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MEMORANDUM FOR THE PRESIDENT
THROUGH THE HONORABLE ERSKINE BOWLES

FROM: ` ` WILLIAM V. CORR, CHIEF OF STAFF

ON BEHALF OF: SECRETARY DONNA E. SHALALA

SUBJECT: ` ` WEEKLY REPORT March 17 23.

DATE: ` ` March 13, 1997.

FACT OF THE WEEK. The health of older Americans continues to improve dramatic
ally,
according to current findings from the National Long Term Care Survey (NL
TCS)a 12year
longitudinal survey designed to study changes in the health and fu
nctional status of older
Americans (age 65+). Researchers estimate that 1.2 mi
llion fewer older people were disabled in
1994 than would have been expected ba
sed on disability rates observed in 1982. The number of
older people with func
tional problems in 1994 stood at 7.1 million, not the 8.3 million who
would hav
e been impaired if health had not improved over the last few years. The decrea
se in
disability is also accelerating: the annual declines in disability between
n 1989 and 1994 were
greater than those of the 1980s. The 1994 survey and anal
ysis, which was funded by the National
Institute on Aging, will be released on
March 17 (embargoed until publication on March 17th).

I. KEY DEPARTMENT NEWS

Child Support Incentives. On March 13, HHS is submitting its plan to Congress

on new incentives for states to improve child support collections. The new incentive funding system, based upon five criteria, is intended to measure the true performance of states child support programs more accurately than the current system, which is based solely on the cost effectiveness of enforcement programs. The new welfare law requires HHS to prepare a child support incentive plan for consideration and legislative action by Congress. We anticipate media interest in the report.

Cloning. The National Bioethics Advisory Commission (NBAC) will meet in Washington on Thursday and Friday, March 13 and 14, in public session to begin deliberations regarding the ethics associated with the prospect of cloning human beings and possible steps to prevent abuses. The Commission is to report its findings and recommendations to the President before the end of May. The morning of March 13 will be devoted to brief committee reports on the status of other NBAC activities and a presentation in basic terms of the science and technology of cloning. The remainder of the two-day session will be devoted to hearing the perspectives of invited religious leaders and ethicists and to receiving testimony from members of the public.

#XN\ PXP#New York Medicaid Waiver. HCFA and Departmental staff are continuing to work with the State on the terms and conditions of the New York Section 1115 waiver. The waiver may be approved in the next couple of weeks.

FY 1997 Head Start Expansion Funding. Next week the Head Start Bureau of the Administration on Children, Youth and Families will invite Head Start Grantees to apply for financial assistance to expand Head Start enrollment. Only current Head Start grantees are eligible to submit applications to compete for a total of \$200 million that is available to expand enrollment in current service areas. Two separate announcements will be issued in the Federal Register to invite new proposals for Early Head Start projects and to provide Head Start services

in jurisdictions that do not have Head Start programs and are not served by a Head Start grantee.#XN\ PXP#

#XN\ PXP#FDAs Draft Guidelines on Clinical Testing. FDA expects shortly to announce proposed

guidelines to expedite development of new uses of drug and biologic products. Draft guidelines will be made available for public comment. In these draft guidelines, the agency will ask for comments on the nature of the scientific evidence that needs to be provided to FDA when companies seek to increase the number of safe and effective uses being added to product labeling.

The guidelines are being issued in an effort to help reduce the barriers that companies face in submitting applications for approval of new uses for their products. #XN\ PXP#

Ryan White Formula Grants to be Awarded. During the week of March 16, Ryan White Title

II formula grants of approximately \$230 million will go to the 50 States, the District of

Columbia, Puerto Rico, Guam and the Virgin Islands for services. Another \$160 million is

expected to be earmarked for State AIDS Drug Assistance Programs, bringing the formula grants total to an anticipated \$398 mil

lion. Grantees were informed about the amount of their formula grants early in

this fiscal year. HRSA is also awarding early next week Ryan White CARE Act Title

III grants totalling \$5,075,951 to 15 community health care organizations to support

outpatient early intervention, primary care, and substance abuse services for low-income

individuals living with HIV/AIDS. The organizations represent approved but unfunded

applications from HRSA's FY 1996 solicitations.

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<DL!T\$&)\+-0d24#XN\ PXP#Medicare Managed Care Appeals Process Lawsuit. On

March 3, the U.S. District Court for

the District of Arizona entered a judgment

order in Grijalva v. Shalala, a nationwide class action

of Medicare HMO enroll

ees challenging HMO appeals procedures. In its October 17, 1996

ruling in the

case, the Court held that Medicare beneficiaries had certain notice rights, and the

right to an expedited appeal under certain circumstances. The court asked plaintiffs to submit a

proposed judgment order, and invited the Secretary's comments on this order. The Secretary

submitted a brief and declaration objecting

to aspects of plaintiffs' proposed order, and submitted

an alternative order.

The order entered by the court last week addresses most of the objections raised

sed by the Secretary to the plaintiffs' proposed order, and requires notice and expedited appeals procedures that are largely consistent with HCFA policy. #XN \ PXP#

#XN \ PXP# Kurdish Asylees Update. Since September, three groups of people have been evacuated from Northern Iraq. They are often referred to as Quick Transit (QT) I (consisting of employees of the United States Government and their families), QT II (members of the Iraqi opposition and their families), and QT III (employees of United States based and funded nongovernmental organizations and their families). All of the QT I group (approximately 2,180 people) have been resettled in the U.S. We are in the process of resettling the remaining evacuees from QT II and QT III (approximately 4,437 people). Our goal for camp closure is April 15. #XN \ PXP#

Asthmatics Warned about Sulfites in Canned Tuna. On March 7, following an industry alert that most white (albacore) tuna and a limited amount of light tuna contain sulfites not declared on the product labels, FDA warned sulfite-sensitive asthmatics and other sulfite-sensitive consumers that canned tuna products may contain undeclared sulfites. The sulfites do not present a risk to individuals who are not asthmatic or otherwise sulfite sensitive. The industry has informed FDA it has now discontinued use of raw materials containing sulfites.

FDA Proposes a Timeframe for Final Rules on Health Claims. On March 17, in response to a recent judicial decision, FDA will publish a proposed rule to provide a timeframe for the publication of final rules on health claims. In the wake of its adoption of regulations on health claims for dietary supplements, FDA was sued several times on the grounds that the regulations violate the First Amendment. In a recent decision, the court concluded that FDA's regulations were supported by a government interest in preventing the spread of unsubstantiated health claims, but the court noted that once the agency proposed to allow a particular health claim, it had no timeframe for the issuance of a final rule and ordered FDA to establish a reasonable time limit for the issuance of a final rule for a health claim on dietary supplement labels. FDA is proposing to establish

lish a timeframe of 270 days.

FDA Approves the First Home Test for Blood Clotting. On March 13, FDA approved the ProTime Microcoagulation System, made by International Technidyne Corp., the first home test for use with blood thinning medicine. The convenient new test is intended for use by heart patients and others who are taking the blood thinning drug warfarin (Coumadin) to prevent clotting. It is a simple finger stick test in which the user pricks his finger with a needle to draw blood, then runs the sample through a small, hand-held electronic device which displays the results on a screen. The test is already cleared by FDA for use in physician offices, clinics and nursing homes to test for blood coagulation. The new system will now be available by prescription for home use under a doctor's supervision. Blood thinners are used to treat people with artificial heart valves, irregular heart beat and other conditions that lead to excessive blood clotting.

FDA Advisory Panels. On March 14, an FDA advisory panel will discuss Medtronic, Inc.'s application for a deep brain stimulator to treat tremors due to Parkinson's disease. On March 20-21, another advisory panel will discuss self-monitoring and management of blood glucose levels by diabetics, including noninvasive and invasive blood glucose monitors. #XN\ PXP#

Electric and Magnetic Fields (EMF) Science Review Symposium. On March 24-27, the National Institute of Environmental Health Sciences (NIEHS) will cosponsor the first of a series of three scientific symposia for the critical evaluation of the scientific literature as well as for an assessment of the weight and strength of the evidence concerning human health effects associated with EMF exposures. The first symposium, Theoretical Mechanisms and In Vitro Research Findings, will focus on the use of cell cultures to study the ways EMF affects biological systems. The NIEHS will use the symposia's discussion reports as well as the working group document in preparing its report to Congress on the extent to which exposure to EMF affects human health.

Department Meeting with State on TennCare. Late last month, HCFA and SAMHSA

officials visited Tennessee to review the States TennCare Partners Program and the status of the States mental health programs. Preliminary findings indicated that access to mental health and substance abuse services is impaired. Moreover, the State is not effectively monitoring the program. The Department will meet with Tennessee senior officials on March 17 to begin discussing corrective actions.

Sumaya Named Deputy Assistant Secretary for Health. Dr. Ciro Sumaya, Administrator of the Health Resources and Services Administration (HRSA), has been named Deputy Assistant Secretary for Health, effective March 17. On the same date, Dr. Earl Fox, Deputy Assistant Secretary for Health, Disease Prevention and Health Promotion, will become the Acting Administrator of HRSA.

Claxton Returns to HHS. Gary Claxton, who served at HHS from 1993-95, has returned to become Deputy Assistant Secretary for Health Policy under the Assistant Secretary for Planning and Evaluation.

II. AGENCY WORK ON PRESIDENTIAL INITIATIVES

#XN\ PXP#Electronic Signatures and Regulatory Documents. FDA soon will publish a final rule which allows FDA-regulated industry to maintain required records electronically and to submit, under certain circumstances, electronic records and electronic signatures as equivalents to paper records and signatures written on paper. Firms that adopt the electronic technologies will realize substantial savings from simplified recordkeeping and speeding the filing of applications and other regulatory documents.#XN\ PXP#

III. NOTABLE CONGRESSIONAL ACTIVITY

Congressional Visit to NIH. On March 17, members and staff of the House Commerce Subcommittee on Health and Environment will visit the NIH campus. Members and their staff will meet with Dr. Harold E. Varmus, Director, National Institutes of Health, and other NIH representatives.

#XN\ PXP#Healthy Start. On March 13, the House Government Reform and Oversight Subcommittee on

Human Resources and Intergovernmental Relations is conducting a hearing on the evaluation and expansion of the Healthy Start program. A number of Department representatives are testifying.

Research Systems. On March 13, the Senate Committee on Agriculture, Nutrition and Forestry is holding a hearing on successful research systems that may be applicable to agricultural research. Wendy Baldwin, Deputy Director for Extramural Research, National Institutes of Health, is testifying.

Medicare Financing. On March 13, the Senate Finance Subcommittee on Health Care is holding the fourth hearing in its series on the longterm financial condition of the Medicare program. No Department witness has been invited to testify.

Medicare's Preventative Benefits. On March 13, the House Ways and Means Subcommittee on Health is holding a hearing on legislation to increase and improve the preventative health benefits offered to Medicare recipients. No Department witness has been invited to testify.

Reauthorization of Substance Abuse and Mental Health Services Programs. On March 18, the House Commerce Subcommittee on Health and the Environment will hold a hearing on reauthorization of SAMHSAs expiring program authorities. Nelba Chavez, Administrator, Substance Abuse and Mental Health Services Administration, will testify.

Implementation of the Government Performance and Results Act. On March 18, the House Government Reform and Oversight Subcommittee on Human Resources and Intergovernmental Relations will hold a hearing on the Department's implementation of the Government Performance and Results Act. June Gibbs Brown, Inspector General, HHS, will testify.

FDA Operations. On March 19, the Senate Labor and Human Resources Committee will hold a hearing on the Food and Drug Administration's use of resources, [and] efficiency of operations,.... Michael Friedman, Deputy Commissioner for Operations, FDA, will testify.

#XN\ PXP#Medicare Managed Care Hearing. On March 19, the Senate Finance Committee will hold a

hearing on Medicare managed care with a focus on HCFA administrative actions to assure beneficiary protections and quality care as well as the Presidents 1998 proposals affecting managed care. The HCFA Administrator, Bruce Vladeck, will be the witness.#XN\ PXP#

Child Support Incentive Funding. On March 20, the House Ways and Means Subcommittee on Human Resources will hold a hearing on recommendations concerning the child support incentive funding formula. David Gray Ross, Deputy Director, Office of Child Support Enforcement, Administration for Children and Families, will testify. Indian Health Service Appropriations. On April 8, the House Appropriations Subcommittee on Interior will hold a hearing on FY 1998 budget proposals for the Indian Health Service. Michael Trujillo, Director, Indian Health Service, may be invited to testify.
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IV. SECRETARYS SCHEDULE/SUBCABINET TRAVEL

Secretarys Schedule:

March 15. Secretary Shalala will attend the Gridiron Dinner, in Washington.

March 17. Secretary Shalala is tentatively scheduled to hold a roundtable discussion with 1520 HHS Academy Seniors and watch a play at Eastern High School in Washington, D.C. The Secretary will also address the opening session of the American Medical Associations national leadership conference, in Philadelphia.

March 18. Secretary Shalala will have meetings with Pete Peterson, Ambassador to Vietnam and Baltimore Mayor Kurt Schmoke. The Secretary will also address the Congressional Urban Caucus.

March 20. Secretary Shalala will participate in a breakfast event commemorating the 25th Anniversary of the Older Americans Act. The Secretary will attend an event on Sudden Infant Death Syndrome with Mrs. Gore. She will also give remarks at the Department awards ceremony for the Combined Federal Campaign, and meet with Representative Bilirakis.

March 21. Secretary Shalala will meet with the Attorney Generals Advisory Committee of United States Attorneys to discuss health care fraud. The Secretary

will also meet with HUD
Secretary Cuomo.

Subcabinet Travel:

March 17. Ann Rosewater will deliver the keynote address at the joint Family Service America/National Association of Homes and Services for Children policy conference and legislative summit.

#XN\ PXP#March 17. Robyn I. Stone, acting as Assistant Secretary for Aging, will deliver remarks at the 47th National Council on the Aging's annual meeting in Chicago. Dr. Stone's presentation is entitled, "The Future of the Older Americans Act."#XN\ PXP#

#XN\ PXP#March 17. Dr. Nelba Chavez, Administrator, SAMHSA, will present opening remarks at the Center for Substance Abuse Prevention's 1996 Exemplary Prevention Program Awards Ceremony in Washington, D.C. General McCaffrey, Director, ONDCP, is also expected to speak and participate in the ceremony. #XN\ PXP#

#XN\ PXP#March 19. Robyn I. Stone, acting as Assistant Secretary for Aging, will deliver remarks at the opening session of the 1997 Mississippi Joint Conference on Aging annual training conference, in Biloxi, Mississippi.#XN\ PXP#

#XN\ PXP#March 25. June Gibbs Brown, Inspector General, will speak at the Annual Directors Symposium of the National Association of Medicaid Fraud Control Units, in Arlington, Virginia.#XN\ PXP#

#XN\ PXP#March 26. Bruce Vladeck, Administrator, Health Care Financing Administration, will address the American Society of Aging's 43rd annual meeting in Nashville, Tennessee. He will discuss the future of HCFA's long-term care strategy. #X P7XP# #XN\ PXP#

V. PRESS MEDIA INQUIRIES AND REPORTS OF INTEREST

Washington Post Reporter to Visit Hansens Disease Center: Washington Post reporter Sally Squires and a photographer are scheduled to visit the Hansens Disease Center in Carville, La., throughout the week of March 17. Carville is the location of the only surviving Public Health Service hospital. It specializes in treatment of tropical diseases, including Hansens disease

(leprosy). Her report will feature an historical perspective on technology and treatment advances developed at the center, residents and the facility.

Alzheimers Disease Study and Research. In the March issue of the journal Neurology, researchers report on a 15 year study showing that antiinflammatory drugs such as ibuprofen appear to reduce the risk of Alzheimers disease. The study was the first to look at a large number of patients over a substantial period of time, allowing scientists to eliminate a number of biases found in earlier studies. The March 12 issue of the Journal of the American Medical Association, a special issue dedicated to Alzheimers disease, contained an editorial by several National Institute on Aging scientists examining important new findings.

Hepatitis G Virus. In the March 13 issue of the New England Journal of Medicine, researchers report on a study which shows that hepatitis G virus (HGV), the most recently discovered hepatitis virus, might not cause the liver disease. While the team concluded that HGV is a common, persistent, transfusiontransmissible virus, 73 percent of patients infected had no evidence of liver diseases and another 16 percent had enzyme levels too low to be classed as hepatitis. Further study is needed to clarify the findings.

VI. FREEDOM OF INFORMATION ACT REQUESTS

None to report.

Weekend Contact:

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(The duty officer receives calls placed to the Secretarys and Deputy Secretarys
Offices)#XN\ P#XP#===== END ATTACHMENT 1 =====