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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Dasha31@aol.com to Mrs. Gore [partial] (1 page)	10/30/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Automated Records Management System
Default (In Vitro or Infertility)
OA/Box Number: 1100000

FOLDER TITLE:

[8/8/1996 - 2/17/2000]

2013-0365-F
wr10697

RESTRICTION CODES

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

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

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

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

RR. Document will be reviewed upon request.

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

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

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Toni S. Hustead (CN=Toni S. Hustead/OU=OMB/O=EOP [OMB])

CREATION DATE/TIME: 8-AUG-1996 09:57:46.00

SUBJECT: Re: Paperworks

TO: Alexandra Lehr (CN=Alexandra Lehr/OU=OMB/O=EOP @ EOP [OMB])

READ:UNKNOWN

CC: Lavonne D. Sampson (CN=Lavonne D. Sampson/OU=OMB/O=EOP @ EOP [OMB])

READ:UNKNOWN

CC: ZAVADA_D (ZAVADA_D @ A1 @ CD @ LNGTWY [EOP]) (OMB)

READ:UNKNOWN

CC: BLAYLOCK_J (BLAYLOCK_J @ A1 @ CD @ LNGTWY [EOP]) (OMB)

READ:UNKNOWN

CC: Lynn C. Ross (CN=Lynn C. Ross/OU=OMB/O=EOP @ EOP [OMB])

READ:UNKNOWN

CC: Dennis L. Stout (CN=Dennis L. Stout/OU=OMB/O=EOP @ EOP [OMB])

READ:UNKNOWN

CC: KEENAN_A (KEENAN_A @ A1 @ CD @ LNGTWY [EOP]) (OMB)

READ:UNKNOWN

TEXT:

Sounds good. Thanks.

Alexandra Lehr

08/08/96 09:50:17 AM

Record Type: Record

To: Toni S. Hustead/OMB/EOP

cc:

Subject: Paperworks

I recommend clearing the following two paperworks

OIRA is currently clearing two surveys from the Department. The first survey is a Survey of Health Promotion and Preventative Medicine. This fulfills a Congressionally mandated reporting requirement on health promotion and disease prevention services received by veterans. This is a

four page survey on the rates that veterans were offered and received critical health promotion and disease prevention (PL 102-585 Sec 511). VA published this survey in the Federal Register and has received no responses. I recommend clearing this survey.

The second survey is a study of the Army Chemical Corps Vietnam Health Study. Studies indicate that this group of Vietnam veterans suffer unusually high rates of illness compared with non-Vietnam vets. The study will focus on the and relationship between health outcomes and possible exposure to herbicides (Agent Orange). In particular, the study will focus on cancer, pregnancy outcomes, birth outcomes, childhood cancer and infertility. In 1993 the National Academy of Sciences (NAS), who publishes the reports on Agent Orange, recommended that this particular study on the Army Chemical Corps be carried out. I also recommend clearing this survey.

Let me know if you have any questions. Otherwise I will let Allison Eydt know.

RECORD TYPE: FEDERAL (XCHANGE MAIL)

CREATOR: Vivian Grishkot (CN=Vivian Grishkot/OU=WHO/O=GOV [HHS])

CREATION DATE/TIME: 3-MAY-1995 16:42:27.00

SUBJECT: Women's Issues

TO: Timothy G. Zayac (CN=Timothy G. Zayac/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: Cheryl Rodman (CN=Cheryl Rodman/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: LeeAnn Inadomi (CN=LeeAnn Inadomi/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: Chloe Sladden (CN=Chloe Sladden/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: Lawrence R. Jurcich (CN=Lawrence R. Jurcich/OU=WHO/O=GOV [OA])
READ:NOT READ

TO: Cornelius F. Johnson (CN=Cornelius F. Johnson/OU=WHO/O=GOV [NEOB])
READ:NOT READ

TO: Linda M. Tolkan (CN=Linda M. Tolkan/OU=WHO/O=GOV [EOP])
READ:NOT READ

TO: John K. Riordan (CN=John K. Riordan/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: Admin User (CN=Admin User/OU=WHO/O=GOV [OA])
READ:NOT READ

TO: Deborah J. Behr (CN=Deborah J. Behr/OU=WHO/O=GOV [OA])
READ:NOT READ

TO: Stephen B. Silverman (CN=Stephen B. Silverman/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: Phillip M. Caplan (CN=Phillip M. Caplan/OU=WHO/O=GOV [WHO])
READ:NOT READ

TO: Jason S. Goldberg (CN=Jason S. Goldberg/OU=WHO/O=GOV [WHO])
READ:NOT READ

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

PRINTER FONT 12_POINT_COURIER

Tab A: Programs Targeted at/of Interest to Women and Accomplishments
Tab B: HHS Representatives on Women's Issues
Tab C: Key Contacts/Coordinators for Additional Information
Tab D: Lobby Groups on Women's Issues
Tab E: Key Issues Being Lobbied
Tab F: Other Information of Interest

HORIZONTAL_PITCH 8
PRINTER FONT 14_POINT_COURIER
AN AGENDA FOR WOMEN
HORIZONTAL_PITCH 10
PRINTER FONT 12_POINT_COURIER
Department of Health and Human Services

WOMEN'S HEALTH BUDGET

The Clinton Administration has placed a high priority on expanding resources available to address women's health concerns. The Department of Health and Human Services (DHHS) spends over \$1.7 billion on a wide range of activities related to women's health.

WOMEN'S HEALTH FOCUS

In 1994, the Administration set an important precedent by establishing a senior level health position in HHS dedicated to addressing inequities in research on and services related to women's health. The Deputy Assistant Secretary for Health, Office on Women's Health (OWH) provides leadership, direction, and support for a comprehensive women's health agenda that focuses on research, service delivery, and professional and consumer education, and; coordinates women's health policies and programs across the agencies and offices of the Public Health Service (PHS).

NATIONAL ACTION PLAN ON BREAST CANCER

In October 1993, President Clinton received petitions signed by 2.6 million Americans urging the Administration to take action against the rising toll breast cancer is taking on the nation.

In direct response, less than two months later, DHHS Secretary Donna E. Shalala convened a national conference on breast cancer.

The product of that conference was the development of the National Action Plan on Breast Cancer (NAPBC). The Plan provides a framework and plan for activities in three major areas:

- ? Delivery of health care,
- ? Conduct of research, and
- ? Enactment of policy.

The document represents a statement of national opportunities upon which to build and strengthen knowledge, resources and commitment in the prevention, diagnosis, treatment, care, and, ultimately, elimination of breast cancer as a threat to American women. Moreover, the NAPBC affirms the importance of public-private collaborations to fight breast cancer and promote breast health by involving the participation of consumer, health care professional and scientific organizations, as well as the Federal government in this \$10 million initiative.

The OWH is coordinating implementation of the Plan. Six major areas of activity have been identified:

- ? Information dissemination about breast health and breast cancer to scientists, consumers and practitioners using state-of-the-art information superhighway resources;
- ? National patient data registry and tissue bank;
- ? Expansion of biomedical and behavioral research into the etiology of breast cancer;
- ? Enhancing the range and scope of clinical trials and improving women's access as participants;
- ? Addressing the needs of individuals carrying the breast cancer susceptibility gene(s); and,
- ? Ensuring consumer involvement across all levels of policy development, research, and clinical trials.

Other aspects of the campaign against a disease that is expected to strike one in eight women in her lifetime include:

- ? An FY 1995 budget that includes \$387 million for breast cancer research, a 29 percent increase over FY 1994. The FY 1992 budget for breast cancer research was \$155 million.
- ? \$20 million in FY 1995 to continue implementation of the FDA's Mammography Quality Standards Act (MQSA), ensuring all women access to safe and effective mammography services, including certification of mammography facilities by the Food and Drug Administration's (FDA) to ensure high-quality, reliable mammography; continued financial support for the Center for Disease Control's (CDC) State Breast Cancer Screening and Education Program; and funding for Medicare coverage of mammography services.
- ? Development and dissemination of Clinical Practice and Consumer Guidelines on mammography by the Agency for Health Care Policy and Research in collaboration with FDA release of its "seal of approval" for MQSA-approved mammography facilities.

- ? A Capitol Hill briefing was sponsored by the OWH and the National Cancer Institute in October 1994 on "New Frontiers in the Early Detection of Breast Cancer" to explore how imaging technology from the defense, intelligence, space and computer graphics industries might be applied to the early detection of this disease. Since that time, further meetings have been undertaken to strengthen linkages to the defense and intelligence communities and to further the investigation of imaging techniques for application to breast cancer early detection.

MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA)

In December 1993, President Clinton signed legislation authorizing the FDA to publish standards for mammography under the 1992 MQSA. The new regulations, effective October 1, 1994, establish quality standards on equipment, personnel, and record keeping, and a certificate system for more than 10,000 U.S. facilities that perform mammography and interpret films. The purpose of these regulations is to promote quality mammography,

which is essential for early diagnosis of breast cancer.

HYSTERECTOMY

The OWH, in collaboration with other agencies of the PHS, has developed a state-of-the-art report to Congress detailing PHS activities related to the use of hysterectomy, alternative uterus-conserving medical and surgical interventions, and the range of malignant and benign conditions that currently lead to the use of hysterectomy, the second most common major surgical procedure now performed on American women. In addition to the report, a consumer pamphlet to help educate women about their choices in treatment is under development.

WOMEN AND HIV/AIDS

At the direction of President Clinton, Secretary Shalala estab

lished the National Task Force on AIDS Drug Development to examine ways to increase and encourage the development -- through innovative and novel approaches, including public-private partner

ships -- of therapies for the prevention, diagnosis, treatment and supportive care of people with HIV/AIDS. The 15-member panel includes representatives from government, the pharmaceutical industry, academia, medicine and AIDS-affected communities. The Task Force has studied and made recommendations to ensure the inclusion of women in all phases of clinical trials and other activities related to AIDS drug devel

opment. These recommendations are designed to ensure that barriers to the inclusion of women in AIDS drug trials are eliminated, that every effort is made to accrue adequate numbers of women into AIDS drug trials, that such accrual in fact occurs, and that data gathered during the course of clinical trials is analyzed appropriately in a by-gender manner.

Also of interest, the FY 1995 budget includes \$21 million for research on female-controlled barriers against HIV infection and other sexually transmitted diseases compared to no funding for this initiative in FY 1992.

WOMEN IN CLINICAL TRIALS

Traditionally, the participation of women in clinical trials has been restricted. The rationale for such a policy has been concern for an unborn fetus. However, the ramifica

tion of this past policy has been that limited information was available with regard to the safety and efficacy of certain drugs and devices in women. The PHS has made great strides in an effort to reverse this practice. In July 1993, the FDA published a guideline for the study and evaluation of gender differences in the clinical evaluation of products (drugs, biologics and devices). This

guideline removed the 1977 restriction on the participation of women of childbearing potential in the early phases of clinical trials; and, it specified the necessity of analyzing safety and efficacy data with respect to race, age and gender. To further strengthen its commitment for a more comprehensive review of regulated products, the FDA articulated a policy that it will refuse to file a new product application that has not been fully analyzed for gender, race and age differences. A monitoring system is in development which will ensure that these changes are implemented.

Similarly, the National Institutes of Health (NIH) published its guidelines on women in clinical trials in March 1994. These guidelines were designed to ensure that women and members of various ethnic minorities are represented in all areas of human subject research. In addition, phase III trials are expected to incorporate predicted differences with respect to gender, age or ethnicity in the design of new clinical trials.

The aim of both these guidelines is to have more comprehensive information on regulated products for the target population that will ultimately receive them.

THE NATIONAL INSTITUTES FOR HEALTH (NIH) WOMEN'S HEALTH INITIATIVE

This initiative, the largest clinical research study ever conducted in either men or women, has begun to examine the major causes of death, disability and frailty in post-menopausal women: heart disease, breast and colon cancer and osteoporosis. This multi-year study will examine the effect of dietary patterns and supplements, exercise, hormone replacement therapy, and behavioral interventions to prevent major disorders and promote good health for women. An emphasis to include minority women at each clinical site is a major component of the study.

HEALTH CARE REFORM FOR WOMEN

Women remain over-represented in low-wage, hourly and part-time positions that do not provide health insurance coverage or other work-related benefits, although they comprise over 51 percent of

the population and 45 percent of the workforce. As a result, many basic and long term health services essential to women are unavailable or available only on a limited basis.

Women who live in poverty or in geographic/social isolation (e.g., homeless, incarcerated women), and women who are members of racial and ethnic minority groups, have less financial and organizational access to services, lower utilization rates for all types of services, less preventive care, and poor health status in terms of morbidity and mortality compared to other social groups of women. For example, Black and Hispanic women have lower utilization rates for breast and cervical cancer screening. Women in rural areas are less likely to receive early prenatal care than women in urban areas. Women with children -- the fastest growing group among the homeless -- have no regular source of primary health care.

Any Administration supported health care reform effort will

guarantee comprehensive health services, including clinical preventive services and reproductive health care, to all women regardless of their health, ability to pay, or marital or employment status.

MINORITY WOMEN'S HEALTH

In 1991, the death rate from breast cancer for minority women was 31.9 per 100,000 women, 19 percent higher than for white women. Although Black and Hispanic women make up 21 percent of all U.S. women, they constitute 74 percent of U.S. women diagnosed with AIDS since 1981. Minority women are at a higher risk of maternal death than white women.

HHS is ensuring that grantees under the Ryan White CARE Act of 1990 develop accessible services for disadvantaged women with HIV/AIDS. An FY 1995 appropriation of \$2.5 million will fund the "Patient Outcome Research Team" project to evaluate ways to prevent low birthweight among infants of minority and high-risk women. The NIH are implementing Public Law 103-43 (NIH Revitalization Act of 1993), signed by President Clinton on June 10, 1993, which requires that women and minorities, including subpopulations of minorities, be included in all clinical research supported by NIH. Health education projects for women of color were sponsored in several PHS regions by the OWH. HHS cosponsored the first National Minority Women's Conference in April 1994 at the NY Academy of Sciences, and convened a National American Indian and Alaska Native Conference on the Status of Minority Women's Health in May 1994.

WOMEN AND MENTAL HEALTH/SUBSTANCE ABUSE

Women are twice as likely as men to experience certain mental illnesses, including depression and panic disorders, and also suffer more often from phobias and eating disorders. One in 14 women will be clinically depressed in her lifetime. DHHS spent an estimated \$66.2 million during FY 1994 for biomedical and behavioral research on mental illnesses that affect women.

A National Women's Resource Center, supported by PHS agencies, was developed in FY 1994 to improve services for substance abusing women and their children, and to disseminate information on women's substance abuse and mental health prevention and treatment. Substance abuse prevention demonstration programs for adolescent women were established by PHS.

DHHS sponsored a conference on Psychosocial and Behavioral Factors in Women's Health: Creating an Agenda for the 21st Century.

WOMEN'S HEALTH AND THE ENVIRONMENT

An Interagency Coordinating Committee has been established by PHS in cooperation with other federal departments to evaluate and foster work on issues related to women's health and the environment. The group has developed an inventory of governmental activities on this issue and is developing a strategic plan to foster initiatives and programs to address how home, work, and atmospheric pollutants and other environmental factors adversely affect women's health, and to develop strategies to eliminate these hazards.

TEEN PREGNANCY

The Clinton Administration's Work and Responsibility Act of 1994 contained important components targeted to preventing adolescent pregnancy and childbearing. To emphasize the importance of delayed sexual activity and responsible parenting, the bill proposed that a national campaign be launched against adolescent pregnancy. Such a campaign would bring together local schools, communities, families and churches to send a strong signal that it is wrong to become a parent before one is able to provide for and nurture a child. Middle and high schools in disadvantaged areas would receive grants to develop ongoing and innovative adolescent prevention programs.

The Act also advocated broader initiatives which would seek to change the circumstances in which high-risk young people live and the ways they see themselves. These initiatives would address economic opportunity, as well as health and education issues.

FAMILY PLANNING

Through a network of over 4,000 clinics nationwide, the Title X family planning program provides services to about 4 million poor women each year -- approximately one-third are teenagers. The program has developed and put into place new program priorities emphasizing outreach to hard-to-serve populations such as substance abusers and homeless persons, those at risk of contracting or spreading sexually transmitted diseases or HIV, and adolescents. In conjunction with the CDC, the program is supporting a national infertility prevention program.

The Administration also is committed to preventing adolescent pregnancy and to promoting ideals of responsibility for our young people. The Administration has consistently voiced support for encouraging adolescents to postpone parenthood until they are prepared to support and nurture their children. To this end, the Department's Adolescent and Family Life Program has a statutory mandate to fund projects that encourage delay of sexual activity. HHS also promotes initiatives to provide comprehensive health education and health services necessary to both prevent pregnancy and sexually transmitted diseases and to promote general health and well being.

The Family Planning Program, provides contraceptive and pregnancy services and routine gynecological screening to low-income women (\$193 million appropriated for FY 1995, compared to \$150 million in FY 1992).

ELIMINATING THE "GAG" RULE

On January 22, 1993, in the first week of his Administration, President Clinton instructed DHHS to issue regulations lifting the ban on abortion counseling by Title X (family planning) program grantees.

INTERNATIONAL CONFERENCE ON POPULATION AND DEVELOPMENT

The United States government played a leadership role in articulating a new approach to population policy. The new approach enjoys the support of a majority of the world's nations. The Cairo Program of Action calls for extending integrated primary, maternal and child health services to all, and ensuring universal access to prenatal care, immunization coverage, and

programs to combat malnutrition. Such programs are urged to pay particular attention to the most vulnerable and underserved groups in the populations, and to remove barriers to access. Improved family planning and reproductive health services are a cornerstone of the Program of Action's recommendations to improve health. The Program of Action asks governments to assess the extent of unmet need for family planning services and to provide

universal access to the full range of safe contraception and reproductive health services. The Program does not promote abortion "as a means of family planning," but it does recognize the need to address unsafe abortions as a critical public health concern.

U.S. PATENT RIGHTS FOR RU-

486

On January 22, 1993, President Clinton signed a Presidential Memorandum directing DHHS to assess initiatives to promote the testing and licensing of mifepristone (RU-486) in the United States. DHHS efforts resulted in the May 1994 announcement by Secretary Shalala that the French pharmaceutical company, Roussel Uclaf, was donating without remuneration, its United States patent rights for the drug to the Population Council, Inc., a not-for-profit corporation. The donation does not mean RU-486 has been approved for use in the United States. The Population Council must conduct clinical trials, identify a manufacturer, and submit a new drug application to FDA. The donation is a big step in the direction of providing women in America access to the full range of safe and effective alternatives to surgical abortion. In addition to medical abortion, the drug also is under study for contraception, Cushing's syndrome, endometriosis, meningioma, and breast cancer. The Population Council announced on October 27, 1994, that clinical trials have begun in the United States. They are being conducted under a protocol that has been reviewed and approved by the FDA.

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH

On January 22, 1993, President Clinton issued a directive to the Secretary of DHHS ending a five-year moratorium on Federal funding of therapeutic transplantation research that uses human fetal tissue derived from induced abortions. Secretary Shalala immediately notified the NIH of the President's action, and then formally revoked the moratorium on February 1, 1993. At the same time, the Secretary, through the Acting Assistant Secretary for Health, directed the NIH to develop interim guidelines based on the recommendations of the 1988 Human Fetal Tissue Transplantation Research Panel to ensure that Federal funding of human fetal tissue transplantation research does not encourage the choice of abortion. Accordingly, the NIH prepared and transmitted to the Acting Assistant Secretary for Health, interim policy guidelines based on the recommendations of the 1988 Human Fetal Tissue Transplantation Research Panel and the Advisory Committee to the Director. Currently, the NIH funds approximately 129 studies at a total cost of about \$12 million. This represents about .12 percent of the NIH budget.

MEDICAID AND MEDICARE

The Department's Medicare and Medicaid programs, managed by the Health Care Financing Administration (HCFA), finance health insurance for the elderly, poor and disabled. Over one quarter of all U.S. women receive benefits from these programs. Approximately 16 percent of all U.S. women are Medicare beneficiaries, and approximately 14 percent are Medicaid recipients.

Women constitute the majority of recipients of both the Medicare and Medicaid programs. Six out of ten Medicare beneficiaries are women, and six out of ten Medicaid beneficiaries are women. At age 65, almost all U.S. women become eligible for the Medicare program. Approximately 14 percent of women over 65 are Qualified Medicare Beneficiaries, which means that the Medicaid program will cover certain expenses that Medicare does not cover.

HCFA's overriding interest concerning the advancement of women pertains to the promotion of women's health care and well-being, with a particular focus on our most vulnerable women -- the elderly and poor. HCFA strives to promote the advancement of wellness care for women (screening mammography benefit, pap smear benefit) by including these services in the Medicare and Medicaid package of covered services, and providing education about the benefits derived from using these services.

MEDICAID INITIATIVES

Over the last year, a number of states have been granted welfare reform demonstration waivers. HCFA has approved the extension of Medicaid benefits for many beneficiaries (many of whom would be women) who, upon entering the workforce, would otherwise lose their Medicaid health benefits when losing their welfare status.

Access to Prenatal Care and Effective Health Supervision

This past decade has seen a significant expansion of Medicaid eligibility and enhancement of covered prenatal services for low income pregnant women. Last year about 33 percent of the nation's births were paid by Medicaid.

State Medicaid agencies and HCFA help reduce infant mortality and improve maternal and infant health by providing comprehensive coverage of pregnancy-related services and services for other conditions that might complicate pregnancies. They also have brought more eligible pregnant women into risk-specific health care, such as pregnant teens and substance abusing pregnant women, and more infants into early health supervision. These initiatives have been accomplished by:

? Extending Medicaid eligibility to pregnant women and children with incomes below 133 percent of the Federal poverty level, and by giving States the option of covering persons in families with incomes up to 185 percent of the Federal poverty level; States also may receive a waiver to cover pregnant women and children with incomes higher than 185 percent of the Federal poverty level and many have done so;

? Providing up to 12 months of both Medicaid benefits and

transitional child care assistance for most families who leave the rolls as a result of employment.

- ? Streamlining eligibility procedures;
 - ? Conducting community outreach campaigns; and
 - ? Enhancing Medicaid coordination with other programs for pregnant women and children such as the Maternal and Child Health, the Childhood Immunization Initiative, Special Supplemental Food Program for Women, Infants, and Children, and Community/Migrant Health Centers.
- Hyde Amendment

In December 1993, HHS implemented the change to the Hyde amendment made in the FY 1994 appropriations bill. This change obliged states to pay for abortions for poor women whose pregnancies resulted from rape or incest, as well as for abortions of pregnancies which endangered the life of the mother. Initially, 30 states were not in compliance with this change. However, through the efforts of HHS, as well as numerous court decisions in our favor, the number of States out of compliance is six as of January 23, 1995. In addition, the Labor, Education, and HHS FY 1995 appropriations bill contains the same language.

MEDICARE INITIATIVES

OBRA 89 authorized Medicare coverage of screening Pap smears effective July 1, 1990. In June 1990, HCFA issued national guidelines to its Medicare contractors on coverage of screening Pap smear services.

The Omnibus Budget Reconciliation Act (OBRA) of 1990 amended the Social Security Act to establish requirements for the provision of screening mammography services to women under the Medicare program. The benefit became effective January 1, 1991. Screening mammography procedures may be furnished in a freestanding facility, mobile unit, or on the premises of a health care institution (e.g., hospital or nursing facility).

The HCFA and the PHS have joined with First Lady Hillary Clinton in launching an older women's education campaign to promote the availability of biennial breast cancer mammography screening under the Medicare program. While the benefit has been available for four years, its use has been limited. A full-scale "launch" of this initiative will occur in May, 1995, around Mother's Day.

WELFARE REFORM

On June 14, 1994, President Clinton unveiled his welfare reform proposal, Work and Responsibility Act of 1994, designed to change fundamentally this country's approach to the current welfare system. The proposal would make welfare a transitional system leading to work and would help young mothers move from dependence to independence. The combination of work opportunities, the Earned Income Tax Credit, health care reform, child care, and improved child support would demonstrably improve the lives of millions of women and children.

Women's organizations were actively involved as part of the consultation process around the drafting of the President's welfare reform proposal. The Chairs of the Working Group on

Welfare Reform, Family Support and Independence, Mary Jo Bane, David Ellwood and Bruce Reed, as well as issue group staff, met with a variety of women's groups including representatives from the National Women's Law Center, Wider Opportunities for Women, Institute for Women's Policy Research, Women's Legal Defense Fund, Black Women's Health Project, NOW Legal Defense Fund and Women Work (formerly the National Displaced Homemakers' Network). Involving women's groups in its effort to reform the welfare system will continue to be a priority, as women are one of the main groups affected by the welfare reform initiatives.

FAMILY PRESERVATION AND SUPPORT SERVICES PROGRAM

In August 1993, Congress enacted the Omnibus Budget Reconciliation Act of 1993 which created the Family Preservation and Support Services program, an early Administration initiative. On October 4, 1994, HHS announced the publication of the proposed rule to implement this program. This new program aims to promote family strength and stability, enhance parental functioning, and protect children through funding a capped entitlement for states and eligible Indian Tribes. Over five years, almost \$1 billion is available for the development of comprehensive plans to improve and expand the delivery and coordination of services to children and families.

? Family preservation services typically are activities that help families alleviate crises that might lead to out of home placement of children because of abuse or neglect.

? Family support programs, often provided at the local level by community-based organizations, alleviate stress and help parents care for their children's well-being before a crisis occurs. They connect families with available community resources and supportive networks and include respite care for parents, tutoring, health, and home visiting programs. Funding can be used to develop, establish, expand, and operate family preservation services and community

-based family support services. These services should be directed towards: assuring the safety of all family members, enhancing parents' ability to create safe and nurturing homes that promote healthy child development, assisting children and families to resolve crises, and avoiding unnecessary out

-of

-home placement of children.

All states, 39 Indian Tribes, Puerto Rico, and the District of Columbia have been awarded grants.

CRIME BILL PROGRAM -

-

DOMESTIC VIOLENCE AND VIOLENCE AGAINST WOMEN

President Clinton signed the Crime Bill in September 1994,

strengthening HHS's ongoing efforts to help prevent violence and crime. The Crime Bill authorizes \$1.4 billion to support these programs over the next six years.

These programs include preventive activities that protect women and children, including domestic violence and rape prevention programs. Other HHS programs offer positive alternatives to youth and increased business and employment opportunities for low-income people and communities. HHS involvement in the Crime Bill is reflected in four key provisions of the Bill, only the first of which receives attention here: Domestic Violence and Violence Against Women; Family and Community Schools; National Community Economic Partnership; and the Ounce of Prevention Council.

Domestic violence and violence against women programs will help provide critical services to women who are, or are at risk of becoming, victims of violence in their homes and in the community. A 24-hour, National Domestic Violence Hotline for victims will be established to help women protect themselves and their children. State grant funds will be available for rape prevention and education, information, and assistance programs. Funds will also support the establishment of community- and school-based programs. Authorized funding is in excess of \$500 million.

FAMILY VIOLENCE PREVENTION

The Child Abuse, Domestic Violence, Adoption, and Family Services Act of 1992 (P.L. 102-295) amended and reauthorized the Family

Violence Prevention and Services Act, which was enacted as Title III of the Child Abuse Amendments of 1984 (P.L. 98

-457). Through this legislation, HHS makes grants to State agencies, territories, and Indian Tribes for the provision of shelter services to victims of family violence and their dependents. Family violence prevention and services funds will continue to supplement many of the Crime Bill's provisions to help and educate women and youth. These funds also have allowed states and Tribes to expand current service programs for battered women and establish additional shelters and service centers in rural and underserved areas and on Native American reservations and in Alaskan Native Villages.

State agencies distribute the family violence prevention and services funds at the local level. There are approximately 1,500 shelters for battered women and HHS provides funding for a majority of them. During FY 1994, Family Violence Prevention and Services grants were made to 57 states and territories, and to 80 Native American Tribes and 5 consortia, accounting for a total of 107 awards to Tribes.

HEAD START

On May 18, 1994, the Head Start program was reauthorized and the infant toddler initiative, an outgrowth of the Head Start Advisory Committee on Quality and Expansion, was mandated. HHS is launching an exciting new initiative to provide additional

Federal support to families with infants and toddlers. Beginning in FY 1995, grants will be awarded to provide early, continuous, intensive and comprehensive child development and family support services to low-income families with children under age three. This initiative will consolidate Head Start's existing programs for pregnant women and for families with infants and toddlers. The new initiative will include the Comprehensive Child Development Program and the Parent Child Centers and it will strengthen the Migrant Head Start program. It will also add new resources to create additional new programs to model quality child development and family development services for pregnant women, young children, and their families.

Three percent of Head Start's budget will be set aside for this initiative in FY 1995, 4 percent in FYs 1996 and 1997, and 5 percent in FY 1998.

In FY 1995, the Clinton Administration requested \$4 billion to fund Head Start programs. We received \$3.5 billion, or a \$210 million increase over FY 1994.

CHILD SUPPORT ENFORCEMENT

The Child Support Enforcement program establishes paternity for children. Establishing child support orders and enforcing those orders affect an increasing number of women each year. Within the past five years, the Title IV-D child support caseload has risen from 11.9 million to 17 million. According to recent estimates, about 85 percent of custodial parents are female. Preliminary data from FY 1993 reflect the following: about \$9 billion was collected for child support; \$6.5 billion was collected on behalf of non-AFDC (non-welfare) families; \$453 million was provided to AFDC families as "disregard" payments; about 4.5 million absent parents were located; paternity was established for more than 550,000 children; and more than a million support orders were established.

Final regulations implementing provisions of the Omnibus Reconciliation Act of 1993 with address paternity establishment, medical support provisions, and expanded opportunities for unwed parents to voluntarily acknowledge or otherwise establish paternity in a less complicated and more timely manner.

The Work and Responsibility Act of 1994 also addressed a number of child support issues under three main categories:

- ? Establish awards in every case;
- ? Ensure fair award levels; and
- ? Collect award that are owed.

Proposed demonstrations included child support assurance, mediation, and education about access and visitation issues.

CHILD CARE

HHS has announced the establishment of the Child Care Bureau within the Administration for Children and Families' Administration on Children, Youth and Families (ACYF). This bureau will consolidate and administer all ACF child care programs under one umbrella. Child care is a critical service for women, children and families. This consolidation will allow HHS to coordinate child care services more effectively and to provide leadership on this important issue.

Currently, ACF administers a variety of programs to help low-income families obtain child care services. These include: the Child Care and Development Block Grant; At-Risk Child Care; child care administered under Aid to Families with Dependent Children (AFDC) and Job Opportunities and Basic Skills Training (JOBS); Transitional Child Care; and other child care activities.

In addition, the Clinton Administration requested \$1 billion in the Child Care and Development Block Grant program for FY 1995. This program provides low-income families with the financial resources to find and afford quality child care for their children. Congress actually appropriated \$935 million, a \$42 million increase, or 4.7 percent over FY 1994.

AGING AMERICA, THE INITIATIVE ON OLDER WOMEN
Women comprise 60 percent of today's 65 plus population. By the year 2000, it is expected that there will be five women for every two men over the age of 75. Almost three-quarters of elderly persons living below the poverty line are women -- in 1990 2.7 million women age 65 and over had incomes below the poverty level. Older women tend to be at a disadvantage with respect to income security for a variety of reasons.

The Initiative on Older Women will focus on highlighting the many contributions of older women and will develop an action agenda for addressing their needs in critical areas including income security, health care, domestic violence/elder abuse, housing and caregiving. To these ends, the Administration on Aging (AoA) has:

- ? Developed inter-agency agreements with both the ACF and the Department of Justice to collaborate in efforts against domestic abuse,

- ? Funded an Older Women's Policy and Resource Center at Brandeis University, and

- ? Hosted, in September 1994, a "Celebration of Older Women" honoring the accomplishments of women in public and community service, intergenerational caregiving, and successful aging. Honorees included Senator Barbara Mikulski (D-MD), Representative Connie Morella (R-MD), Maggie Kuhn (founder of the Gray Panthers), and Elizabeth and Sarah Delany (sisters aged 101 who have written a best selling book).

Tab B
HHS Representatives on Women's Issues

Administration on Aging:
Fernando Torres-Gil
Assistant Secretary for Aging
Portia Porter Mittelman
Principal Deputy Assistant Secretary for Aging
Moya Benoit Thompson
Special Assistant to the Assistant Secretary and
Legislative/Public Affairs Liaison
Anna Kindermann

Special Assistant to the Assistant Secretary for Policy and
Legislative Analysis

Public Health Service:

Felicia H. Stewart, M.D.

Deputy Assistant Secretary for Population Affairs

Susan J. Blumenthal, M.D., M.P.H.

Deputy Assistant Secretary for Health (Women's Health)

Ruth Merkat, Ph.D.

Director, Office on Women's Health

Food and Drug Administration

Vivian Pinn, M.D.

Associate Director for NIH for Research on Women's Health

Mary C. Knipmeyer, Ph.D.

Associate Administrator for Women's Services

Substance Abuse and Mental Health Services Administration

Tab C

Key Contacts/Coordinators for Additional Information

Sarah Kovner

Special Assistant to the Secretary

690-6347

Nora Andrews

Policy Coordinator, Office of the Executive Secretary

690-7160

Tab D

Lobby Groups on Women's Issues

See attached

Tab E

Key Issues Being Lobbied

The following is a list of key DHHS lobby issues:

- ? Reauthorization of the Family Planning Program
- ? Emergency Post-coital Contraception -- On November 28, 1994, the Center for Reproductive Law and Policy filed a citizens' petition with the FDA on behalf of several medical groups and health care providers, including the American Public Health Association and Planned Parenthood of New York. The petition urged the FDA to require relabeling of several oral contraceptives for use as morning after pills. The petition argues that FDA's failure to require manufacturers to provide information on such emergency use endangers women's health and increases rates of unintended pregnancy and abortion.
- ? Anti-choice
- ? Women and AIDS/HIV

Tab F: Other Information of Interest

===== END ATTACHMENT 1 =====

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Lisa M. Duffey (CN=Lisa M. Duffey/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME: 2-APR-1997 13:09:44.00

SUBJECT: Science Division Weekly Report -- March 21

TO: Angela Phillips Diaz (CN=Angela Phillips Diaz/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Timothy L. Newell (CN=Timothy L. Newell/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Kerri A. Jones (CN=Kerri A. Jones/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Rosina M. Bierbaum (CN=Rosina M. Bierbaum/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Susanne Bachtel (CN=Susanne Bachtel/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Jonathan Foster (CN=Jonathan Foster/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Henry C. Kelly (CN=Henry C. Kelly/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Jerry M. Melillo (CN=Jerry M. Melillo/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: Clifford J. Gabriel (CN=Clifford J. Gabriel/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TO: John H. Gibbons (CN=John H. Gibbons/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TEXT:
Science Division Weekly Report Page 1 March
21, 1997

March 21, 1997

MEMORANDUM FOR JACK GIBBONS

FROM: CLIFF GABRIEL

SUBJECT: Science Division Report

1. Biennial Science and Technology Report

The Biennial Science and Technology Report has received final clearance from OMB and the West Wing. The report is out for bid for printing. Delivery is expected by 28 March. Distribution and mailing lists for the Congress, Executive branch, media, and non-governmental groups are scheduled to be finished by 26 March.

2. Children,s Initiative

The Children,s Initiative report is now under review by the full NSTC. We currently plan to have the report ready to be released in time for the 17 April White House Conference on the Brain and Early Learning.

3. Fission Research (Nuclear Energy Program at DOE)

To replace the terminating Light Water Reactor Research Program, DOE has proposed a new start called Nuclear Energy Security R&D. The program office has contracted with some knowledgeable experts to review the program plan. Charlie Curtis is expected to move to expand the group to include people outside the fission community and convene it as a SEAB subpanel charged to produce a strategic and restructuring plan for fission R&D. Holdren's PCAST subcommittee will be establishing some big picture context. John Ahearne is on both the DOE review and planning group and the PCAST Energy Panel.

4. Improving Math and Science Education

In his speech to the Michigan legislature on 6 March, the President noted his Directive to the Department of Education and the National Science Foundation to lead an interagency group in identifying and coordinating federal resources, as well as the nonprofit sector, to help students meet high standards in math. The Directive requires recommendations on an action strategy, linked to the current status of improvements in math education. The strategy will be developed with guidance from DPC (staffed by Bill Kincaid) and OSTP (staffed by Daryl Chubin), in 90 days.

A working group comprised of staff from the respective agencies met 7 March and was charged by Mike Cohen. The group agreed that science should be coupled to math, and discussed the activities that address critical areas of need C teaching, curriculum, instructional materials, and technology C to promote world-class teaching and learning in math and science. After the meeting Chubin and Kincaid drafted and circulated a draft framework, which the group discussed at its 14 March meeting. Judy Sunley (NSF) and Tom Corwin (DoEd) will co-chair the working group, which will draft objectives to attach to the four components of the framework, review documents, get briefings, and develop a range of policy levers to be described in the recommendations accompanying the action strategy due to the President in early June. The next meeting is scheduled for 25 March at NSF, when the framework will be updated and a timeline will be distributed.

5. Antarctica

Norm Augustine testified before a special hearing of the full House Science Committee on 12 March 1997. Augustine told Bev Hartline that he remains interested in meeting with the Vice President, to ensure the White House is supportive, and says it is a high priority for him. He expects to release the Panel report in April, which contains 22 findings and 12 recommendations, and supports all the major conclusions of last year's NSTC study. Regarding the South Pole Station, the Panel is recommending that it be replaced with a \$120 million station, to be built between FY 1998 and FY 2002. The Panel recommends that over this period \$95 million needs to be added to NSF's budget, with the remainder of the costs borne by the scientific program through cost savings and a temporary reduction. The \$95 million includes the \$25 million in the FY 1998 budget request, and peaks with a need for \$33 million in FY 1999. Committee members (Gordon, TN, and Bartlett, MD) expressed interest in allowing manufacturers of products used successfully in Antarctica to advertise this performance and pay the government for the privilege. Other questions addressed prioritization of the science, funding and scope of the South Pole replacement station, and the geopolitical importance of our presence in Antarctica. Finally, on 13 March, Secretary of State Madeleine Albright sent a letter to Congress reaffirming State Department support for an active and influential U.S. presence in Antarctica.

6. Cloning/NBAC

Media coverage of the President's ban on cloning human beings has been positive. There also has been strong recognition of the importance of biomedical applications of cloning technology.

NBAC has an ambitious schedule of meetings in order to respond to the President's request for advice on cloning of human beings by the end of May. Rachel Levinson has been attending the meetings. At the 13-14 March meeting, PETA representatives took over the podium briefly to protest unethical treatment of animals posed by the reported new cloning technology. The interagency response to the Advisory Committee on Human Radiation Experiments is tentatively scheduled for release on 28 March, with Secretaries Shalala and Peña in attendance. Format is not yet finalized. NBAC is mentioned in background material.

7. Gulf War

The Presidential Advisory Committee met this week in Salt Lake City. The majority of the discussion and testimony focused on possible low level exposure to chemical weapons following the demolition of the ammunition storage depot in Khamisiyah. CIA reported that early modeling efforts showed the downwind plume to extend up to 170 miles, which is far greater than previously reported. Both CIA and DOD stressed that there is much uncertainty associated with this model, however. DOD stood by its claim that the 50 kilometer radius from the demolition site is a more realistic distance for exposure and has based its notification efforts accordingly. The PRD on military health preparedness is still under review. We have received concurrences from VA, DOD, OMB, and HHS, and we are still waiting to hear from the NSC.

8. Research Misconduct Update

Almost all of the major agencies that conduct R&D have been briefed on the proposed research misconduct policies. Sybil Francis briefed the Department of Energy on 27 February and the Department of Education on 5 March. We have received written responses to the proposed policies from HHS, USDA, and NASA and expect responses from DOD, NSF, and DOE in the next week or so. We are scheduling a briefing for the Department of Transportation sometime in the next month.

9. University Event

On 3 March, the Science Division hosted a meeting between members of the Science Coalition and representatives from major S&T agencies. Approximately 60 representatives from universities and professional societies were in attendance and listened to presentations and discussions on agency FY98 budgets. Agency representatives included Neal Lane (NSF), Wendy Baldwin (NIH), Jim Decker (DOE), Bob Robertson (USDA), Andy Crawson (DOD), and Jack Fellows (OMB).

10. Federal Lab Review

The draft status report on the Federal Laboratory Review has been distributed to OSTP ADs, OMB, agency reps from DOD, DOE, and NASA for review before it will be finalized and transmitted to you this month. Comments have been received from DOD, DOE, NASA, and OMB (Energy).

11. National Research Council Board on Physics and Astronomy

As part of its decadal survey of physics, the Board on Physics and Astronomy is planning to emphasize education in physics. Major topics to be addressed include K-12 education, educating undergraduate non-physics majors, and undergraduate and graduate training for physics majors. Leon Lederman is chairing this subgroup, and is planning a meeting in Washington, DC in April or May. The Board's next meeting will be at the NRC's Georgetown Facility on 25-26 April, and will include a seminar at 4 pm 25 April by Wolfgang Ketterle (MIT) on the atom laser he demonstrated recently.

12. Russian Gallium

The 60 tons of gallium used for the SAGE neutrino experiment continues to be under pressure. We are informed that Minister Fortov obtained a 10-day delay in the transfer, which should have expired in mid-March. This gallium is extremely pure and it would be a substantial loss to science if it were sold for commercial purposes.

13. EMF RAPID (Research and Public Information Dissemination Program)

The Federal EMF Interagency committee met 18 March. This group is planning a series of Science Review Symposia, and is concerned about Congressional action on funding and extension of RAPID's mandate for the legislated five years (through 1998), and will draft a letter to you. The first symposium focuses on in vitro research, and will occur next week in North

Carolina. No one from OSTP plans to attend. The draft letter to you refers to the group's plans for its completion phase (now through 1998) and points out that the recent NRC report recommends that additional research is needed, although media coverage deemphasized this aspect.

14. Corn Genome Initiative

On Wednesday, I met with congressional staff and members of the National Corn Genome Initiative and discussed their interest in establishing a \$143 million program over five years to map and sequence the corn genome. Senators Bond and Harkin are strong supporters of this Initiative and will put forward authorizing language and will attempt to earmark \$10 million from the Agricultural Research Service in FY98.

15. NSF Authorization Hearings (House Science Subcommittee on Basic Research)

NSF Authorization Hearing (House) * March 5, 1997

The Hearing was chaired by Ehlers (MI), and attended by Barcia (MI), Rivers (MI), Doyle (PA), and Luther (MN). Neal Lane (accompanied by Joe Bordogna) and Richard Zare (NSB Chair) testified. Areas of member concern included NSF's very small share of Next Generation Internet, successful management of NGI given that five agencies have to cooperate, avoiding cost overruns on facilities construction, and the planned reduction from four, to two, high end supercomputer centers (selection in progress now). Areas of interest included Zare's indication that the NSB planned to take a greater role in science policy, criteria used to determine that a research area is ready to be turned over to the private sector with public funding phasing out, and whether or how NSF factored social, ethical, and religious factors into its proposal selection process (constituent concern). An additional NSF authorizing hearing is scheduled on major initiatives * the MMA, Polar Cap Observatory, NGI, and supercomputer centers (9 April).

NSF Authorization Hearing (House Science Subcommittee on Basic Research): Math, Science and Engineering Education Programs) March 17, 1995

The 90-minute hearing featured four outside witnesses and was a veritable testimonial to NSF's catalytic effect on science, math, and technology teaching and learning, Kindergarten through undergraduate. NSF was lauded not only for providing project support, but moreover, for projecting a vision of high standards and coordination, and imposing discipline on performers by demanding results, expecting capacity-building system-wide, encouraging leveraging across sectors and organizations, and disseminating and evaluating practices and models that work in various K-12, community college, and university classrooms. Eight different NSF programs were lauded by name. The six Members present were all supportive, with Boehlert lamenting the modest increases in the FY 98 budget proposal for pre K-12 programs (and blaming OMB, not NSF). Other issues raised included the teaching-research tradeoff among university faculty, assurance of wide access to innovative NSF-funded materials, the woeful preparation of teachers in physical science, and the value of magnet schools.

16. Revision of OMB Circular A-21

As promised in February 1995, OMB intends to publish for comment proposed revisions to A-21 by 1 July. Rachel was briefed by OMB on 20 March on the current version of points to be addressed in the notice. OMB will convene a small group of agency representatives next week to discuss the proposed revisions. OSTP will participate in an informal discussion with university reps on 3 April, to which you are invited. We will plan a briefing for the Committee on Fundamental Science in the near future.

Outreach

Gabriel

On 27 March, I will present an OSTP perspective on S&T priorities to the USDA Research, Economics and Education Advisory Committee.

Hartline

Bev Hartline spoke about Building Jefferson Lab: A New Facility in the US Science Portfolio at Virginia Commonwealth University on 7 March 1997.

On 10 March she met with the Laboratory Advisory Committee for the Pacific Northwest National Laboratory, chaired by Governor Celeste. The committee was meeting in Washington to learn from various people in the Administration and Congress about "Perspectives on Federal Priorities, Policies, and Programs." The advisory committee members were particularly interested in the PCAST energy study; the use of outcome measures and incentives to promote productivity and excellence at the labs; partnerships; issues associated with universities, graduate studies, and international student enrollment; the Congressional response to Administration budget increases in areas Congress has termed 'industrial welfare'; and ways to make the resources of each national lab available nationally.

On 13 March she visited the Naval Research Lab with Tom Fuhrman (NSIA), and they received informative briefings and lab tours sampling structural chemistry, plasma-sheet radar mirrors, molecular beam epitaxy and surface analysis, fiberoptic sensors, nanometer-scale technology, and chemical-specific microsensors.

Levinson

On 13 March, Rachel spoke about biotechnology at the East-West Initiative, a bipartisan Congressional effort to brief high-tech industry representatives on relevant government activities.

Chubin

Chubin presented a lunch time talk 4 March to an NSF workshop on AA Perspective on Graduate Education. The talk focused on the role of the federal agencies in human resource development, K-graduate school, and included notice of the human resources chapter in the biennial S&T report and of the university-federal partnership PRD, particularly the examination of stresses in graduate education. On 14 March, Chubin presented a policy overview and moderated a panel at the Sloan Foundation-Commission on Professionals in Science and Technology Workshop on
& Postdocs and Career Prospects,⁸ held at AAAS.

cc: Associate Directors
Angela Phillips Diaz
Tim Newell
Jon Foster

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:18-APR-1997 17:51:16.00

SUBJECT: clarification of current legal prohibitions

TO: nbac-members (nbac-members @ lists.princeton.edu @ inet [UNKNOWN])
READ:UNKNOWN

TEXT:

Last Sunday, it was suggested that some clarification of the current prohibitions on human embryo research might be useful. Hope this helps. Please note: Congressional approps. language expires at the end of this fiscal year and applies only to DHHS. The President's prohibition has no time limit and, although it is not clear, I am assuming that it covers other agencies in addition to NIH.

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

Human Embryo Research

On December 2, 1994, the President directed NIH not to allocate Federal funds for the "creation of human embryos for research purposes." Congress addressed this issue in DHHS's FY 96 and FY 97 Appropriations bills. The legislative language codifies the President's ban and extends the prohibition to cover "research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero" (P.L. 104-91 and P.L. 104-208). Because it appears in an appropriations bill, this language expires September 30, 1997, unless reintroduced and passed in another bill. The second provision of the Congressional ban addresses research on all human embryos and prohibits a larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

The second provision applies to embryos the same standards that are currently in place for research involving human fetuses. Research involving human fetuses is governed under DHEW 45 CFR part 46.208(a), "No fetus in utero may be involved as a subject in any activity covered by this subpart unless: (2) The risk to the fetus imposed by the research is minimal, and the purpose of the activity is the development of important biomedical knowledge

e which cannot
be obtained by other means." Minimal risk is defined as, "The probability and
magnitude of
harm or discomfort expected in the research is no greater in and of themselves
than those
ordinarily encountered in daily life or during the performance of routine physi
cal or
psychological examinations or tests." Therefore, research that would involve m
anipulation
of the preimplantation embryo that might result in its death, injury, or harm,
is precluded
under the Congressional ban, regardless of the source of the embryo.

Taken in sum, these provisions prohibit virtually all human embryo researc
h that might
be conducted with Federal funds. Due to the large demand for in vitro fertiliz
ation to circumvent
certain male and female causes of infertility, there is considerable work under
way in this area in
the private sector, funded by patients. There are no standards in place govern
ing such
procedures, other than FDA requirements for approval of the component drugs and
devices.

===== END ATTACHMENT 1 =====

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Rachel_E._Levinson@oa.eop.gov (Rachel_E._Levinson@oa.eop.gov [UNKNOWN])

CREATION DATE/TIME:18-APR-1997 18:02:16.00

SUBJECT: clarification of current legal prohibitions

TO: nbac-members@lists.Princeton.EDU (nbac-members@lists.Princeton.EDU [UNKNOWN])

READ:UNKNOWN

TEXT:

Message Creation Date was at 18-APR-1997 17:55:00

Last Sunday, it was suggested that some clarification of the current prohibitions on human embryo research might be useful. Hope this helps. Please note: Congressional approps. language expires at the end of this fiscal year and applies only to DHHS. The President's prohibition has no time limit and, although it is not clear, I am assuming that it covers other agencies in addition to NIH.

The following attachments were included with this message:

TYPE : FILE
NAME : EMBRYO.TXT

Subject: EMBRYO
MIME-version: 1.0
Content-type: TEXT/PLAIN; CHARSET=US-ASCII
A1-type: DOCUMENT
Human Embryo Research

On December 2, 1994, the President directed NIH not to allocate Federal funds for the "creation of human embryos for research purposes." Congress addressed this issue in DHHS's FY 96 and FY 97 Appropriations bills. The legislative language codifies the President's ban and extends the prohibition to cover "research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero" (P.L. 104-91 and P.L. 104-208). Because it appears in an appropriations bill, this language expires September 30, 1997, unless reintroduced and passed in another bill. The second provision of the Congressional ban addresses research on all human embryos and prohibits a larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

The second provision applies to embryos the same standards that are currently in place for research involving human fetuses. Research involving human fetuses is governed under DHEW 45 CFR part 46.208(a), "No fetus in utero may be involved as a subject in any activity covered by this subpart unless: (2) The risk to the fetus imposed by the research is minimal, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means." Minimal risk is defined as, "The probability and magnitude of harm or discomfort

expected in the research is no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Therefore, research that would involve manipulation of the preimplantation embryo that might result in its death, injury, or harm, is precluded under the Congressional ban, regardless of the source of the embryo.

Taken in sum, these provisions prohibit virtually all human embryo research that might be conducted with Federal funds. Due to the large demand for in vitro fertilization to circumvent certain male and female causes of infertility, there is considerable work under way in this area in the private sector, funded by patients. There are no standards in place governing such procedures, other than FDA requirements for approval of the component drugs and devices.

RECORD TYPE: FEDERAL (NOTES MAIL),

CREATOR: bkramers@worldnet.att.net (bkramers@worldnet.att.net [UNKNOWN])

CREATION DATE/TIME: 4-FEB-1998 20:07:38.00

SUBJECT: Re: fda jurisdiction over cloning -Reply

TO: nbac-members@lists.Princeton.EDU (nbac-members@lists.Princeton.EDU [UNKNOWN])

READ:UNKNOWN

TEXT:

WILLIAM RAUB wrote:

>

> Note to Betty Kramer:

>

> In an exchange of comments with Alta, you wondered whether FDA has
> or might assert jurisdiction regarding genetic tests. The answer to
both > is "yes".

>

> Under the medical-device statute, FDA now regulates those genetic tests
> that are packaged as kits. The process involved is essentially
identical to > the premarket review for other in-vitro diagnostic devices
and is similar in > many regards to the premarket review for drugs and
biologics.

>

> To date, FDA has not exerted what it views as its latent authority
(again > via the device statute) to regulate those genetic tests that are
offered as

> services but not packaged as kits (including the so-called "home
> brews"). That may change in the near future. In response in part to the
> recommendations of a Task Force convened under the auspices of the
> Human Genome Project, the FDA later this year may issue a Notice of
> Proposed Rule-Making that, if subsequently enacted as a regulation,
> would make genetic-testing services as well as kits subject to FDA
> oversight.

>

> Further, any FDA action must occur within a larger context; for
regulation > of genetic testing is a DHHS-wide issue. The primary reason
is that, in > addition to the FDA role, HCFA and CDC are involved through
the Clinical

> Laboratory Improvement Amendments of 1992 (CLIA). In particular, the
> "analytic validity" of genetic tests offered by clinical laboratories
already > is subject to CLIA-based rules.

>

> I chair an interagency work group within the DHHS to develop a
> "regulation lite" approach to the burgeoning field of genetic testing.
Our > goal is to effect a coordinated use of three extant authorities [
medical

> devices (FDA), clinical laboratories (CDC and HCFA), and
> human-subjects protection (NIH and FDA)] in a way that protects the
> public from flawed tests and unscrupulous testers while fostering
> continued research, development, evaluation, and commercialization in

> this area, which holds so much promise for medicine and health.

>

> Lily Engstrom and I would be pleased to discuss this further with you

> and other Commissioners if you would find that helpful.

Bill--Thank you very much for your response. In your closing paragraph, you state that the "regulation lite" approach would protect the public "from flawed tests and unscrupulous testers". This does/does not include diagnostic tests for which there is no therapeutic remedy? This is an area that concerns me greatly because I see in conversations with people that they assume the existence of a test for a genetic mutation includes a known therapy. Would your work group plan to address this as well or does that remain an uncovered area? Thank you. Bette Kramer

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Carol Greider <cgreider@jhmi.edu> (Carol Greider <cgreider@jhmi.edu> [UNKNOWN])

CREATION DATE/TIME:14-JAN-1999 09:46:39.00

SUBJECT: Re: stem cells from fetal tissue

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

>my brain is tickled by the thought that the problem with using stem cells
>from fetal germ cells might have to do with the fact that imprinting is
not
>complete yet; carol, can you help me get this right?

I'm not sure what you are asking exactly.

Currently there are two published ways to derive human "ES cells" from
EITHER early human embryos OR from fetal germ cells. Once derived an ES
cell is an ES cell. If it has the property of being able to contribute to
all of the cell types in an embryo when injected it is 'pluripotent'.

Since the experiment has not been done with humans to determine if these
cells can contribute to all tissues (And probably SHOULD not be done), we
will not know for sure exactly what tissue they can and can not contribute
to in an adult human. However that is not a problem as long as they can be
differentiated in vitro to form the cells needed for a particular therapy
that is all that is needed for most proposed medical treatment uses.

I am not sure that anything is known about the degree of imprinting in the ES
cells derived from blastocytes vs those from primordial Germ cells. It is
also not clear to what degree proper imprinting might be needed for the
cell based therapies that have been proposed.

Hope that helps.
Carol

Carol W. Greider, Ph.D.
Associate Professor
Department of Molecular Biology and Genetics
Johns Hopkins University School of Medicine
617 Hunterian Building
725 N. Wolfe Street
Baltimore, MD 21205

e-mail: cgreider@jhmi.edu
phone: (410) 614-6506

fax: (410) 614-2987

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME:30-JUN-1999 13:05:30.00

SUBJECT: RE: suggestion for chapter 3

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Thanks Carol....

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Carol Greider [SMTP:cgreider@jhmi.edu]
Sent: Wednesday, June 30, 1999 12:24 PM
To: NBAC Members E-list
Subject: suggestion for chapter 3

NBAC-

Harold asked me to look at where in the report things needed to be changed to address my concern that IVF created embryos and SCNT embryos are not the same.

I made a number of suggestions about changes in chapter 2 and chapter 6 yesterday on the computers at the meeting. I realized however, reading the report again on the way home, that chapter 3 also has a section on SCNT. I suggest omitting from page 20 line 19 to the end of that section. I have written an alternative section that follows below.

I am also Faxing some additional minor changes to Kathi in chapter 3 that address this issue. any suggestions or revisions to this text is welcome.

Somatic cell nuclear transfer of a diploid nucleus into an oocyte

has also been suggested as a method to generate embryos from which ES cells could be derived. Tissues derived from such cells would be useful in avoiding graft rejection if the donor nucleus were taken from the patient who will receive the tissue. While fertilization of an egg with a sperm in vitro clearly results in a human zygote that will divide to become an embryo, and has the potential to develop into a human if implanted, it is less clear whether the embryo created by SCNT has that potential. The fact that this technique can produce living animals such as sheep and cows argues that it is likely that the cell which results from insertion of an adult nucleus into an oocyte is a zygote and can become an embryo. However some have argued that it is not clear that a zygote produced in this manner is similar to an embryo created by fertilization since there are significant differences in the ability to generate different animals in these experiments and we do not know the potential of the human cell. Because NBAC and others have concluded that there are moral concerns that should preclude the generation of a child by SCNT at this time (ref cloning report), it is not possible to know whether the cell created in this manner has the potential to become a human. Because of the previous animal work showing the potential of SCNT to create an animal in some situations, many would argue that similar concerns about the creation of embryos for research purposes apply to embryos created by SCNT. Thus because of moral concerns outlined above about the creation of life for research purpose only, this category of research is disturbing to some people. Research in the future however may define conditions under which SCNT can be carried out while culturing the cells in such a manner that the resulting cell is immediately directed to differentiate into a specific tissue and thus preclude further development into an embryo. Thus perhaps, in the future, it will be possible to use SCNT into an oocyte without the creation of an embryo.

One major distinction between IVF and SCNT embryos is that while creation of embryos by IVF would only generate more embryos, generation of embryos by SCNT would generate a specific kind of cell which might be very useful in treating disease by allowing autologous transplant of a specific tissue type. Thus in balancing issue of moral concern over the creation of

an
embryo and the value to society of the SCNT embryo, the potential
therapeutic
value uses of ES cells from SCNT embryos needs to be evaluated carefully.
At the
present time there is not sufficient scientific evidence to evaluate this
potential, however within the next several years such information should
accumulate.

Carol W. Greider, Ph.D.
Professor
Department of Molecular Biology and Genetics
Johns Hopkins University School of Medicine
617 Hunterian Building
725 N. Wolfe Street
Baltimore, MD 21205

e-mail: cgreider@jhmi.edu
phone: (410) 614-6506
fax: (410) 614-2987

There is something fascinating about science. One gets such
wholesale
returns of conjecture out of such a trifling investment of fact.

- Mark Twain

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Bernard Lo, M.D." <bernie@itsa.ucsf.edu> ("Bernard Lo, M.D." <bernie@itsa.ucsf.edu> [UNKNOWN])

CREATION DATE/TIME:16-JUL-1999 13:36:33.00

SUBJECT: Comments on recommendations

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

I agree with the amendments suggested by Steve, Diane, Larry, and Jim, as well as Carol's section.

I have a few suggestions; since I was unable to attend on Wed, I apologize if some of these ideas may have already been discussed.

In #6, rather than restrict, should we say designate. It seems that the concern is naming an individual to receive the ES cells, not excluding people (such as left-handed, green haired persons).

In #7, can we say something about the sale of embryos from infertility treatments? As written, it seems that the embryos may refer only to embryos from fetal cadavers. Perhaps "embryos from all sources," so that we include those created specifically for research in the private sector as well. This may be going beyond what was discussed Wed; if so, my apologies for missing the discussion. Because of the high costs of infertility treatment, selling "excess" embryos is a real concern; this could be discussed in the commentary.

In #12, in the commentary, it would be good to particularly highlight informed consent by women who are providing oocytes that are used in the derivation of research embryos. Many of the recommendations in #5 can be applied in this context as well.

Bernard Lo, M.D.
Professor of Medicine
Room C-126
521 Parnassus Ave.
University of California San Francisco
San Francisco, CA 94143-0903
Ph: 415-476-5370
Fax: 415-476-5020

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME:16-JUL-1999 13:53:03.00

SUBJECT: RE: Comments on recommendations

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Thanks for the comments Bernie.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Bernard Lo, M.D. [SMTP:bernie@itsa.ucsf.edu]
Sent: Friday, July 16, 1999 1:34 PM
To: NBAC Members E-list
Subject: Comments on recommendations

I agree with the amendments suggested by Steve, Diane, Larry, and
Jim,
as

well as Carol's section.

I have a few suggestions; since I was unable to attend on Wed, I
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Bernard Lo, M.D.

Professor of Medicine

Room C-126

521 Parnassus Ave.

University of California San Francisco

San Francisco, CA 94143-0903

Ph: 415-476-5370

Fax: 415-476-5020

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Kathi E. Hanna" <khanna@chesapeake.net> ("Kathi E. Hanna" <khanna@chesapeake.net> [UNKNOWN])

CREATION DATE/TIME: 6-SEP-1999 22:02:36.00

SUBJECT: FOOTNOTE/PERSONAL STATEMENT FROM ALEX CAPRON

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Alex has requested that the following personal statement be placed in chapter 4 of the report. Alex, if I have any of this wrong, please let me know by noon tomorrow (Tuesday, 9/7).

Thanks, Kathi

TEXT FROM CHAPTER 4, TO HELP YOU FIND WHERE THE ASTERISK/FN GOES:

[3] Synergy from a Combined Federal Effort for Research Involving Use and Derivation. [CHAPTER 4, PAGE 29]

Federal funding provides the opportunity for collaboration and coordination

among a much larger group of researchers. Moreover, the availability of federal funding would likely increase greatly the number of scientists carrying out ES and EG cell research and thus increase the chance of important findings. Federal support for research will encourage basic research on the biology of stem cells, in addition to the product-oriented research typically supported by biotechnology firms that are focused on developing marketable products. However, in the long run, advances in the basic biology of stem cells-e.g., increased understanding of the conditions and signals that lead stem cells to differentiate or of the detailed mechanisms of differentiation- are essential for therapeutic advances. Such basic research will require long-term efforts, which traditionally have been

supported by NIH. PUT ASTERISK/FN HERE.

THEN ASTERISK/FN WOULD READ

Commissioner Capron notes that as described it is likely that this limited exception to the ban would allow the federal government to better enforce the distinction between research using embryos that are being discarded after infertility treatments and using embryos that were created solely for research purposes. Of course, even if NIH funds only "use" research, it could still try to require that the ES cells used not be derived from embryos created for research purposes. But its moral leverage is undermined by its own rationale: By insisting that federal funding of research using human ES cells does not implicate federal sponsors in the process by which the ES cells have been derived, it limits its ability to mandate that one process rather than another be used. Plainly, federal law could restrict

federal support to activities that do not, for example, cause unlawful pollution; by extension, the limitation could extend to activities that do not purchase materials that were produced in processes that pollute. In the present case, however, the appropriations rider bans federal support for research that creates or destroys human embryos, which means that a federal agency cannot claim to be implementing federal policy were it to limit funding to research that uses only those ES cells that were derived from discarded embryos but not from embryos created for the purpose of deriving ES cells. Thus, NIH may be hard pressed to justify differentiation based on the type of embryos from which ES cells are derived, thereby losing an opportunity to oversee the derivation process directly and to enforce an important ethical distinction. Adopting a limited exception to the embryo research ban solely for research to derive ES cells from embryos remaining from fertility programs would also avoid relying on the theoretical line between derivation and use research that underlies the NIH policy. Such a line is difficult to defend in practical terms when the question is not whether an activity is inherently licit or illicit but whether it ought to be paid for with federal research dollars. Any such line is merely theoretical because the funding provided for research using ES cells would of course flow directly to researchers deriving those cells, perhaps even in an adjacent laboratory. The only difference would be that the federal funds would not go directly as salary and laboratory expenses for the derivation process but indirectly in the form of funds to purchase the ES cells (which funds would then pay salaries, laboratory expenses, and so forth).

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Larry Miike <lhmiike@aloha.com> (Larry Miike <lhmiike@aloha.com> [UNKNOWN])

CREATION DATE/TIME: 7-SEP-1999 01:08:46.00

SUBJECT: Re: FOOTNOTE/PERSONAL STATEMENT FROM ALEX CAPRON

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

I request that the footnote be changed slightly to make it clear that the entire text is from Alex; currently, it could be interpreted that the first sentence is attributed to Alex, with the rest as a commission opinion. Therefore, I recommend that the footnote begin along the following lines: Commissioner Capron makes the following observations: " ." In other words, after the introductory phrase, enclose the entire rest of the footnote in quotation marks.

larry

----- Original Message -----

From: Kathi E. Hanna <khanna@chesapeake.net>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Sent: Monday, September 06, 1999 4:02 PM

Subject: FOOTNOTE/PERSONAL STATEMENT FROM ALEX CAPRON

>

> Alex has requested that the following personal statement be placed in
> chapter 4 of the report. Alex, if I have any of this wrong, please let me
> know by noon tomorrow (Tuesday, 9/7).

>

> Thanks, Kathi

>

> TEXT FROM CHAPTER 4, TO HELP YOU FIND WHERE THE ASTERISK/FN GOES:

>

> [3] Synergy from a Combined Federal Effort for Research Involving Use
and

> Derivation. [CHAPTER 4, PAGE 29]

> Federal funding provides the opportunity for collaboration and
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> among a much larger group of researchers. Moreover, the availability of

> federal funding would likely increase greatly the number of scientists

> carrying out ES and EG cell research and thus increase the chance of

> important findings. Federal support for research will encourage basic

> research on the biology of stem cells, in addition to the
product-oriented

> research typically supported by biotechnology firms that are focused on

> developing marketable products. However, in the long run, advances in the

> basic biology of stem cells-e.g., increased understanding of the
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> and signals that lead stem cells to differentiate or of the detailed

- > mechanisms of differentiation- are essential for therapeutic advances.
- Such
- > basic research will require long-term efforts, which traditionally have been
- > supported by NIH. PUT ASTERISK/FN HERE.
- >
- > THEN ASTERISK/FN WOULD READ
- >
- > Commissioner Capron notes that as described it is likely that this limited
- > exception to the ban would allow the federal government to better enforce
- > the distinction between research using embryos that are being discarded
- > after infertility treatments and using embryos that were created solely for
- > research purposes. Of course, even if NIH funds only "use" research, it
- > could still try to require that the ES cells used not be derived from
- > embryos created for research purposes. But its moral leverage is undermined
- > by its own rationale: By insisting that federal funding of research using
- > human ES cells does not implicate federal sponsors in the process by which
- > the ES cells have been derived, it limits its ability to mandate that one
- > process rather than another be used. Plainly, federal law could restrict
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- > and laboratory expenses for the derivation process but indirectly in the
- > form of funds to purchase the ES cells (which funds would then pay
- salaries,
- > laboratory expenses, and so forth).
- >
- >
- >

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Annette Heath <aheath@etcrier.net> (Annette Heath <aheath@etcrier.net> [UNKNOWN])

CREATION DATE/TIME: 17-FEB-2000 11:52:26.00

SUBJECT: In Vitro Fertilization

TO: law-lib@ucdavis.edu (law-lib@ucdavis.edu [UNKNOWN])

READ: UNKNOWN

TEXT:

I have an attorney looking for a contract form between a doctor (has control of the eggs) and the patient who will receive them. We have looked California Legal Forms and Am Jur Legal Forms. In both sets we were only able to locate forms dealing with artificial insemination. Any suggestions of examples would be appreciated.

Thank you
Annette Heath
Kern County Law Library
Bakersfield, CA
aheath@etcrier.net

- att1.htm===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

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<STYLE></STYLE>
</HEAD>
<BODY bgColor=#ffffff>
<DIV><FONT size=2>I have an attorney looking for a contract form between a
doctor (has control of the eggs) and the patient who will receive them. W
e
have looked California Legal Forms and Am Jur Legal Forms. In both sets w
e
were only able to locate forms dealing with artificial insemination. Any
suggestions of examples would be appreciated.</FONT></DIV>
<DIV> </DIV>
<DIV><FONT size=2>Thank you</FONT></DIV>
<DIV><FONT size=2>Annette Heath</FONT></DIV>
<DIV><FONT size=2>Kern County Law Library</FONT></DIV>
<DIV><FONT size=2>Bakersfield, CA</FONT></DIV>
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href="mailto:aheath@etcrier.net">aheath@etcrier.net</A></FONT></DIV>
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```

===== END ATTACHMENT 1 =====

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Gayle O'Connor <goconnor@courtlink.com> (Gayle O'Connor <goconnor@courtlink.com> [UNKNOWN])

CREATION DATE/TIME:17-FEB-2000 12:28:06.00

SUBJECT: RE: In Vitro Fertilization-REPLY

TO: law-lib@ucdavis.edu (law-lib@ucdavis.edu [UNKNOWN])

READ:UNKNOWN

TO: 'Annette Heath' <aheath@etcrier.net> ('Annette Heath' <aheath@etcrier.net> [UNKNOWN])

READ:UNKNOWN

TEXT:

This form may be of help. <http://www.ivf.com/ivfpr.html>
<<http://www.ivf.com/ivfpr.html>>

Gayle O'Connor, Legal Industry Marketing Specialist
CourtLink
electronic access to our nation's court records

telephone: 425 - 974 - 5000 x243
facsimile: 425 - 974 - 1419
mailto:goconnor@courtlink.com <mailto:goconnor@courtlink.com>
<http://www.courtlink.com/> <<http://www.courtlink.com/>>

-----Original Message-----

From: Annette Heath [mailto:aheath@etcrier.net]
Sent: Thursday, February 17, 2000 8:35 AM
To: law-lib@ucdavis.edu
Subject: In Vitro Fertilization

I have an attorney looking for a contract form between a doctor (has control of the eggs) and the patient who will receive them. We have looked California Legal Forms and Am Jur Legal Forms. In both sets we were only able to locate forms dealing with artificial insemination. Any suggestions of examples would be appreciated.

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Annette Heath
Kern County Law Library
Bakersfield, CA
aheath@etcrier.net <mailto:aheath@etcrier.net>

- att1.htm===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

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<META content="MSHTML 5.00.2314.1000" name=GENERATOR>

<STYLE></STYLE>

</HEAD>

<BODY bgColor=#ffffff>

<DIV><SPAN

class=480340317-17022000><SPAN

class=100315416-17022000>This form may be of help. http://www.ivf.com/ivfpr.html</

FONT></DIV>

<DIV> </DIV>

<P>Gayle O'Connor, Legal

Industry Marketing Specialist
<FONT color=#ff0000

face="Times New Roman" size=2>Court<FONT color=#000080

face="Times New Roman" size=2>Link
<I><FONT color=#000080

face="Times New Roman" size=2>electronic access to our nation's court

records</I> </P>

<P>telephone: 425 - 974

- 5000 x243
<FONT color=#000000 face="Times New Roman"

size=2>facsimile: 425 - 974 - 1419
<U><FONT color=#0000f

f

face="Times New Roman" size=2>mailto:goconnor@courtlink.com</

U>

<U><A

href="http://www.courtlink.com/"

target=_blank>http://www.courtlink.com/</U> </P>

<BLOCKQUOTE

style="BORDER-LEFT: #000080 2px solid; MARGIN-LEFT: 5px; MARGIN-RIGHT: 0px; PAD
DING-LEFT: 5px">

<DIV align=left class=OutlookMessageHeader dir=ltr><FONT face=Tahoma

size=2>-----Original Message-----
From: Annette Heath

[mailto:atheath@etcrier.net]
Sent: Thursday, February 17, 2000 8:35

AM
To: law-lib@ucdavis.edu
Subject: In Vitro

Fertilization

</DIV>

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<DIV> </DIV>

<DIV>Thank you</DIV>

<DIV>Annette Heath</DIV>
<DIV>Kern County Law Library</DIV>
<DIV>Bakersfield, CA</DIV>
<DIV>ah Heath@et crier.net</DIV>
<DIV> </DIV></BLOCKQUOTE></BODY></HTML>

===== END ATTACHMENT 1 =====

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "NIH OLIB (OD)" <olib@OD.NIH.GOV> ("NIH OLIB (OD)" <olib@OD.NIH.GOV> [UNKNOWN])

CREATION DATE/TIME:30-OCT-2000 17:30:10.00

SUBJECT: FERTILITY RESEARCHERS DISCOVER NEW GENE ESSENTIAL FOR FEMALE FERTILITY

TO: HHS PRESS@LIST.NIH.GOV (HHS PRESS@LIST.NIH.GOV [UNKNOWN])

READ:UNKNOWN

TEXT:

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

NIH NEWS RELEASE

EMBARGOED BY JOURNAL

Monday, October 30, 2000

5:00 p.m. EST

Contact:

Robert Bock

(301) 496-5133

FERTILITY RESEARCHERS DISCOVER NEW GENE ESSENTIAL FOR FEMALE FERTILITY

Fertility researchers at the National Institute of Child Health and Human Development (NICHD) have found that a gene in female mice is essential for their egg cells to later develop beyond the two-cell stage after fertilization. This finding could lead to new insights into the causes of unexplained infertility in women. The finding may also provide an important lead for developmental biologists studying how an organism progresses from a single cell to a complex organism.

Zhi-Bin Tong, M.D, and his colleagues at NICHD's Developmental Endocrinology Branch published their findings in the November issue of "Nature Genetics". The researchers reported the discovery of the gene itself in a previous paper. In the current study, the researchers reported on the function of the gene -- showing that female mice must have the gene to enable their early embryos to develop normally. This is the first report in mammals that a substance produced by the mother controls the development of her offspring. The gene is called "Mater" (pronounced mah-ter), short for "maternal effect" gene.

"It is remarkable that such a fundamental secret of nature

was uncovered as a direct result of clinical research into the causes of infertility," said Duane Alexander, M.D., Director of the NICHD. "The discovery opens up promising new areas not just in developmental biology, but in the search for causes of unexplained infertility."

The researchers have been studying premature ovarian failure, a condition that causes infertility and hormone deficiency in otherwise healthy young women, according to the leader of the research team and the study's senior author, Lawrence Nelson, M.D., of NICHD's Developmental Endocrinology Branch. Premature ovarian failure is a condition that causes infertility and hormone deficiency in otherwise healthy young women. The discovery was a byproduct of research into the origin of "autoimmune" premature ovarian failure in mice. These mice destroy their own ovaries by sending out an immune attack against them. The product of the "Mater" gene is the target of the immune attack.

To determine the function of the protein the "Mater" gene codes for, the researchers developed a strain of mice that lacked both copies of the gene. The researchers developed the mice using "knockout" technology, which allows them to eliminate genes from an organism. According to Dr. Nelson, the resulting female mice develop normally, yet are infertile. In the "Nature Genetics" paper, the researchers reported breeding the mice with genetically normal male mice. As expected, the resulting fertilized eggs divided to form two cells. However, Dr. Nelson said, instead of progressing to the three-and-four cell stage, the embryos lacking "Mater" remained at the two-cell stage. Male mice lacking the "Mater" gene were able to reproduce normally, as were female mice having only a single copy of the "Mater" gene.

"Our results demonstrate that "Mater" is a novel maternal effect gene required for embryonic development beyond the 2-cell stage in mice," the researchers wrote. The investigators are working to identify a similar gene in humans, which, if abnormal, might be a cause of unexplained infertility in women.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Dasha31@aol.com (Dasha31@aol.com [UNKNOWN])

CREATION DATE/TIME:30-OCT-2000 13:07:49.00

SUBJECT: (no subject)

TO: Mrs.Gore@Whitehouse.GOV (Mrs.Gore@Whitehouse.GOV [UNKNOWN])

READ:UNKNOWN

TEXT:

Dear Mrs Gore,

Please consider for a moment, of think of all the years of wonder and enjoyment you have had with Al and your family, the day you found out you were first pregnant, the day that you felt the baby move and the day your first child was born, and the days they were all born.... Do you remember when they took their first steps and said their first words? Do you remember the joy you felt when you heard them or saw them do those things?? Do you remember the joy you felt when they went on to do all those wonderful things that we want our children to do... go to school and do well, go on that first date, and go to prom. Then when your daughter got married, do you remember the joy you felt when you watched Al walk her down the aisle. Then do you remember the day that she and her husband announced that they were pregnant and that you were going to be a grandma?

Now sit back, and think, what would your life have been like if you and Al were unable to have your children. Would you have adopted? You would probably have been able to easily afford it, but what if you could not. What if you didn't have the funds after doing all of the tests and perhaps infertility treatments? What would your lives have been like without your children?

As an infertile person, who has tried for years to build a family, my husband and I have moved forward with adoption and are currently in the process of our first adoption. Because most insurance companies don't cover infertility treatments, we did spend most of our savings on our Infertility treatments, we are fortunate that we are able afford the cost of an adoption, but it will be a little bit of a strain. This is why I am writing to you, not only on my behalf, but on the behalf of thousands of other Americans who like me are unable to have their own children and choose adoption. Currently there is a bill on the floor, it is the H.R. 531 The Hope for Children Act. The intent of this bill is to increase the amount of allowable for qualified adoption expense to ten thousand dollars from the current five thousand, and to adjust

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Dasha31@aol.com to Mrs. Gore [partial] (1 page)	10/30/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Automated Records Management System
Default (In Vitro or Infertility)
OA/Box Number: 1100000

FOLDER TITLE:

[8/8/1996 - 2/17/2000]

2013-0365-F
wr10697

RESTRICTION CODES

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

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

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

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

RR. Document will be reviewed upon request.

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

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

the limitations on such credit for inflation.

I am asking you to support this bill and help it find its way to the Presidents desk and get his signature. By doing so you would make such an impact on the lives of thousands of familles, forever familles.

[001]

Thank you so very much for your support.

Sincerely

