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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Barry Grayson to President Clinton (1 page)	09/21/1999	P6/b(6)
~~002. note~~	~~re: POTUS note (1 page)~~	~~10/19/1999~~	~~P5~~ Opened 4/6/15
003. letter	Percy Malone to President Clinton re: address and phone number (partial) (1 page)	05/03/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
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Devorah Adler
OA/Box Number: 20147

FOLDER TITLE:
POTUS Notes [Folder 9]

2012-0463-S
rc818

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MOREHOUSE SCHOOL OF MEDICINE
Office of the President

THE PRESIDENT HAS SEEN
8-30-99

cc Reed Jennings Podesta

The Honorable William Jefferson Clinton
President of the United States
The White House
Washington, D.C. 20500

720 Westview Drive, S. W. Atlanta, Georgia 30310-1495

MOREHOUSE SCHOOL OF MEDICINE

Office of the President

August 18, 1999

The Honorable William Jefferson Clinton
President of the United States
The White House
Washington, D.C. 20500

Dear President Clinton:

Thank you for your administration's commitment to solving the problem of health status disparities which exist among the nation's ethnic minorities and individuals living in medically underserved communities.

In an effort to combat the persistent problem of health status disparities in America, Congressman Jesse Jackson, Jr., has introduced H.R. 2391, the National Center for Research on Domestic Health Disparities Act. This important legislation would elevate the Office of Research on Minority Health at the National Institutes of Health (NIH) to a National Center. This increased authority would enable the new center to play a stronger leadership role in promoting minority health research at NIH. This bipartisan measure is being co-sponsored by over 75 House members.

Given your well known initiative to reduce health status disparities, I wanted to bring H.R. 2391 to your attention and ask that you and the Department of Health and Human Services support this much-needed legislation. I would deeply appreciate it if you would review the bill and advise me of your position at your earliest convenience.

Sincerely,

Louis W. Sullivan, MD
President

THE FOLLOWING ORGANIZATIONS HAVE ENDORSED H.R. 2391, THE NATIONAL CENTER FOR DOMESTIC HEALTH DISPARITIES ACT:

CONGRESSIONAL BLACK CAUCUS

CONGRESSIONAL HISPANIC CAUCUS

CONGRESSIONAL ASIAN PACIFIC CAUCUS

CONGRESSIONAL PROGRESSIVE CAUCUS

BLACKS IN GOVERNMENT; NIH CHAPTER

ASSOCIATION OF MINORITY HEALTH PROFESSIONS SCHOOLS

NATIONAL MEDICAL ASSOCIATION

NATIONAL HISPANIC MEDICAL ASSOCIATION

NATIONAL ASSOCIATION OF HISPANIC SERVING HEALTH PROFESSIONS SCHOOLS

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ASSOCIATION OF SCHOOLS OF ALLIED HEALTH PROFESSIONS

NATIONAL MEDICAL FELLOWSHIPS

U.S. SURGEON GENERAL DR. DAVID SATCHER

FORMER U.S. SECRETARY OF HEALTH AND HUMAN SERVICES DR. LOUIS W. SULLIVAN

HISPANIC HEALTH COALITION

NATIONAL COALITION OF HISPANIC HEALTH AND HUMAN SERVICES ORGANIZATIONS

INTRODUCED ON JUNE 30TH WITH 69 ORIGINAL COSPONSORS,
THERE ARE 75 CONGRESSIONAL COSPONSORS TO H.R. 2391;
68 DEMOCRATS, 1 INDEPENDENT, AND 6 REPUBLICANS.

FOR MORE INFORMATION CONTACT:

DALE P. DIRKS (202) 544-7499
RONNY B. LANCASTER, M.B.A., J.D. (404) 752-1760

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NEW YORK UNIVERSITY
SCHOOL OF MEDICINE

Institute of Reconstructive Plastic Surgery
560 First Avenue, New York, NY 10016

PRESIDENT WILLIAM CLINTON

Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies

Summary of Recommendations

Official Publication of the American Cleft Palate-Craniofacial Association

April 1998

INTRODUCTION

In 1991, the American Cleft Palate-Craniofacial Association (ACPA) received funding from the Maternal and Child Health Bureau[1] to develop standards for the special needs of children born with cleft lip/palate and other craniofacial anomalies. Following a consensus conference and widespread peer review process, the ***Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies*** *was developed and published. A summary of the recommendations of this report follows.*

SUMMARY

PARAMETERS FOR EVALUATION AND TREATMENT OF PATIENTS WITH CLEFT LIP/PALATE OR OTHER CRANIOFACIAL ANOMALIES

The complex needs of a child with a cleft lip/palate or any other craniofacial anomaly are best met by a dedicated cleft or craniofacial team of health care providers with special expertise and experience in the care of such disorders. The professionals on these teams provide care regularly for a reasonable number of patients in a facility with the resources necessary for such care.

Audiologic Care

Individuals with craniofacial anomalies may have congenital abnormalities of the auditory structures and an increased incidence of ear disease. These children are at high risk for hearing disorders that may occur intermittently or become permanent, and that vary from mild to severe. Hearing loss can have a significantly adverse influence on speech and language development, educational and psychological status, and eventually on social and vocational status. For these reasons, these children require ongoing audiologic surveillance beginning at one month of age and continuing through adolescence. Tympanometric and audiometric measures should be obtained. Treatment may involve myringotomies and placement of ventilation tubes, hearing aids, auditory training systems, bone conduction amplification, and external, middle, and inner ear surgery.

Cleft Lip/Palate Surgery

In addition to primary surgical closure of the cleft lip and cleft palate which is initiated within the first 12 months of age, many patients will require secondary surgical procedures involving the lip, nose, palate, and jaws that usually are staged from infancy through adulthood. In all cases, surgical techniques should be individualized according to the needs and condition of the patient. Surgical procedures should be coordinated to minimize the number of anesthetic exposures and hospitalizations. Evaluation of complications (morbidity and mortality) of cleft lip and palate repairs should be completed on an annual basis and subject to peer review. The major factor in the quality of surgical outcome is the skill, training, and experience of the cleft care team. An anesthesiologist knowledgeable and experienced in pediatric anesthesia must be present for all surgical procedures. Additional procedures for cleft lip/palate may include pre-surgical maxillary orthopedics, lip adhesion, pharyngoplasty, tonsillectomy/adenoidectomy, orthodontic maxillary expansion, alveolar bone grafting, nasal reconstruction including nasal septal surgery, and jaw surgery in conjunction with pre- and postoperative orthodontics.

Craniofacial Surgery and Maxillofacial Surgery

The complex nature of many types of craniofacial anomalies often necessitates multiple operative procedures at different stages of growth and development. Reduction of morbidity and mortality from craniofacial operations requires establishment of a dedicated surgical team, frequent performance of operative procedures, and adequate support facilities. Longitudinal follow-up is necessary for these patients, at least into adolescence, even when the intervention has been successful with respect to the anatomic defect. Specific components of the pre-, peri-, and postoperative evaluations of craniofacial surgery should be based upon the type of anomaly and the craniofacial zone(s) affected. Treatment involves reconstructive surgery to the craniofacial region, and may include hard and soft tissue remodeling, reconstruction, grafting, distraction, and implantation. Secondary procedures are often necessary due to the effects of growth, attainment of maturity or persistent residual deformities. An anesthesiologist knowledgeable and experienced in pediatric anesthesia must be present for all surgical procedures.

Dental Care

Patients with craniofacial anomalies require dental services as a direct result of the medical condition, and dental treatment is an integral part of the habilitative process. Provision of dental services for these patients includes not only primary care but routine maintenance throughout life. The necessary procedures focus on monitoring craniofacial growth and dental development, on maintaining a healthy dentition and periodontium, and on correcting jaw relationships and dental occlusion when necessary in order to achieve optimal function and appearance. Dental care begins once the primary dentition erupts and continues into adolescence. Treatment requires diagnostic records (study models, cephalometric radiographs, photographs, and, at times, computer imaging) to monitor dentofacial growth and dental development, preventive and restorative dental treatment, and, when indicated, orthodontic treatment, alveolar bone grafting, orthognathic

(jaw) surgery, and prosthetic and periodontal interventions.

Genetic/Dysmorphology Services

A comprehensive clinical genetic evaluation is a key component in the management of patients with congenital craniofacial anomalies and should include diagnosis, recurrence risk counseling, and counseling regarding prognosis. Complex syndromes involving craniofacial anomalies may not fully express clinical manifestations that can be recognized in the first year of life. Thus, genetic screening and follow-up evaluations will be necessary for some patients until puberty. Patients who are first seen by the team at later ages should also be evaluated.

Nursing Care

Nursing assessment, interventions, and ongoing follow-up evaluations are integral to the long-term care needs of the child or individual with congenital craniofacial anomalies and the family. Assessments of feeding, interventional teaching, and follow-up of nutritional and growth assessments are examples of the nursing services provided. In addition to these direct nursing services, members of the craniofacial team bear the responsibility for education of hospital and community nurses in feeding and other aspects of the special care that may be required.

Otolaryngologic Care

Comprehensive care of children with craniofacial anomalies typically requires long-term monitoring of the ears, nose, and throat due to the prevalence of ear disease, ear malformations, and upper airway problems. Physical examinations and airway assessments begin perinatally for patients with airway compromise or within the first 6 months of life for those with stable airways and continue through adolescence. Such assessments may require endoscopy, radiologic studies, airflow studies, CT scans, MRI's, and polysomnography. Structural and functional laryngeal problems may exist in these patients, and may require medical as well as surgical treatment. Adenoidectomy and/or tonsillectomy may be indicated for airway obstruction but only after careful velopharyngeal functional assessment. Other oropharyngeal and laryngotracheal procedures may be necessary as well.

Pediatric Care

Pediatric care provided within the context of the team, along with a primary care physician, is fundamental in assuring that the health needs of the child with craniofacial anomalies are fully identified and appropriately treated. Physical examinations should be provided on a regular basis, parental questions regarding health issues should be addressed, and referrals to appropriate specialists should be made in cooperation with the primary physician.

Psychological and Social Services

Accomplishing the goals for treatment of the patient with craniofacial anomalies requires periodic assessment of psychological needs of both the parent and family. Psychological tests must be administered and interpreted under the supervision of a licensed psychologist, preferably a person familiar with craniofacial anomalies and related speech and hearing disorders. Psychosocial screening interviews should be conducted periodically to assess parental competence and nurturance, child management skills, parent-child relationships, and the emotional and behavioral adjustment of the child. The high rate of learning disorders in children with craniofacial conditions requires that each child be screened for potential learning disorders beginning in infancy until cognitive competence has been established. Each family should be referred for psychological evaluation and, as appropriate, intervention when problems are identified through the screening procedures.

Speech-Language Services

Children who have craniofacial anomalies are at high risk for speech-language disorders. Evaluation of speech and language development provides information that is needed by the team in the planning of treatment, including surgical, dental, and speech management, and in the assessment of treatment outcome. Speech-language evaluations should occur within the first year of life, and then often enough to assure adequate documentation of each child's progress and to develop appropriate recommendations for intervention. Evaluation of velopharyngeal function, conducted with the participation of the team speech-language pathologist, is required for many patients and may include articulatory performance, aerodynamic measures, videofluoroscopy, nasopharyngoscopy, and nasometric studies.

[1] Maternal and Child Health Bureau, Title V, Social Security Act, Health Resources and Services Administration, U.S. Public Health Service, Department of Health and Human Services, Grant #MCJ-425074.

Copies of the entire document, ***Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies*** may be obtained by contacting:

American Cleft Palate-Craniofacial Association
1829 East Franklin Street, Suite 1022
Chapel Hill, North Carolina 27514
(919)933-9044
Fax (919)933-9604

The American Cleft Palate-Craniofacial Association

The American Cleft Palate-Craniofacial Association (ACPA) was founded in 1943 by a group of Pennsylvania dentists who attended a course at Penn State on the construction of speech appliances for children with cleft palate. The purpose of the organization, as stated in the original Preamble to the Constitution, was to "encourage...the improvement of scientific clinical services to persons suffering from cleft palate and associated deformities." It was apparent from the first meeting that improving services was largely dependent on cooperation and communication among the three primary disciplines involved in the treatment of cleft lip and palate: surgeons, dentists, and speech pathologists.

Today, the Association has a membership of over 2,600 in 40 countries. Membership is open to qualified individuals who are involved in the treatment and/or research of cleft lip, cleft palate, and other craniofacial anomalies. Members represent over 30 health care disciplines. Their mission is *"to optimize care of persons affected by craniofacial anomalies through education, stimulation of research, and the promotion of interdisciplinary collaboration and team care."*

For more information on cleft lip/palate, craniofacial anomalies, and team care contact:

OUR NEW ADDRESS
Am. Cleft Palate-Craniofacial Assn.
104 South Estes Drive, Suite 204
Chapel Hill, NC 27514
(919) 933-9044

Facsimile (919)933-9604
E-mail cleftline@aol.com

Printed in the United States

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Craniofacial Association

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Website: www.cleft.com

FACT SHEET

About the Association

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The Association holds a general scientific meeting of the membership every year. Over 100 papers are presented at the annual meetings on such subjects as intervention outcomes, cleft lip and palate surgery, craniofacial surgery, psycho-social development, genetics, and bone grafting.

The official publication of ACPA is the bi-monthly *Cleft Palate-Craniofacial Journal*. It is an international, interdisciplinary, professional journal reporting on clinical and research activities in cleft palate and other craniofacial anomalies, together with research in related laboratory sciences.

The Association is governed by a 16-member Executive Council which establishes Association policy. The council is supported by 21 committees and a staff of five.

Officers of the Association are:

President	Marilyn C. Jones, M.D., Children's Hospital of San Diego, San Diego, CA
President-Elect	John E. Riski, Ph.D., Scottish Rite Children's Medical Center, Atlanta, GA
Past President	Katherine Dryland Vig, F.D.S., D'Orth, Ohio State University, Columbus, OH
Vice President	Don LaRossa, M.D., Children's Hospital of Philadelphia, Philadelphia, PA
Vice President-Elect	Leslie A. Will, D.M.D., M.S.D., Harvard School of Dental Medicine, Boston, MA
Secretary	Kim S. Uhrich, M.S.W., C.C.S.W., University of North Carolina, Chapel Hill, NC
Treasurer	Michael J. Buckley, D.M.D., M.S., University of Pittsburgh, Pittsburgh, PA
Historian	Donald V. Huebener, D.D.S., St. Louis Children's Hospital, St. Louis, MO
Editor	Jerald Moon, Ph.D., University of Iowa, Iowa City, IA
Executive Director	Nancy C. Smythe, ACPA/CPF National Office, Chapel Hill, NC

About the Cleft Palate Foundation

The Cleft Palate Foundation was founded by its parent Association in 1973 to be the public service arm of the professional Association. Its primary purpose is "to enhance the quality of life for individuals with congenital facial deformities and their families through education, research support, and facilitation of family-centered care."

The Foundation's major activities include the operation of the CLEFTLINE and the dissemination of publications. The CLEFTLINE is an 800 toll-free service providing information and referral to parents of newborns with cleft lip, cleft palate, and other craniofacial anomalies, and to affected adults. Referrals are made to cleft palate/craniofacial teams and to parent support groups. Brochures and fact sheets on various aspects of cleft lip, cleft palate, and other craniofacial anomalies are provided free to families.

The Foundation also conducts parent/patient liaison projects, public education activities, and awards annual research grants to junior and senior investigators.

The Foundation is supported solely through tax-deductible contributions. It is governed by a six-member Board of Directors and supported by seven committees.

Officers of the Foundation are:

President	Earl J. Seaver, Ph.D., Northern Illinois University, DeKalb, IL
Secretary	Kim S. Uhrich, M.S.W., C.C.S.W., University of North Carolina, Chapel Hill, NC
Treasurer	Michael J. Buckley, D.M.D., M.S., University of Pittsburgh, Pittsburgh, PA
Executive Director	Nancy C. Smythe, ACPA/CPF National Office, Chapel Hill, NC
Honorary Chair	Stacy Keach, Malibu, CA

About Cleft Lip and Palate

Cleft lip and cleft palate comprise the fourth most common birth defect in the United States. One out of every 700 newborns are affected by cleft lip and/or palate.

A cleft lip is a separation of the two sides of the lip. The separation often includes the bones of the upper jaw and/or upper gum. A cleft palate is an opening in the roof of the mouth in which the two sides of the palate did not fuse or join together as the unborn baby was developing. Cleft lip and cleft palate can occur on one side (unilateral cleft lip and/or palate) or both sides (bilateral cleft lip and/or palate). Because the lip and the palate develop separately, it is possible for the child to have a cleft lip, a cleft palate, or both cleft lip and palate.

Cleft lip and palate are congenital or birth defects which occur very early in pregnancy. The majority of clefts appear to be due to a combination of genes and environmental factors. The risks of recurrence of a cleft condition are dependent upon many factors which include the number of affected persons in the family, the closeness of affected relatives, the race and sex of all affected persons, and the severity of the clefts.

Children born with a cleft frequently require a number of different types of services, e.g., surgery, dental/orthodontic care and speech therapy, which need to be provided in a coordinated manner over a period of years. This coordinated care is provided through interdisciplinary cleft palate/craniofacial teams — professionals from a variety of health care disciplines who work together on the child's rehabilitation.

For information, call the CLEFTLINE: 1-800-24-CLEFT.

THE PRESIDENT HAS SEEN
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In the Ethics Storm on Human Embryo Research

By NICHOLAS WADE

NASHVILLE — On the white paper tablecloth, Brigid Hogan is sketching a diagram with the children's Crayolas the restaurant has thoughtfully provided. The daughter of two artists, she draws rapidly and precisely. The structure of an embryonic lung billows across the table. Words like "sprouty," "breathless," "branchless," playful names for the genes that control the process, appear alongside arrows and curlicues.

Watching this gentle English biologist reach for another Crayola, it is hard to believe she could ever occasion a threat, let alone one Congress has deemed so severe that it has thrice passed a law to thwart it.

A leading expert on the embryology of the mouse, Dr. Hogan was the scientific co-chairwoman and principal author of a National Institutes of Health report on human embryo research. The report, published in 1994, presciently described the benefits to be expected from the study of embryonic stem cells, the primordial human cells that were first isolated last November, and it said biologists should be allowed to derive the cells from the surplus embryos created in fertility clinics. Some biologists hope the cells will provide a universal repair kit for human tissues.

The idea of destroying human embryos, even surplus ones, was daring enough, but the report went on to recommend letting embryos be created by mixing eggs and sperm in a dish, a procedure that could help treat infertility.

President Clinton swiftly repudiated the notion of creating human embryos for research purposes. And Congress was so perturbed by the report that for the last three years it has specifically forbidden the National Institutes of Health to pay for any research in which a human embryo is destroyed.

The agency now believes it can legally finance researchers to use the cells, though not to derive them, under rules recommended by a group of experts, including Dr. Hogan. The guidelines are expected to be issued imminently but abortion opponents hope to have Congress override them.

A clash of competing values was perhaps inevitable as biologists started to part the veils around the mystery of life's earliest moments. The report by Dr. Hogan and her colleagues, who included ethicists as well as biologists, precipitated the maelstrom because it was a ringing scientists' manifesto, a public declaration of the various types of human embryo research that were about to become technically feasible and the medical benefits to be expected from each.

Dr. Hogan works at Vanderbilt University Medical Center in Nashville and holds a coveted fellowship from the Howard Hughes Medical Institute, a munificent patron of biomedical researchers. In her office overlooking a graceful courtyard on the Vanderbilt campus, she seems far removed from the political fray set off by her panel's report.

"I think it is a tremendous shame that people funded by the National Institutes of Health cannot work on embryonic stem cells," she said. But she has no present plans to do so herself. Apart from one foray into human embryology, an attempt to derive stem cells from fetuses, her chief interest has always lain with the mouse.

As a scientist, her purpose is to understand how embryos develop. For the most part, that requires genetic manipulations that would be unacceptable with human embryos. But because people seem to be constructed with a very similar set of genes, research by mouse embryologists like Dr. Hogan is laying the groundwork for understanding and repairing the many human imperfections caused by defects in the embryo-shaping genes.

Dr. Hogan's interests in embryos are esthetic as well as practical. Ever since she was a girl growing up near High Wycombe, a town 28 miles northwest of London, she has viewed embryos as things of particular beauty. "I carry a picture of a mouse embryo in my wallet to look at if I'm feeling low, like people carry pictures of their family," she said.

She studied biochemistry at Cambridge University and did postdoctoral work at Massachusetts Institute of Technology on sea urchins. But the genetics of sea urchins are not well understood, and besides, she said, "You don't feel that warmly about the sea urchin embryo." On returning to England, Dr. Hogan switched to the mouse, which was then becoming easier to study because of new advances.

Although scientists are supposed to be able to reproduce another's work by following the recipes given in published articles, there are often details of technique that never get written down. Dr. Hogan soon realized that there was a whole body of arcane lore, known only to specialists, about how to mate mice and manipulate their embryos. During a meeting at the Cold Spring Harbor Laboratory on Long Island, a leading teaching center for biologists, she mentioned to its director at the time, James Watson, the idea of holding a course there to teach researchers how to do mouse embryology.

Dr. Watson abruptly left the table where they had been talking, leaving her to wonder what she could have said to offend him. But a few minutes later, the time necessary to visit his business office, Dr. Watson returned, saying, "It's all organized." Dr. Hogan began teaching a summer course, now in its 16th year.

Dr. Watson's enthusiasm was not mirrored at the National Institute of Medical Research in London, where she then worked. "At Cold Spring Harbor, everything is organized to get things done," she said. "In the N.I.M.R., people thought you were a nuisance if you asked for anything."

During Christmas vacations, the institute's building was closed for two weeks, and those who wanted to work had to bring in their own heaters. Dr. Hogan recalled how her ankles would burn while the rest of her shivered. She decided one Christmas Eve that she could not be competitive in such circumstances. Writing round to friends, she heard of a job at Vanderbilt, where she moved in 1988.

With a group of 11 people, including graduate and postdoctoral students, she is trying to reverse-engineer the mouse by analyzing the genetic program that guides its development from an egg. Mouse researchers now have many powerful techniques at their disposal. They can remove a gene, creating a strain of "knock-out" mice that by their physiological defects may reveal what the gene is meant to do. Or they can replace a gene with one that makes a blue stain that shows when and in which tissues the gene is active.

With colleagues at Vanderbilt and elsewhere, Dr. Hogan has found that a particular gene, known as BMP-4, must be switched on if the embryo is to set aside germ cells for the next generation of mice. She is also studying the development of organs like the lung and the lens of the eye. Both require interactions between cells belonging to two of the three sheets of tissue of which the early embyro is formed. These interactions are governed by specific genes, whose roles she is trying to define.

Though she focuses on the mouse, Dr. Hogan is keenly interested in how the techniques she and colleagues have developed may be applied in medicine. Now that human embryonic stem cells have been isolated, they allow human embryos to be manipulated with the same mastery as mouse embryos, although of course most of the changes made to mouse embryos would be ethically unacceptable in humans.

Dr. Hogan agrees with researchers who believe that human embryonic stem cells are likely to be useful in repairing ordinary tissues in adults or in a fetus. But she opposes the use of altered embryonic stem cells to make changes to an individual's germ line, as is done routinely in making knock-out mice. "I think the technique is far too risky and is unlikely to ever be perfected to the stage when it is absolutely 100 percent reliable, which is what one would have to insist on," she said.

Sitting at a dual-eyepiece microscope, Ray Dunn, one of Dr. Hogan's graduate students, shows a visitor the magical moment when the mouse embryo changes from a blob to a being. Up to six days after fertilization, the embryo is a tiny white opalescent cylinder, still far more like an egg than an animal. But by the eighth day it has billowed out into a tier of buds and whorls, visibly destined to form head, heart, limbs and tail. Human embryos look much the same, though they have a more flattened-out appearance.

Though embryologists are far from being able to understand how a mouse or human is put together, the problem does not seem insoluble. Five families of signaling genes, many used over and over again at different stages of development, seem to control a major part of the mouse embryo's development.

When all the developmental genes and their functions are known and entered in the databases, won't the mystery of life be dispelled and its awe destroyed? Dr. Hogan doesn't think so. The embryo, she said, "is to me the most beautiful thing in the world, quite exquisitely beautiful, and the idea that one could eventually describe how it is formed and grows just in terms of molecules and genes and pathways doesn't detract from the beauty at all, makes it more awesome, in fact."

The New York Times

TUESDAY, SEPTEMBER 28, 1999

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Extensive Effort Seeks to Clarify Medicare Maze

Complex New Choices Baffling the Elderly

By ROBIN TONER

WASHINGTON, Sept. 26 — In a vast public education campaign, the biggest in the 34-year history of Medicare, the Federal Government is mailing handbooks to 39 million Medicare beneficiaries this month to try to guide them through the increasingly complicated world of health care.

Backed up by toll-free telephone service, (800) 633-4227, an expanding Internet site (www.medicare.gov) and outreach efforts with more than 200 local and national groups, the new campaign is intended to aid an aging population that, experts say, is often ill-equipped to handle the brave new world of health care choices envisioned by Congress.

Nancy-Ann Min DeParle, the administrator of the Health Care Financing Administration, which oversees Medicare, has suggested that this may be the "biggest peacetime education program the Federal Government has ever undertaken."

But the challenge facing this new campaign, which was delayed last year for more research, is daunting. Many health planners and lawmakers on Capitol Hill dream of a nation of well-informed, elderly consumers taking advantage of a competitive marketplace that offers them a choice of health plans. But many experts say, there is significant confusion among the elderly about the costs and benefits of these choices.

"I am not a managed care basher," said Shoshanna Sofaer, a professor of health care policy at Baruch College of the City University of New York, who is advising the Federal Government on its education efforts. "But I'm saying we really do have to recognize that it's going to be difficult and take a while for people to get this stuff. And for a significant percentage, they're never going to get it, because they're cognitively impaired, they're too frail, or they just don't have the energy to invest in understanding these things."

Call it the complexity factor, or what happens when political theory (choice is good) collides with reality (choice is confusing).

Carol Cronin, director of beneficiary services for Medicare, estimates that 70 percent of the Medicare beneficiaries have the choice between traditional Medicare and at least one H.M.O. About 16 percent of the total are in an H.M.O. And while the market has been in turmoil in the past few years, with the managed care industry complaining that the Government pays it too little for Medicare beneficiaries and many H.M.O's leaving the program, more and more of the nation's elderly are expected to end up in H.M.O.s.

Help lines, like the Medicare Rights Center in New York, say they are flooded with calls from the elderly, or their frustrated adult sons and daughters, trying to determine which health care plan is best for them. "It's all incredibly complicated not only for seniors but for everyone, including me," said Diane Archer, executive director of the center.

Eleven Medicare beneficiaries, five in H.M.O.s and six in traditional Medicare, assembled at the John Booth Senior Center in Baltimore last week and offered a glimpse of life on the front lines.

Ruth Dominiak, 79, a retired credit investigator, said she had looked at the new Medicare guide and understood some of it, but confessed: "I don't understand managed care at all. It's like reading Greek."

Catherine McGurrin, 79, a retired real estate agent who is happily enrolled in an H.M.O., said she thought the guide would help in making decisions, but added that she also relied on family members and friends.

"You talk to other women: 'Where do you go?'" Ms. McGurrin said. "You get five or six people you talk to, maybe three of four of them say one thing, it more or less points you in that direction."

Charles Linz, 72, a retired General Motors electrician, said he got a lot of health care information from retiree meetings at his old employer.

Everyone agreed that health care had become more complicated. Most had war stories about being trapped in voice mail systems trying to get answers. "Blue Cross Blue Shield, if you live long enough to get through to a human being, they'll answer questions," Mrs. Dominiak said. "You got to push this, and push that."

Helen Mirabile, a 79-year-old retired sewing machine operator, said she still did not understand some of her bills. She added with a rueful laugh, "I just pay them."

The new Medicare guide, "Medicare & You 2000," is part of an information campaign mandated by Congress in the 1997 legislation that was intended to open the Medicare market to even more kinds of health plans than now exist. The estimated cost of the education effort in this fiscal year is $133 million. The guides are the result of months of market testing, focus groups, expert reviews and research, much of which discovered that many Medicare beneficiaries have only a sketchy understanding of the basic program, let alone the new managed care choices.

Focus group studies done for the Kaiser Family Foundation, a health research group, show that even many of the elderly who are already in H.M.O.s "don't understand the rules that govern their care," said Patricia Neuman, a Kaiser analyst. Focus groups also show their adult sons and daughters are "very angry over how confusing the program is," Michael Perry, a pollster, said.

Those who counsel older Americans say they sometimes do not understand the tradeoffs they make, for example, getting prescription drug coverage by joining an H.M.O. but giving up a full choice of doctors.

"We're making it more complicated for people, and we're also making it more consequential," Ms. Sofaer said. One of the messages in the new Medicare campaign is that people do not have to choose. "If you are happy with the way you get your health care now, you don't have to do anything," says a recorded voice on the Medicare toll-free line. Live counselors are available during work hours Monday through Friday.

The new guide, which comes in 26 regional versions and is being mailed to 32 million households, features basic information on what the traditional program covers, the options for Medigap insurance to supplement it and the basics on managed care plans. It also includes information on the managed care plans available in a beneficiary's region, as well as data on the quality of the plans, for example, mammography rates and consumer ratings of how well the doctors communicate.

It includes a three-page summary at the front, beginning with "Welcome to Medicare & You!" which tries to lead the beneficiary through the basics in particularly simple language. But insurance is inherently difficult, and before long, the handbook is in the thicket of benefit periods and Part A and Part B.

It describes the choice between traditional Medicare and managed care plans (H.M.O's), which is politically fraught on Capitol Hill, this way: "In most plans, you can only go to doctors, specialists, or hospitals on the plan's list. Plans must cover all Medicare Part A and Part B health care. Some plans cover extras, like prescription drugs. Your costs may be lower than in the Original Medicare plan."

Beyond the handbook, more information is available on the Internet, although Ms. Cronin acknowledged that it was more likely to be used by family members, friends and state insurance counselors, than by older people themselves.

Advocates of managed care contend that the market will work best only when consumers have a wealth of such information upon which to base their decision. But Bob Blendon, an expert on public attitudes and health at Harvard, said studies showed that older Americans are less likely than younger people to make consumer decisions on the basis of statistical data.

In fact, Dr. Lee Newcomber, senior vice president for health policy at United Healthcare, which has a large Medicare business, said, "You really have to do a face-to-face conversation with a senior to really help them through it." Once enrolled at his company, elderly beneficiaries are assigned to a personal service representative "so they call the same person whenever they have a question," Mr. Newcomber added.

To a large extent, experts say, this confusion will be eased by time, as more and more of the people entering Medicare have experienced managed care in their working lifetimes. Already, Ms. Cronin said, newer retirees have less of an information gap, "so, in effect, we have two generations within this current Medicare population."

In the meantime, calls to the toll-free lines, which are staffed in Iowa and Wisconsin, are climbing. "It's up to about 17,000 to 20,000 a week, and the handbook is just starting to arrive," Ms. Cronin said last week.

The New York Times

MONDAY, SEPTEMBER 27, 1999

THE PRESIDENT HAS SEEN
10-5-99

C Jennings

What about this?

BC

Copied
Jennings
Podesta

September 24, 1999

The Honorable William Jefferson Clinton
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear Mr. President:

During the 105th Congress, you provided leadership and worked successfully with Congressional leaders to enact the Balanced Budget Act of 1997 (BBA 97). That law helped put the federal government on a course of fiscal discipline that is resulting in major economic dividends benefitting all Americans. With respect to the Medicare program, we collaborated on the most significant set of reforms in payments to providers and private health plans that has occurred since the program was first enacted. These changes had the salutary effect of temporarily stabilizing the rates of growth in Medicare spending and extending the solvency of the Part A Hospital Insurance Trust Fund.

As is occasionally the case with major legislation, we have learned that there are some unintended consequences. As a result, certain provider and health plan payment adjustments may be required under Medicare in order to protect beneficiaries' access to quality health care services and plans. It is my intention to propose shortly a package of legislative adjustments in areas where steps must be taken to improve payment equity to providers and to protect the availability of privately offered Medicare+Choice plans. In this regard, although you did not specify policies, it was helpful that the Administration's recently released Medicare reform proposal set aside $7.5 billion over 10 years to address concerns in these areas.

Our review indicates that several areas of legitimate concern could clearly be addressed by the Executive Branch administratively, thereby freeing the Congress to concentrate on those matters which can only be addressed legislatively. I urge you to review the enclosed list of

administrative adjustments and advise me of your willingness to take steps within the Administration to address these matters. As necessary, the Congress can and will act on other related matters. However, I am confident that in the spirit of the BBA 97 agreements, including a shared concern for fiscal responsibility, you will want to collaborate with us in resolving these concerns. Thank you for your consideration.

Sincerely,

William V. Roth, Jr.
Chairman

Enclosure

Administrative Adjustments to Improve Medicare Provider Payment Equity, and to Stabilize the Medicare+Choice Program

Hospitals

Proposal -- Fair Transition for Outpatient Payment Changes: Develop and administer a budget neutral, multi-year transition method for implementation of the hospital outpatient prospective payment system (scheduled for July, 2000), including a policy to maintain the scheduled reductions in beneficiary cost-sharing liabilities for services received in hospital outpatient departments.

Obtain an expert and independent evaluation of the clinical soundness and payment equity implications of the proposed Ambulatory Payment Category (APC) system, including its appropriateness for unique categories of providers, such as cancer hospitals. If a delay in implementation or exemption of certain classes of providers is warranted under the review, inform the Congressional Committees of jurisdiction by June, 2000.

Explanation: The Balanced Budget Act of 1997 (BBA) required the Secretary to implement a prospective payment system (PPS) for hospital outpatient department services by January 1, 1999. The proposal issued by the Administration represents a major change in Medicare payment policy for outpatient services and may result in significant changes in hospital payments. This requested adjustment is needed to provide hospitals a reasonable period to adjust operations to meet these funding changes, while maintaining corrections to the amount that beneficiaries are required to pay in coinsurance for hospital outpatient services.

There is also concern about the methodology of the proposed APC classification system. Before such drastic changes to current payment policy are implemented, an independent review of the proposal is appropriate.

Proposal -- Limit Scope of Hospital Transfer Policy: Freeze the payment policy for hospital transfers at the current set of 10 Diagnosis Related Group categories.

Explanation: The BBA gave the Secretary of HHS authority to classify discharges from acute-care hospitals to post-acute care facilities within a group of 10 Diagnostic Related Groups (DRGs) as "transfers." Beginning in 2001, the Secretary would have authority to expand this policy to more than the initial 10 DRGs. As other payment policy changes from the BBA continue to be monitored, it is unnecessary to expand the transfer policy in the foreseeable future.

Skilled Nursing Facilities

Proposal -- Higher Payments for Complex Cases: Establish payment refinements to selected Resource Utilization Groups as the Skilled Nursing Facility (SNF) PPS is implemented. These changes should be targeted to improve reimbursement for medically complex cases, with special attention to the unique problems of patients requiring complex treatments and prosthetics.

Explanation: The BBA phases in a PPS that pays for covered SNF services on a per diem rate. The General Accounting Office has indicated that the current rate may not adequately reimburse for services provided to medically complex patients.

Physician Payments

Proposal -- Corrections Due to Erroneous Spending Projections: Provide immediate advice on administrative options for improving annual updates in payment for physician services to correct for erroneous projections.

Explanation: Implementation of new payment methodologies established in the BBA produced inappropriate payment reductions to physicians due to failures to adjust for erroneous administrative projections used to set rates. This particular problem could be remedied through changes in the year-to-year administrative payment projection and adjustment process.

Home Health Agencies

Proposal -- Proration of Payments: Relieve home health agencies of the inappropriate responsibility for tracking patients that secure services from more than one agency in order to prorate payments.

Explanation: New home health payment systems created by the BBA called for tracking the number of home health services beneficiaries receive from different facilities, so that payment amounts could be prorated. However, the BBA does not specify that this tracking is the responsibility of the agencies. Such responsibility would be more appropriately assigned to the fiscal intermediaries.

Proposal -- Equitable Recovery Schedules for Overpayments: Provide for extended repayment schedules for agencies that incurred significant Medicare overpayments due to difficulties in adjusting to major BBA 97 payment system changes.

Explanation: There is recognition of the need for more flexible overpayment schedules for certain home health agencies facing large overpayment amounts due to the changes in payment systems contained in the BBA.

Ambulatory Surgical Centers (ASCs)

Proposal -- Fair Payment for ASCs: Do not implement payment policy changes for ASCs until 1999 industry survey data is analyzed and properly incorporated into any proposed changes.

Explanation: In a proposed rule, the Administration is proposing changes to the payment policy for ASCs based upon 1994 survey data. It would be more appropriate to implement proposed changes after the 1999 survey data is complete.

Medicare+Choice

Proposal -- Fair Transition for Health Plans: Revise phase-in schedule for risk-adjusted payments to extend the transition by at least two years and to prevent any single plan from experiencing more than a 5-10% shift in Medicare payment rates attributable to the risk-adjuster in any single year.

Explanation: The BBA required HCFA to develop and implement a health-based risk-adjustment system by January 2000 to increase payments to plans that enroll sicker patients and to decrease payments to plans that enroll healthier patients. The implementation may cause significant changes in the annual payments to plans and thus the premiums beneficiaries would be charged. This proposal would provide for a more gradual transition to risk adjustment and protections for both beneficiaries and plans.

THE PRESIDENT HAS SEEN
10-13-99

USPHS/CDC/NCCDPHP
Division of Oral Health

CDC
CENTERS FOR DISEASE CONTROL

Carmen Jaramillo, DDS
ASPH Fellow

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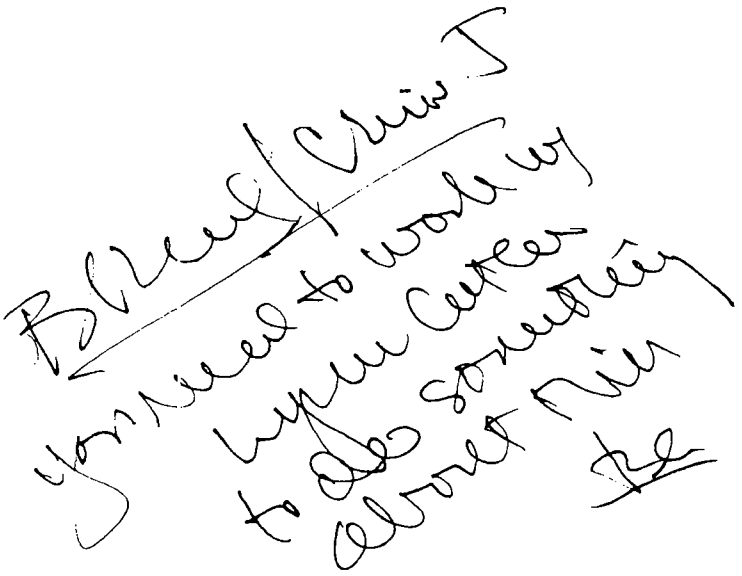
Surgeon General's
Conference on
Oral Health
June 12-13, 2000
WASH. D.C.

THE PRESIDENT HAS SEEN

10-18-99



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'Children's insurance' largely invisible in Indian country

By Mark Anthony Rolo
Today staff

Decent healthcare has always been hard to find on the reservation The lack of affordable insurance and the severe shortage of medical benefits provided by Indian Health Services are a daily reality in most Indian communities.

So two years ago when the federal government began offering free-to low-cost insurance for children, nationwide, you would think Indian families would have been some of the first in line to sign up.

Not true.

In 1997 when the federal government created the Children's Health Insurance Program (CHIP) it was the largest expansion in children's healthcare in 30 years. Not since the creation of Medicaid has there been such a significant financial commitment from the federal government towards insuring children's health.

Over the course of five years, $24 billion would be provided to states to cover an estimated 11 million uninsured children. It was specifically designed to offer extensive coverage for families that could not afford private insurance, and who earned too much to qualify for Medicaid.

Clearly, CHIP would serve a large population of needy families with children, and especially Indian children. But today, CHIP is nearly invisible in Indian country. Few families even know the program exists.

What is particularly disturbing to Indian health care workers is that families are missing out on a full coverage plan that far exceeds basic IHS services. Those enrolled in CHIP receive preventive and specialty services such as eye exams, mental health and expanded dental services. Currently, most IHS facilities only provide primary care. And in addition to the often crowded waiting rooms, many hospitals and clinics have limited days and hours when they are open.

"Most families live in communities with small clinics that have fixed hours But with CHIP, students get 24-hour coverage," said Phillip Smith, IHS Director of Maternal and Child Health

According to Smith, the reason is because the insurance program does not take into account the unique needs Indian people.

Initiated by the Clinton administration, CHIP was intended to be a collaboration between the federal government and states. States were responsible identifying their insurance needs and come up with a plan to implement program But in those states where reservations are located, state health offic neglected to bring tribal representa to the table.

Because states did not seek tribal consultation in developing the insurance program for their areas, considerations on how to make CHIP accessible to Indian families were never integrated For instance, a big part of setting up the insurance program in each state has been designating specific hospitals and clinics as providers for CHIP services. In those states with reservation communities, IHS clinics were not listed as places to enroll children in the insurance program.

And for those few families that did sign up a child in CHIP, using the service has meant going off the reservation because IHS facilities were not designated providers of CHIP.

But in this back-to-school season, the federal government has re-launched CHIP hoping to enroll more children to date, only 1.5 million children are enrolled in CHIP.

IHS officials say there are a number of reasons why CHIP has not attracted more Indian families, such as a complicated and lengthy application process. But a big reason Indian families have not taken advantage of California's CHIP services is because the insurance program requires a monthly premium payment of about $15. Many families on marginal incomes simply find the program too costly.

Some tribes have agreed to cover the cost for their tribal members.

Still, CHIP is a hard sell in Indian country Steve Mader, who oversees IHS in California said in order to get eligible Indian children enrolled in the program it will require more interest and attention from tribes. "It's going to be a slow process of education for everyone tribal leadership, the communities and individuals," he said. "It's not going to happen overnight."

10-19-99

C Jennings
What's the deal here?
Did I sign off on this?
Did we know it was
coming now? Not good
timing —
RC

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Podesta

CLINTON PROPOSES A DISCOUNT SYSTEM ON MEDICARE COSTS

'PREFERRED PROVIDERS'

Doctors and Hospitals Object, Saying Measure Would Put Cost Ahead of Quality

By ROBERT PEAR

WASHINGTON, Oct. 18 — In a break from three decades of Medicare policy, the Clinton Administration asked Congress today to steer Medicare patients to certain doctors and hospitals that offer discounts on the price of care they provide to people who are elderly or disabled.

Under legislation drafted by the Administration and sent to Congress, Federal officials would give Medicare beneficiaries a list of preferred doctors and hospitals that had agreed to offer discounted rates to the Government and to reduce the fees charged to patients.

Administration officials said these health care providers would attract more patients, making up in volume for the lower charges.

The White House and some Democrats, like Senator Bob Graham of Florida, say the proposals would save money and would allow Medicare to compete more effectively with private health plans.

But many Republicans oppose the idea, which has also provoked an outcry from doctors and hospitals. Critics say the Government would emphasize price over quality and would steer Medicare patients to mediocre doctors and hospitals that offered the biggest discounts.

Since the creation of Medicare in 1965, beneficiaries have been able to seek treatment from almost any licensed doctor or accredited hospital. Until now Medicare has provided little financial incentive for choosing a particular doctor or hospital in its fee-for-service program.

In its proposal, the Administration was asking Congress for broad powers to pick and choose providers who would coordinate the care of Medicare patients who choose to participate in the special arrangement.

Under current law, when Medicare beneficiaries go to the doctor, they must pay a deductible, now $100 a year, and after that they pay 20 percent of the Government-approved amount for most physician services. Medicare pays the remaining 80 percent.

Likewise, when beneficiaries go to the hospital, they pay a deductible, now $768, and Medicare pays most of the remaining costs for the first 60 days of hospital care. Under the Administration's proposal, the Government could reduce or eliminate the

Continued From Page A1

patient's share of the bill when patients use a doctor or a hospital designated as a "preferred provider."

Doctors and hospitals that wanted to be named as "preferred providers" would have to meet new Federal standards for the quality of care. The Secretary of Health and Human Services would also establish "standards for the quality of health care items and services" provided to Medicare beneficiaries . The proposal does not specify how quality would be measured.

But critics said that price would often be the dominant factor because it was much easier to measure cost than quality.

Administration officials insist that their proposals would not require or coerce beneficiaries to do anything, and that patients could decide for themselves whether to participate in the arrangements or keep things the way they are now. Patients would enroll voluntarily, but could be locked into one of the arrangements for six months or a year.

Here are other details of the Administration's proposal:

¶The Government would designate hospitals across the country as centers of excellence and encourage Medicare patients to use them for high-cost procedures like heart surgery or hip replacement, provided the Government saved money.

¶The Government would hire specialists to coordinate care needed by Medicare patients who choose to participate for the treatment of conditions like congestive heart failure, high blood pressure, coronary artery disease, asthma and diabetes.

¶Federal officials could use competitive bidding to obtain discounts on medical equipment and other goods and services. Medicare often pays more than the retail price for common items.

President Clinton had expressed interest in these proposals in June, when he had unveiled a plan to redesign Medicare and add prescription drug benefits.

White House officials said the proposals would modernize Medicare and save money by using selected techniques of managed care to control costs in the fee-for-service program, which still served 84 percent of the 39 million beneficiaries.

The proposals did not mention any possible affect on people who buy private insurance, or Medigap policies, to pay expenses not covered by Medicare.

The Senate Finance Committee and the House Ways and Means Committee plan to vote this week on legislation to restore some money cut from Medicare in 1997, and the committees may consider the Administration's proposals then.

White House officials said they hoped that the committees would accept the President's proposals, which could offset some of the cost of undoing cuts made in 1997.

A measure breaks with three decades of policy.

Two members of the Finance Committee, Mr. Graham and Senator John H. Chafee, Republican of Rhode Island, support the President's proposal to revamp the buying of goods and services in the traditional Medicare program.

Representative Pete Stark, Democrat of California, said that an experimental project in Polk County, Fla., had shown that competitive bidding and similar techniques could save money without harming the quality of care.

But there was also strong criticism. Dr. Nicholas T. Kouchoukos, president of the Society of Thoracic Surgeons, said heart surgeons were "extremely troubled" by the proposal because they feared that "excellence would take a back seat to discounted pricing." It was, he said, totally inappropriate to send elderly patients to the "lowest bidder."

Richard J. Pollack, executive vice president of the American Hospital Association, said Mr. Clinton's proposal could reduce access to services in areas where the local hospital did not win a contract with Medicare.

In March, 10 of the 17 members of a Federal advisory commission headed by Senator John B. Breaux recommended that Medicare compete directly with private health plans. To enhance such competition, the panel said, Medicare officials should make more of the purchasing tools available to private health plans, including the ability to sign contracts with selected health care providers who offer high-quality services and lower prices.

In an interview tonight, Senator Breaux, a Louisiana Democrat, said the President's proposal, taken by itself, was "like robbing Peter to pay Paul." The Government, he said, would cut payments to some doctors and hospitals so it could redistribute the money to others.

The Mayo Clinic in Rochester, Minn., is an obvious candidate for designation as a "center of excellence." But Bruce M. Kelly, director of Government relations for the Mayo Foundation, said Mr. Clinton's proposal was flawed because it failed to consider that the centers of excellence would attract complicated cases costing more than the average.

"It is unrealistic to think that the centers of excellence would take the tougher cases and agree to be paid less," Mr. Kelly said.

The New York Times

TUESDAY, OCTOBER 19, 1999

Jack Mills -- Wow! You've been great in your recent remarks regarding physical education. He hopes it is your intent that the President's Council be the leader in the initiative to "find ways to encourage young people to get and stay fit." They are willing and up to the task. Updates on the PEP bill: The list of co-sponsors is up to 33. He has personally visited many Senate and House members, as have the other three Council members. He had a meeting with **Secretary Shalala** which went great! She pledged her personal support and gave him some ideas. He also met with **Congressman Goodling**, Chair of the Education and Work Force Committee. He has a daughter who is a pro tennis player and both were very supportive. P.E. has become a major topic, and the Council will continue to work at it.

MILLS communications, inc.

Will List

President Bill Clinton
The White House
Washington, D. C.

Dear President Clinton,

Wow! You have been great in your recent remarks regarding Physical Education.

The Friday TV show on The Music subject you also mentioned P. E. Then the talk at the Olympic Training Center that included the directives to the Secretaries of Education and Health and Human Services, plus your remarks about the need for P. E. were right on.

I hope it is your intent that the Presidents Council be the leader in the initive to "Find ways to encourage young people to get and stay fit". We are willing, up to the task and besides that is what we are about.

Some other updates on the PEP bill.

The list of Co sponsers is now at 33 up from 19 originally. We have had all been working on this, the Sporting Goods group, the teachers organizations and a small group of the Presidents Council. I have personally visited many Senate and House members as have the other three Council members.

I had a meeting last week with Secretary Shalala which went Great! She pledged her personal support and gave me some ideas, this was prior to your directive, so I am sure she is even more supportive now.

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columbia, south carolina 29203

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columbia, sc 29224

803-736-1141
fax 803-788-1051

MILLS
communications, inc.

I also met with Congressman William Goodling, Chair of the Education and Work Force Committee, he too was very supportive of our cause. He has a daughter who was a Pro Tennis player I knew so we had a nice discussion. 27 House members are also Co Sponsers.

The timely News Week article came out this week also.

We at the Presidents Council are so excited with all the recent happenings, P. E. has become a major topic. Your support is now well documented and is helping us tremendously.

We will continue to work at this, I offer my personal help to the Presidents Council to make this coalition with the other agencies effective.

Thanks again for your help in promoting Physical Fitness.

Regards,

Jack M. Mills

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'Pharmacogenomics' Also Raises Issues of Race, Privacy

By Rick Weiss
Washington Post Staff Writer

A1

Unlike most doctors, Georgetown University physician and pharmacologist David Flockhart enjoys talking about his patients who didn't get better from the medicines he prescribed, or who got even worse because of side effects.

There was the woman who suffered excruciating pain after surgery no matter how much codeine he prescribed.

The patient whose tendons became so inflamed from taking a common antibiotic years ago that she remains debilitated to this day.

The woman who took Prozac only to find her blood pressure going through the roof.

Flockhart likes these sorry stories because they highlight the great potential of "pharmacogenomics," a new field of medicine he and others are pioneering that promises to reduce treatment failures by matching medicines to patients' personal genetic codes.

Among the many vaunted medical benefits promised by the Human Genome Project—the $2 billion effort to spell out the entire human genetic blueprint, whose virtual completion is expected to be announced on Monday—none is as close to broad clinical use as pharmacogenomics.

The new science seeks to solve a simple but long-standing problem: Medicines are made and sold on a "one size fits all" basis, even though people vary substantially in how they respond to those compounds. As a result of this variability, more than 100,000 Americans die every year from side effects of properly prescribed medicines and another 2 million are made seriously ill.

Now, with scientists identifying more and more genes that control individual responses to drugs, some leading-edge medical centers are starting to make prescribing decisions on the basis of patients' genetic makeup. Five years from now, some experts predict, it will be common for patients to take genetic tests before their doctors decide which drug, or what dose, to prescribe for them. That's far sooner than anyone expects to see similar success rates in the more widely touted but failure-plagued field of gene therapy, which aims to treat people by giving them new genes.

Drug companies, as well as patients, stand to gain from the pharmacogenomic revolution. By testing new and experimental drugs only in volunteers whose genes preordain a positive response, companies can generate data that will prove irresistible to the Food and Drug Administration, streamlining today's long and costly drug approval process. Some companies also hope to profit from sales of the genetic tests that will be used to match patients with appropriate drugs.

But like so many advances in genetics, pharmacogenomics raises difficult questions, too. As the first attempt to meld the contentious field of genetic testing with the everyday practice of medicine, it will serve as a test case of how society will deal with issues of genetic privacy and discrimination.

"Many people are already nervous about their genetic profiles falling into the wrong hands, for example, but so far few people have had a reason to take such tests. How will people react when a genetic test is required just to get a proper prescription?

Of equal concern, some of the gene patterns relevant to pharmacogenomics are ethnically linked, raising issues of racial stereotyping and access to care. One fear is that profit-conscious pharmaceutical companies will use pharmacogenomics to aim their drug development efforts toward genetic subgroups of people who can best afford to pay for them, further marginalizing already underserved minorities.

"What happens when the patient comes in and says, 'I hear there's a great new drug for asthma,' and the doctor says . . . 'Yeah, but it's only for whites?' " asked Mark Rothstein of the University of Houston's Health Law & Policy Institute.

"Pharmacogenomics alters medicine's legal landscape, too. At what point should doctors and drug-makers be liable for *not* taking genetic information into account? Already a group of patients has sued the maker of a Lyme disease vaccine, claiming that people with a particular genetic signature should not have been given the vaccine because they are especially prone to getting serious side effects from the shot.

All told, experts said, pharmacogenomics presents a challenge to society for precisely the same reason it offers so much promise: because it focuses on people's differences.

"We believe strongly that this is a new era and the dawning of a golden age of personalized medicine," said Elliott Sigal, a senior vice president at Bristol-Myers Squibb, one of several pharmaceutical companies that have launched pharmacogenomics programs. "It does raise important issues for society in terms of privacy, discrimination and insurance issues," Sigal said. "I think the government will have to deal with these issues."

Custom Treatment

Flockhart's surgical patient presents a classic example of the need for pharmacogenomics. After undergoing surgery on her ovaries, she was given codeine, the most commonly prescribed painkiller in America.

"She wanted more and more of the stuff," Flockhart recently recalled. Before long, he said, "she was labeled a drug abuser."

The truth was far simpler. Tests ultimately showed she was among the 7 percent of Caucasians in this country who harbor an inactive form of a gene called CYP 2D6, which helps break down many common medicines, including codeine. Unable to metabolize the codeine into its desired breakdown product, morphine, the woman got no relief.

Flockhart's patient on Prozac had the same genetic variation, but in her case it led to an effective overdose instead of undermedication. That's because Prozac, like codeine, is also broken down with the help of the 2D6 gene. Since she could not metabolize the antidepressant, the woman suffered an overaccumulation of the drug, with high blood pressure and other side effects.

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With the recent advent of simple tests that can reveal a person's genetic subtype from a drop of blood or a cheek swab, Flockhart said, "we're beautifully set up to look at variations in these things from person to person. It's a real opportunity to help a lot of people."

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The childhood cancer was universally fatal a few decades ago, but with the advent of a drug called 6-mercaptopurine, more than 80 percent of children can now be permanently cured. In the years since that drug's introduction, though, two problems have plagued doctors: Why doesn't the drug work in every child, and why does it cause serious and even fatal side effects in some?

The answers finally arose with the tools of pharmacogenomics.

Mercaptopurine, it turns out, is broken down in the body by an enzyme abbreviated TPMT. But 10 percent of Caucasians and blacks carry a variant of the TPMT gene that renders the crucial enzyme relatively ineffective, and an additional one in 300 of these children lack the gene and the enzyme altogether. (The variant is almost unknown in Asians.) Unable to metabolize the drug, these children essentially overdose on even small doses, and often die from the immune system suppression that ensues.

At the Mayo Clinic and at St. Jude Children's Research Hospital in Memphis, doctors now routinely test for TPMT activity in leukemic children before treating them. Children with especially high levels of the enzyme—who are, in essence, breaking down the drug before it has a chance to kill their cancers—are given doses up to 50 percent higher than normal in order to get a therapeutic effect. And those who are effectively overdosing on the drug because of their relatively inactive TPMT genes are getting doses as low as one-fifteenth normal, providing all the anti-cancer efficacy of a normal dose but without the extra side effects they once endured.

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Philosophical Shift

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The recent shift by federally funded and privately financed gene researchers away from the genome project and over to the search for SNPs represents more than a scientific change of course. It brings with it a philosophical change of perspective that will focus not on people's similarities but on their differences.

That shift is necessary if personalized gene-based medicine is to take off. But it also brings new possibilities for genetic bias and discrimination.

"The great promise of pharmacogenomics is that it will target drugs and therapies to individuals," said Morris Foster, a University of Nebraska anthropologist who is studying the field's potential impact on society. "But the way it may work out is it will just end up emphasizing social identifiers like race and ethnicity . . . and exacerbate social inequities."

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Last winter, several patients brought a class action suit against SmithKline Beecham, the maker of a Lyme disease vaccine, claiming that the company should have warned people about evidence that the shot can cause a severe form of arthritis in certain people.

Federal records show that the FDA advisory committee that recommended the vaccine's approval spent considerable time looking at preliminary evidence that people with a genetic hallmark called HLA-DR4 might be especially likely to experience the severe reaction.

Ultimately, however, the researchers who tested the vaccine for SmithKline convinced the officials that the data were too weak to believe. Now, in what may be the first intersection of pharmacogenomics and the law, they will have to defend that conclusion in court.

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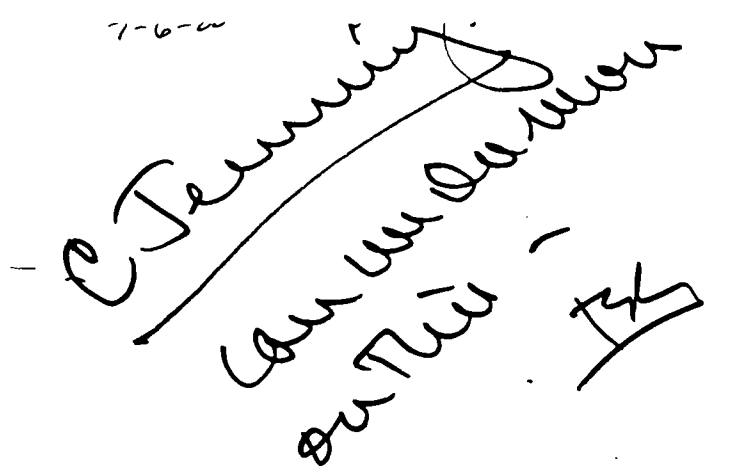

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The Summit Gamble

NEXT WEEK at Camp David, President Clinton will sit down with Israeli Prime Minister Ehud Barak and Palestine Liberation Organization Chairman Yasser Arafat to try to narrow the "significant differences" that remain between the two sides as they attempt to work out a final status agreement by the self-imposed target date of Sept. 13. "Significant" is Mr. Clinton's diplomatic understatement. The two sides remain far apart on such critical issues as the ultimate fate of Palestinian refugees, Israeli settlements on the West Bank and Gaza and the status of Jerusalem.

In recent weeks, the rhetoric on both sides has escalated. Mr. Arafat, emboldened by the European Union's promises of recognition, threatens to declare a Palestinian state on or before Sept. 13—deal or no deal with Israel. Mr. Barak says that Israel can respond with "unilateral" measures of its own—presumably including annexation of large chunks of the West Bank still under Israeli control. All too easily, this standoff could turn violent.

Mr. Arafat is digging in his heels at a time when Israel seems prepared to offer substantial concessions on one previously intractable issue, territory, in exchange for a final deal. Perhaps the Palestinian leader senses weakness, or even desperation, on the part of Mr. Barak, whose parliamentary majority is crumbling. Perhaps Mr. Arafat simply can't take yes for an answer on territory, since that would oblige him to compromise on issues (refugees, Jerusalem) about which most Palestinians are still disinclined to compromise.

Mr. Clinton's main objective, then, should be to push Mr. Arafat toward realism—even as he encourages Mr. Barak's flexibility. It is just possible that, if the two leaders are skillfully cajoled and pressed by Mr. Clinton, the summit could serve to defuse the short-term crisis. That will be hard enough. The larger goal—a detailed agreement to end the Israeli-Palestinian conflict once and for all—is harder still. Perhaps the best that can be hoped for is yet another "framework" agreement setting forth general principles that would govern such a settlement—followed by more talks. Even so, Mr. Clinton is right to risk a summit. There are risks to inaction, too; better to keep talking than to resume fighting.

Reducing Pharmacy Errors

FIVE-YEAR-OLD Brendan Ward's prescription called for 50 milligrams of imipramine per teaspoon. A technician at a Leesburg, Va., pharmacy prepared a syrup containing 250 milligrams. The pharmacist dispensed the medication without catching the error. Before putting him to bed on April 5, Brendan's mother gave him two teaspoons. The next morning, she found him dead.

Improperly filled prescriptions are not as rare as some may think. According to Post staff writer Maria Glod, state pharmacy boards estimate that between 2 percent and 5 percent of prescriptions filled last year included some sort of error, ranging from misspellings to dispensing or instruction mistakes.

What's worse, the 2 percent to 5 percent error rate is only a guess. The District doesn't keep track of errors. Drugstores in Maryland and Virginia aren't required to report mistakes either. Most state boards of pharmacy hear of errors only when customers bother to complain or through routine inspections. With the number of prescriptions expected to hit 4 billion by 2004, and given a shortage of qualified pharmacists, more mistakes are in the offing unless authorities find out and fix what is causing them.

Last year's Institute of Medicine report on deaths caused by the mistakes of doctors, pharmacists and others has spurred some action. Maryland is looking into a system of voluntary reporting. Virginia health officials are drafting a measure to set training and supervision standards for pharmacy technicians and are weighing reporting requirements. Congress intervened with legislation to promote voluntary reporting of medical mistakes, including prescription errors.

The industry will point out, correctly, that millions of prescriptions are safely filled every day. But state boards and regulatory authorities have been slow to act, too, as the nonprofit Institute for Safe Medication Practices has noted. With an array of new and stronger drugs on the market, government regulators must come up with a better system to hold down prescription mistakes, and fast. One Brendan Ward is one mistake too many.

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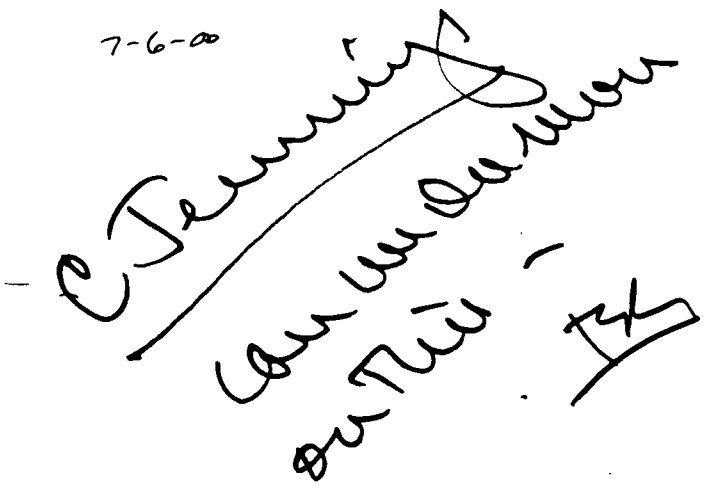

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THE HUMAN BLUEPRINT | *Matching Drugs to Genes*

The Promise of Precision Prescriptions

'Pharmacogenomics' Also Raises Issues of Race, Privacy

By Rick Weiss
Washington Post Staff Writer

Unlike most doctors, Georgetown University physician and pharmacologist David Flockhart enjoys talking about his patients who didn't get better from the medicines he prescribed, or who got even worse because of side effects.

There was the woman who suffered excruciating pain after surgery no matter how much codeine he prescribed.

The patient whose tendons became so inflamed from taking a common antibiotic years ago that she remains debilitated to this day.

The woman who took Prozac only to find her blood pressure going through the roof.

Flockhart likes these sorry stories because they highlight the great potential of "pharmacogenomics," a new field of medicine he and others are pioneering that promises to reduce treatment failures by matching medicines to patients' personal genetic codes.

Among the many vaunted medical benefits promised by the Human Genome Project—the $2 billion effort to spell out the entire human genetic blueprint, whose virtual completion is expected to be announced on Monday—none is as close to broad clinical use as pharmacogenomics.

The new science seeks to solve a simple but long-standing problem: Medicines are made and sold on a "one size fits all" basis, even though people vary substantially in how they respond to those compounds. As a result of this variability, more than 100,000 Americans die every year from side effects of properly prescribed medicines and another 2 million are made seriously ill.

Now, with scientists identifying more and more genes that control individual responses to drugs, some leading-edge medical centers are starting to make prescribing decisions on the basis of patients' genetic makeup. Five years from now, some experts predict, it will be common for patients to take genetic tests before their doctors decide which drug, or what dose, to prescribe for them. That's far sooner than anyone expects to see similar success rates in the more widely touted but failure-plagued field of gene therapy, which aims to treat people by giving them new genes.

Drug companies, as well as patients, stand to gain from the pharmacogenomic revolution. By testing new and experimental drugs only in volunteers whose genes preordain a positive response, companies can generate data that will prove irresistible to the Food and Drug Administration, streamlining today's long and costly drug approval process. Some companies also hope to profit from sales of the genetic tests that will be used to match patients with appropriate drugs.

But like so many advances in genetics, pharmacogenomics raises difficult questions, too. As the first attempt to meld the contentious field of genetic testing with the everyday practice of medicine, it will serve as a test case of how society will deal with issues of genetic privacy and discrimination.

Many people are already nervous about their genetic profiles falling into the wrong hands, for example, but so far few people have had a reason to take such tests. How will people react when a genetic test is required just to get a proper prescription?

Of equal concern, some of the gene patterns relevant to pharmacogenomics are ethnically linked, raising issues of racial stereotyping and access to care. One fear is that profit-conscious pharmaceutical companies will use pharmacogenomics to aim their drug development efforts toward genetic subgroups of people who can best afford to pay for them, further marginalizing already underserved minorities.

"What happens when the patient comes in and says, 'I hear there's a great new drug for asthma,' and the doctor says . . . 'Yeah, but it's only for whites?' " asked Mark Rothstein of the University of Houston's Health Law & Policy Institute.

Pharmacogenomics alters medicine's legal landscape, too. At what point should doctors and drug makers be liable for *not* taking genetic information into account? Already a group of patients has sued the maker of a Lyme disease vaccine, claiming that people with a particular genetic signature should not have been given the vaccine because they are especially prone to getting serious side effects from the shot.

All told, experts said, pharmacogenomics presents a challenge to society for precisely the same reason it offers so much promise: because it focuses on people's differences.

"We believe strongly that this is a new era and the dawning of a golden age of personalized medicine," said Elliott Sigal, a senior vice president at Bristol-Myers Squibb, one of several pharmaceutical companies that have launched pharmacogenomics programs. "It does raise important issues for society in terms of privacy, discrimination and insurance issues," Sigal said. "I think the government will have to deal with these issues."

Custom Treatment

Flockhart's surgical patient presents a classic example of the need for pharmacogenomics. After undergoing surgery on her ovaries, she was given codeine, the most commonly prescribed painkiller in America.

"She wanted more and more of the stuff," Flockhart recently recalled. Before long, he said, "she was labeled a drug abuser."

The truth was far simpler. Tests ultimately showed she was among the 7 percent of Caucasians in this country who harbor an inactive form of a gene called CYP 2D6, which helps break down many common medicines, including codeine. Unable to metabolize the codeine into its desired breakdown product, morphine, the woman got no relief.

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Federal records show that the FDA advisory committee that recommended the vaccine's approval spent considerable time looking at preliminary evidence that people with a genetic hallmark called HLA-DR4 might be especially likely to experience the severe reaction.

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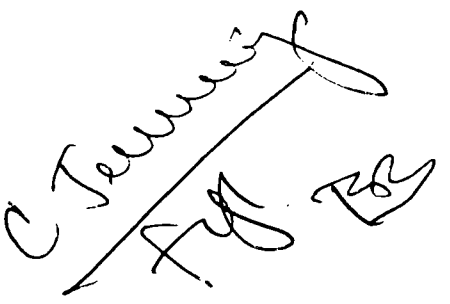
7-6-00



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Jennings
Podesta

THE HUMAN BLUEPRINT | *Matching Drugs to Genes*

The Promise of Precision Prescriptions

'Pharmacogenomics' Also Raises Issues of Race, Privacy

By Rick Weiss
Washington Post Staff Writer A1

Unlike most doctors, Georgetown University physician and pharmacologist David Flockhart enjoys talking about his patients who didn't get better from the medicines he prescribed, or who got even worse because of side effects.

There was the woman who suffered excruciating pain after surgery no matter how much codeine he prescribed.

The patient whose tendons became so inflamed from taking a common antibiotic years ago that she remains debilitated to this day.

The woman who took Prozac only to find her blood pressure going through the roof.

Flockhart likes these sorry stories because they highlight the great potential of "pharmacogenomics," a new field of medicine he and others are pioneering that promises to reduce treatment failures by matching medicines to patients' personal genetic codes.

Among the many vaunted medical benefits promised by the Human Genome Project—the $2 billion effort to spell out the entire human genetic blueprint, whose virtual completion is expected to be announced on Monday—none is as close to broad clinical use as pharmacogenomics.

The new science seeks to solve a simple but long-standing problem: Medicines are made and sold on a "one size fits all" basis, even though people vary substantially in how they respond to those compounds. As a result of this variability, more than 100,000 Americans died every year from side effects of properly prescribed medicines and another 2 million are made seriously ill.

Now, with scientists identifying more and more genes that control individual responses to drugs, some leading-edge medical centers are starting to make prescribing decisions on the basis of patients' genetic makeup. Five years from now, some experts predict, it will be common for patients to take genetic tests before their doctors decide which drug, or what dose, to prescribe for them. That's far sooner than anyone expects to see similar success rates in the more widely touted but failure-plagued field of gene therapy, which aims to treat people by giving them new genes.

Drug companies, as well as patients, stand to gain from the pharmacogenomic revolution. By testing new and experimental drugs only in volunteers whose genes preordain a positive response, companies can generate data that will prove irresistible to the Food and Drug Administration, streamlining today's long and costly drug approval process. Some companies also hope to profit from sales of the genetic tests that will be used to match patients with appropriate drugs.

But like so many advances in genetics, pharmacogenomics raises difficult questions, too. As the first attempt to meld the contentious field of genetic testing with the everyday practice of medicine, it will serve as a test case of how society will deal with issues of genetic privacy and discrimination.

Many people are already nervous about their genetic profiles falling into the wrong hands, for example, but so far few people have had a reason to take such tests. How will people react when a genetic test is required just to get a proper prescription?

Of equal concern, some of the gene patterns relevant to pharmacogenomics are ethnically linked, raising issues of racial stereotyping and access to care. One fear is that profit-conscious pharmaceutical companies will use pharmacogenomics to aim their drug development efforts toward genetic subgroups of people who can best afford to pay for them, further marginalizing already underserved minorities.

"What happens when the patient comes in and says, 'I hear there's a great new drug for asthma,' and the doctor says . . . 'Yeah, but it's only for whites?' " asked Mark Rothstein of the University of Houston's Health Law & Policy Institute.

Pharmacogenomics alters medicine's legal landscape, too. At what point should doctors and drugmakers be liable for *not* taking genetic information into account? Already a group of patients has sued the maker of a Lyme disease vaccine, claiming that people with a particular genetic signature should not have been given the vaccine because they are especially prone to getting serious side effects from the shot.

All told, experts said, pharmacogenomics presents a challenge to society for precisely the same reason it offers so much promise: because it focuses on people's differences.

"We believe strongly that this is a new era and the dawning of a golden age of personalized medicine," said Elliott Sigal, a senior vice president at Bristol-Myers Squibb, one of several pharmaceutical companies that have launched pharmacogenomics programs. "It does raise important issues for society in terms of privacy, discrimination and insurance issues," Sigal said. "I think the government will have to deal with these issues."

Custom Treatment

Flockhart's surgical patient presents a classic example of the need for pharmacogenomics. After undergoing surgery on her ovaries, she was given codeine, the most commonly prescribed painkiller in America.

"She wanted more and more of the stuff," Flockhart recently recalled. Before long, he said, "she was labeled a drug abuser."

The truth was far simpler. Tests ultimately showed she was among the 7 percent of Caucasians in this country who harbor an inactive form of a gene called CYP 2D6, which helps break down many common medicines, including codeine. Unable to metabolize the codeine into its desired breakdown product, morphine, the woman got no relief.

Flockhart's patient on Prozac had the same genetic variation, but in her case it led to an effective overdose instead of undermedication. That's because Prozac, like codeine, is also broken down with the help of the 2D6 gene. Since she could not metabolize the antidepressant, the woman suffered an overaccumulation of the drug, with high blood pressure and other side effects.

The patient with tendinitis carries a different gene variant that triggers painful inflammatory reactions in response to so-called quinalone antibiotics.

Scientists know of six common CYP drug-metabolizing genes, all of which operate in the liver and are responsible for breaking down about a dozen different drugs each. They have also begun to find other genes in other parts of the body, which people can inherit in various forms and which can affect how efficiently these people absorb, transport, use and excrete various medicines.

With the recent advent of simple tests that can reveal a person's genetic subtype from a drop of blood or a cheek swab, Flockhart said, "we're beautifully set up to look at variations in these things from person to person. It's a real opportunity to help a lot of people."

In a few settings, genetic testing is already helping doctors inform their prescribing decisions and

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even save lives.

At the Mayo Clinic in Rochester, Minn., for example, Richard M. Weinshilboum and his colleagues have been using genetic tests to individualize treatments for children with acute lymphoblastic leukemia.

The childhood cancer was universally fatal a few decades ago, but with the advent of a drug called 6-mercaptopurine, more than 80 percent of children can now be permanently cured. In the years since that drug's introduction, though, two problems have plagued doctors: Why doesn't the drug work in every child, and why does it cause serious and even fatal side effects in some?

The answers finally arose with the tools of pharmacogenomics.

Mercaptopurine, it turns out, is broken down in the body by an enzyme abbreviated TPMT. But 10 percent of Caucasians and blacks carry a variant of the TPMT gene that renders the crucial enzyme relatively ineffective, and an additional one in 300 of these children lack the gene and the enzyme altogether. (The variant is almost unknown in Asians.) Unable to metabolize the drug, these children essentially overdose on even small doses, and often die from the immune system suppression that ensues.

At the Mayo Clinic and at St. Jude Children's Research Hospital in Memphis, doctors now routinely test for TPMT activity in leukemic children before treating them. Children with especially high levels of the enzyme—who are, in essence, breaking down the drug before it has a chance to kill their cancers—are given doses up to 50 percent higher than normal in order to get a therapeutic effect. And those who are effectively overdosing on the drug because of their relatively inactive TPMT genes are getting doses as low as one-fifteenth normal, providing all the anti-cancer efficacy of a normal dose but without the extra side effects they once endured.

One result of the new focus on pharmacogenomics is that old definitions of diseases are breaking down. Cancers, for instance, which have traditionally been classified by their location in the body, are increasingly being typed further by their genetic characteristics and drug sensitivities, and medicines are being developed to take aim at those hallmarks. Experts predict that in the next few years a bevy of new genetic tests will show that many other diseases also deserve to be parsed and targeted according to their genetic signatures.

"We're going to learn it's not just 'MS,'" or multiple sclerosis, said Kathleen Giacomini, a University of California at San Francisco researcher who is identifying genes that affect drug absorption and transport in the body. "It's going to be MS a, b, c and d. And we can develop new drugs for each of these types."

Philosophical Shift

The driving force behind the emergence of pharmacogenomics is a little-known follow-up project to the widely hailed Human Genome Project. Unlike the genome project, which sought to spell out a generic "consensus" version of the human genetic sequence, the follow-up project seeks to define the subtle differences in that code from person to person.

The goal is to identify hundreds of thousands of "single nucleotide polymorphisms," or SNPs (pronounced "snips"), which are the tiny spelling variations that occur about once in every 500 to 1,000 letters within the 3 billion-letter human genetic code.

The recent shift by federally funded and privately financed gene researchers away from the genome project and over to the search for SNPs represents more than a scientific change of course. It brings with it a philosophical change of perspective that will focus not on people's similarities but on their differences.

That shift is necessary if personalized gene-based medicine is to take off. But it also brings new possibilities for genetic bias and discrimination.

"The great promise of pharmacogenomics is that it will target drugs and therapies to individuals," said Morris Foster, a University of Nebraska anthropologist who is studying the field's potential impact on society. "But the way it may work out is it will just end up emphasizing social identifiers like race and ethnicity . . . and exacerbate social inequities."

Not all of the genetic variations that affect how a person will respond to various drugs track along racial or ethnic lines. Indeed, doctors could easily run into trouble if they try to use race as a substitute for genetic testing: Think how many people might suppose that Tiger Woods is African American or Caribbean, one geneticist said, when in fact his mother is Thai.

But many relevant genes do correlate with race. While only 7 percent of Caucasians have the 2D6 variant that caused problems for some of Flockhart's patients, for example, more than one in four Asians carry a similar variant.

Those realities present interesting economic and ethical quandaries.

On the economic side, pharmaceutical companies could save millions of dollars by preselecting participants in a clinical trial so that virtually everyone benefited and no one got side effects.

"Efficacy could be proven in small cohorts of a few hundred patients compared to 3,000 or 5,000 as we do now," said Gualberto Ruaño, chief executive officer of Genaissance Pharmaceuticals, a Science Park, Conn., company that is developing genetic tests to predict people's responses to various drugs. "This is going to change the economics of drug development radically."

It would also reverse the current federal regulatory push to include more diverse groupings of people in clinical trials—a push that arose a few years ago in response to concerns that minorities were being left out of the drug approval process. Under the new rubric of pharmacogenomics, though, expert reviewers might deem it unethical to test a new drug on people whose genes suggest they won't respond well to the drug, since those participants' sole purpose would be to demonstrate side effects.

At the same time, any drug that gained approval through such a process would have proven its mettle only in people with a narrow genetic or racial grouping, and would probably be approved by the FDA only for use in those people.

"That could be a problem," said Larry Palmer, a professor at the Cornell University Law School who is studying the legal implications of pharmacogenomics. "You know the drug companies are go-

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The Washington Post
Saturday, June 24, 2000

ing to market it as best they can. And the average practitioner may use it without the deep understanding of the science needed to use it appropriately on the right individuals."

Moreover, given the chance to focus their efforts this way, would companies even bother developing drugs for people with rare genes? It's too soon to say, but there is some evidence that some might not.

About five years ago, for example, pharmaceutical giant Merck & Co. was supporting a small Seattle company called Ostex International to develop a test that could identify women at high risk of osteoporosis. The hope, said Gilbert S. Omenn, executive vice president for medical affairs at the University of Michigan, was to use the test as a marketing tool for Merck's new bone-building drug, Fosamax, which Merck hoped to sell widely to post-menopausal women.

But when early studies with the test indicated that only half of all postmenopausal women might actually need the drug, Omenn said, Merck pulled out of the partnership and left the little company in a state of near financial ruin, from which it is now recovering.

"Merck wanted to say that as soon as women get menopause they should take these drugs," said Thomas O. Bologna, Ostex's CEO. Rather than use an objective test to measure real need, Bologna said, "they decided to rely on salespeople to convince physicians to convince patients to use these drugs."

A Merck spokeswoman said the company's withdrawal from Ostex was not related to marketing concerns but came out of a decision to focus solely on the treatment of osteoporosis, not on methods for diagnosing it.

Others said that even if the big drug companies do end up focusing only on the most common genetic subpopulations, there are plenty of small biotechnology companies that would be happy to find niches that cover even 5 or 10 percent of the population.

Another hurdle that pharmacogenomics must clear is public wariness of genetic tests—especially among minorities, who have traditionally been more mistrustful of such tests.

Proponents say gene tests that predict a person's response to a medicine should not be as controversial as other kinds of gene tests that predict, for example, a person's long-term odds of getting a fatal disease.

"It's not the same as telling someone that they're going to get Alzheimer's disease someday, which freaks people out," said Kathleen Giacomini, the University of California at San Francisco researcher. "This is a more people-friendly kind of genetic test."

A handful of companies are counting on that attitude, and are already developing kits that people will be able to use at home to see which versions of several key drug-metabolizing genes they've inherited. At least one company, PPGx Inc. near Research Triangle Park, N.C., hopes to offer at-home test kits by the end of this year, said the company's CEO, Josh Baker.

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THE PRESIDENT HAS SEEN 7-6-00

NORTH SHORE
LONG ISLAND JEWISH
HEALTH SYSTEM

C Jennings - Pls call him -

ROBERT J. ZUCKERBERG
CHAIRMAN, BOARD OF TRUSTEES

wants to discuss health policy

(516) 465-2570 • Fax: (516) 465-2597 • N.Y.: (212) 902-8820

RBC

Copied
Jennings
Podesta

David S. Weiner
Chief Executive Officer
300 Longwood Avenue
Boston, MA 02115

Children's Hospital Medical Center

The Honorable William J. (
White House
Washington, D.C. 20500

7.9.00

To Burkhardt for
Reply
coordinate w/chris
Jennings
cc: Jennings
DLB

Children's Hospital Medical Center
300 Longwood Avenue
Boston, MA 02115
617-355-8555
617-739-3515 Fax

7-9-00

David S. Weiner
Chief Executive Officer

Children's Hospital Medical Center

July 6, 2000

The Honorable William J. Clinton
White House
Washington, D.C. 20500

Dear Mr. President:

Last year's passage of legislation authorizing federal funding for the teaching missions of children's hospitals was a great moment for Children's Hospital, Boston and the other freestanding children's hospitals across the country. It was also an important victory for children's health.

In proposing and signing this legislation, you set the course for a more secure future for our nation's children's hospitals. You also provided that children could have the pediatric workforce and pediatric academic medical centers they need. The freestanding children's hospitals are the critical infrastructure upon which pediatric medicine in this country rests.

Now, I am asking that you complete this important effort. Start up funding of $40 million was provided in the FY2000 budget, following your budget proposal. In FY2001, the Administration's budget proposed to increase this funding to $80 million. While this is a significant increase, it falls far short of the $285 million that you and Congress authorized for the program.

Full funding for the program is fair and essential for our children's hospitals. It would provide the children's hospitals with the same federal support for GME that is provided to all other teaching hospitals through Medicare, and the children's hospitals' need is definitely imminent. Almost half of the losses on patient revenue in many of our hospitals, including Children's Boston, come from the direct costs of GME alone. Boston Children's, is the leading children's academic medical center and research enterprise in this country, and we must have equitable support for our academic missions if we are to stay strong.

As you revisit your FY2001 budget in light of the growing surplus, I ask that you address the needs of our children's hospitals, as you are other health care providers. A relatively small investment for the federal government can make a very big difference to the future of our institutions and to children's health. Congress has indicated its intent to increase funding for this program as the appropriations process continues. I hope that the White House will actively encourage this goal and work to assure its success.

It was a great honor for me to share in the signing ceremony for the children's hospitals GME legislation last year. You and the first Lady have been wonderful friends and supporters for children's health care and for children's hospitals. Thank you as always for your consideratiion

Sincerely,

David S. Weiner

THE WHITE HOUSE

WASHINGTON

June 28, 2000

The Honorable Percy Malone
Member of the House of Representatives
of the State of Arkansas
518 Clay Street
Arkadelphia, Arkansas 71923-6024

Dear Percy:

Thank you for your letter regarding Secretary Shalala's January 14 statement.

I've asked my health care advisor, Chris Jennings, to consider your recommendation for a clarifying letter from Secretary Shalala. My Administration remains committed to working with states and the disability community to develop and implement innovative plans to ensure that individuals with disabilities receive services in a setting that best meets their needs. However, I also support appropriate placements in center-based care.

Please know that I will keep your thoughts in mind. Hillary and I send our best.

Sincerely,

cop.ed
Jennings

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Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. letter	Percy Malone to President Clinton re: address and phone number (partial) (1 page)	05/03/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20147

FOLDER TITLE:
POTUS Notes [Folder 9]

2012-0463-S
rc818

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]

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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]

Staff
Sec

[603]

REPRESENTATIVE
Percy Malone
P6/(b)(6)

Phone:
870-246-4141 Business
P6/(b)(6) Residence
870-246-6616 FAX

DISTRICT 36

Counties:
Part of Clark County
Part of Nevada County

COMMITTEES

Public Health, Welfare and Labor
Human Services Subcommittee

Insurance and Commerce
Financial Institutions Subcommittee

Joint Committee on Energy

Chairperson,
Joint Budget

STATE OF ARKANSAS

House of Representatives

May 3, 2000

The Honorable President Bill Clinton
1600 Pennsylvania Avenue
Washington, D.C. 20500-2000

Re: Request for DHHS letter to Governors

Dear President Clinton:

I send herewith copy of a letter from HHS Secretary Donna Shalala dated January 14, 2000 and sent to all Governors.

The Secretary's letter encourages support for services in community settings for disabled persons, a laudable goal; it does not, however, indicate support for the option of ICF/MR care.

Arkadelphia has an ICF/MR facility. I am intimately familiar with the disabled persons served there, the center's dedicated staff and the center itself, which is licensed under HCFA.

Secretary Shalala's letter is being used by advocates to show that DHHS policy does not encourage the option of ICF/MR care. I request a clarifying letter from Secretary Shalala to the Governors affirming that:

> "States may choose to utilize their Medicaid funds to provide appropriate services in a range of settings from institutional to fully integrated community support."
>
> Letter to State Medicaid Directors
> from Timothy Westmoreland, HCFA
> and Thomas Perez, HHS OCR

Arkansas' human development centers serve our state's most impaired citizens. It is a concern that Secretary Shalala's letter is being used to show that the Administration does not support the option of center-based care.

I look forward to your response.

Sincerely,

Percy Malone
State Representative

5-10-00
To Burkhardt for reply
~~Agency Liaison~~ ?
Yes ✓ No ___

BC Sig

S.
coordinate w/ Cabinets + Chris Jennings

DEPARTMENT OF HEALTH & HUMAN SERVICES

January 14, 2000

Dear Governor:

In recent years, we have made great strides in enabling individuals with disabilities to participate fully in our communities by removing barriers to access in employment, public accommodations, and state and local government programs. Many States have led the way in designing innovative and fiscally responsible ways to enable more persons with disabilities to receive necessary services in their communities instead of in institutions.

Our country's progress in this regard reflects a shared belief that no person should have to live in a nursing home or other institution if he or she can live in his or her community. The recent Supreme Court decision in Olmstead v. L.C. affirms this shared value, by finding that unnecessary institutionalization of individuals with disabilities is discrimination under the Americans with Disabilities Act (ADA). In the decision, the Court explained that a State may be able to meet its obligation under the ADA by having comprehensive, effectively working plans ensuring that individuals with disabilities receive services in the most integrated setting appropriate to their needs.

We encourage you to develop and implement such plans, and to involve individuals with disabilities and other stakeholders in the process of design and implementation. This Department stands ready to assist you in these efforts. To begin that process, attached is a letter from the Department of Health and Human Services to all State Medicaid Directors regarding the Olmstead decision. I want to also encourage you to share this letter with other state agencies operating programs affected by the Olmstead decision, since the ADA applies to all state programs.

The Department is committed to continuing to work in partnership with you, individuals with disabilities and all other stakeholders to ensure that States have in place effective, fiscally responsible policies designed to increase access to community-based services. As you identify your priorities for the coming year, I hope you will continue to place substantial emphasis on developing programs and services for individuals with disabilities that will further our shared goal of integrating individuals with disabilities into the social mainstream, promoting equality of opportunity and maximizing individual choice.

I deeply appreciate the leadership that you and your colleagues have provided, and I look forward to working with you as we continue to make progress in this important area.

Sincerely,

/s/ Donna E. Shalala

6-26-00

Mickey Ibarra

THE WHITE HOUSE
WASHINGTON

'00 JUN 19 P4:38

I'd really like to help Ed Rice — Howard Dean

BC

Copied Ibarra Jennings Podesta

Recommended Phone call to:

Gov. Howard Dean
(D – VT)
Spouse: Judy

This call is OFFICIAL

Call recommended by Mickey Ibarra (202-456-7060)

CONTACT INFORMATION:

Governor's Immediate Office:	(802) 828-3333	(Personal Assistant: Kate O'Connor)
Governor's Mansion:	(802) 862-8654	

Recommended Phone Call to VT Governor Howard Dean re Vermont Pharmacy Rebate Amendment

6-26-00

egarding the Vermont Pharmacy Rebate Amendment, and OMB officials.

l a proposal to HCFA to expand the pharmacy wn as the "Vermont Health Access Plan") to provide ient and rebate structure to two groups in Vermont: ercent of the Federal Poverty Level (FPL) without omes up to 300 percent of FPL without drug verage. These two groups are not traditionally Medicaid beneficiaries in Vermont.

- Under this proposal, beneficiaries would have the ability to purchase drugs at a price that is equivalent to the price that Medicaid pays. The State anticipates that 37,550 Medicare covered beneficiaries and an additional 31,350 individuals under 300 percent FPL would be eligible for this expansion.

- We are only at the preliminary phase of the review. A number of major concerns have been raised, including: (1) how this proposal interacts with the Congressional prescription drug debate – your Medicare principals have not yet considered its implications; and (2) do we want to, for the first time, allow for a partial-benefit Medicaid benefit expansion. We have opposed this in the past because of concerns about picking apart Medicaid's comprehensive

6-26-00

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THE WHITE HOUSE
WASHINGTON

Copied
Ibarra
Jennings
Podesta

Recommended Phone call to:

Gov. Howard Dean
(D – VT)
Spouse: Judy

This call is OFFICIAL

Call recommended by Mickey Ibarra (202-456-7060)

CONTACT INFORMATION:

Governor's Immediate Office:	(802) 828-3333	(Personal Assistant: Kate O'Connor)
Governor's Mansion:	(802) 862-8654	

PURPOSE OF CALL

You are returning Gov. Dean's phone call regarding the Vermont Pharmacy Rebate Amendment, which is currently being reviewed by HHS and OMB officials.

BACKGROUND

- On March 17, 2000, Vermont submitted a proposal to HCFA to expand the pharmacy program of its 1115 demonstration (known as the "Vermont Health Access Plan") to provide coverage and extend the Medicaid payment and rebate structure to two groups in Vermont: (1) Medicare beneficiaries above 150 percent of the Federal Poverty Level (FPL) without drug coverage; (2) other adults with incomes up to 300 percent of FPL without drug coverage. These two groups are not traditionally Medicaid beneficiaries in Vermont.

- Under this proposal, beneficiaries would have the ability to purchase drugs at a price that is equivalent to the price that Medicaid pays. The State anticipates that 37,550 Medicare covered beneficiaries and an additional 31,350 individuals under 300 percent FPL would be eligible for this expansion.

- We are only at the preliminary phase of the review. A number of major concerns have been raised, including: (1) how this proposal interacts with the Congressional prescription drug debate – your Medicare principals have not yet considered its implications; and (2) do we want to, for the first time, allow for a partial-benefit Medicaid benefit expansion. We have opposed this in the past because of concerns about picking apart Medicaid's comprehensive

benefits. In addition to these concerns, the Office of General Counsel at HHS is looking into any legal impediments that may exist.

- HCFA officials have been in direct contact with Governor Dean, the Vermont Secretary of Human Services as well as the Vermont Health Commissioner. In addition, Mickey Ibarra spoke to Governor Dean at length about this proposal last week.

- OMB and HHS will continue the review process, with a final recommendation expected in the near future.

TALKING POINTS

- I understand that you have submitted a proposal to expand your prescription drug coverage. I'd like to hear a little more about it.

After the Governor describes his plan:

- That's a very interesting proposal. My staff and HCFA are looking at it carefully, though I'm told that the review is only at its preliminary stage right now. We need to sort out how this would interact with the Medicare prescription drug plan that we're trying to get through Congress, and we have to look at some other issues relating to both Medicare and Medicaid.

- I know that this is very important to you – rest assured that we will give these proposals serious consideration and be back in touch with you soon.

THE PRESIDENT HAS SEEN
6-27-00

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Jennings
Podesta

Now, the Hard Part: Putting the Genome to Work

By NICHOLAS WADE

The human genome is in hand. The set of instructions embodied in the ancient chemical deoxyribonucleic acid, at least 3.5 billion years in the making, has been made fully visible for the first time.

The manual with the specifications for the human species comes in 24 tapes of DNA, one for every chromosome, each carrying one long, punctuation-free sentence in evolution's four-letter programming code. On first inspection, these ancient texts are as incomprehensible as a message from another planet.

And the genome, as any message from another world, will surely change this one when its full meaning is understood.

Although exploration of the genome has already begun, it will be decades before every detail is thoroughly known.

The first practical impacts will be in health. The genome is widely expected to revolutionize the practice of medicine. Its sequence is already being mined for the levers of the body's own communications system, including the signals that direct cells to repair damaged tissue and fight off invaders. The use of these signals as drugs may develop into a new mode of therapy, one that Dr. William Haseltine, president of Human Genome Sciences, has termed "regenerative medicine."

Another predicted advance, though not so immediate, is that of personalized medicine — treatment and preventive programs that are tailored to the individual based on a genomic analysis.

But the genome's writ reaches beyond

We know now how DNA is arranged. But how does it do what it does?

medicine and will in time redefine knowledge of ourselves, our history, our innate capacities and our relationship to the rest of creation. The conditions of human existence, the reach of human abilities, the purpose of life — at least in a biological sense — have boundaries that are engraved in the genome's gnomic text.

In defining the human species, the genome assumes distinctive flourishes in the major ethnic groups that developed as humans spread throughout the world, and specifies the genetic endowment of individuals. All individuals, save identical twins, are unique because their genomes are one of a kind. These underlying differences, for good and for ill, can now be spelled out for the first time.

In making the announcement yesterday at the White House, President Clinton emphasized the similarities, rather than the differences, inherent in the results.

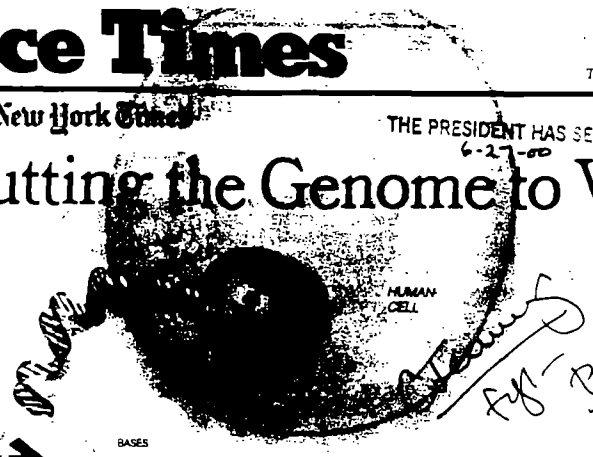
"In genetic terms all human beings, regardless of race, are more than 99.9 percent the same," Mr. Clinton said. "Modern science has confirmed what we first learned from ancient faiths. The most important fact of life on this earth is our common humanity."

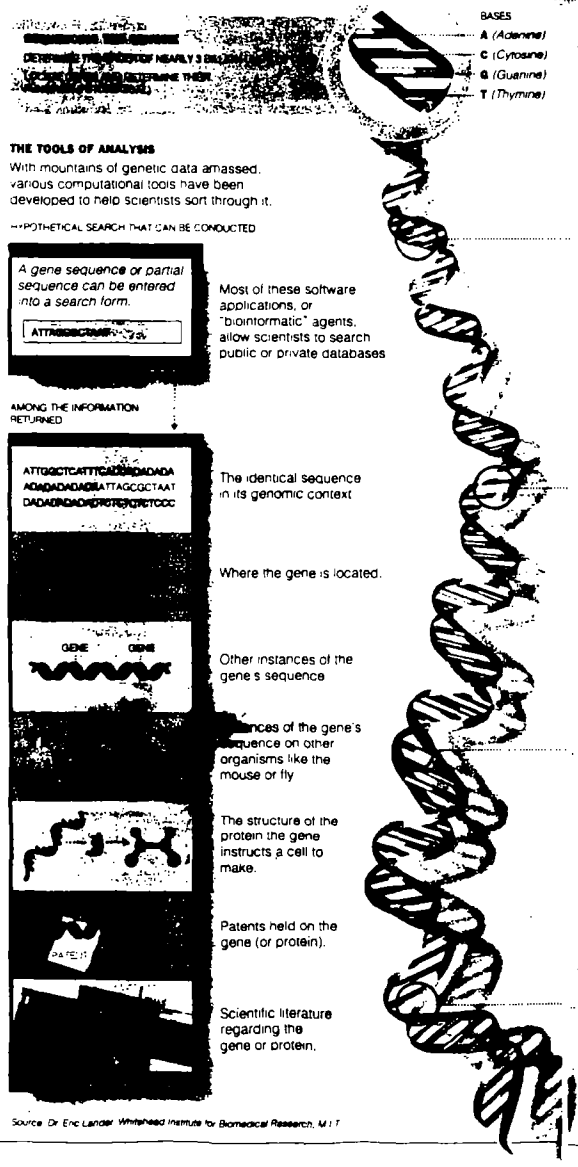
For the many who are fascinated by their origins and family history, the human genome will provide answers. Already a company that is called Oxford Ancestors (www.oxfordancestors.com) offers to tell people which of 30 founding human lineages

Continued on Page 4

A New Era Begins

Scientists have nearly finished sequencing the entire human genome, but putting all the bits of DNA in order is only the first phase in the effort to compile a complete operating manual of the human machine. A multifaceted analysis of the genome, already under way, is the next step.





Source: Dr. Eric Lander, Whitehead Institute for Biomedical Research, M.I.T.

THE TYPES OF ANALYSIS

Identifying Genes

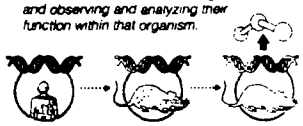
It is unknown how many genes there are on the human genome, and many genes whose sequences have been determined have functions that are unknown. Several approaches to discovering gene location and function are in use, including those that utilize the cell's basic machinery.

GENE LOCATIONS
Messenger RNA, transcribed from DNA, carries instructions for making proteins. It can be isolated, decoded and then matched with the identical sequence on the genome.

Comparing Organisms

Decoding the genomes of other organisms provides a model against which the human genome can be tested. Genes that go awry in a human cancer cell, for instance, closely match the genes that control cell division in baker's yeast. Since the machinery that controls these processes is highly similar in both organisms, scientists study the model organism to learn more about humans.

ANIMAL COMPARISON
Genes can be studied by finding identical sequences in other organisms and observing and analyzing their function within that organism.



Mapping Proteins

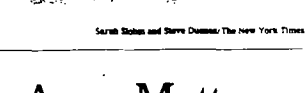
Genes contain instructions for the production of proteins. These proteins become the structural components of cells and the enzymes that cause chemical changes in the body. The ability to isolate or produce a protein for further study allows scientists to create a catalog of how the cell behaves.

PROTEIN MAPS
Proteins interact with other proteins to do their work in the cell. Scientists can determine the function of a protein by observing whether or not it binds with a protein whose function is known.

Comparing Humans

Tiny variations in the genetic code are what make us unique. Changes of one chemical unit in a gene's sequence, called single nucleotide polymorphisms (SNPs), can influence an individual's risk for disease. Gene [illegible] will help identify disease genes and may lead to better diagnosis and treatments.

SNPs
Scientists have created special chips coated with DNA strands that detect genetic variations or, SNPs, when an individual's DNA is tested against them.



Sarah Stokes and Steve Duenes/The New York Times

Reading the Book of Life

Incomplete, Project Is Already Paying Off

Most Ills Are a Matter Of More Than One Gene