from Rachel Levinson of our staff in whom I have great confidence. Along with all the others who are after your ear, I hope you will give her thoughts a well-deserved fair hearing. My special thanks.

PS.

BCC: Terry - I had to promise
to send this - Best pitch if
you don't agree. Jeff

On page 2, 4th full paragraph, you state, "We have not and we must not ever shrink from exploring the frontiers of science and basic knowledge." This is good. Moreover, on page 4 you make these points:

"Science has no soul of its own. It is up to us to determine if it will be used as a force for good or evil."

"We must do nothing to stifle our basic quest for knowledge."

These are also good. These passages and others make the fine point that science is value-neutral (which might be a clearer way to explain it than science has no soul of its own, but I think that's what is being conveyed) and it is the use of science, not science by itself, that must be governed to ensure that the benefits flow to all Americans.

That's why certain phrases on page 4 are not consistent with the point made above. These phrases are:

"Science can spark a nuclear or biological war" I would substitute "fuel" for "spark"

Likewise, "First, science and its benefits must be directed towards making life better for all Americans." Directing science is the same as restricting it, which we have already determined to be counterproductive. How about:

"First, the benefits of science must be directed towards....."

And I think there is a typo in the next sentence beginning with "Their..." Could this read:

"The opportunities and benefits flowing from science should be available to all."

Similarly: "We also know that in years past, too often, science mirrored the sickness of society..." This is a very strong point but the blame should be pointed at people, not science.

Could it be changed to read:

"We also know that in years past, science was used to mirror the sickness of society" Or was subverted

One concern about the AIDS vaccine: Having a vaccine will be fantastic and will prevent the spread of HIV, but it does nothing for the hundreds of thousands of people living with AIDS right now. Rather than risk disenfranchising them, could the sentence reading:

"Only a truly effective HIV vaccine will totally eliminate the threat of AIDS" be modified simply by deleting the underlined phrase and substituting diminish or something that recognizes that there is still a problem ?

U.S. DEPARTMENT OF EDUCATION*White House Initiative on Historically Black Colleges and Universities**600 Independence Avenue, S.W.**The Portals Building, Suite 605**Washington, DC 20202-5120**Phone (202)708-8667**Fax (202) 708-7872***FAX TRANSMISSION**

To: Terry Edmonds

Date: 5-15-97

Company: _____

Fax: 456-1213

From: Catherine LeBlanc

**IF RE-TRANSMISSION IS NECESSARY,
PLEASE CALL THIS OFFICE IMMEDIATELY**

Message: Terry, suggested talking points for
the Morgan Commencement

Hard Copy Will Be Sent Under Separate Cover:

Yes ☐ No ☐Page: 1 of 2

708-8981
Margaret Ward

SUGGESTED TALKING POINTS, MORGAN STATE UNIVERSITY COMMENCEMENT

Dr. Earl Richardson, President of the University, has been a strong supporter of the Administration's educational initiatives and a very active advisor to the U.S. Department of Education as the former chairman of the National Association for Equal Opportunity in Higher Education (NAFEO - the association of all historically black colleges), and as a member of the President's Board of Advisors on Historically Black Colleges and Universities.

Under Dr. Richardson's leadership, Morgan has experienced unprecedented growth and has risen to national prominence as a major producer of African American graduates in the sciences, engineering, business and education. The University produces a significant number of Fulbright Scholars as well as students who pursue the doctorate degree.

Morgan's success in graduating large numbers of African American baccalaureates in the sciences and engineering is derived from the same formula for success employed at other historically black colleges and universities: they provide a supportive, nurturing academic and social environment, which, when merged with high expectations for achievement and the presence and influence of accomplished role models of color, produce a blossoming of intellectual promise untapped by some of the more traditional approaches to teaching and learning.

Morgan, like other historically black colleges, has benefitted significantly from the strongest Executive Order ever issued on black colleges. Working closely with agencies like the U.S. Departments of Energy and Transportation, Morgan has been able to expand and enhance its research and curriculum offerings for students and faculty.

To keep our economy strong we must keep that strategy in place. That is why I am so proud that we have reached a bipartisan agreement to balance the federal budget for the first time since President Johnson was in the White House. It brings the deficit down to zero over the next five years, but it also reflects our values -- preserving and protecting Medicare and Medicaid, expanding health coverage to five million uninsured children, protecting the environment, and helping move people from welfare to work, providing tax relief for families.

All of those values are important. But, to me, the very heart of this balanced budget agreement is its historic investment in education. This agreement includes the most significant increase in education funding in 30 years. Even more important, it provides the single largest increase in higher education since the G.I. Bill in 1945, the landmark legislation that gave opportunity to millions of Americans and gave birth to our great middle class. That was my goal for this budget -- to dramatically expand opportunity through education, to give all our children the tools to succeed.

Education has always been the heart of opportunity in this country. And it is the embodiment of everything we must do to prepare for the 21st century. Nothing will do more to open the doors of opportunity to every American and prepare them for unimagined new work and careers. Nothing will do more to instill a sense of responsibility in every American as they work to make the most of their education. And nothing will do more to build a strong, united community of all Americans -- for if we all have the tools to succeed, we can move forward together, as one America.

That is why I insisted that America's balanced budget also be an education budget. I am pleased to say that it meets that test. While it puts our fiscal house in order, this agreement opens the schoolhouse door wider than ever before. If Congress holds firm to the basic agreement we have reached -- the details of which are already moving through Congress at an expedited pace -- we will go a long way toward preparing our children for the 21st century.

The balanced budget agreement will fund our America Reads challenge, which will mobilize one million volunteer reading tutors to ensure that every 8-year-old can pick up a book and say, "I can read it myself." It includes our Technology Literacy Initiative, which will help us finish the job of wiring every classroom and school library to the Internet by the year 2000, so that children in the poorest inner-city school districts and in the most remote rural schools have access to the same vast store of knowledge.

It includes \$35 billion in tax relief for higher education -- including our HOPE Scholarship tuition tax credit and our \$10,000 education tax deduction. It includes the largest increase in Pell Grant scholarships for deserving students in three

There have been amazing recent advances in S&T

Science should be equated with opportunity -- not with negativity. It's human choice that determines whether S&T benefits or injures people.

An informed citizenry is the only effective defense against S&T harm.

Principles:

- 1) The opportunities and benefits of S&T should be available to all. We must use our human power of choice to apply S&T only in ways beneficial to all.
- 2) Discoveries should not be used to harm or discriminate against individuals or groups.
- 3) Technology should not be used to abridge the rights of people's privacy, dignity or autonomy.
- 4) Science and religious faith are complimentary and compatible pursuits that should empower and enrich each other in each individual's life.

301-402-2700

Dr. Harold Varmus

Bob
Barstien
Jonathan
Caplan
6081221

$$\begin{array}{r} 1933.33 \\ 1891.72 \\ \hline 41.61 \end{array}$$

$\begin{array}{r} 300 \\ 76 \\ 70 \\ 100 \\ \hline 546 \end{array}$	$\begin{array}{r} 1733 \\ 546 \\ \hline 1187 \\ 350 \\ \hline 837 \end{array}$
---	--

200-S
150-M

Hillary Stott
862-9233

Bob Scherman
Report on



OFFICE OF SPEECHWRITING

TO: DR. HAROLD VARMUS

Fax # 301-402-2700 Phone # _____

FROM: TERRY EDMONDS

Fax # (202) 456-5709

Phone # (202) 456-2777

NOTES:

POTUS has this draft.

Thanks,
Terry

202-456-2499

7 PAGES TOTAL

UNAUTHORIZED USE OF THESE MATERIALS
IS SUBJECT TO FEDERAL PROSECUTION.

REVISED

5/16/97 12:00 pm

'97 MAY 16 AM 11:43

**PRESIDENT WILLIAM J. CLINTON
COMMENCEMENT ADDRESS ON SCIENCE IN THE 21st CENTURY
MORGAN STATE UNIVERSITY
BALTIMORE, MARYLAND
MAY 18, 1997**

Acknowledgments: Dr. Earl Richardson, President; Judge Harry Cole, board chair; Governor Glendening; Mayor Schmoke; elected officials – including city council, which voted to ban cigarette billboards near schools; Reps. Elijah Cummings, Ben Cardin; Sens. Sarbanes, Mikulski; Board of Regents; Faculty and staff; distinguished alumni: Judge Cole; Judge Robert Bell, Chief Judge of Maryland's highest court; Kweisi Mfume; Earl Graves; Richard Dixon, State Treasurer; Terry Edmonds, White House staff.

I am pleased to deliver my first commencement address at an Historically Black University. In our past, when the doors of colleges were closed to all but white students, Morgan State and the nation's other HBCUs gave young African Americans the education they deserved and the pride they needed to rise above cruelty and bigotry. In our present, HBCUs produce the lion's share of our black doctors, judges, and businesspeople – and Morgan State graduates most of the black scientists and engineers in Maryland. And in our future, I am certain that HBCUs will play an even greater role in moving our country forward.

But, Morgan State is not just a great Historically Black University -- Morgan State is a great American university. You have produced some of this country's finest leaders. Not just the African American community, but our entire American community would be diminished without great Morgan grads like Parren Mitchell, Kweisi Mfume and Earl Graves. The halls of justice would be diminished without great judicial leaders like Judge Bell and Judge Cole. And without Morgan, I would never have had the good fortune to work with Terry Edmonds who, remarkably, is the first African American ever to serve as a presidential speechwriter.

All of you graduate today into a world brimming with promise and rich with opportunity. As I said in my State of the Union Address, the enemy of our time is inaction. We must use this moment of great hope and prosperity to prepare our people for the challenges of the 21st Century. This spring, here and in commencement addresses across the country, I will seek to focus our attention on those great and powerful forces that can pull us apart, or that can become our greatest strength in the years ahead. I will discuss our diversity, and how we can make sure that it brings us together rather than divides us. I will discuss America's continuing obligation to lead the world, especially our obligation to help build a strong and united Europe in the wake of the Cold War.

And we know that above all else the 21st century, in its texture, in its promise and in its reality, will be molded by science, shaped by technology, powered by knowledge. These are

potent, transforming forces; they can be used for good or for ill; and we must master them if we are to make the most of this new century.

We enter that century propelled by new and stunning developments. In the past year alone, we saw the cloning of Dolly, the sheep. The Hubble Telescope is bringing into focus dark corners of the cosmos never seen before. Innovations in computer technology and communications are creating what Bill Gates calls the world's new "digital nervous system." Cures for our most dread diseases – diabetes, cystic fibrosis -- seem within reach. And last week, we saw a computer named Deep Blue, defeat the world's reigning chess champion. I hope they don't make a computer that can play golf.

The past half century has seen some of mankind's greatest breakthroughs, as we split the atom, spliced genes, created the microchip, explored the heavens. For half a century, we struggled to harness forces as powerful as the sun, in an effort to keep them from destroying the planet. Today, at long last, nuclear and computer technology are realizing their greater value as servants of a better life, not masters of a bitter destruction.

If the last 50 years were the age of physics, the next 50 years will be the age of biology. We are now embarking on our most daring exploration ever -- unraveling the mysteries of our inner world and charting new routes to the conquest of disease. And our great challenge will be to harness the power of biology, our increasing knowledge about the cell, the brain and life itself so that we can reap the amazing benefits while avoiding the pitfalls that exist with the very promise of new technology.

We have not, and we must not ever shrink from exploring the frontiers of science and basic knowledge, no matter where it leads us. But as we consider how to use the fruits of that knowledge, we must also never retreat from our commitment to human values, the good of society, and our basic sense of right and wrong. Today let us commit: in the 21st Century, science must serve humanity – never the other way around.

In that new century, America's future, indeed the world's future, will be powerfully influenced by science and technology.

Where once nations measured their strength by the size of their armies, their arsenals and their GDPs, in the world of the future, it is science and knowledge that will matter most. Fully half the growth in economic productivity over the past half century can be traced to research and technology. That is why it is so important that the balanced budget agreement I reached with the leaders of Congress funds the increase I requested for science and technology in my 1998 budget and reaffirms our long-term commitment in this important area.

Science is about more than material wealth or the acquisition of knowledge; it is about our dreams.

Ours is a nation defined by the great goals we set. Often these goals can seem beyond our reach. But it is the very act of reaching for that far horizon -- of imagining our future and striving to realize it -- that will define us. We are a restless, questing people. We have always believed, with Thomas Jefferson, that freedom is "the first born daughter of science." And with our willpower, our resources and a great national effort, we have always reached those horizons, and set out for new ones.

Thirty-six years ago, President Kennedy looked to the heavens and proclaimed that the flag of peace and democracy, not war and tyranny must be the first to be planted on the moon.

Today, let us look within and step up to the challenge of our times -- a challenge with consequences far more immediate for the life and death of millions around the world. AIDS will soon overtake tuberculosis and malaria as the leading infectious killer in the world. Even here in this country, where new and effective anti-HIV strategies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies and could well become even more dangerous. Only a truly effective HIV vaccine will totally eliminate the threat of AIDS.

So, let us set a new national goal for this era of science. Today, let us commit ourselves to developing an AIDS vaccine within the next ten years. There are no guarantees; it will take energy, it will take focus; it will demand great effort from our greatest minds. But we have made strides in recent years. It is no longer a question of whether we can develop an AIDS vaccine -- it is a question of when. And if America commits to find an AIDS vaccine within the next decade, we will do it.

I am prepared to do all I can to make this happen. Our scientists at NIH and at our research universities have been at the forefront of this battle. Today, I am pleased to announce that NIH will establish a new AIDS vaccine research center dedicated to this crusade. At the summit of industrialized nations in Denver next month, I will enlist other nations to join us in a worldwide effort to find a vaccine to stop one of the world's greatest killers. And we will challenge America's pharmaceutical industry, which leads the world in innovative research and development, to work with us and make the successful development of an AIDS vaccine part of its basic mission.

The 21st Century will be the century of biology. Together, we can make an AIDS vaccine its first great triumph.

This is just one example of the great advances that will be made possible by our focus on science and technology. In this and so many other ways, science will enrich our existence. It is how we will work with other nations to address global climate change. It is how we will break our reliance on limited sources of energy. It is how we will once again make giant strides to free ourselves and future generations from the tyranny of disease and hunger and ignorance that today enslaves too many around the world.

So today, at the edge of this new century, let us pledge to learn more and do more in the realm of science. But let us also pledge to redouble our vigilance, to make sure that the knowledge of the 21st Century serves our most enduring human values.

Science often moves faster than our ability to understand its implications. Each new discovery, each new breakthrough, can create a new maze of moral and ethical questions. We are only just beginning to figure out how to answer those questions.

The Internet can be a new town square -- or it can be a new Tower of Babel. The same computer that can put the Library of Congress at our fingertips, can also be used by purveyors of hate to spread blueprints for bombs. The same knowledge that is developing new life-saving drugs can be used to create poisons of mass destruction. Science can enable us to feed billions more people in comfort and safety -- or it can spark a nuclear or biological war. And it can do so by accident as well as on purpose.

Science has no soul of its own. It is up to us to determine if it will be used as a force for good or evil.

Let me be clear: We must do nothing to stifle our basic quest for knowledge. Human curiosity is the driving force behind all human discovery. It is a fundamental principle of our democracy. In the last century, the spirit and benefits of scientific inquiry have propelled us from field to factory to cyberspace.

But, how we use the fruits of science and how we apply it to human endeavors is not properly the domain of science alone -- or scientists alone. I believe we must apply the same ethical and moral principles that have guided every great religion, our great democracy, our very sense of right and wrong. We need a great national conversation about these principles. We must decide together how to apply them to the dazzling new discoveries of science. Here is what I think those principles should be.

First, science and its benefits must be directed towards making life better for all Americans, and never just the privileged few. Their opportunities and benefits should be available to all. Lack of money or social status must never be a barrier to the benefits of science and technology. Science that does not move us all forward is science that will hold us all back. Science must not create a new line of separation between the haves and have nots -- those with and without the tools and understanding to learn technology. In the 21st century, the school that does not have the link to the Internet or the child who does not have access to a computer will be like the 18th century child without schoolbooks. That is why we are ensuring that every child in every school, no matter how rich or poor, will have the same access to technology.

We also know that in years past, too often science mirrored the sickness of society at large. Here at one of America's great black universities, let me underscore what I said a few days ago at the White House: We must never allow our citizens to be unwitting guinea pigs in scientific experiments without their consent, that put them at risk -- whether it is the withholding

of syphilis treatment from the black men of Tuskegee or the Cold War experiments that subjected some of our citizens to dangerous doses of radiation. We must never go back to those awful days when eugenics and racial stereotyping here and in Europe resulted in discrimination and worse against those judged to be inferior. Our greatness is measured not only in how we do right, but also in how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies and take action. Together, we must say, never again.

The second principle I believe we should apply is this: none of our discoveries should be used to label or discriminate against any group or individual. Increasing knowledge about the great diversity within the human species must not change the basic belief upon which our ethics, our government and our society are based: All men are created equal. Period. End of story.

With stunning speed, scientists are now moving to unlock the secrets of our genetic code. Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. But, it might also be used by insurance companies and others to discriminate and stigmatize groups of people. We know that in the 1970s some African Americans were denied health care coverage by insurers and jobs by employers because they were identified as sickle cell anemia carriers. We also know that one of the main reasons women refuse genetic testing for susceptibility to breast cancer is their fear that insurance companies may either deny them coverage or raise their rates. No insurer should be able to use genetic data to underwrite or discriminate against any American seeking health insurance. This should not just be a matter of principle, it should be a matter of law. In the coming weeks, I will send legislation to the Congress to prohibit insurance companies from using genetic screening information to determine premium rates or eligibility for health insurance.

Our third principle must be this: Technology should not be used to break down the wall of privacy and autonomy free citizens are guaranteed in a free society.

The right to privacy is one of our most cherished freedoms. As society has grown more complex, and as people have become more interconnected in every way, we have had to try even harder to respect the dignity and autonomy of each individual. Today, when marketers can follow every aspect of our lives -- from the first phone call we make to the time our security system says we have left the house, to the video camera at the toll booth and the charge slip we leave for lunch -- we cannot afford to forget this most basic lesson. As the Internet reaches to touch every business and every household, and we face the frightening prospect of private information or even medical records instantly being made available to the world, we must develop new protections for privacy to meet this new reality.

And fourth, we must always remember that science is not God. Our deepest truths remain outside the realm of science. We must temper our euphoria over the recent breakthrough in animal cloning with sobering attention to our most cherished concepts of faith and humanity. My own view is that each human life is unique, born of a miracle that reaches beyond laboratory science. I believe we must respect this profound gift and resist the temptation to replicate

ourselves. But this is a decision no President should make alone. That is why I have asked our distinguished National Bioethics Advisory Commission, headed by President Harold Shapiro of Princeton, to conduct a thorough review of the legal and ethical issues raised by this new cloning discovery. They will give me their recommendations within the next few weeks.

These are the principles that should guide us if we are to master the powerful forces of change in the century to come. Science that produces a better life for all and not the few. Science that honors our tradition of equality. Science that respects the privacy of the individual. Science that never confuses faith in technology with faith in God. If we hold fast to these principles, we can make this time of change a moment of dazzling opportunity for all.

In conclusion, let me say this: Science will only serve the values of all Americans, if all Americans are given a chance to participate in science. We cannot move forward without the voices and talents of everyone in this stadium and, especially those graduates who are going on to pursue careers in science and technology. African Americans have always been at the forefront of American science. Nothing -- not slavery, not discrimination, not poverty -- has ever been able to hold back the scientific urge or the creative genius of African Americans.

Benjamin Banneker was a self-taught mathematician/surveyor/astronomer, who published an annual almanac and helped design the city of Washington. George Washington Carver was born a slave, but went on to become one of this nation's greatest agricultural scientists. Ernest Everett Just of Charleston, South Carolina, is recognized as one of the great biologists of all time. And Charles Drew lived through the darkest days of segregation to become a pioneer in blood preservation. They showed us all how America's diversity is its greatest strength. Now it is your time. It is up to you, to honor their legacy, to live their dreams, to be the investigators, the doctors, and the scholars who will help keep our science rooted in our values.

Thank you and God bless you all.

Chicago
"True science knows no bounds. It penetrates into every domain without fear and serves all men without prejudice or favor. It's work is to substitute facts for appearances, demonstrations for impressions, and beneficial realities for those many things ignorance and greed proclaim to be impossible. For suffering humanity it is hope and promise."

O. W. Holmes (~~from Harry Caudill~~)

Chief Justice Holmes

(532)

BusinessWeek

MARCH 10, 1997

A PUBLICATION OF THE MCGRAW-HILL COMPANIES

\$3.50

THE BIOTECH CENTURY



Cloning animals is just the beginning. Thanks to fundamental advances in genetics, biology will define scientific progress in the 21st century. It's all happening faster than anyone expected.

EOP LIBRARY DEOB BLDG ROOM 308
WASHINGTON DC 20502-0001#BXBBGDD***3-01G1
00600 1105247334#DEC99 DIE 0078
205

AL REPORT

PAGE 78

The grand, tumultuous pageant of human history is, in a large part, propelled by technology. Metalworking and improved agriculture carried civilization out of the Stone Age. In the 19th century, the Industrial Revolution gave rise to mighty machines and sprawling cities. In the 20th century, physics became king. Physicists split the atom, explored the bizarre worlds of relativity and quantum theory, and harnessed the power of tiny chips of silicon. Along the way, they transformed the world with the atom bomb, the transistor, the laser, and the microchip. But now, many experts believe, humankind is poised to ride a new wave of scientific knowledge in the headlong rush to the future. "This was the century of physics and chemistry," proclaims 1996 Nobel prize-winning chemist Robert H. Curl of Rice University. "But it is clear that the next century will be the century of biology."

On Feb. 22, that century was suddenly upon us—arriving years sooner than any one expected, not like a lion but in the guise of a lamb. A previously obscure 52-year-old Scottish embryologist, Ian Wilmut, stunned the world by announcing that he and his team at the Roslin Institute outside Edinburgh had created an exact copy—a clone—of an adult Dorset sheep. The historic lamb, created from DNA extracted from the sheep's mammary gland, was named Dolly. "We couldn't think of

SCIENCE OF THE LAMBS: A sheep ovum is injected with an embryonic cell

CONTENTS

A PRIMER DNA for dummies: The basics of genetics 84

THE ETHICS When science fiction meets social reality 84

THE COMPANIES Start-ups with a keen eye on commerce 90

There's a revolution brewing in the lab,
and the payoff will be breathtaking

21ST CENTURY

anyone with a more impressive set of mammary glands than Dolly Parton," says Wilmut.

Wilmut's trick was to replace the genes in a normal sheep oocyte, or egg, with DNA from an adult sheep mammary gland. He prodded the egg to grow and inserted it into the womb of another sheep. Last July, Dolly was born—an exact genetic copy of the adult whose mammary gland was tapped for DNA.

Wilmut and other scientists say that in principle, the same technique should work for any other mammal—including humans. Dr. Jon W. Gordon, an obstetrics

HEMOPHILUS This bacterium, which causes meningitis and childhood ear infections, was the first organism for which researchers identified the entire genome—the complete set of genes. One goal: pointing the way toward new drugs and vaccines.

the “troubling” implications of cloning.

And yet, the headline-grabbing lamb represents only a tiny slice of what's just around the corner in biology during the coming century. Science is on the brink of an unprecedented explosion in its ability to understand and manipulate life. Until recently, researchers were forced to painstakingly search for genes one by one. The effort to nab the cystic fibrosis gene took 10 years and cost more than \$150 million, for example. To isolate one obesity gene required a decade of work.

Now, however, gene sleuths are approaching from the other direction.

They are deciphering the entire genetic code—known as the genome—of a wide variety of organisms, from humans to microbes. As these genomes are being decoded, or “sequenced,” researchers are separating the individual genes and beginning to discover what each of them does.

Already, the fully sequenced genomes of six microorganisms have been published, and the cost is now as low as \$300 per gene. Some 50 more, including those of the devastating malaria parasite and other disease-causing organisms, will be finished by the end of the 1990s. And thanks to the ambitious Human Genome Project and similar efforts in plants and animals, scientists will hold in their hands the complete blueprints of everything from nematodes and mustard plants to mice and men by the first decade of the 21st century—all neatly catalogued in computer databases.

Eric Lander at the Whitehead Institute for Biomedical Research in Cambridge, Mass. likens these complete genomes to the periodic table of elements, the basis for 20th-century research in chemistry. Stanford University geneticist Richard M. Myers says having the genomes “is expanding people's imaginations, allowing them to think on a grand scale, asking and answering questions they would never have dreamed of before.” Adds Monica Riley, senior scientist at the Marine Biological Laboratory in Woods Hole, Mass.: “In the near future, we will know every-

thing that goes into making up a living cell. It's an exhilarating time to be doing science.” No one doubts that the payoff will be immense. By 2003, farmers

Special Report

THE BIOTECH CENTURY

researcher at the Mount Sinai Medical Center in New York, notes that cloning a human might not be so simple. Some genetic experiments that work in mice don't work in rats, and vice versa—suggesting that all mammals are not quite the same. And the first step, he said, will be for others to repeat Wilmut's dazzling experiment—to be certain that the results are correct.

If Wilmut's work is confirmed, it suddenly becomes possible to imagine some mind-bending consequences. Improvements in sheep and cattle ranching would be only the beginning. If the cloning of humans ever became practical, grieving parents might conceivably choose to clone a dying child. Some individuals might make a desperate grab for immortality by trying to clone themselves. Already scientists are joking that the richest and most egotistical among them are hopping the next plane to Scotland. “It's an incredible development,” says Arthur L. Caplan, director of the Center for Bioethics at the University of Pennsylvania. “Unfortunately, we don't have the legal and ethical basis to handle it yet.” Two days after the cloning was announced, President Clinton asked for a national commission to review what the White House called

technique should work for any other mammal—including humans. Dr. Jon W. Gordon, an obstetrics

A ROADMAP FOR BIOTECH RESEARCH

The new biotechnology allows scientists to get at the most basic functions of life, deep inside the complex interactions of genes. Here are some key developments.

DOLLY Dr. Ian Wilmut and his colleagues at the Roslin Institute added new genes to 277 eggs before they got one to grow into the world's most famous sheep. Researchers elsewhere will now be rushing to duplicate the feat.

thing that goes into making up a living cell. It's an exhilarating time to be doing science.” No one doubts that the payoff will be immense. By 2003, farmers

may be growing plants that make enough plastic to reduce our dependence on oil. The massive amount of information holds the promise of a slew of new drugs and treatments—and a far deeper understanding of human behavior, health, and disease. "It gives us tremendous hope we can finally win the battle against bacteria," says J. Craig Venter, president of the Institute for Genomic Research (TIGR), a pioneer in gene sequencing.

Moreover, the spillovers could reach outside biology. Motorola has a team of researchers exploring the potential of gene splicing and genome engineering for computing. The idea is to use the DNA molecule as the basis for computers vastly more powerful, for some calculations, than today's digital machines. University scientists have already built primitive DNA computers. Even further afield, the genome information will illuminate previously dim corners of history—by analyzing genetic variations among populations. "We can ask: 'Where did we come from? How many migrations did our ancestors make out of Africa?'" ex-



YEAST, DROSOPHILA, C. ELEGANS

Two of these simple organisms—fruit flies and tiny round worms—are very close to being sequenced; yeast has been done. Many genes are remarkably similar to ours, offering new clues to fight disease.

plains Mary-Claire King, a gene hunter at the University of Washington.

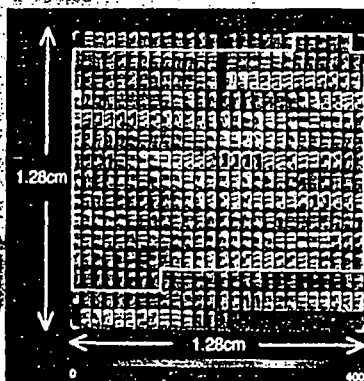
Of course, none of this will be easy. The discovery of a gene or the elucidation of a complicated biological pathway may be only a small step toward a cure or useful medicine. The gene for sickle-cell anemia is one example. It was identified 20 years ago, but there still

are no cures. Now, with thousands of new genes being discovered every year, pharmaceutical and biotech companies are awash in potential targets for drugs. "But drug discovery has turned out to be a bear," says Larry M. Gold, chief scientist of NeXstar Pharmaceuticals Inc.

What's more, the biological century will bring myriad moral and legal conundrums. Should doctors, for example, test for genetic conditions or predispositions they can do virtually nothing about? Will employers and insurance companies get access to

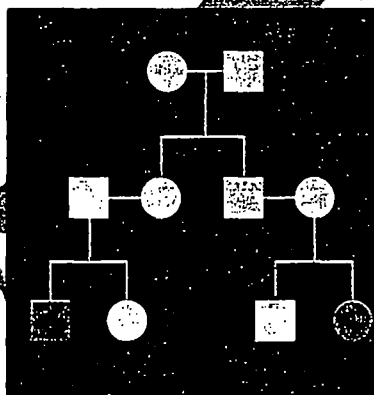
MUSTARD WEED

Researchers have begun to decipher the complete genome of one plant—the mustard weed, known scientifically as *Arabidopsis*. The eventual result could be supercrops or trees that would yield such products as plastics and drugs.



DNA CHIPS

The marriage of microchips and DNA is a natural. Researchers are using chips to rapidly identify genetic variations in specific tissues. Comparing diseased and healthy tissue can reveal causes of disease.



FAMILY TREES

Researchers are now using large families, often from genetically isolated communities, together with powerful computer technology, to identify genes involved in more complex disorders such as diabetes and heart disease.

the results of those tests? Should they be able to use that information to deny employment or insurance coverage? Already, British companies say they have been using genetic information to set rates and eligibility criteria for buyers of life insurance (page 84).

These hurdles and dilemmas, however, are far from the minds of many scientists toiling in university and company labs to understand the biology laid bare by the new genetic information. What they see instead is the chance to transform not just science but the world of the next century, just as the microchip changed this one. And the story really starts with one of the simplest forms of life—bacteria.

In July, 1995, Venter's team made history by completing the first full gene sequence of a living organism other than a virus. The bacterium was *Hemophilus influenzae*, which causes meningitis and children's ear infections. In the two

years since, researchers have used the sequence to uncover what Venter calls a "remarkable biological mechanism that could totally change the basis of vaccine and drug development."

Geneticist Richard Moxon of Oxford University discovered that the bug is essentially preprogrammed for constant

evolution. Like all cells, its genes contain the information to make proteins. But special sequences

tucked in its genome cause the process to go awry periodically, creating new forms of key proteins. That enables *H. influenzae* to evolve on an hourly basis, evading the human immune system. Standard vaccines also target these proteins, which is why they don't work very well. The trick will be mining the genome to dig out more obscure proteins that the bug can't change so rapidly. Researchers at MedImmune Inc. in Gaithersburg, Md., are using this strategy to develop better vaccines.

PINCH OF YEAST. Drug companies are also interested in searching the genome for places to attack with new types of antibiotics. To help put a price tag on this sort of genetic information, Genome Therapeutics Corp. in Waltham, Mass., recently sold the sequence of *Helicobacter pylori*, the bug that causes ulcers and possibly stomach cancer, to Swedish pharmaceutical giant Astra for a cool \$22 million.

Higher up the evolutionary ladder, sequencing the genomes of creatures like yeast, nematodes, and fruit flies is leading to advances. Once nature finds a biological pathway that works, she tends to use it over and over. As a result, "the majority of human disease genes that have been found have counterparts in yeast" and other simple organisms, explains S. Michal Jazwinski, professor of biochemistry and molecular biology at Louisiana State University in New Orleans. Just as important, the animals can be experimented on to understand these shared genes and biological pathways, something that can't be done in people. Geneticist Michael Wigler of Cold Spring Harbor Laboratory in New York used yeast to figure out the biology of a gene, called

DNA FOR DUMMIES: THE BASICS YOU NEED TO KNOW

The blueprint of life is **DNA**. Its famous double helix is a long, long chain built by linking together four simple molecules. The order in which those molecules are linked determines the information contained in the DNA. It is the **SEQUENCE** of those molecules that molecular biologists are now busily decoding. All of the DNA in an organism is referred to as the organism's **GENOME**.

GENES are DNA chains made up of hundreds or thousands of simple molecules. Each gene contains instructions to make another type of crucial molecule, a **PROTEIN**. Proteins include everything from hormones such as insulin—which regulates blood-sugar levels—to enzymes that help digest the food we eat. Some proteins turn other genes on and off, which then affect still other genes, creating complicated feedback loops.

Individual proteins are but tiny cogs in incredibly complex biological systems. Consider the immune system, in which thousands of genes and proteins work together to field an

ras, that when mutated causes human cancers.

Scientists at NemaPharm, in Cambridge, Mass., are using the nematode *C. elegans* in a similar fashion. One target: Alzheimer's disease. Researchers have found a human gene, dubbed presenilin, that is linked to the disease. The gene is also present in the worm. So NemaPharm scientists are now disabling the worm's gene to figure out what it was doing—and how it interacts with other genes. "We're looking for suppressors of the gene," explains Timothy J. Harris, research and development chief at Sequana Therapeutics Inc., which recently bought NemaPharm. And when the entire *C. elegans* genome is sequenced by early 1998, says Harris, the worm "will be helping us in all our internal R&D programs at Sequana." That includes searching for the human

COMMENTARY

WHEN SCIENCE FICTION BECOMES SOCIAL REALITY

Of all the worrisome scenarios the genetic age has conjured, none is more deeply embedded in the popular psyche than the Frankenstein myth, with its moral that dire consequences await the scientist who dares to play God. For at least 20 years, scientists and biotech entrepreneurs have dismissed the fears of man-made life as science fiction, saying that whole-mammal cloning was impossible and would be until well into the 21st century.

But when Dolly, the cloned sheep, preened for her first photographs last week, the public learned that all sorts of genetic mischief, including mammal cloning, in fact is quite possible. "The symbolic significance is greater than the real significance," says Barbara A. Koenig, director of the program on Ge-

nomics, Ethics & Society at Stanford University.

Koenig believes Dolly's near-term impact could be significant for couples unable to bear children. Many couples have shown how far they will go to get genetically related offspring rather than adopt an unrelated child. Some seem willing to bear any expense and undergo the most difficult and risky medical procedures. Given that desperation, they may try to find a scientist willing to experiment with cloning.

AMBIGUOUS RESULTS. For ethicists, this will only add to a plate already full of issues that biotechnology has already raised: In the biotech century, those questions will become even more urgent. Perhaps the most fundamental questions right now are these: Exactly

what kind of medical knowledge can be gleaned from genetic information today? And what can be done with it?

The truth is that most genetic tests are inconclusive. The diagnoses they yield often show no more than a slightly increased or decreased risk of someone's getting a particular illness. A perfect example is breast cancer. A gene that increases the risk of breast cancer was recently identified, marking an important scientific breakthrough.

One of Koenig's current projects is to study the ethical implications of testing women for mutations in this gene, which appear in some breast cancer patients. "My main fear is the overuse and commercialization of diagnostic tests before we have enough information," she says. Finding mutations could

army of cells and antibodies (another type of protein) against intruders. The DNA in each of the body's cells contains all the genetic information to produce a person. But in any given cell, only some of the genes are switched on; the rest are dormant. That's what makes a liver cell, say, different from a skin cell—different sets of genes are turned on in each.

Scientists despair of understanding exactly how humanity's 80,000 genes flip on and off in the amazing molecular dance that leads to a human being. But they are uncovering the genes and proteins that underlie small pieces of this grand puzzle—so-called **BIOLOGICAL PATHWAYS**. One famous pathway is the process by which cells turn the sugar glucose into enough energy to run a marathon.

But genes can also go horribly wrong. A "misspelling" in just one letter—an improper or missing link in the DNA chain—is a **MUTATION**. A change in a single link of the thousands in a gene can produce disease. Sickle-cell anemia, for instance. Other diseases are more complex. Heart disease, cancer, and Alzheimer's are

due to mutations in several genes.

Much of the effort in genetics today is directed at finding these faulty genes—and then figuring out how their flawed

proteins make biological pathways go awry. Aiding the search is something called a **GENETIC MAP**. Much like an atlas, a genetic map shows the locations of genes and fragments that have been identified. Each of these can be used as a signpost, or **MARKER**, to help identify genes that might be related to disease.

Just as it's easier to get to Evanston if you know it's near Chicago, it's easier to find a gene if you start from a marker nearby. When gene sleuths are tracking an inherited disease in a family, they look for markers present only in family members with the disease. When they find those markers, they know they are close to the genes.

Finding genes this way is costly and time-consuming. That's why researchers have begun blindly sequencing the entire genome, link by link. That way they will find thousands of new genes and all of the extra genetic information that sits between genes. This vast amount of new information opens the door to the most basic understanding of life.

By John Carey in Washington

genes that code for conditions from asthma to obesity.

The new genomics also is having a more direct impact on the diagnosis and treatment of human disease. One tack, used by companies like Human Genome Sciences Inc. (HGS) in Rockville, Md., is to pluck out all the genes that are actually turned on in a cell. Many of them are unknown. By figuring out their function, researchers may stumble across potential new drugs and drug targets. HGS, for instance, is about to begin clinical trials with previously unknown proteins that help heal wounds or fight arthritis. And HGS partner SmithKline Beecham has used the method to find promising new drugs against osteoporosis and other diseases.

Meanwhile, other companies are using technology to create what are known as DNA arrays, or DNA chips. The basic idea

is to put thousands of different pieces of DNA onto a silicon chip, each at a different spot. The chips are designed in such a way that they can find the genetic differences between, say, a cancer cell and its noncancerous precursor. Using this method, Darwin Molecular Corp. researchers in Bothell, Wash., have found some 500 genes that are altered when prostate cells turn cancerous. Those genes may hold the clues to better diagnostic tests or to biological processes that could be blocked to stop the cancer.

On a lower-tech level, the expansion of genetic knowledge also is aiding more traditional searches for human disease genes. In an approach called positional cloning, scientists first search for large families that suffer from an inherited disease. Then they look for bits of genetic material shared by the

lead women who aren't actually at high risk for breast cancer to seek mastectomies without proper medical justification, for example.

Right now, controversy is raging in Britain, where an association of insurers has announced that applicants for life insurance must disclose the results of any genetic tests they've taken. The association has also said that those results will affect premium costs and underwriting decisions. There have been calls for government intervention and fears that high-risk individuals who really should take these tests to help doctors plan their treatments will now avoid them.

It all hit home for Brit Stephen Frost, who not only must live with the unnerving knowledge that he has a 50-50 chance of developing Huntington's chorea—the best accuracy a test currently can provide—but who says his former employer, an insurer, made life so miserable for him that he had to quit his job once his diagnosis became known.



It doesn't help that on the research side the consideration of the bioethical questions has been spotty and half-hearted for years. President Clinton's call for a new group to study the ethics of cloning could lead to consideration of other research projects—such as research with viable human embryos.

At the more practical implementation level, insurance companies are at the front line today of the ethics controversy over genetic testing. But employers are close behind them. As biology tells us more and more about who we are and how we work, employers will want to know which of their workers are carrying genetic time bombs.

The problem is the genetic information available so far is incomplete and difficult to interpret. But even when much better information is available, its misuse could pose a far greater threat than Frankenstein ever did.

By Joan O'C. Hamilton in San Francisco, with Julie Flynn in London

family members carrying the disease. When they find those "markers," they know the gene must be nearby.

Until recently, these searches have been hampered by a dearth of markers. But in the past few years, researchers have been mapping new markers by the thousands. "We used to say, 'We can't find the disease genes because there are not enough markers,'" says Howard Jacob of the Medical College of Wisconsin. "We fixed that. We used to say, 'It's too expensive.' And we fixed that."

That's why researchers are scouring the world, searching for families or isolated groups with rare inherited diseases. At the University of Washington, for instance, King is closing in on a gene that causes deafness in families from Costa Rica. Séquana scientists are using people from Tristan da Cunha to nab genes for asthma. A group of Germans who used to live in Russia have a unique gene for Alzheimer's. Such family lineages may soon help scientists find not just the genes for diseases caused by single defects, but for more complicated conditions like manic depression, high blood pressure, or heart disease. "We're making progress toward the real frontier of the more complex disorders," says Dr. Francis Collins, director of the Human Genome Project at the National Institutes of Health.

CANCER HELP? While all these disease-causing genes are rare, elucidating their mechanisms may have widespread usefulness. In the case of the breast cancer gene called BRCA-1, only a small portion of breast cancer victims actually inherit mutations. But the protein encoded by the gene may play a major role in noninherited forms of breast and ovarian cancer. Dr. Jeffrey Holt, professor of cell biology at Vanderbilt University in Nashville, Tenn., has shown that mice with ovarian cancer live much longer when given a normal version of the gene. Washington's King now wants to start a clinical trial in ovarian cancer patients to see whether the technique



Gene research promises new drugs, new treatments—and a far deeper understanding of human health and behavior

CRAIG VENTER'S TEAM COMPLETED THE FIRST DNA SEQUENCE OF A BACTERIUM

works in people. "This shows how we can use the gene to develop a therapy," she says.

In addition to new

Special Report

THE BIOTECH CENTURY

medicines, this information offers a new window into human history. "As people move around the world, their genes move with them," explains King. Geneticists have shown, for instance, that one breast-cancer mutation predates the destruction of the second temple of Israel. Another mutation moved from the Baltic to America to Israel in Jewish migrations.

Yet the explosion of genetic knowledge will reverberate far beyond new drugs or history. "The biological century will arrive on three fronts—medicine, environmental remediation, and agriculture," predicts TIGR's Venter.

Take pollution cleanups. New studies show that, during the course of evolution, nature has repeatedly added or excised clumps of genes from microorganisms, much like an engineer adding and deleting software routines while fine-tuning a computer. But if nature can do it, so can today's gene jockeys, creating a new field dubbed "genome engineering."

One bug now being sequenced at TIGR can withstand astonishing amounts of radiation. By inserting the string of genes coding for the uranium-gobbling pathway, scientists might fashion a cell that can clean up highly radioactive waste.

Venter and other visionaries have dreams of a greener, more productive economy created with the help of organisms capable of doing everything from cleaning up waste to making methane—natural gas—from inorganic fuel, solving our pressing pollution problems. Genome engineering "isn't science fiction anymore," says Venter.

Indeed, the first steps are already being taken. Four years ago, Chris Somerville, head of plant biology at the Carnegie Institution of Washington, slipped a gene for making plastic into *Arabidopsis*, a type of mustard plant. The gene turned the plant into a biological plastics factory. Now, Monsanto Co. scientists are turning the concept into commercial reality. "We're expecting to see it planted in thousands of acres by 2003," says Somerville.

Just as exciting is a recent discovery by Calgene scientists of the gene for the enzyme controlling the formation of cellulose in plants. After

30 years of fruitless biochemical search for the enzyme, "this is our first break in understanding how to control biomass," Somerville explains. Genetically boosting the enzyme could make it possible to create trees with much higher proportions of cellulose—the plant kingdom's structural fiber—and less than the normal amounts of other cell wall components. Because these secondary components are what make the pulp- and papermaking process polluting and inefficient, scientists say, the engineered trees could help clean up a major industry. Beyond that, "there is a mad scramble in plant biology to find the most useful genetic sequences," says Somerville. "The world hasn't even seen the tip of the iceberg."

DOLLY'S DEBUT. Of course, the world did get a stunning glimpse of a bold new future in agriculture with Ian Wilmut's Dolly. According to biological dogma, the feat was unlikely at best. The reason: All cells possess a full complement of genes, and thus the basic instructions to create an entire organism. But during the delicate dance of development, when embryonic cells become skin, or heart, or brain, all the genes not needed for these new specialized functions are turned off. And most textbooks say they can't be turned back on again.

Wilmut and his team found a way. They extracted cells from the mammary glands of an adult sheep. Then they starved the cells. That apparently changed the complicated protein scaffolding around the cells' DNA, which plays a key role in determining which genes are active or inactive. In essence, he coerced the specialized cells into believing they had returned to a stage in which all things are possible. The genes that had been turned off were primed to turn on again.

From there, it was a simple matter of using standard high-tech methods. Wilmut took the nuclei, and thus all the genes, out of sheep oocytes. Then he placed each oocyte next to one of the treated mammary gland cells. One pulse of electricity caused the two cells to fuse, dumping the adult

sheep's genes into the egg. Another pulse prodded the oocyte to embark on the journey to make Dolly, the clone.

The process still has plenty of bugs. It took no less than 277 tries to make Dolly. "They killed a lot of embryos and made a lot of malformed sheep," says Pennsylvania's Caplan.

Special Report

THE BIOTECH CENTURY

DNA CHIPS. But the feat does help pave the way to barnyards filled with new types of livestock. Companies like Alexion Pharmaceuticals Inc. in New Haven and PPL Therapeutics PLC in Scotland already have altered pig genes to make hearts, kidneys, and other organs that could be transplanted into humans, and they have engineered cows that make drugs in their milk. The cloning process will enable these so-called transgenic animals to be duplicated much faster than by traditional breeding. "It's not an overnight revolution, but there is significant potential for research and improvement of domestic animals," says Christopher Bidwell, an animal geneticist at Purdue University.

Some scientists believe that the biological century will usher in a new era in electronics as well. The lure of genes as the basis of computation is that the twisting helixes are jam-packed with information—millions of times more than on the densest microchip. True, performing a mathematical calculation might take an hour using DNA, compared with a fraction of a second for silicon, said Dan Boneh of Princeton University at a recent meeting on DNA computing. Chips can do only one thing at a time, compared with a DNA computer, which can theoretically do 100 million billion things at once. But DNA still has a long way to go before it can hope to challenge silicon.

Already, the world is racing headlong into the biotech century. And not even the scientists leading the way know where it all might lead. TIGR's Venter wonders whether we even possess the intellect to understand how humanity's 80,000 genes can work together in intricate harmony to produce a being that is capable of contemplating its own origins and destiny. But it is clear that as we enter the new millennium, biotechnology is about to weave its own threads into the great tapestry of human history.

By John Carey in Washington, Naomi Freundlich in New York, and Julia Flynn in Roslin, Scotland, with Neil Gross in New York

WANT TO LEARN MORE?

University of Pennsylvania bioethicist Arthur Caplan and BW's John Carey will answer questions about this Special Report on America Online in the Globe on Sunday, Mar. 2, at 9 p.m. EST.

FINDING A CURE IN DNA?

Biotech companies embrace projects that examine links between genes and disease

The British company PPL Therapeutics PLC, which holds the rights to the controversial sheep-cloning technology, saw its stock jump with the arrival of Dolly on the world stage. But it is far from clear whether PPL will profit from its technology. Researchers say it is too early to know exactly what the commercial applications will be.

Some of the young companies embracing and driving the biotech revolution may, however, ultimately produce huge rewards for their backers. These are the companies working in the field of genomics, delving into the mystery of the human genome and trying to pull out clues to what causes human disease. They have become darlings of Wall Street and of large pharmaceutical companies hungry for new drugs. Cynthia Robbins-Roth, a biotech industry consultant, estimates that the six largest genomics companies have deals worth up to \$1 billion with their bigger pharmaceutical brethren. Many are locked in fierce competition to find genes involved in

diabetes, cancer, Alzheimer's disease, schizophrenia, and other disorders.

"CHALLENGE." The key hurdle for these companies is to go beyond genome sequencing to so-called functional genomics—using a variety of laboratory techniques to identify how particular genes work—and how they go wrong. "If you're not doing this, then you're not going to be competitive," says Wole M. Fayemi, an analyst at Genesis Merchant Group Securities in San Francisco.

The race to find function is not an easy one. "It's a tremendous challenge," says David Galas, chief scientist at Darwin Molecular Corp. in Bothell, Wash. Daniel Cohen, the founder of Genset in Paris, says his company has found 100 mutated genes "and none are good targets for drugs."

In the process of hunting down those targets—places where drugs could be used to correct disorders—researchers are discovering that computer technology is a crucial tool. But some classical biological experiments with the likes



At Exelixis, researchers put nine human disease genes into fruit flies; seven led to a visible change in the insects' appearance

A TECHNICIAN PERFORMS RESEARCH ON FRUIT FLY GENES AT EXELIXIS IN CAMBRIDGE, MASS.

of fruit flies, yeast, and other simple organisms are also moving back to the forefront.

To identify which genes are worthy of further study, researchers try to determine which are related to human disease. In the past, this kind of experiment involved meticulously studying one biological pathway at a time. Now, companies such as Affymetrix in Santa Clara, Calif., InCyte in La Jolla, Calif., and others are designing so-called DNA chip arrays that let researchers look at thousands of genes simultaneously and pinpoint which ones are turned on or off in a disease.

The information coming out of these arrays is powerful, but it doesn't get at the biological underpinnings of disease. That's where simple organisms come in.

For example, Exelixis in Cambridge, Mass., is studying fruit flies. Scientists there have inserted nine human disease genes—including one for cancer and another for obesity—into fruit flies and found that seven of them lead to a visible change in the flies' appearance. By identifying other fruit fly genes that also produce this change, researchers can begin reconstructing biological pathways that lead to disease. The hope



Rising from sellers of research to providers of product is the trick

DNA SAMPLES FROM DIABETIC PATIENTS ARE REVIEWED BY A SEQUANA THERAPEUTICS SCIENTIST

up to \$68 million with SmithKline Beecham for access to its yeast work.

The larger genomics companies are beefing up their functional side—often by striking deals with startups. Last October, Sequana Therapeutics Inc., a genomics firm in La Jolla, Calif., bought NemaPharm, a startup that specializes in nematodes. According to Timothy J. Harris, Sequana's vice-president for research and development, Glaxo was so excited by this purchase that they cut a second deal with Sequana for access to the nematode work. The worms are especially helpful in the study of Alzheimer's disease and other neurological ills. Sequana also has made forays into fruit flies, yeast, and other organisms.

Dr. Robert Tepper, vice-president of biology at Mil-

lenium Pharmaceuticals, has experiments running in flies, yeast, and mice. But he's excited about Millenium's work involving human disease via population studies and the growing integration of mammalian cells with microchips. "Given a choice, I'd rather rely on these," he says. He shares the worry with Genset's Cohen that there's no guarantee treatments for a fly will be applicable to a human being.

PROMISES. Although companies may disagree about the best strategy for divining the workings of genes, they agree that the range of new technologies—from the fruit flies to complex arrays of DNA-studded computer chips—are the wave of the future. "A gene sequence doesn't do squat to cure patients," says Remi Barbier, chief financial officer at Exelixis.

Questions remain on whether genomics companies can rise from sellers of research data to providers of product. But by integrating technologies into their programs, they have taken the first step. "The outlook remains extremely promising," for functional genomics companies, says Elizabeth Silverman, a biotech analyst at Punk, Ziegel & Knoll in New York. "It's a technology that's at the bottom of its curve in terms of its contribution to drug discovery and development."

By Naomi Freundlich in New York

Special Report

THE BIOTECH CENTURY

is to find a key step in a disease pathway that can be interrupted by a drug.

Other companies use baker's yeast to determine gene function. Yeast genes have far more in common with human genes than side-by-side photographs of the two might suggest. With this in mind, Cadus Pharmaceutical Corp. in Tarrytown, N. Y., is using yeast to determine the function of some 400 genes that code for so-called receptors—molecules on the outside of cells where the cells receive messages. Many disorders are related to improper working of these receptors, making them good targets for drug development. On Feb. 27, the public company announced that it is signing a deal worth

THE SEARCH FOR FUNCTION

Much of the promising work on commercial applications of genetics is occurring at small companies. Some are already publicly traded; others might help their larger partners strike it rich.

AFFYMETRIX* SANTA CLARA, CALIF. DNA chips. Deals with Hoffmann-La Roche, Merck, and Glaxo.

CADUS* TARRYTOWN, N.Y. Studying yeast. Deals with SmithKline Beecham, Bristol-Myers Squibb, and Solvay.

EXELIXIS* CAMBRIDGE, MASS. Fruit flies. Private co. raised \$16 million, IPO expected next year. No announced deals yet.

GENSET* PARIS Strength is in finding regulatory regions for genes. Deals with Synthelabo, Johnson & Johnson.

HUMAN GENOME SCIENCES* ROCKVILLE, MD. Strong sequencing company. Deals with SKB and Merck DGaA.

INCYTE* PALO ALTO, CALIF. Combines huge DNA database with chips. Deals with Pfizer, Upjohn, and 8 others.

MILLENNIUM* CAMBRIDGE, MASS. Gene hunters plus strong functional capabilities. Deals with Hoffmann-La Roche, Lilly.

NEMAPHARM CAMBRIDGE, MASS. Studying nematodes, now owned by Sequana. Deal with Glaxo.

DATA: BW

DON'T BE AFRAID OF GENETIC RESEARCH

The widespread hand-wringing over what must be one of the greatest scientific feats ever—the cloning of an animal—is sad testimony to the growing politicization of genetic research. Instead of celebration, there is a chorus of Cassandra and a wave of worry. President Clinton talks of the “troubling” implications of cloning, and an army of bioethicists worldwide immediately warns of society’s being unprepared for the Frankensteinian implications of replicating life.

When Scottish embryologist Ian Wilmut stunned the world by creating Dolly, an exact living copy of a lamb—he put a spotlight on science’s recent explosion in understanding life and how to alter it. It goes way beyond cloning. Just as the past hundred years made up the century of chemistry and physics, so will the next be the century of biology. Imagine new medicines, better crops, and even biocomputing. Gene-altered animals could produce hearts for transplants and drugs for treatment. Disease-resistant rice and wheat could sharply raise yields. What better model is there for storing information than the sequence of links in the chains of DNA (page 78)?

Yet genetic research, while it fascinates, also scares people. Such movies as *The Boys from Brazil*, about cloning new Hitlers, and *Jurassic Park*, about the dangers of replicating dinosaurs, touch something deep in many people, who are uneasy about the manipulation of life. Even *Multiplicity*, a comedy about a harried man cloning himself so that he may

double- and triple-task through life, shows one copy turning out to be a dumb, drooling, defective human being.

This distrust of using biological science to tamper with life has haunted genetic research from the start. Despite centuries of animal and plant breeding, opposition to gene-altered tomatoes and potatoes delayed their introduction for years. The U.S. Congress has virtually banned all government-funded embryo research, thanks to the politics of abortion. France and Germany have banned genetically altered food and drugs. The result? The research shifted offshore. The thousands of parents who now have children thanks to in vitro fertilization can thank British researchers for their families.

There is no question that the notion of individuals cloning themselves is not only repugnant but also raises important questions. Should humans be cloned to provide body parts for dying children? Is replication reproduction or slavery? The legal questions alone boggle the mind.

Fear of the future should not quell the budding biological revolution. Thanks to the Human Genome Project and similar projects for animals and plants, scientists are poised to know the complete blueprint of life. Rejecting this knowledge in a reactionary spasm of scientific know-nothingism would be a tragedy of immense proportions. It would choke the human spirit of adventure, of challenging the old, and pushing the envelope of what can be done. The world should embrace the biological revolution, not cringe from it.

THE POWER STRUGGLE IN CHINA

When both the liberal *New Republic* and the conservative *Weekly Standard* magazines agree that China is an enemy, and Republicans in Congress accuse CEOs doing business with China of being greedy, it is clear that the consensus governing U.S. policy toward China for the past 25 years is breaking down. Asia is a growing flash point for conflict, and the U.S. must decide what its goals are in the Pacific Rim and what kind of relationship it wants to have with China.

U.S. policy should go beyond the stale debate over engagement vs. containment to address the three major issues of importance to Asia today: the rise of Chinese power and its nature; the staying power of the U.S. in the region; and the possible return of Japan to militarism. (Surprising as it may seem to Americans and Europeans, many Asians view Japan warily because it refuses to apologize for its World War II behavior and has today the region’s largest navy and air force.)

No one knows what path China will take following the death of Deng Xiaoping, but the U.S. can help shape the future by turning China’s desire to enter the World Trade Organization into an opportunity for furthering pluralism. Reformists want to downsize the huge state-owned sector, create an independent Parliament, build a new legal system,

and open the entire economy to market forces. Before the Tiananmen Square massacre in 1989, these reformers had a serious chance of taking power in China. They can again. The old ex-Communist Party elite, however, is fighting to retain the state-owned sector because it is the foundation of their power and wealth. A mercantile economic policy favors their rule. By insisting on serious WTO entry rules, the U.S. can bolster the reformers, help spread the pluralism-producing solvent of market capitalism, and peacefully integrate China into the global system. Nothing is more important to U.S. policy in 1997 than China and the WTO.

America’s military commitment to keeping the balance of power stable in Asia is critical as well. An arms race is under way all over the region, buttressing the power of generals everywhere, especially in China. The U.S. must show Asia a long-term commitment to blocking military projections of power by any country. By persuading, cajoling, and insisting that the “game” be an economic one based on free-market rules, the U.S. can help channel the rising power of China into internationally acceptable forms of competition. This is a foreign policy goal worthy of consensus from all groups in America, including its chattering class.



Might want to add Ernest
Just to the list as least of
as p 6 - He is a father of
modern biology and one of
the great biologists of all
time -

Ernest Everett Just

Born: August 14, 1883

Died: October 27, 1941

Birthplace: Charleston, SC

Ernest Everett Just: Zoologist, Biologist, Physiologist, Research Scientist.

FACES OF SCIENCE African Americans in the Sciences

Ernest Everett Just was born in Charleston, South Carolina on August 14, 1883 to parents Charles Frazier and Mary Matthews Just. He prepared for college at Kimball Hall Academy, New Hampshire, where he completed the four-year course of study in only three years. In the graduating Dartmouth College class of 1907, Ernest Just was the only person to be graduated *magna cum laude*. He won special honors in botany and history, with honors in botany and sociology. In his freshman year at Dartmouth he received the highest marks in the entire freshmen class in Greek; Ernest was conferred as the Rufus Choate scholar for two years. In 1907, Dr. Just began to teach at Howard University. Beginning in 1909, he began to conduct research as a research assistant during the summer months for Professor Frank Rattray Lillie, the second director of the Marine Biological Laboratory at Woods Hole, Massachusetts. In 1916, Ernest Just received the Degree of Doctor of Philosophy *magna cum laude* from the University of Chicago in experimental embryology, with a thesis on the mechanics of fertilization.

Contributions on the physiology of development were the legacy of Dr. Just's research. His work on the subjects of fertilization, experimental parthenogenesis, hydration, cell division, dehydration in living cells, the effect of ultra violet rays in increasing chromosome number in animals and in altering the organization of the egg with special reference to polarity.

He was one of the authors of *General Cytology*, published in 1924. The list of authors includes among other eminent zoologists

- Dr. Frank R. Lillie of the University of Chicago
- Dr. T.H. Morgan, President of the National Academy of Sciences
- Dr. M.H. Jacobs, Director of Marine Biological Laboratory, Woods Hole, Massachusetts
- Dr. E.G. Conklin of Princeton University

In 1924 Dr. Just was selected from among the biologists of the world by a group of German biologist to contribute to a monograph on fertilization, one of a series of monographs by specialists working on fundamental problems of the function and structure of the cell. He is a contributor to Volume Two of Dr. Jerome Alexander's three-volume series on Colloid Chemistry. From 1920-1931 Dr. Just was the Julius Rosenwald Fellow in Biology of the National Research Council. Under this grant program he engaged in research as an adjunct researcher of the Kaiser Wilhelm Institute for Biology, Berlin-Dahlem, working under Professor Max Hartmann department. He also worked at the marine biological laboratories in Naples and in Sicily. In 1930, Dr. Just lectured at the Eleventh International Congress of Zoologists, held at Padua, Italy. The lecture was entitled *The Role of Cortical Cytoplasm in Vital Phenomena.*, which was based on the fifty published papers written by Dr. Ernest Just.

In his scholarly work Dr. Just showed all the traits of a true scholar. He was unostentatious and was modest in his personality. His inherent ability, scientific training, creative imagination, and industry were the basis for success in his field of zoology.

"If we are to judge his accomplishments by standards set up by men of science, it can be said that Dr. Just is an eminent scientist. If we are to judge his value to Negro education by what he has accomplished in the realm of science, it can be said that to Negro youth especially, he demonstrates the possibility of human achievement regardless of race or color. In the language of Dean Kelly Miller in an appreciation of Dr. Just, *What boots it that Euclid was a Greek, Newton an Englishman, Marconi an Italian or Gutenberg a German? Their genius has enriched the blood of mankind regardless of place, time, race or nationality.*"
George R. Arthur. *Ernest Just, Biologist.*, *The Crisis*, February 1932, p. 46.

Dissertation Title: Studies of Fertilization in Platynereis megalops.

Memberships:

- Vice-President, American Zoological Society
- Recipient of the first Spingarn Medal (1915) for his research in Biology
- National Research Rosenwald fellow in Biology (1920-1931)
- Ecological Society
- Phi Beta Kappa
- Omega Phi Psi, Founder and faculty advisor, Howard University (November 17, 1911)
- Editor, *Protoplasm* -- an international journal published in Berlin
-- devoted to the work done on the physical chemistry of the cell --
- Collaborator of *Cytologia* -- published in Japan.
- Editor, *Physiological Zoology*
- Editor, *Biological Zoology* -- official organ of the Marine Biological Advancement of Science

Selected Publications

Basic Methods for Experiments in Eggs of Marine Animals.

Ernest E. Just. (Philadelphia, PA: P. Blakiston's Son & Co.), 1939. 89 pages.

QL 58 J88 Middleton Library

Mary E. Glynn
Julie E. Mason
April Melody
Darby E. Stott
Julia R. Green
Laura D. Schwartz
Pauline M. Abernathy
Lori E. Abrams
Lori Anderson
Brenda M. Anders
Eli G. Attie
Kris M Balderston
Beverly J. Barnes
David S. Beaubaire
Marsha E. Berry
Lanny A. Breuer
Laura Capps
Joseph W. Cerrell @ OVP@EOP
Steven A. Cohen
Michelle Crisci
Carolyn Curiel
Suzanne Dale
Lanny J. Davis
Marilyn DiGiacobbe
James A. Dorskind
Jennifer D. Dudley
Christopher A. Dwan
Dorinda A. Salcido
James T. Edmonds
Anne M. Edwards
Rahm Emanuel
Karen E. Finney
Jay K. Footlik
Ben A. Freeland
Jeremy M. Gaines
Michael A. Gill @ OVP@EOP
Adam W. Goldberg
Jason S. Goldberg
Ricardo M. Gonzales
Donald Goldberg
Richard Hayes
Russell W. Horwitz
Thomas D. Janenda
Brian J. Johnson
Michele Jolin
James M. Teague
David E. Kalbaugh
William R. Kincaid
Angus S. King
Joshua A. King
Nicholas B. Kirkhorn
Catherine T. Kitchen
Jim Kohlenberger @ OVP@EOP
Heidi Kukis @ OVP@EOP
Sara M. Latham
G N. Lattimore
Christopher J. Lavery
Anne H. Lewis

5/16/97 12:00 pm

PRESIDENT WILLIAM J. CLINTON
COMMENCEMENT ADDRESS ON SCIENCE IN THE 21st CENTURY
MORGAN STATE UNIVERSITY
BALTIMORE, MARYLAND
MAY 18, 1997

Acknowledgments: Dr. Earl Richardson, President; Judge Harry Cole, board chair; Governor Glendening; Mayor Schmoke; elected officials – including city council, which voted to ban cigarette billboards near schools; Reps. Elijah Cummings, Ben Cardin; Sens. Sarbanes, Mikulski; Board of Regents; Faculty and staff; distinguished alumni: Judge Cole; Judge Robert Bell, Chief Judge of Maryland's highest court; Kweisi Mfume; Earl Graves; Richard Dixon, State Treasurer; Terry Edmonds, White House staff.

I am pleased to deliver my first commencement address at an Historically Black University. In our past, when the doors of colleges were closed to all but white students, Morgan State and the nation's other HBCUs gave young African Americans the education they deserved and the pride they needed to rise above cruelty and bigotry. In our present, HBCUs produce the lion's share of our black doctors, judges, and businesspeople – and Morgan State graduates most of the black scientists and engineers in Maryland. And in our future, I am certain that HBCUs will play an even greater role in moving our country forward.

But, Morgan State is not just a great Historically Black University -- Morgan State is a great American university. You have produced some of this country's finest leaders. Not just the African American community, but our entire American community would be diminished without great Morgan grads like Parren Mitchell, Kweisi Mfume and Earl Graves. The halls of justice would be diminished without great judicial leaders like Judge Bell and Judge Cole. And without Morgan, I would never have had the good fortune to work with Terry Edmonds who, remarkably, is the first African American ever to serve as a presidential speechwriter.

All of you graduate today into a world brimming with promise and rich with opportunity. As I said in my State of the Union Address, the enemy of our time is inaction. We must use this moment of great hope and prosperity to prepare our people for the challenges of the 21st Century. This spring, here and in commencement addresses across the country, I will seek to focus our attention on those great and powerful forces that can pull us apart, or that can become our greatest strength in the years ahead. I will discuss our diversity, and how we can make sure that it brings us together rather than divides us. I will discuss America's continuing obligation to lead the world, especially our obligation to help build a strong and united Europe in the wake of the Cold War.

And we know that above all else the 21st century, in its texture, in its promise and in its reality, will be molded by science, shaped by technology, powered by knowledge. These are potent, transforming forces; they can be used for good or for ill; and we must master them if we are to make the most of this new century.

We enter that century propelled by new and stunning developments. In the past year alone, we saw the cloning of Dolly, the sheep. The Hubble Telescope is bringing into focus dark corners of the cosmos never seen before. Innovations in computer technology and communications are creating what Bill Gates calls the world's new "digital nervous system." Cures for our most dread diseases – diabetes, cystic fibrosis -- seem within reach. And last week, we saw a computer named Deep Blue, defeat the world's reigning chess champion. I hope they don't make a computer that can play golf.

The past half century has seen some of mankind's greatest breakthroughs, as we split the atom, spliced genes, created the microchip, explored the heavens. For half a century, we struggled to harness forces as powerful as the sun, in an effort to keep them from destroying the planet. Today, at long last, nuclear and computer technology are realizing their greater value as servants of a better life, not masters of a bitter destruction.

If the last 50 years were the age of physics, the next 50 years will be the age of biology. We are now embarking on our most daring exploration ever -- unraveling the mysteries of our inner world and charting new routes to the conquest of disease. And our great challenge will be to harness the power of biology, our increasing knowledge about the cell, the brain and life itself so that we can reap the amazing benefits while avoiding the pitfalls that exist with the very promise of new technology.

We have not, and we must not ever shrink from exploring the frontiers of science and basic knowledge, no matter where it leads us. But as we consider how to use the fruits of that knowledge, we must also never retreat from our commitment to human values, the good of society, and our basic sense of right and wrong. Today let us commit: in the 21st Century, science must serve humanity – never the other way around.

In that new century, America's future, indeed the world's future, will be powerfully influenced by science and technology.

Where once nations measured their strength by the size of their armies, their arsenals and their GDPs, in the world of the future, it is science and knowledge that will matter most. Fully half the growth in economic productivity over the past half century can be traced to research and technology. That is why it is so important that the balanced budget agreement I reached with the leaders of Congress funds the increase I requested for science and technology in my 1998 budget and reaffirms our long-term commitment in this important area.

Science is about more than material wealth or the acquisition of knowledge; it is about our dreams.

Ours is a nation defined by the great goals we set. Often these goals can seem beyond our reach. But it is the very act of reaching for that far horizon -- of imagining our future and striving to realize it -- that will define us. We are a restless, questing people. We have always believed,

I am prepared to do all I can to make this happen. Our scientists at NIH and at our research universities have been at the forefront of this battle. Today, I am pleased to announce that NIH will establish a new AIDS vaccine research center dedicated to this crusade. At the summit of industrialized nations in Denver next month, I will enlist other nations to join us in a worldwide effort to find a vaccine to stop one of the world's greatest killers. And we will challenge America's pharmaceutical industry, which leads the world in innovative research and development, to work with us and make the successful development of an AIDS vaccine part of its basic mission.

The 21st Century will be the century of biology. Together, we can make an AIDS vaccine its first great triumph.

This is just one example of the great advances that will be made possible by our focus on science and technology. In this and so many other ways, science will enrich our existence. It is how we will work with other nations to address global climate change. It is how we will break our reliance on limited sources of energy. It is how we will once again make giant strides to free ourselves and future generations from the tyranny of disease and hunger and ignorance that today enslaves too many around the world.

So today, at the edge of this new century, let us pledge to learn more and do more in the realm of science. But let us also pledge to redouble our vigilance, to make sure that the knowledge of the 21st Century serves our most enduring human values.

Science often moves faster than our ability to understand its implications. Each new discovery, each new breakthrough, can create a new maze of moral and ethical questions. We are only just beginning to figure out how to answer those questions.

The Internet can be a new town square -- or it can be a new Tower of Babel. The same computer that can put the Library of Congress at our fingertips, can also be used by purveyors of hate to spread blueprints for bombs. The same knowledge that is developing new life-saving drugs can be used to create poisons of mass destruction. Science can enable us to feed billions more people in comfort and safety -- or it can spark a nuclear or biological war. And it can do so by accident as well as on purpose.

Science has no soul of its own. It is up to us to determine if it will be used as a force for good or evil.

Let me be clear: We must do nothing to stifle our basic quest for knowledge. Human curiosity is the driving force behind all human discovery. It is a fundamental principle of our democracy. In the last century, the spirit and benefits of scientific inquiry have propelled us from field to factory to cyberspace.

But, how we use the fruits of science and how we apply it to human endeavors is not properly the domain of science alone -- or scientists alone. I believe we must apply the same ethical and moral principles that have guided every great religion, our great democracy, our very

sense of right and wrong. We need a great national conversation about these principles. We must decide together how to apply them to the dazzling new discoveries of science. Here is what I think those principles should be.

First, science and its benefits must be directed towards making life better for all Americans, and never just the privileged few. Their opportunities and benefits should be available to all. Lack of money or social status must never be a barrier to the benefits of science and technology. Science that does not move us all forward is science that will hold us all back. Science must not create a new line of separation between the haves and have nots -- those with and without the tools and understanding to learn technology. In the 21st century, the school that does not have the link to the Internet or the child who does not have access to a computer will be like the 18th century child without schoolbooks. That is why we are ensuring that every child in every school, no matter how rich or poor, will have the same access to technology.

We also know that in years past, too often science mirrored the sickness of society at large. Here at one of America's great black universities, let me underscore what I said a few days ago at the White House. We must never allow our citizens to be unwitting guinea pigs in scientific experiments without their consent, that put them at risk -- whether it is the withholding of syphilis treatment from the black men of Tuskegee or the Cold War experiments that subjected some of our citizens to dangerous doses of radiation. We must never go back to those awful days when eugenics and racial stereotyping here and in Europe resulted in discrimination and worse against those judged to be inferior. Our greatness is measured not only in how we do right, but

also in how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies and take action. Together, we must say, never again.

The second principle I believe we should apply is this: none of our discoveries should be used to label or discriminate against any group or individual. Increasing knowledge about the great diversity within the human species must not change the basic belief upon which our ethics, our government and our society are based: All men are created equal. Period. End of story.

With stunning speed, scientists are now moving to unlock the secrets of our genetic code. Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. *inherited tendencies towards diseases* But, it might also be used by insurance companies and others to discriminate and stigmatize *that information* *against* *individual groups of people* groups of people. We know that in the 1970s some African Americans were denied health care coverage by insurers and jobs by employers because they were identified as sickle cell anemia carriers. We also know that one of the main reasons women refuse genetic testing for susceptibility to breast cancer is their fear that insurance companies may either deny them coverage or raise their rates. No insurer should be able to use genetic data to underwrite or discriminate against any American seeking health insurance. This should not just be a matter of principle, it should be a matter of law. *And to that end, I urge Congress to pass by such a law* *In the coming weeks, I will send legislation to the* Congress to prohibit insurance companies from using genetic screening information to determine premium rates or eligibility for health insurance.

Our third principle must be this: Technology should not be used to break down the wall of privacy and autonomy free citizens are guaranteed in a free society.

The right to privacy is one of our most cherished freedoms. As society has grown more complex, and as people have become more interconnected in every way, we have had to try even harder to respect the dignity and autonomy of each individual. Today, when marketers can follow every aspect of our lives -- from the first phone call we make to the time our security system says we have left the house, to the video camera at the toll booth and the charge slip we leave for lunch -- we cannot afford to forget this most basic lesson. As the Internet reaches to touch every business and every household, and we face the frightening prospect of private information or even medical records instantly being made available to the world, we must develop new protections for privacy to meet this new reality.

And fourth, we must always remember that science is not God. Our deepest truths remain outside the realm of science. We must temper our euphoria over the recent breakthrough in animal cloning with sobering attention to our most cherished concepts of faith and humanity. My own view is that each human life is unique, born of a miracle that reaches beyond laboratory science. I believe we must respect this profound gift and resist the temptation to replicate ourselves. But this is a decision no President should make alone. That is why I have asked our distinguished National Bioethics Advisory Commission, headed by President Harold Shapiro of Princeton, to conduct a thorough review of the legal and ethical issues raised by this new cloning discovery. They will give me their recommendations within the next few weeks.

These are the principles that should guide us if we are to master the powerful forces of change in the century to come. Science that produces a better life for all and not the few. Science that honors our tradition of equality. Science that respects the privacy of the individual. Science that never confuses faith in technology with faith in God. If we hold fast to these principles, we can make this time of change a moment of dazzling opportunity for all.

In conclusion, let me say this: Science will only serve the values of all Americans, if all Americans are given a chance to participate in science. We cannot move forward without the voices and talents of everyone in this stadium and, especially those graduates who are going on to pursue careers in science and technology. African Americans have always been at the forefront of American science. Nothing -- not slavery, not discrimination, not poverty -- has ever been able to hold back the scientific urge or the creative genius of African Americans.

Benjamin Banneker was a self-taught mathematician/surveyor/astronomer, who published an annual almanac and helped design the city of Washington. George Washington Carver was born a slave, but went on to become one of this nation's greatest agricultural scientists. Ernest Everett Just of Charleston, South Carolina, is recognized as one of the great biologists of all time. And Charles Drew lived through the darkest days of segregation to become a pioneer in blood preservation. They showed us all how America's diversity is its greatest strength. Now it is your time. It is up to you, to honor their legacy, to live their dreams, to be the investigators, the doctors, and the scholars who will help keep our science rooted in our values.

Thank you and God bless you all.

Senator Santorum's legislation once again?

THE PRESIDENT: Well, of course. I have nothing to add to what I have said on this all along. What I need to do is to be convinced that no woman will be grievously harmed by this legislation, and that no woman will be put in the position, for example, of being so harmed that she will never be able to have further children because of this legislation. You know what my concerns are; I've made them abundantly clear.

I must say, I regret that Senator Daschle's legislation did not pass because it would have reduced the number of abortions by far, far more -- light-years more than the Santorum bill. The Santorum bill may not reduce the number of abortions by one.

So what we don't want to do is to, in effect, not reduce the number of abortions in the third trimester, which the Supreme Court permits us to do, and which I've invited the Congress to do ever since I got here, and at the same time put a lot of women's health at risk in a way that is unwise and unconstitutional.

Q Mr. President, what are your thoughts on Mobutu losing power in Zaire?

THE PRESIDENT: Well, I want to make a couple of points on it. It does appear that he has left Kinshasa. The United States position is clear: We want to see a transition to a genuine democracy. The second point I want to make is that President Mandela of South Africa has done a superb job of exercising leadership in this area, and the United States is supporting him and his efforts. And I want the whole world to get behind the leadership that Nelson Mandela is showing there

and to do what we can to support Africa in taking one of the largest and most important nations in Africa and promoting a democratic transition. That is what I think is important.

Thank you very much.

END

11:35 A.M. EDT

Message Sent To: _____

Mary E. Glynn
Julie E. Mason
April Melody
Darby E. Stott
Julia R. Green
Laura D. Schwartz
Pauline M. Abernathy
Lori E. Abrams
Lori Anderson
Brenda M. Anders
Eli G. Attie
Kris M Balderston
Beverly J. Barnes
David S. Beaubaire
Marsha E. Berry
Lanny A. Breuer
Laura Capps
Joseph W. Cerrell @ OVP@EOP
Steven A. Cohen
Michelle Crisci
Carolyn Curiel
Suzanne Dale
Lanny J. Davis
Marilyn DiGiacobbe
James A. Dorskind
Jennifer D. Dudley
Christopher A. Dwan
Dorinda A. Salcido
James T. Edmonds
Anne M. Edwards
Rahm Emanuel
Karen E. Finney
Jay K. Footlik
Ben A. Freeland
Jeremy M. Gaines
Michael A. Gill @ OVP@EOP
Adam W. Goldberg
Jason S. Goldberg
Ricardo M. Gonzales
Donald Goldberg
Richard Hayes
Russell W. Horwitz
Thomas D. Janenda
Brian J. Johnson
Michele Jolin
James M. Teague
David E. Kalbaugh
William R. Kincaid
Angus S. King
Joshua A. King
Nicholas B. Kirkhorn
Catherine T. Kitchen
Jim Kohlenberger @ OVP@EOP
Heidi Kukis @ OVP@EOP
Sara M. Latham
G N. Lattimore
Christopher J. Lavery
Anne H. Lewis

Patricia F. Lewis
Michael D. Malone
Laura S. Marcus
Doris O. Matsui
Andrew J. Mayock
Anne E. McGuire
Cheryl D. Mills
Megan C. Moloney
Kevin Moran
Jonathan Murchinson
Peter R. Orszag
Carole A. Parmelee
Sally P. Paxton
Jonathan Prince
Peter O'Keefe
Brian A. Reich
Charles F. Ruff
Virginia N. Rustique
Evan Ryan
Stuart Schear
Douglas S. Sheorn
David Shipley
Jake Siewert
Joshua Silverman
Brian D. Smith
Craig T. Smith
Richard Socarides
Douglas B. Sosnik
Todd Stern
Michael J. Sullivan
Sylvia M. Mathews
Lisa Tamagni
Virginia M. Terzano @ ovp@eop
terri tingen
Barry J. Toiv
Jodie R. Torkelson
June G. Turner
Dag Vega
Lorraine A. Voles @ ovp@eop
Michael Waldman
Angelina Walker @ ovp@eop
Teresa Wildman
SUNTUM_M @ A1@CD@LNGTWY
COGDELL_C @ A1@CD@LNGTWY
backup @ wilson.ai.mit.edu@INET@LNGTWY
wh-outbox-distr @ clinton.ai.mit.edu@INET@LNGTWY
BARBUSCHAK_K @ A1@CD@LNGTWY
BARTHOLOME_M @ A1@CD@LNGTWY
BARTHOLOW_T @ A1@CD@LNGTWY
BLINKEN_A @ A1@CD@LNGTWY
CAPLAN_P @ A1@CD@LNGTWY
CUTLER_L @ A1@CD@LNGTWY
FULLER_W @ A1@CD@LNGTWY
GILLESPIE_C @ A1@CD@LNGTWY
GRAY_W @ A1@CD@LNGTWY
GRIBBEN_J @ A1@CD@LNGTWY
HAAS_L @ A1@CD@LNGTWY
JOHNSON_DT @ A1@CD@LNGTWY

JOHNSON_WC @ A1@CD@LNGTWY
LIZIK_C @ A1@CD@LNGTWY
MOFFETT_J @ A1@CD@LNGTWY
NAPLAN_S @ A1@CD@LNGTWY
RILEY_R @ A1@CD@LNGTWY
SAMBURG_T @ A1@CD@LNGTWY
NAPLAN_S @ A1@CD@LNGTWY
SHEPARD_S @ A1@CD@LNGTWY
SMITH_BD @ A1@CD@LNGTWY
STUMPF_D @ A1@CD@LNGTWY
WEINER_R @ A1@CD@LNGTWY
WOZNIAK_N @ A1@CD@LNGTWY
usia01 @ access.digex.com@INET@LNGTWY
1 = US@2 = WESTERN UNION@3 = @5 = ATT.COM@*ELN\62955104@MRX@LNGTWY
62955104 @ eln.attmail.com@INET@LNGTWY
73030.21 @ compuserve.com@INET@LNGTWY
INFOMGT @ A1@CD@LNGTWY
newsdesk @ usnewswire.com@INET@LNGTWY
usnwire @ access.digex.com@INET@LNGTWY

Brenda M. Anders

05/16/97 01:47:25

PM

Record Type: Record

To: James T. Edmonds/WHO/EOP

cc:

Subject: WEAA interview

At your convenience, please call Larry Shorter or Rosalyn at 410-319-3564 to do a 2-3 minute interview on the Morgan State commencement. Please call me with any questions or to let me know when you've finished the call. Thanks, Brenda 6-5654

Brenda M. Anders

05/16/97 02:28:27

PM

Record Type: Record

To: James T. Edmonds/WHO/EOP

CC:

Subject: WEAA-- Revised

I just spoke directly with the station, and the reporter just left early because of an emergency. Rosalyn Nelson would like to talk to you Monday anytime between 6am-3pm. Rosalyn is on the air every 10 minutes before the hour, so any time between 0:00 and 0:50 would be great. The news room line is 410-319-3139.

—
THE WHITE HOUSE
WASHINGTON

TERRY—

THE PACKAGE FROM
HHS ARRIVED,—I GAVE A
COPY OF THE VARMUS
COMMENCEMENT SPEECH TO
MICHAEL. ALSO, THE BIG
NOTEBOOK WAS SENT TO
MICHAEL, HE SAID TO GIVE
IT TO YOU BECAUSE HE'LL
GET ANOTHER ONE. IF YOU
HAVE ANY QUESTIONS ASK
MICHAEL.

—CHRIS

Sandra Martinez

CHRONOLOGY

Tuskegee Syphilis Study

- 1926 - Public Health Service (PHS) survey of incidence of syphilis begun in Macon County, Alabama, one of several sites in the United States.
- 1930 - Macon County Syphilis Control Demonstration Project begun. PHS received funding from the Rosenwald Fund. Treatment was a combination of neoarsphenamine and mercury. None of the 1400 patients received the full course of treatment.
- 1932 - Funding for the control demonstration project from Rosenwald Fund ended.
- 1932 - Tuskegee Syphilis Study begun. This was a study of untreated syphilis in approximately 400 black men who were at least 25 years of age and had syphilis for 5 years or longer. Funded by the Public Health Service. Undertaken to compare the course of untreated syphilis in black men with the results of an Oslo study on untreated syphilis in whites. The study was supposed to last 6 - 12 months. Plan was to document course of disease and use that information to obtain funding for treatment. The Alabama Department of Health agreed to study with stipulation that some treatment be provided. Tuskegee Institute and local white physicians in Macon County also agreed to the study.
- 1933 - The Study continued past the original 6 - 12 months. It was decided to continue the study until the men died. Control group of 200+ men without syphilis added to the study.
- 1947 - Penicillin widely available for the treatment of syphilis.
- 1950 - Recommendation for the use of penicillin in late syphilis established.
- 1957 - Responsibility for Study transferred to the Communicable Disease Center (now Centers for Disease Control and Prevention [CDC]).
- 1972 - News of the study reported in the New York Times, Los Angeles Times, and Washington Star. Tuskegee Syphilis Study Ad Hoc Panel composed by the Public Health Service to investigate the Study.
- 1972 - Study terminated by the Department of Health, Education, and Welfare (now the Department of Health and Human Services).
- 1973 - Public Health Service directed to provide necessary medical care. Men and their families contacted and given information about the study. Men and their families offered comprehensive health assessments and lifetime medical services. Tuskegee Health Benefit Program congressionally established and administered by CDC. Class action lawsuit filed by Mr. Fred Gray on behalf of the living Study participants and heirs of deceased participants.

- 1974 - National Research Act signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- 1974 - Federal regulations developed to review and approve research involving human subjects.
- 1975 - Class action suit settled. Cash payment of \$37,500 to every living man with syphilis who was alive on July 23, 1973; \$15,000 to the heirs of each of the deceased men with syphilis; \$16,000 to every member of the class of living controls who was alive on July 23, 1973; and \$5,000 to the heirs of each of the deceased controls.
- 1979 - The Belmont Report summarizing the basic ethical principles governing research involving humans is released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- 1996 - Tuskegee Syphilis Study Legacy Committee established and report issued with their recommendations that "President Clinton publicly apologize for past government wrongdoing to the Study's living survivors, their families, and to the Tuskegee community," and that a strategy be developed "to redress the damages caused by the Study to transform its damaging legacy."



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

F A C S I M I L E

DATE

5/7/97

TO

NAME AND ORGANIZATION

E. M. Raza

FROM:

MARY BETH DONAHUE
DEPUTY CHIEF OF STAFF
DHHS
Telephone: (202) 690-7431
FAX: (202) 401-5783

Tasklog

RECIPIENT'S FAX NUMBER ()

456 7431

NUMBER OF PAGES (INCLUDING COVER SHEET):

12

COMMENTS:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

MAY 9 1997

NOTE TO ELIZABETH DRYE

Attached please find the following 3 documents pertaining to the White House event for the Survivors of the Tuskegee Study that can be used as background material as you put together fact sheets.

1. Action Steps for Annoucement by President following the Apology
2. Chronology of the Tuskegee Study
3. Draft Directive from Secretary Shalala to the Operating and Staff Division Heads in the Department

We will forward brief write-ups on the Survivors and their families, as well as Qs and As, next week.

Please call me with any questions.

Mary Beth Donahue

DRAFT 5/9/97 (2:00 pm)—MEMORANDUM TO OPDIV AND STAFFDIV HEADS

*from
Sec HHS*

Subject: Ethics in Human Subjects Research

As you know, on May 16, 1997, the President formally apologized to the remaining survivors and relatives of nearly 400 impoverished African-American men who were left untreated for syphilis, even when penicillin became widely available, while participating in a Public Health Service research study generally known as the Tuskegee Syphilis Study.

It has been almost a quarter of a century since the Study was halted; however, its negative legacy still impedes our efforts to conduct critically necessary basic and applied research, particularly involving minorities, and to provide the best health care and services to all of our citizens. This event has become a metaphor in racial and ethnic minority communities for suspicion and mistrust of government and health care, in general, and research, specifically.

The President's apology brings symbolic closure to this tragic episode in our history. However, we must now do all that we can to restore trust by ensuring and demonstrating our commitment to the highest ethical principles in the Department's activities, especially in the conduct of research involving human subjects.

Much has been done to ensure the protection of human subjects, such as passage in 1974 of the National Research Act which created the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, the creation of the Office for the Protection from

Research Risks, the promulgation of regulations for the protection of human research subjects (45 CFR 46), and most recently, the creation of the President's National Bioethics Advisory Commission which is supported by the Department of Health and Human Services. As charged by the President, the Commission serves as the central forum for discussion of ethical issues, and is reexamining current regulations, policies, and procedures to ensure that all possible safeguards are in place to protect all persons who volunteer to participate in research studies.

To build on these efforts, we will undertake the following action steps as outlined by the President:

- HHS will work with Tuskegee University to establish a Center for Bioethics in Research and Health Care at Tuskegee University.
- HHS will offer fellowships to promising students, with special outreach to attract minority students, to receive postgraduate training in bioethics, and will also develop a short-term ethics training program as a component of research fellowship programs.
- HHS will collaborate with other partners, e.g. educational or research institutions, to develop materials for bioethics courses and related training materials to enable research institutions to strengthen their efforts in bioethics training as it relates to research.
- HHS will develop and disseminate strategies to assist researchers in their outreach to communities--especially minority communities--to foster partnership and enhance the

involvement of minorities in research studies.

These steps will be undertaken to strengthen the informed use of bioethical principles in the conduct of research, involve more individuals, especially minorities, in bioethics, and increase communication and partnerships among researchers and communities. I view this as an opportunity to ensure that the research activities conducted or funded by this Department are based on ethical principles. Through these efforts and the commitment of each and every one of us, we can rebuild trust while protecting the well-being and dignity of all persons whom we serve.

Donna E. Shalala

with Thomas Jefferson, that freedom is “the first born daughter of science.” And with our willpower, our resources and a great national effort, we have always reached those horizons, and set out for new ones.

Thirty-six years ago, President Kennedy looked to the heavens and proclaimed that the flag of peace and democracy, not war and tyranny must be the first to be planted on the moon.

Today, let us look within and step up to the challenge of our times -- a challenge with consequences far more immediate for the life and death of millions around the world. AIDS will soon overtake tuberculosis and malaria as the leading infectious killer in the world. Even here in this country, where new and effective anti-HIV strategies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies and could well become even more dangerous. Only a truly effective HIV vaccine will totally eliminate the threat of AIDS.

So, let us set a new national goal for this era of science. Today, let us commit ourselves to developing an AIDS vaccine within the next ten years. There are no guarantees; it will take energy, it will take focus; it will demand great effort from our greatest minds. But we have made strides in recent years. It is no longer a question of whether we can develop an AIDS vaccine -- it is a question of when. And if America commits to find an AIDS vaccine (within the next decade,) we will do it.

Varmus OK
except this

DRAFT

Suggestions for What the President Will Include in an Apology for the Tuskegee Syphilis Study

The following steps are designed to strengthen bioethics training, involve more minorities in bioethics, and increase communication and partnerships among researchers and communities.

Fellowship and Training Program:

We need more bioethicists who are experts in teaching the design and conduct of ethical human subjects research. Furthermore, minorities are under-represented in the field of bioethics. We need to diversify the field by increasing the number of individuals, especially minorities, who have postgraduate training in bioethics and who will eventually become recognized leaders in the field.

Therefore, the President will state that the Department of Health and Human Services (HHS) will offer fellowships in September 1998 to promising students to receive postgraduate training in bioethics and that special efforts will be undertaken to recruit minorities into these fellowship programs.

*NIH does not want to include specific programmatic detail here. Programmatic details will be described in the announcement to the applicant community. For the purposes of this document, it is entirely adequate to say that there is a fellowship and a short-term training program available in September 1998.

DRAFT

2

The National Institutes of Health (NIH) is currently developing a short-term training program to focus on bioethics. The goal of such training is to increase the understanding of the relevance of ethics in the conduct of research. The short-term mechanism has the potential of involving a broad base of the research community.

Within 60 days after the apology, the NIH will announce the establishment of the bioethics training program and solicit applications from the research community to participate in this program. Furthermore, the Centers for Disease Control and Prevention (CDC), NIH, and the Health Resources and Services Administration (HRSA) will convene a meeting of the three agencies to discuss collaborative efforts with academic institutions on bioethics training. This fellowship program will be promoted as a Departmental fellowship in bioethics. The first group of fellows will be selected and supported for the academic year beginning in September 1998.

Community Participation in Research:

Research involving human volunteers is essential for developing the new knowledge needed to combat the health problems facing this Nation and the world. The successful conduct of research is enhanced by partnership with the communities that is built upon a trusting relationship. However, there is compelling evidence that today many communities do not have this trust. As a result,

DRAFT

(3)

many people, especially minorities, are unwilling to participate in research which ultimately could improve the health of these communities.

Therefore, the President will ask the Secretary, HHS, to develop and disseminate strategies to assist researchers in their outreach to communities, especially minority communities, as a step toward increasing their partnership and collaborative participation in research. The Department has already identified a number of successful approaches for involving communities in research. For example, Project STAR in Durham, North Carolina, where CDC is collaborating with the community in research on AIDS and HIV infection, and an NIH study of coronary heart disease risk factors involving 4000 minority participants in Jackson, Mississippi, and the NIH outreach to minorities on cancer treatment through the minority community-based cancer oncology program and the National Black Leadership Initiative on Cancer. The long-term effect of building partnerships with communities is to foster trust between the community and the government which supports much of this research.

Within 90 days of the apology, the Secretary will convene workshops involving academic researchers and community organizations to develop additional innovative strategies for enhancing community participation in research and to discuss case studies of successful and unsuccessful community outreach. The proceedings from these workshops will be made readily accessible

DRAFT(4)
192

to researchers and the public, e.g., via the Internet and other means of public communication.

Bioethics Training Courses and Materials:

Successful training in bioethics in research will require appropriate courses and training materials. There is a need for more information about how to incorporate community perspectives into the planning and conduct of research. Therefore, the President will request that CDC, NIH, and HRSA collaborate with other partners to develop additional materials for bioethics courses, highlight existing high quality bioethics programs, and encourage sharing of knowledge, training, and curricula within the research community.

The Belmont Principles--respect for persons, beneficence, and justice form the framework of training courses in bioethics. The training will focus on ethical principles underlying the conduct of research; the complexities of applying the Belmont principles to the processes of informed consent and risk/benefit analysis; ethical responsibilities inherent in selecting a research question and a research design; ethical selection of participants; and methods for increasing community participation in research. The goal of such training is to provide researchers with the tools to apply these ethical principles in the recruitment and retention of participants in research.

DRAFT

Within 90 days of the apology, CDC, NIH, and HRSA will make recommendations on bioethics training materials for use in research institutions. The goal of such training is to provide researchers with the tools to apply ethical principles to gain greater participation of minority communities. The new training materials will be completed within one year. In addition, these agencies, in collaboration with professional societies, will (develop strategies to disseminate information) on bioethics training.



Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	To Michael Waldman & Terry Edmunds [sic] (partial) (1 page)	05/09/97	P6/b(6)

COLLECTION:

Clinton Presidential Records
Speechwriting
Terry Edmunds
OA/Box Number: 10988

FOLDER TITLE:

Genetic Screening [3]

2006-0462-F
ry674

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 9, 1997

NOTE TO MICHAEL WALDMAN & TERRY EDMUNDS:

Dr. Varmus has asked that we send the attached materials for you to use in developing the President's Morgan State University commencement address. He has marked passages that he thinks would be helpful to you.

Dr. Varmus will try to reach you by phone later today. You should also feel free to call him at home (b)(6) any time over the weekend.

[001]

Attachments

THE WHITE HOUSE
WASHINGTON

April 29, 1997

Copied
Baer
Lewis
Waldman
Blinken
Streett
Palmieri
COS

One but (don't think we can do event at Selover's well known do not miss it! in '93
'97 APR 29 PM 4:45
How about Chicago?

MEMORANDUM FOR THE PRESIDENT

CC: ERSKINE BOWLES, SYLVIA MATHEWS AND JOHN PODESTA

FROM: DON BAER, ANN LEWIS, MICHAEL WALDMAN, ANTONY BLINKEN, STEPHANIE STREETT AND JENNIFER PALMIERI

SUBJECT: COMMENCEMENT ADDRESSES

This memo provides a framework for a series of commencement addresses you could deliver between now and mid-June. One proposal we have been developing, included in Mark Penn's agenda at the most recent political meeting, is to use this year's commencement speeches to return the focus of the press and public to the central theme of your State of the Union address -- preparing America for the 21st Century.

We believe that we can further this goal by creating a package of three commencement addresses. Each would focus on a separate subject vital to the American people in the 21st Century, and could contain strong news to ensure enthusiastic coverage. But each would also return to your broader message -- the need to take advantage of the forces of change, so that they work for us, not against us.

Working closely with the Domestic Policy Council, the Press Office, Political Affairs, Public Liaison and the Race/Reconciliation working group, we have identified the following sites and subjects for your consideration:

Sunday, May 18	Morgan State University -- Science and Technology
Saturday, May 31	West Point -- Foreign Policy vision/NATO enlargement
Saturday, June 14	UC San Diego -- Race and Reconciliation

As you have indicated, the June 6 Sidwell Friends graduation will be closed to the press and therefore not a message event.

Morgan State -- Science and Technology. This is the site recommended by the Scheduling, Public Liaison and Political offices. It would be your first commencement address at a historically black college. (The school is headed by Dr. Earl Richardson, a member of your Board of Advisors on Historically Black Colleges.)

THE PRESIDENT HAS SEEN

5-1-97

No subject better conveys your focus on the future than science and technology, yet it is a subject you have rarely addressed in a concentrated way. This speech is a big opportunity for you to reflect on the new wonders of science and the Information Age -- but also the ethical dilemmas they pose and the need to harness them so that they work for us, not against us (e.g. computers vs. freedom of speech, cloning vs. natural selection). This is an ideal site for such a speech; traditionally a leading producer of African-American teachers, Morgan State has increasingly focussed on the sciences and now enrolls 60% of all African-American engineering majors in Maryland. This topic would also be a follow-up to your May 16 meeting with survivors of the Tuskegee Study. Terry Edmonds, who attended Morgan State, agrees with us that giving a speech on a topic of general interest at a historically black college -- rather than focussing on a race-related topic -- would be seen as a sign of respect by the African-American community.

The following policy announcements could be included if they are ready in time:

✓ A diabetes initiative (as discussed at a recent political strategy session), since this disease is of special concern to African-Americans;

✓ Lead-in to the National Bioethics Committee's cloning report, due the following week, or announcement of its findings if we are able to speed up the report's release, which would draw major attention to this speech;

✓ New legislation on genetic screening, placing limits on use of genetic information by insurance companies for underwriting purposes.

Education and religion options. Another possible topic for Morgan State is education, your top priority, which is not currently reflected in this proposed package of commencement addresses. However, this period will not be without a major education event; we will soon propose to you an education town hall meeting for late May (including strong news announcements), which would give us an opportunity to push your standards agenda in a high-profile way during this period. We will also explore "turnaround" school options, including the school you mentioned in Corpus Christi, Texas -- either as a possible venue for a town hall meeting, or as a separate event sometime in late June. An additional commencement option which some have suggested is a major address on religion, although it is not clear what you would say that goes beyond your highly-acclaimed 1995 speech on religious liberty.

Recommendation: that you deliver a May 18th commencement address at Morgan State University on science and technology.

Agree ✓ Disagree _____ Discuss _____

West Point -- Foreign Policy Vision/NATO Enlargement. This is an opportunity to deliver one of the major foreign policy addresses of your second term -- presenting your vision of the demands of American leadership in the 21st Century, making a strong case for NATO enlargement, and also framing your major foreign policy actions from May through July to make

clear the larger purposes that unite them (with the NSC, we will put forward a themes memo showing how to pull this all together). This would be paired with a speech you would deliver two days earlier in the Hague to commemorate the 50th anniversary of the Marshall Plan -- billed as "President Clinton's major address to the people of Europe on the future of American-European relations." The West Point speech would be your major address to the American people on the same subject. (The contents of both will obviously depend on negotiations regarding NATO and Russia).

Please note that there is a strong feeling among your foreign policy advisers that you need to press the case publicly for NATO enlargement. Given the timing of this speech, that argument would definitely be newsworthy.

Recommendation: that you deliver a May 31st commencement address at West Point on foreign policy vision and NATO enlargement.

Agree ☒ Disagree ☐ Discuss ☐

UC San Diego -- Race and Reconciliation. This could be the place where you announce actions relating to race and reconciliation, and deliver a strong One America speech -- focussed on harnessing the increasing diversity of our nation as our greatest strength. One recommendation is that you deliver such a speech in California -- the gateway to much of the world and the embodiment of American diversity. UC San Diego itself is very diverse (3% African-American, 29% Asian, 12% Latino), as is the surrounding San Diego metropolitan area (9% African American, 11% Asian, 19% Hispanic).

Giving a race-related speech at a University of California campus will undoubtedly raise two controversial issues -- the UC Regents' affirmative action policy and Proposition 209. However, this would enable you to address these issues directly, and we believe this should not prevent you from giving an address at UC San Diego. In fact, UC San Diego recently signed onto a letter printed in the New York Times in support of affirmative action.

It should be noted that a number of other western, racially diverse schools -- including the Universities of Washington, Oregon, Arizona and New Mexico -- were considered and rejected because of scheduling conflicts or policy issues the Administration has pending with particular universities.

Recommendation: that you deliver a June 14th commencement address at UC San Diego on race and reconciliation.

Agree ☒ Disagree ☐ Discuss ☐

Other principals' commencement schedules. For your information, the Vice President

is currently scheduled to address the Naval Academy on May 23. The First Lady is scheduled to speak at the Banneker High School graduation in DC on June 13, and is delivering the commencement address at Ohio University on June 14 -- which, if you agree with the above, would be the same day as your UC San Diego speech.

MEASURING WHAT COUNTS IN SCIENCE

Bruce Alberts
President
National Academy of Sciences

134th Annual Meeting

April 28, 1997

I am delighted to welcome you to our 134th annual meeting. This is always a special opportunity for us to communicate. I have read each of the comments returned by the more than 1,100 members who replied to our recent survey. Each of you will be getting a summary of the results later this morning. This information is critically important to us, and it will help us improve our connections to members.

As many of you have pointed out, it is crucial that the Academy maintain a focus on our most important goals. And one of my obligations as president is to make sure that these goals are clearly articulated. One of the most important of these is to ensure that all of the advice we give to the government is independent of government or other influences, being based solely on science -- not politics. Yet, as I speak, our independence is being threatened by lawsuits, as many of you are well aware. The processes that the Academy has carefully put in place for our studies -- from selecting members of our committees, to subjecting each draft report to rigorous, anonymous peer review -- are fundamental to our ability to provide the best science advice possible. In service to the nation, we must do all that we can to ensure that the important role that we play in helping to inform public policy is preserved.

But in this address, I would like to go beyond the specifics of the moment, and talk about the goals and priorities of this great institution -- emphasizing our responsibilities as scientists in a world that will soon enter a new century. As outlined on the first slide, our current priorities are to:

- 1) Increase the effectiveness of the entire scientific enterprise;
- 2) Dramatically improve science and mathematics education for all Americans; and
- 3) Bring the wise use of science and technology to the center of national and international affairs.

These are ambitious goals, and accomplishing them will entail a long-term commitment from each of us. Let me describe each of these goals, in turn.

Increase the effectiveness of the entire scientific enterprise

If we are to be effective in increasing the vitality of the scientific enterprise, it is important that we analyze carefully how science works, and remind ourselves that it is the result of a highly creative process, very different from the mere measuring and recording of facts. To quote a strikingly thoughtful individual, the mathematician and philosopher of science, Henri Poincaré:

"In fact, what is mathematical creation?... To create consists precisely in not making useless combinations, and in making those which are useful and which are only a small minority. Invention is discernment, choice.... Among chosen combinations, the most fertile will often be those formed of elements drawn from domains which are far apart. -- Most combinations so formed would be entirely sterile. But certain among them, very rare, are the most fruitful of all.... The true work of the inventor consists in choosing among these combinations so as to eliminate the useless ones, or rather to avoid the trouble of making them, and the rules which must guide this choice are extremely fine and delicate."

Embedded here is the key to the dramatically increasing power of modern science: As more

scientific knowledge is acquired about the world, it becomes easier to perform calculations or experiments that create new knowledge, causing knowledge to accumulate at an ever faster rate. Thus, there is an explosion in the number of Poincaré's useful combinations.

Each of us can look back on our own careers in science, see the accelerating pace of discovery, and trace its roots. The next slide is my schematic attempt to track my field for the period 1950-1985, emphasizing how knowledge was combined to create more knowledge, as biologists developed an understanding of how chromosomes replicate at the molecular level ([figure 1](#)). My field is progressing even faster today, in large part because yesterday's discoveries have been used to create a diverse array of new research tools and insights. This difference is illustrated on the next slide ([figure 2](#)).

Even those of us in the midst of the dramatic biological discoveries of the past 30 years were incapable of foreseeing the powerful ways in which different bits of scientific knowledge could be combined. The reason for our lack of foresight was well stated by Einstein, who remarked:

"The history of scientific and technical discovery teaches us that the human race is poor in independent thinking and creative imagination. Even when the external and scientific requirements for the birth of an idea have long been there, it generally needs an external stimulus to make it actually happen; man has, so to speak, to stumble right up against the thing, before the right idea comes."

But with increasing knowledge, a critical problem develops that retards the potential growth of science. Specialization reduces what each of us knows about other fields of science, and it greatly inhibits our ability to make new connections by "stumbling."

This is true even for neighboring fields that are certain to be useful to our own. For example, today my students and colleagues who are experts in cell biology know very little about the biology of human tissues, and vice versa. The situation is worse for more distant areas of science -- consider chemistry and biology, for example ([figure 3](#)).

One of our members, Jared Diamond, has emphasized this point in the current issue of *Discover* magazine. He gives an example of a paper published recently in a major scientific journal:

"The table of contents gives the title: 'Activation of SAPK/JNK by TNF Receptor 1 Through a Noncytotoxic TRAF2-Dependent Pathway.' In that entire title, the word *noncytotoxic* is my sole clue as to the subject of the article. ... Since I have been a professional biologist for 39 years and my research fields include cell biology, I am much more likely to be the article's intended reader than most other scientists. ... I went on to read the rest of the short report, but in the end I still didn't know what it was about."

Diamond goes on to say that the article may well reveal something that could lead him to make a breakthrough in his own research, but that he would never know from reading it. He also points out that most articles in other journals are equally inaccessible.

He ends by agreeing with Poincaré: "Unfortunately, great scientific advances come especially from applying discoveries in one field to another field entirely. ... Research described incomprehensibly loses much of its value."

The urgent need to encourage new connections provides a great opportunity for our own scientific journal, the *Proceedings of the National Academy of Sciences*. Although largely a journal of the life sciences in recent years, our Editor in Chief Nick Cozzarelli is making an intensive effort to widen its scope so that it better represents the scientific disciplines of the entire Academy. In doing so, it will be especially important to ensure that the journal's articles are written so as to be comprehensible to non-experts. If we are successful, our journal will serve as a special place where many new connections are made.

The Academy traditionally has put a great deal of effort into making new connections. In fact, we do this every time that we establish a new study committee at the National Research Council, working

diligently to include every relevant expertise. A similar emphasis on cross-fertilization underlies each of our scientific colloquia, and it has been the driving force behind our enormously successful Frontiers of Science meetings. The Frontiers program is designed to bring together younger scientists -- the future leaders of our scientific enterprise -- and each year's meeting covers a very wide range of topics -- from astrophysics to genetics, for example.

Of course, we also publish interdisciplinary reports that highlight special research opportunities. Consider our report on Atomic, Molecular, and Optical Science. Or the recent report of a workshop, published in the *Proceedings*, that linked researchers working on schizophrenia with a group of Academy members from diverse disciplines who initially knew almost nothing about this devastating disease.

Which leads me to ask: What about our universities? Are they doing enough to ensure intellectual cross-fertilization? Young scientists represent the future of scientific endeavors. The Academy has therefore been making a major effort to produce career and mentoring guides for students, and to make them freely available on our Web site. We also need to help the science departments in our universities recognize that their most important role is to educate a cohort of energetic young people who leave the university with a healthy new mix of skills and knowledge -- for example, computer scientists or chemists who also have a deep understanding of biology.

Unfortunately, however, our university science departments tend to promote research that confines scientific interactions to within a single department. Wherever this occurs, it inhibits the type of stumbling that Einstein talks about, and it should therefore be energetically counteracted by university leadership.

Let me recount a recent success story at my own university, the University of California, San Francisco.

UCSF, like nearly all medical schools, was organized into the standard set of "basic science" departments which had been established some 50 years earlier: biochemistry, anatomy, physiology, pharmacology, and microbiology. It was universally agreed that the revolution in biology had long ago eliminated the intellectual justification for dividing the faculty and the students along these five lines. But to merge departments seemed to be more trouble than it was worth.

What took place instead was a complete reorganization of our central education mission, our graduate programs. In the past 10 years, we have established a new set of interdisciplinary graduate programs based on broad research areas: cell biology, structural biology, neuroscience, and so on. These programs themselves were not so unusual. What was unusual was the simultaneous abolition of all of the old graduate programs that were department-based.

Today, our departments still exist. But their major role is administrative -- most importantly, they no longer serve as a barrier to the "accidental" exchange of ideas. The whole vitality of the intellectual climate has thereby been enormously stimulated.

What about the government's role in the vitality of the scientific enterprise? The Academy needs to help our government maintain the appropriate strength and diversity in the nation's scientific portfolio. We have therefore been tracking the true federal investment in new knowledge -- through the federal science and technology budget analysis that was recommended by our 1995 Committee on Allocating Federal Funds for Science and Technology, chaired by Frank Press. The results show that, in the period between 1994 and 1998, biological research funding will have risen by 9 percent, while research in the agencies that support the other sciences will fall by about 10 percent in real dollar terms (figure 4). Clearly, the American public is motivated to support biomedical research. We biologists must therefore do much more to emphasize the tremendous contributions to biology and biomedicine that come from advances in the physical and social sciences, as well as in math, computer science, and engineering. This is one important focus for our new "Beyond Discovery" series, whose aim is to increase the general understanding of science. This type of educational outreach is fully consistent with our important function as an adviser to government.

We are continuously emphasizing the importance of a robust federal investment in science, engineering, and medical research during this period of budgetary constraint. The Governing Board of the National Research Council recently produced a series of six papers, "Preparing for the 21st Century," that synthesize important findings from nearly 100 reports produced by the Academy complex. One of these papers focuses on science and engineering research in a changing world. In a joint statement issued with the papers, Wm. A. Wulf, president of the National Academy of Engineering, Kenneth Shine, president of the Institute of Medicine, and I reiterated our strongly held view that the present world leadership of the United States in science and technology cannot be maintained with a weakened federal investment in research. We also emphasized that more attention must be placed on rigorous merit review, so that our precious federal dollars go toward funding only the best proposals and projects. Both these papers and the "Beyond Discovery" series have been distributed widely to members of Congress and to key policy-makers.

Dramatically improve science and math education for all Americans

I would now like to turn to the second major area of focus for the Academy: education. In December 1995, the National Research Council finished the daunting, four-year task of preparing the National Science Education Standards for kindergarten through 12th grade. The Standards stress learning science by doing science: that is, science as inquiry.

The aim is to make this kind of science a core activity for all students. This is important for creating wiser citizens and a more productive work force. It also is important for achieving the type of public understanding of science that will sustain public support of our enterprise.

What are the major barriers that prevent us from attaining the vision set forth in the National Standards? The data from the recent Third International Math and Science Study (TIMSS) is very helpful in this regard. As indicated on the next slide, this major study involved 41 countries, whose eighth-grade students were randomly sampled (figure 5).

Among the many countries surveyed, the United States' performance in science and math was about average. This is not because a particular cohort of students in the U.S. performed especially poorly. Even if we look only at the top performers -- those in the top 10 percent of the nearly 300,000 students in the survey -- the United States still looks average (figure 6). Countries such as Korea and Japan placed up to a third of their students in the world's top 10 percent; but only 5 percent of our students made it into this top group in math, and 13 percent in science.

Why did we do so poorly? For me, the most informative part of this survey was a series of videotapes, in which randomly selected teachers in the United States and Japan were observed teaching their eighth grade mathematics classes, and then scored by experts. As you can see on the next slide, none of the 100 U.S. teachers surveyed had taught a high-quality lesson (figure 7). What is worse, 80 percent of the U.S. lessons, but only 13 percent of the Japanese lessons, received the lowest rating.

What is especially distressing to me is this: We have had National Standards in Mathematics since 1989, released by the National Council of Teachers of Mathematics and disseminated widely by our Mathematical Sciences Education Board. Most of the U.S. teachers claim that they are familiar with these standards, and yet very few of the teachers who were videotaped showed evidence of this in their teaching. This means that we cannot hope to change the way teachers teach simply by having them read education standards. Real change requires a major effort in professional development, in which master teachers demonstrate new ways of teaching, allow the teachers to try the new methods, and then help them to continuously improve their practice. School systems must come to view themselves as professional development organizations. At a national level, we need to recognize and reward those school systems that serve as models in this regard. For example, in District 2 on the east side of Manhattan, 3 percent of the school budget each year is devoted to professional development, and the focus of the whole system is on increased student learning.

But there is a deeper lesson from the TIMSS results, one that is directly applicable to the professional lives of many Academy members. It is too easy to blame the teachers for the poor state of science and mathematics education. It is no wonder that so few of our precollege teachers teach science as inquiry. Almost none of them have ever experienced inquiry-based teaching themselves! We must accept a healthy portion of the responsibility for this state of affairs. Those of us who work at universities set the standards by which college science and mathematics are taught. We have given little thought to the fact that science teaching is almost entirely done by lecturing: after all, we were the "A" students who learned well in this way. But research findings tell us that most students require an active involvement in developing ideas, in order to gain any understanding of permanent value.

My field of biology provides a great example of how we fail to capture and hold student interest in science. As our knowledge of biology has exploded, the size of the textbooks used for introductory biology classes has grown accordingly. Biology 1 is generally believed to be a course in which all of biology must be covered in a single year, and under great pressure, biology classrooms therefore march through all of genetics, cell biology, ecology, evolution, and so on -- a task that becomes ever more daunting with each passing year of scientific discovery. There are more new vocabulary words to be learned than there are in a first-year course in a foreign language. The superficial coverage of all topics makes it impossible to teach any of them for any real understanding.

The college course has also created a monster with profound implications for the rest of our educational system, because it sets the model by which high school and middle school life science courses are taught. As a result, each of these courses also uses a textbook that covers all of biology.

To quote an astute observer of today's classrooms, professor of education Charles Anderson:

"Science as represented in most textbooks seems to be pretty dull and disconnected stuff, certainly not something that most children would want to find out about in their spare time. Even more troubling, the culture of most classrooms where those textbooks are used has little in common with the culture of adult science. Most adult scientists, for example, spend relatively little time copying facts and definitions out of books, yet that is the primary activity of many students in science classes. For many children, exposure to science textbooks and to the culture of science classrooms results not in understanding, but in alienation from science."

This brings me to what I believe to be the major limiting factor in science education reform. Until we teach science as an inquiry-based process in our introductory courses in college, we will have to rely on a massive retraining of teachers by school districts, if we are ever to expect our nation's science teachers to teach according to the National Science Education Standards.

Through our Committee on Undergraduate Science Education chaired by Bradley Moore, the Academy has been attempting to convey this message to colleges and universities. Two of our recent publications are especially relevant. One is *From Analysis to Action*, a report of a major convocation chaired by Donald Kennedy which calls for major changes in our college courses. The other is *Science Teaching Reconsidered*, a handbook that is designed to help professors try teaching methods other than the standard lecture. On its cover is a photograph that reminds us of Eric Mazur's physics course given to hundreds of students in a large lecture hall at Harvard. He interrupts his lecture every 15 minutes with a conceptual question, which the students discuss for a few minutes in small groups. Mazur reports great success in keeping the students involved and increasing their understanding.

Bring the wise use of science and technology to the center of national and international affairs

The last of my three priorities has long been central to the Academy. Those who understand the role of science and technology in a productive economy have a very clear vision of its importance for all nations. To build stable societies, one needs to make wise use of natural resources and to use water and produce food and energy in sustainable ways. To do so will require constant intervention by individuals

trained in science and technology. It is not sufficient to make use of outside experts who fly in and out of a country as paid advisers. The expertise must be strongly integrated into the fabric of each society. Without such wisdom at the local level, development brings with it a destructive emphasis on short-term consumption, with little concern for the long-term provision of natural resources.

We soon will have available to us remarkable new technologies that will make possible economical, nearly instantaneous communication throughout the world -- requiring only a low-cost computer and a modem. This rapidly developing communications network could create a qualitatively different type of world science, in which local experts in Africa, for example, can gain rapid access to appropriate science, technology, and medical advice, regardless of where that information is located. This point has been emphasized in our just-released National Research Council report, *Bits of Power*. The study committee, chaired by Steve Berry, stressed that efforts to expand computer network access in poor countries will benefit all nations, because scientists throughout the world have valuable information to share.

The National Research Council and the Academies have been placing great emphasis on increasing our interactions with important international agencies, including the State Department and the World Bank. We are making steady, but slow, progress. To get their attention, we need to do a much better job of explaining to international policy-makers how scientists and engineers can make major contributions to all areas of international development. And, we should repeatedly emphasize Jacob Bronowski's crucial observation that: "Science has humanized our values." As we spread science and its values throughout the developing world, we not only provide a strong force for sustainable development; we also support democracy.

Scientists throughout the world share a common culture, which enables us to feel easily at home with all scientists, regardless of their country of origin. Last January, the five officers of this Academy participated in an intensive two-day meeting in Beijing with the leaders of China's scientific enterprise. Our discussions were remarkably open and frank, and we found that we shared a wide range of interests. At this time in world history, when the cultural and historical differences between, and within, nations seems to be increasingly causing conflicts, it is reassuring to know at least one culture -- that of science -- is shared worldwide. Remembering the close personal relationships between U.S. and Soviet scientists that helped to diffuse tensions throughout the Cold War, we can dream about creating a strong network of international connections among all scientists that can serve as a conduit to world peace.

Viewed in this way, an important focus for the Academy's international activities becomes the creation of close personal ties among today's leaders of our respective scientific enterprises, as well as among the younger scientists who will be tomorrow's leaders. Indeed, we are already hard at work on this goal. Some of the current activities of the Office of International Affairs are shown on the next slide (figure 8). Here I have selected activities that have brought scientists together to work on meaningful challenges, thereby creating lasting bonds among scientists worldwide.

For scientists to be more influential at home and abroad, it also is important that we work to enhance our connections to the rest of society. I have tried to make this clear by means of a simple diagram (figure 9). We tend to define the scientific community today as containing only those individuals who do scientific research. As I have emphasized on other occasions, this is a narrow and counterproductive view of science. It is both in the interest of our nation and in the interest of scientists to expand our view of our community, so that it includes science teachers, science journalists, and others who use science -- in government and in many other professions. In addition, we must work to increase the amount of overlap between this enlarged scientific community and other elements of our society. Through such connections, we can give our fellow citizens a much better understanding of science and its values. We can also spread our values more widely.

Measuring what counts

Throughout this talk, I have repeatedly emphasized that scientists need to pay more attention to

community building of all kinds: among scientists of diverse disciplines, among scientists with similar interests throughout the world, and between scientists who do research and those who use science in other ways. I would like to end my talk by emphasizing a major responsibility of scientists, which is so important that I will state it as a theorem and corollary.

Theorem: What is measured in high-stakes assessments has a profound effect on human behavior.

Corollary: We must be exceedingly careful to make sure that we measure what counts!

If we are to increase the effectiveness of the scientific enterprise, we must pay close attention to helping our young scientists make the type of unexpectedly useful connections that Poincaré described. To this end, our evaluation systems must do more to encourage innovation and risk-taking. Given an increasingly competitive environment, and an unfortunate sense that the quantity of one's publications is being measured, most young scientists will do the safe thing by continuing along the research paths of their professors. As a result, in some fields of biology today, we often find that the same observations are published simultaneously by three or four different laboratories. Meanwhile, there are vast unexplored areas of research that no one seems to be probing.

Therefore, I suggest that all evaluations of excellence in science explicitly include a focus on innovation and uniqueness. For example, researchers seeking funding should be asked to do more than just describe their planned experiments in grant applications. They should also be asked to explain in what ways their work is unique, and to point out those aspects that they believe to be most innovative.

We also need to measure what counts when we assess student learning. We cannot have science taught as inquiry so long as our college entrance exams test for word associations and memorization. Today's vocabulary-laden high-school textbooks teach to the tests; likewise, the tests reflect the textbooks. This self-reinforcing feedback loop must be broken -- starting with new tests.

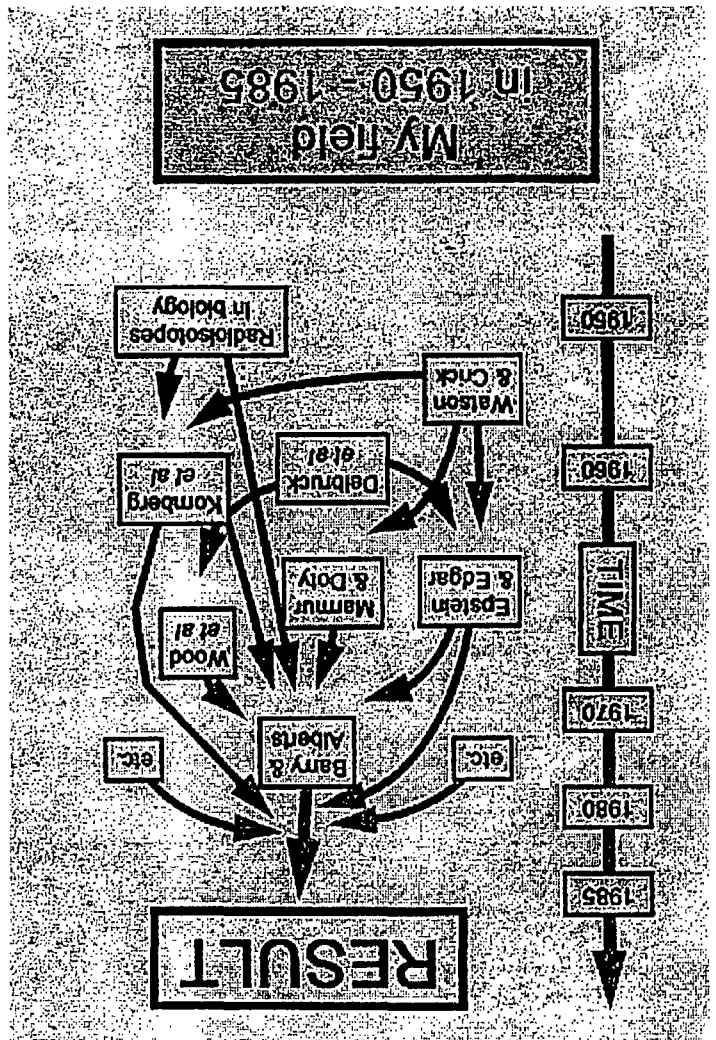
Internationally, we cannot hope to attain sustainable world economies until we find a better measure for economic success than the Gross National Product (GNP). After all, a developing nation can easily increase its GNP by harvesting all of its forests for lumber. It is widely recognized that we need much more sophisticated measures of national productivity. In fact, the National Research Council presently has several study committees that are hard at work on these issues. One of these is our Board on Sustainable Development, led by Ed Frieman and Robert Kates.

Why have I chosen to end my talk with this discussion of measuring what counts? Precisely because for U.S. science, and indeed for much of international science, it is the 2,100 members of this Academy who largely determine what is most valued in the scientific enterprise. It is we whose judgments influence the career paths of many younger scientists -- and it is we who often determine who is, and who is not, considered a scientist. If we convey the message that those who do not do scientific research are not part of our community, then science teachers and others will remain isolated and unsupported. If we fail to value the type of science that is needed to promote wise international development and the efficient use of resources, then this type of science can not flourish to solve world problems. And if we fail to appreciate the types of science done outside of our own disciplines, or place little value on the bold attempts of younger scientists to stray from conventional research topics, we shall hinder rather than help forge the path toward novel discoveries.

The views of the members of our Academy are more important to the future of the world than you may think. We must carefully consider what we value, and then do what we can to make sure that these are the values by which our society measures itself. Only then can we hope to move the nation and the world in directions that we can proudly defend to our grandchildren.

Return to [What's New](#)

Figure 1



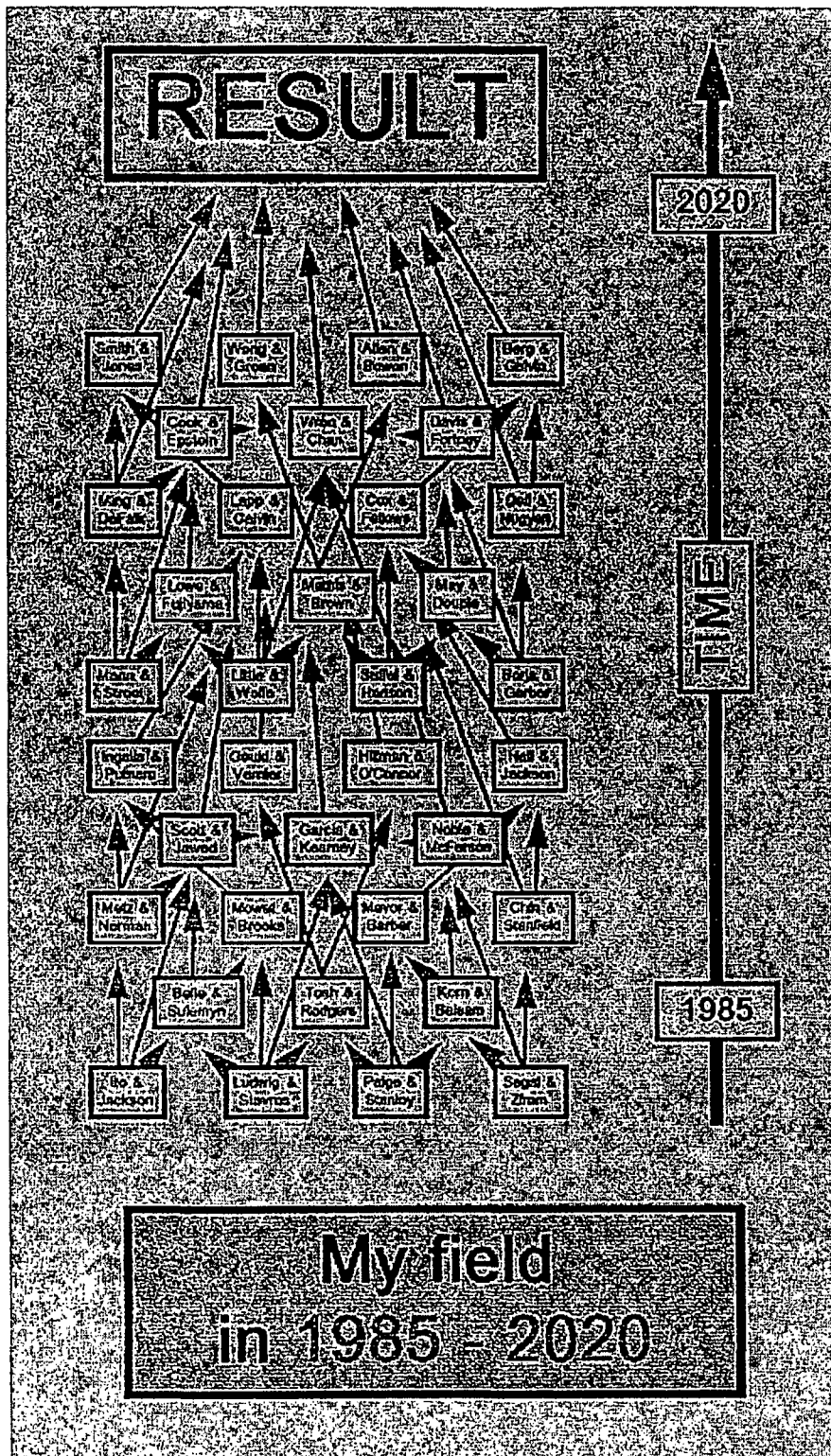


figure 2

THE CREATIVE PROCESS

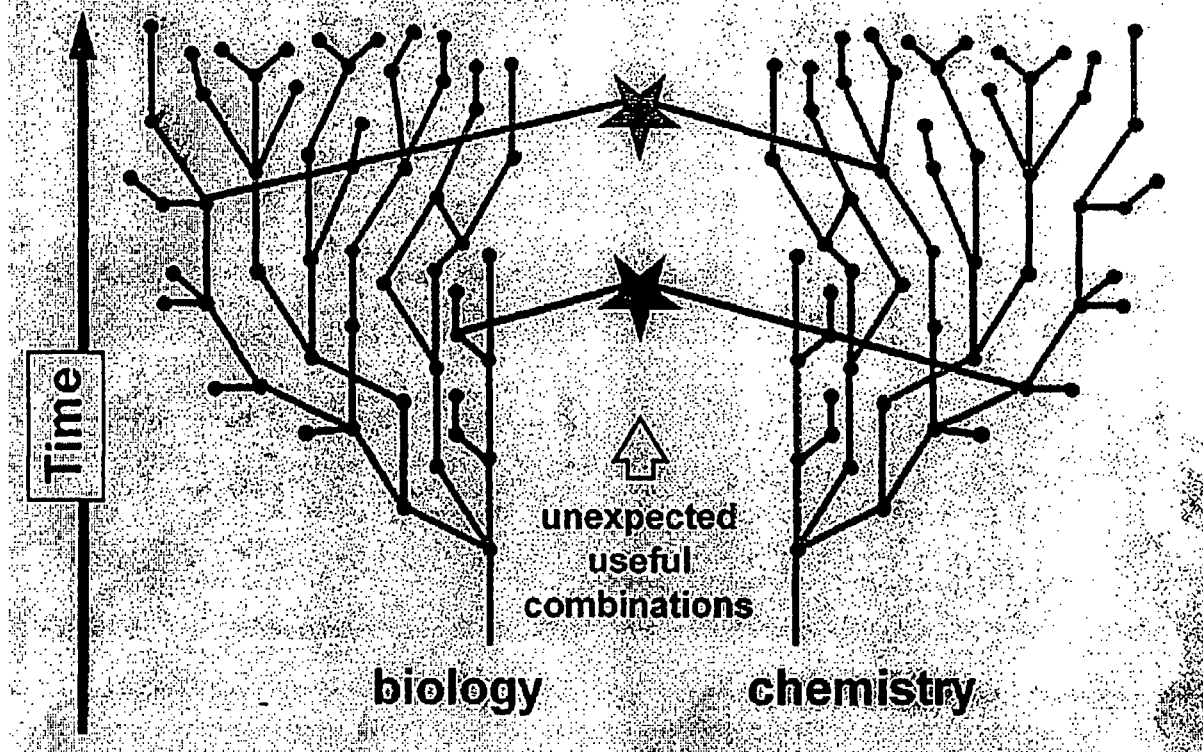


figure 3

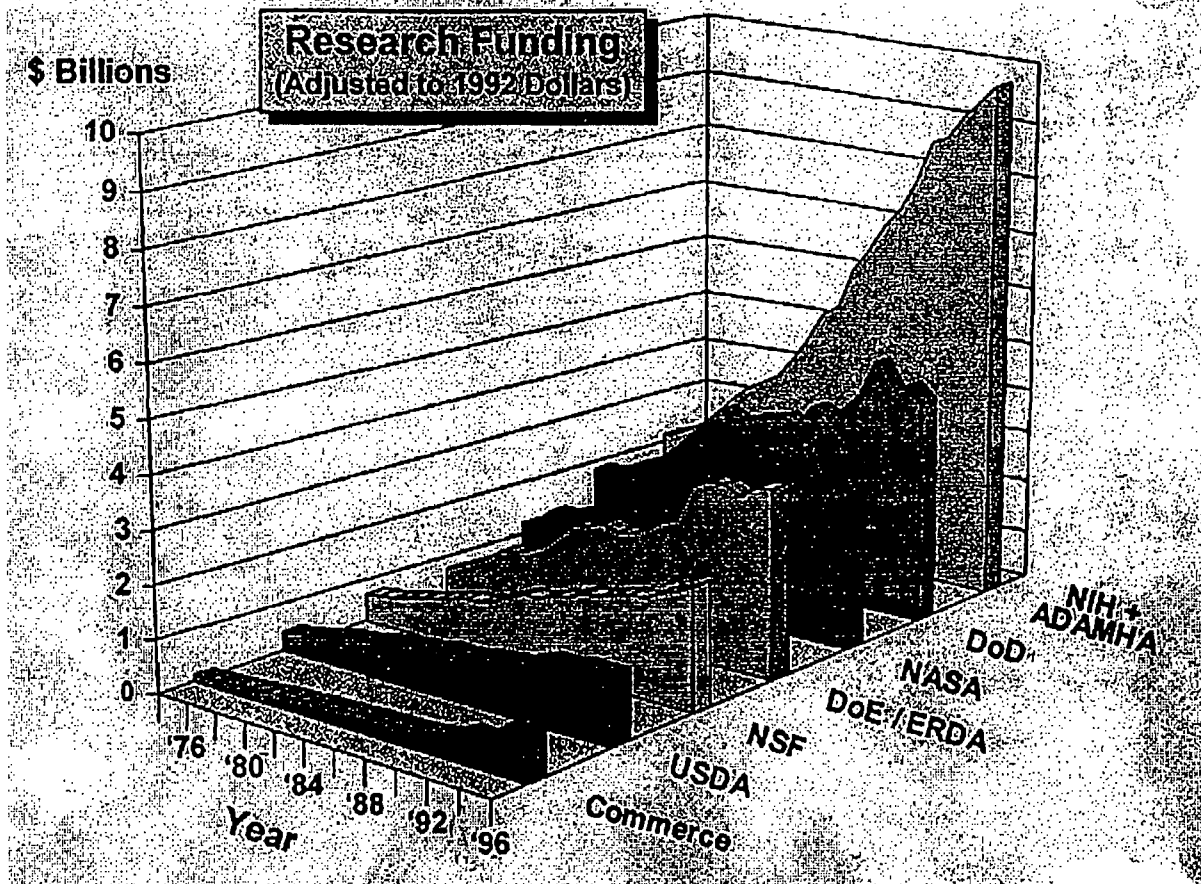


figure 4

Percent of Students from Selected Nations Scoring Among the Top 10 Percent of Eighth Graders in the 41 TIMSS Countries

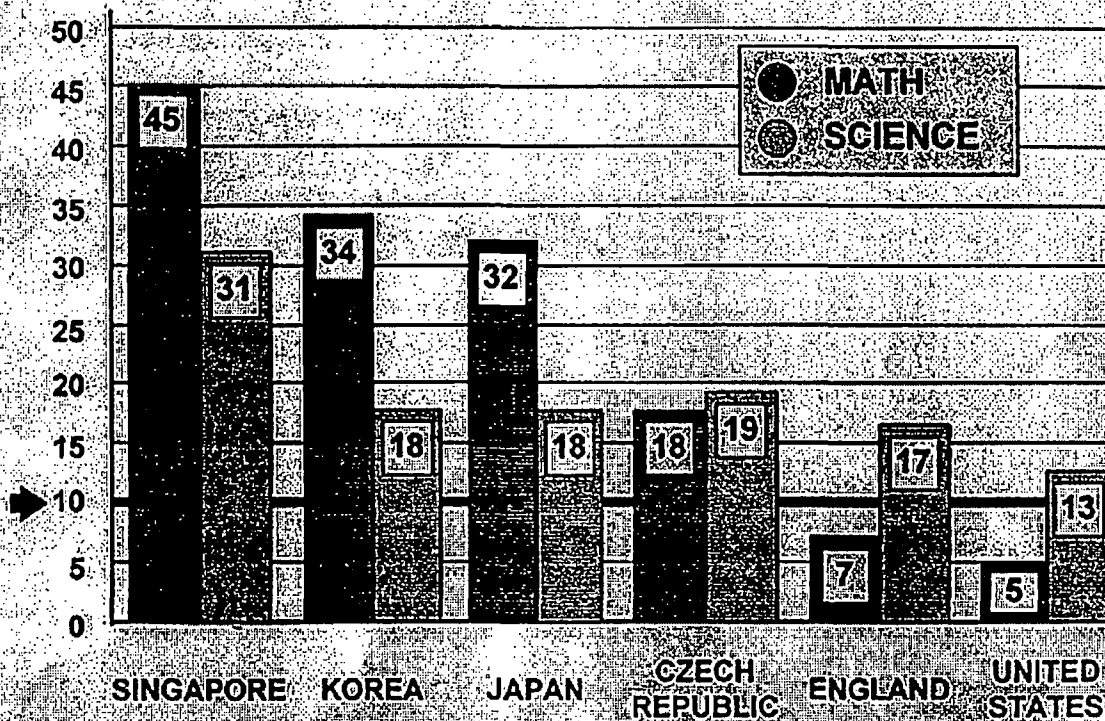


figure 5

Expert Judgments of the Quality of the Mathematical Content of Eighth-Grade Lessons

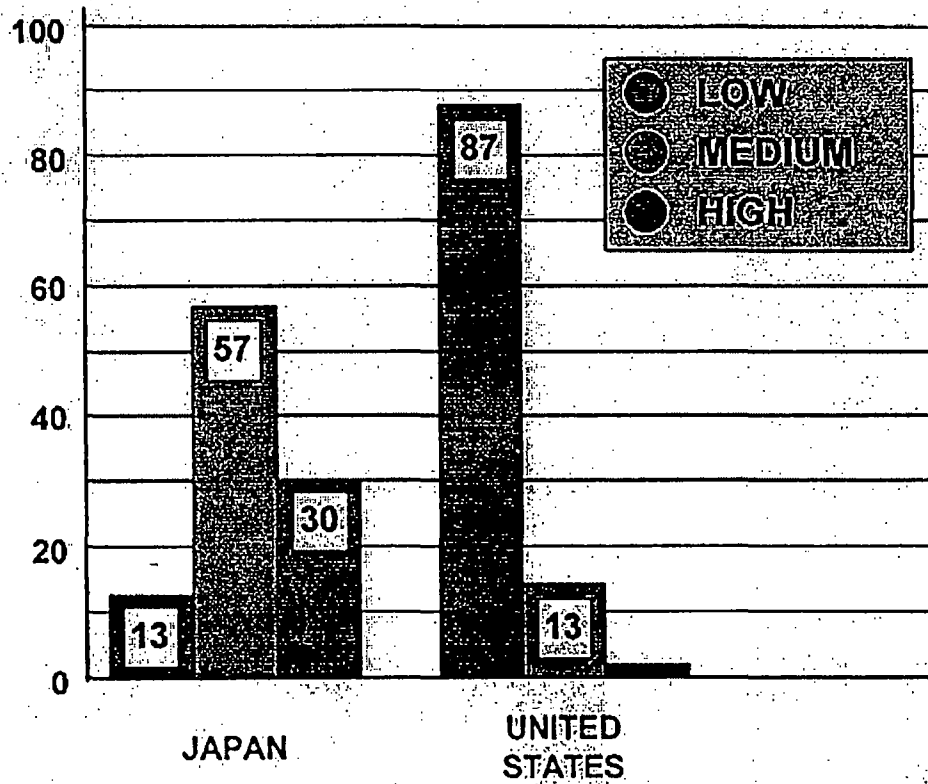


figure 6

MAKING NEW CONNECTIONS BETWEEN SCIENTISTS ACROSS THE WORLD

- **Three new "Frontiers of Science" annual meetings, connecting 40 future leaders of U.S. science with their counterparts in Germany, Japan and China, respectively.**
- **Young investigator program, in which teams of 6 to 10 scientists conduct joint summer studies focusing on particular sustainability issues.**
- **Middle East collaborations -- joint study nearly completed on sustainable water resources, using committee that includes three members each from Israel, Jordan, and the West Bank and Gaza.**
- **Collaborations with Mexico using joint committees to study the Mexico City aquifer, oceanographic research, and environmental issues along the Mexico-U.S. border -- as well as to review the graduate programs at the Universidad Nacional Autónoma de México (UNAM).**

figure 7

ENLARGING THE U.S. SCIENTIFIC COMMUNITY AND ITS CONNECTIONS

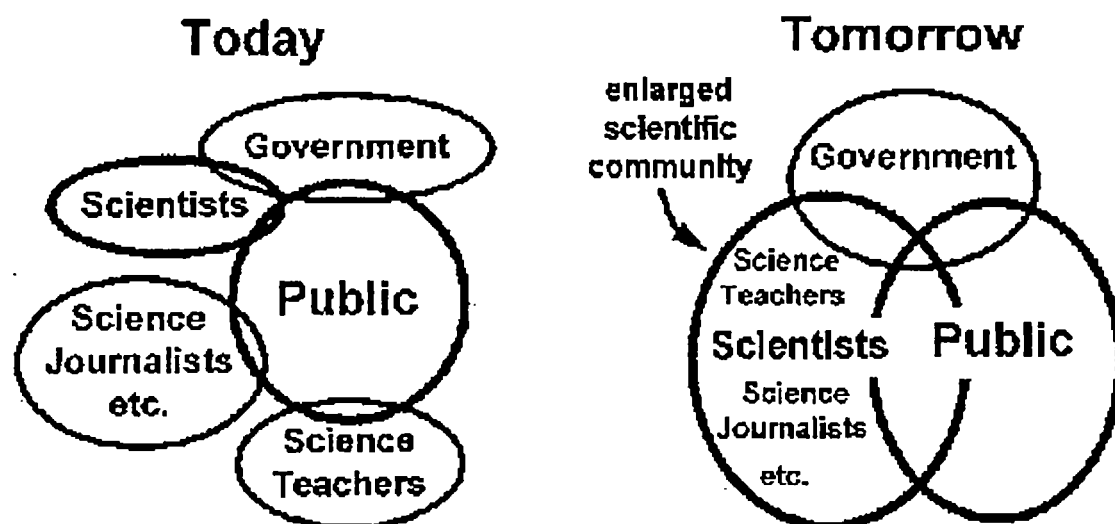
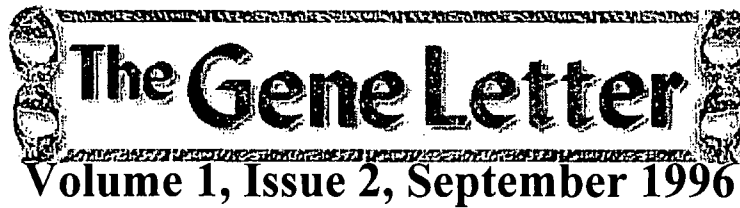


figure 8



The Gene Letter

Volume 1, Issue 2, September 1996

An Overview of Genetic Screening and Diagnostic Tests in Health Care

Genetic testing is increasingly being offered to individuals at all stages of the life cycle. Many of the genetic tests used today involve either medical or surgical procedures (such as amniocentesis) performed to provide information, with varying degrees of accuracy, on the health of a developing baby, children or adults. These tests can either be screening tests or diagnostic tests. The difference between the two is important to understand.

A genetic *screening* test provides a signal or an alert to the possible existence of a health condition. By itself a screening test cannot give any definite information. It can only suggest which individuals ought to be offered further diagnostic tests to confirm the presence or absence of a specific condition. A genetic *diagnostic* test can tell with greater certainty whether or not certain health problems exist.

An overview of genetic tests currently used in health care is provided below along with highlights of some of the ethical issues raised by testing.

Pregnant Women

Prenatal Genetic Testing

Genetic screening and diagnostic tests have increasingly been introduced into prenatal care. These tests are performed on pregnant women to provide information, with varying degrees of safety and accuracy, on the health of the fetus. In the rare situation that results reveal an actual fetal disability, women are confronted with complex decisions, such as continuing a pregnancy and planning for the birth of the child, planning for special needs adoption, fetal surgery or organ donation, or electing to end the pregnancy with an abortion. Highlights of the prenatal genetic tests currently available for pregnant women, include:

Maternal serum alpha-fetoprotein (MSAFP) screening, a blood *screening* test performed between 16-18 weeks gestation that is used to identify women who may have a higher than usual chance of carrying a fetus with a neural tube condition (such as spina bifida or anencephaly). This test has become a routine part of prenatal care in most prenatal settings;

Enhanced MSAFP (referred to by proprietary names such as Fetoscreen, DownScreen, Triple Screen and AFP Plus), is a relatively new blood *screening* test that measures the levels of alpha-fetoprotein in addition to one or two other biochemical markers (unconjugated estriol and human chorionic gonadotrophin) in a woman's blood to determine the probability (with 60-65% accuracy) of the presence of fetal Down syndrome;

Fetal ultrasound (sonography), is an imaging technique composed of nonionizing radiation (sound waves) that involves the placement of a transducer, either on a woman's abdomen or inserted vaginally, in order to provide a picture on a television-like screen. Ultrasound provides a "window to the womb" and is now used throughout pregnancy for many reasons, including pregnancy confirmation and dating, examination of the fetus at different stages of development, assessment of the structure and position of the placenta

and other internal organs, and as an adjunct to various other reproductive genetic procedures. A recent study revealed that the routine use of ultrasound in uncomplicated pregnancies does not enhance pregnancy outcome and therefore should only be used when there is an appropriate indication;

Amniocentesis, often referred to as an "amnio" or "tap," is a surgical procedure commonly used for prenatal genetic diagnosis. The procedure involves the insertion of a needle into a pregnant woman's uterus in order to remove a sample of amniotic fluid. The amniotic fluid contains cells and substances shed by the fetus that can be analyzed in specialized laboratories to determine the genetic status of the fetus. Cytogenetic, biochemical, or molecular tests may be done to determine the presence or absence of specific conditions. Amniocentesis can also be used for fetal sex identification. Amniocentesis is generally performed between 16 and 18 weeks of pregnancy, however, it is now being offered experimentally in some settings as early as 12 weeks. Although rare, complications of amniocentesis include bleeding and infection. A number of prospective studies have been designed to determine the safety and accuracy of amniocentesis, revealing a fetal loss rate estimated to be about 0.25-0.5 percent;

Chorionic Villus Sampling (CVS), performed under ultrasound guidance between 10-12 weeks gestation, is a diagnostic procedure involving the insertion of a suction catheter (transvaginally or transabdominally) or a needle into a pregnant woman's uterus in order to remove a piece of chorion, the outer tissue of the sac surrounding the embryo. The tissue can be used for chromosomal analysis, biochemical and DNA studies. This test cannot be used to identify the presence or absence of neural tube disorders, such as spina bifida. Some women who have CVS in early pregnancy may also undergo other tests, such as MSAFP screening and amniocentesis in the second trimester. CVS remains controversial because of complications (such as limb deficiencies) that may arise in the developing baby if done too early in pregnancy. According to the Centers for Disease Control and Prevention (CDC) summary statement, "Chorionic Villus Sampling and Amniocentesis: Recommendations for Prenatal Counseling" published in the MMWR (1995), "...studies support the hypothesis that CVS can cause transverse limb deficiencies...Following CVS rates of these is, estimated to be 0.03%-0.10% (1/3000-1/1000), generally have been increased over background rates." As with all invasive tests, this procedure should be performed by an experienced physician.

Percutaneous Umbilical Blood Sampling (PUBS) is a newer experimental method of fetal blood sampling performed from 18 weeks gestation throughout pregnancy. It is done under ultrasound guidance and involves the insertion of a needle through a pregnant woman's abdomen into the umbilical vein. PUBS is used to take direct measurements of fetal blood components, to clarify the results of other tests, or for the delivery of medications. The rate of complications associated with PUBS is higher than with amniocentesis or CVS, and therefore the procedure is used only in special situations; and

Fetal Biopsy is a prenatal procedure originally performed with direct visualization (using a fetoscope) but now conducted under ultrasound guidance. It is used to obtain samples of skin, liver, or muscle cells in order to perform DNA based tests on the developing baby;

Preimplantation genetic diagnosis is among the newer experimental procedure used to detect specific disease causing genes in gametes prior to fertilization or in embryos fertilized *in vitro* prior to implantation in the uterus. This technology helps to distinguish between healthy embryos and those that may possess a disease causing gene thus allowing for the selection of embryos to be placed into a pregnant woman's uterus. This type of genetic testing is mainly being offered to women who conceive with assisted reproductive technologies (such as in vitro fertilization), however, it has been offered as a very early form of prenatal diagnosis to women who are at high risk for having a baby with an inherited condition and who are opposed to pregnancy termination. This test remains in the research stage.

Fetal cell sorting is another experimental procedure under investigation. This procedure involves the withdrawal of a small amount of blood from the arm of a pregnant woman in order to isolate and test fetal cells that appear in the maternal serum. This technology is being developed in order to create a noninvasive form of prenatal testing and to potentially make the use of more invasive procedures obsolete.

Newborns

Neonatal Genetic Screening

Parents are increasingly being confronted with new genetic screening tests performed on newborns. Since 1962, most states have laws *mandating* genetic screening of all newborns at birth. Only a handful of states have regulations allowing for refusal of newborn screening on religious grounds. These tests are usually performed in the hospital nursery by taking a sample of blood from the baby's heel. The samples are checked for a variety of rare disabilities or chemical disorders, called "inborn errors of metabolism," such as phenylketonuria (PKU). Early identification of newborns with inborn errors of metabolism, followed by appropriate treatment (often times dietary), can prevent serious health conditions, such as mental retardation, from occurring.

In recent years, a number of new tests have been added to the newborn screening menu. Many states in the U.S. now screen all newborns for sickle cell disease and thalassemia. The inclusion of screening for other conditions, such as cystic fibrosis, inherited forms of heart disease, and HIV are currently being discussed throughout the country.

Newborn screening raises numerous issues with regard to informed consent, privacy of genetic information and confidentiality of test results. Although the original intent of newborn screening was to identify genetic conditions in order to initiate early treatment and to prevent complications, the identification of new genes and technologies is extending the limits of what can be identified at the time of birth, oftentimes in the absence of treatment. This trend raises a host of novel issues that need to be further analyzed.

Adolescents and Adults

Carrier Screening Tests

Genetic screening programs designed to identify carriers of certain genetic traits are now offered to individuals within specific ethnic groups who have a higher than usual chance of a particular condition appearing in the family. Some examples of carrier screening programs targeted towards specific ethnicities include screening for sickle-cell anemia in Blacks and Cape Verdeans; Tay-Sachs in Jewish persons of Eastern European ancestry and in French Canadians; and thalassemia in people of Mediterranean and Southeast Asian descent.

Carrier screening is also performed on women suspected to carry a gene on the female X chromosome that may result in an X-linked genetic condition, such as Hemophilia (a blood condition) which most often affects males, or Fragile X syndrome (a common cause of mental retardation affecting both males and females). With the recent identification of the cystic fibrosis gene, widespread population based carrier screening programs are expected to be launched in the near future, with early carrier detection projects directed towards childbearing couples.

The implications of carrier screening on women, children, family and social relationships have yet to be fully explored. More information is needed to assess what stage in the life cycle should such information be obtained. For example, there are many issues related to genetic testing of children, including at what age should testing be done and in what way might knowledge of carrier status impact on self-concept. (For more information see,

Wertz, D, Fanos, J, and Reilly, P. "Genetic Testing for Children and Adolescents: Who Decides?" JAMA, September 21, 1994, Vol 272, No 11 pp. 875-881.) Furthermore, since having certain genetic traits may not affect one's health, nor lead to the development of a disease, it is important to consider the benefits and risks of knowing whether the trait is present or not. Subsequent to being labeled as a carrier, some consumers have reported experiences with stereotyping, stigmatization, blame, genetic discrimination, and subsequent problems with low self-esteem. Developments of new tests may exacerbate these issues and needs further exploration.

Premarital Genetic Screening

In some instances, genetic profiles are now being collected to screen potential mates prior to marriage. Premarital genetic screening has been underway in certain religious and ethnic groups for many years. For example, a sect of religious Jews in New York City have a computer information system that maintains the results of Tay -Sachs screening on members of the community. Before a match is made, inquiries into the genetic status of the individuals is made to avoid a marriage between two carriers.

There is potential for expansion of premarital genetic screening programs to assess genetic compatibility as a result of newly identified genes emerging as a result of the Human Genome Project. The ethical and social issues raised by this type of screening require further exploration and analysis.

Presymptomatic and Predictive Genetic Testing

Genetic research is accelerating the rate of new genetic tools used in adult health care settings. For example, *presymptomatic tests* are used to identify individuals with a specific mutation for a health condition, such as Huntington's disease, prior to the onset of symptoms. *Predictive tests* are used to estimate the chances of a particular health condition, such as breast cancer, occurring in later life. As the specific location of genes become known, new direct DNA-based tests will be developed to identify or predict, with varying degrees of accuracy, susceptibility to late onset conditions.

When the gene, mutations in which are responsible for a condition is identified, clinical DNA studies are used for direct analysis to determine whether or not the gene is present. However, for many health conditions still under investigation the exact location of the gene or the precise change that has occurred to the DNA is unknown. When the gene is unknown, indirect tests are used to identify genetic markers or landmarks that are thought to be close to the disease-related gene. Indirect tests can only provide information about the probability of the presence of a gene and therefore are not diagnostic.

To date, presymptomatic genetic testing has primarily focused on single-gene conditions, such as Huntington's disease, and has been applied to situations in which individuals are considered "at risk" because of family history. More recently, new experimental predictive genetic tests have been developed to identify women who have mutations (changes) in a gene, known as BRCA1, which has been estimated to result in up to an 85% life time risk of breast cancer and a 50% life time risk of ovarian cancer. Inherited forms of breast cancer account for between 5%-10% of all breast cancer.

As the technological frontier expands, presymptomatic genetic testing raises complex issues for health. Do we really want to know that one day in the future we may develop a particular illness? Arguments for the pursuit of knowledge about genetic predispositions is that the information could be used for life planning. For example, knowing whether one may be genetically predisposed to cancer might influence approaches to medical care, diet, work or to other aspects of lifestyle in a particular ways that might diminish potential health complications. However, the practical ramifications of predictions raises numerous ethical issues. The psychological and social sequelae of having knowledge about one's future health has not yet been adequately studied. Furthermore, the ability to predict the

occurrence of a condition is far more likely to precede the ability to prevent or treat a condition once it occurs. While identifying individuals "at risk" for adult-onset conditions may become technologically simple, numerous questions remain, such as: Is it ethical to conduct screening when creating a technological fix or "cure" may be very far off? Or, just because a test can be done, should it be?

Given the rapid pace of research in the field of genetics individuals considering genetic testing at any stage of the life cycle need to have up-to-date information about the tests, including their benefits and limitations, their accuracy, associated risks, the conditions which can and cannot be identified, as well as other available options. Genetic counseling is recommended for all individuals considering genetic screening or diagnostic tests. For more information about genetic counseling please see the July issue of **The Gene Letter** and look for the article, "**Medical Genetic Services: What They Are and Where to Find Them.**"

In addition, because the process of informed consent is vital to decision making about genetic testing, also see the article "**Informed Consent for Genetic Testing**" in this issue.

Robin JR Blatt

Main Menu
The Gene Letter