RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: Lisa O. Ross (Lisa O. Ross@EOP@LNGTWY@LNGTWY [UNKNOWN])

CREATION DATE/TIME: 3-MAR-1997 18:15:00.00

SUBJECT: Cloning

CC: Elizabeth Myers (Elizabeth Myers@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Message Creation Date was at 3-MAR-1997 18:15:00

In follow-up to your conversation with Betsy this morning, these groups

would

appreciate a heads up re President's statment on cloning --

Society for the Advancement of Reproductive Technology - Lisa Angerano

863-2439

Women in Science - Katherine Didion, 326-8940

I've already talked with Phylis Greenberger, The Society for the

Advancement of

Women's Health Research, 223-8224

ALSO, The Presdeint's meeting with the Women's Caucus is scheduled for

Thursday, March 6 from 4:00 -5:00 in the State Dining Room. We are

coordinating with Leg affairs, HRC office, and Potus Scheduling. The

meeting

with you, Erskine, Betsy and women's leaders is cancelled for Friday;

postponed until next week. We are working with Marilyn to identify a

family

who has used FMLA for the Campaign Finance Reform event on Wednesday.

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: cgardett (cgardett@os.dhhs.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME: 4-MAR-1997 15:16:00.00

SUBJECT: fwd: CBS: cloning request

TO: Stuart Schear (Stuart Schear@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Following up ...

NIH needs to commit to this interview, if okay with you. As you know, Dr.

Varmus was at this morning's cloning event.

thx - cam

Original Text

From: "Ralbovsky, Don" <RALBOVSD@od1tm1.od.nih.gov>, on 3/3/97 3:54 PM:

To: "cgardett@os.dhhs.gov" <cgardett@os.dhhs.gov>

Cc: "Thomas, Anne" <THOMASA@od1tm1.od.nih.gov>, "'OASPA ATTN G

Schroeder'" <gschroed@os.dhhs.gov>

CBS SUNDAY MORNING producer Bill Skane is preparing "cover story" for Mar

9

on cloning, wants Dr Varmus to be "central character" in the piece, which

will be "advancer" about the Natl. Bioethics Advisory Commn. meeting.

Reporter will probably be Terence Smith; story would address the broad

topic of cloning; Skane wants Varmus to "give the national view of cloning

from the NIH perspective--the scientific and ethical issues."

Dr Varmus is inclined to do the interview, subject to OASPA approval.

CBS

asks callback by tmrw pm.========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01IG3W6QN38W00HPAV@PMDF.EOP.GOV> for
schear_s@a1.eop.gov; Tue, 04 Mar 1997 14:28:15 -0500 (EST)
Received: from os.dhhs.gov (158.70.252.1) by STORM.EOP.GOV (PMDF V5.0-7 #6879)

id <01IG3W6JWTSC000045@STORM.EOP.GOV> for schear_s@a1.eop.gov; Tue,
04 Mar 1997 14:28:09 -0700 (MST)
Received: by os.dhhs.gov; Tue, 04 Mar 1997 14:19:22 -0500 (EST)
X-Priority: 3 (Normal)
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: ELLY.MELAMED (ELLY.MELAMED@eh.doe.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:21-MAR-1997 23:27:00.00

SUBJECT: questions and answers

TO: Elizabeth Drye (Elizabeth Drye@eop [UNKNOWN])
READ:UNKNOWN

TEXT:

The revised set of q/a's is attached. I edited them, also shortened the one on compensation and the one on current protections. I left uranium miners as is. At the end is the additional information on compensation which I pulled out.

I have attached the document in ASCII text. See if you are able to open and read this. If not, I have faxed the document to you. I am also including it as part of this message, without the last bit of additional material on compensation.

DRAFT QUESTIONS AND ANSWERS FOR HUMAN RADIATION EXPERIMENTS EVENT

COMPENSATION

Q: What is being done to provide compensation in connection with the human radiation experiments?

A: The Department of Justice has worked closely with other Departments to resolve the claims that have been made in connection

with the human radiation experiments. In conjunction with the Department of Energy, the Justice Department has reached monetary settlements with the families of the plutonium injection experiments for which the Advisory Committee on Human Radiation Experiments recommended compensation.

Neither the Advisory Committee nor the government was unable to identify any subjects of other experiments for which the Committee also specifically recommended compensation, but the Committee identified other experiments whose subjects should be considered for compensation and established guidelines the government should use in deciding whether to award compensation (see Recommendation 2).

Q: What about the other human radiation experiments for which lawsuits or claims have been filed?

A:. The plutonium injection cases were unique and were singled out by the Advisory Committee as being particularly troubling ethically and deserving of compensation because efforts were made by the government to keep information secret from the subjects or their families to avoid government liabilities or embarrassment. Several other experiments were identified by the Advisory Committee for consideration for possible compensation, subject to further development of the facts surrounding the experiments. That fact-finding continues in a number of these cases, and the United States has agreed to settle several.

ABOUT PAST HUMAN RADIATION EXPERIMENTS

Q: What is the universe of experiments studied by the Advisory Committee?

A: The universe of experiments, as described in the President's charge to Federal agencies and to the Advisory Committee on Human Radiation Experiments (ACHRE) at the beginning of 1995, is government sponsored experiments on individuals involving intentional exposure to ionizing radiation. The primary focus for information retrieval and ACHRE review was on the period from 1944 until 1974. The Committee did not consider common and routine clinical practices that involved incidental exposures to ionizing radiation (e.g. x- rays).

The President's charge also covered intentional releases of ionizing radiation either designed to test human health effects or the extent of human exposure. Several specific environmental releases were also identified as part of the ACHRE charge.

Q: How many experiments does this include?.

A: No one knows exactly how many experiments this includes. The Advisory Committee reported that the government had sponsored several thousand human radiation experiments between 1945 and 1974.

Q: How many people were involved in these experiments?

A: Because only fragmentary information has survived about many of these experiments it was not possible for the Advisory Committee to estimate how many people were involved.

Q: How many people were harmed in the experiments?

A: The Advisory Committee was not in a position to answer this question. In general, they found that the majority of experiments which they identified involved trace amounts of radiation given to adults, similar to those used in research today. These were unlikely to have caused harm. Studies involving higher doses, given for therapeutic purposes, were arguably based on the assumption that the subjects would benefit medically. The Committee identified several possible instances where the deaths of already ill patients may have been hastened by the radiation treatment, but concluded that clear resolution of this question would require examination of individual medical histories, which the Committee did not undertake.

Q: How many people were not informed in advance that they were the subject of an experiment?

A: Only very limited documentation about consent in individual experiments has survived and no estimates can be made. Generally,

the

Committee found that researchers obtained consent from healthy subjects, but not from patient- subjects.

The Advisory Committee did look more broadly at issues of informed consent across the government and found that the government did not have comprehensive policies in place before 1974. Some agencies did have requirements in place well before that date, but these did not cover all types of research subjects, nor did they specify what was meant by consent, or what had to be disclosed by the researcher to the subject. Nor did government agencies generally take effective measures to ensure the implementation of these requirements and policies where they existed.

CLASSIFIED HUMAN SUBJECTS RESEARCH

Q: What portion of past experiments were classified?

A: Only a very small number of past experiments were classified, mainly those that took place during the Manhattan Project and were associated with the war effort. The Advisory Committee's first recommendation was that the government compensate and apologize to subjects or next of kin in three cases from this period where it was felt that efforts were made by the government to keep information secret from the subjects and their families to avoid government liabilities or embarrassment.

However, the fact that the majority of experiments were not classified does not mean that information about them was easily accessible to the public or that the extent and type of government experiments was generally known and made available.

Q: How many people are currently involved in classified human research? How many classified experiments are currently taking place?

A: As far as the Interagency Working Group has been able to determine, there are currently no classified human subject experiments being sponsored by the government and consequently there are no people involved in classified human subject research.

Up to now, there has been no regular reporting requirement in relation to classified human research. Once the President's directive on classified research is in place, the Government will be in a position to closely monitor and regularly report on any classified human subject research that may be taking place.

Q: Would the new Presidential directive on classified human subjects

research have prevented past mistakes?

A: The President's directive requires informed consent in all classified human subjects research without exception. The directive also requires permanent recordkeeping. These and other requirements recommended by the Advisory Committee and implemented by the directive should prevent the mistakes of the past from occurring again.

PROTECTING FUTURE HUMAN SUBJECTS

Q: What steps is the government taking to prevent ethically problematic experiments from taking place in the future?

A: A strong system of Federal oversight, education, and sanctions is currently in place to ensure the protection of the subjects of government sponsored human research. Additional steps include the establishment of NBAC, the new Presidential directive on classified research, and intensified educational and outreach efforts by Federal agencies.

One of the most useful portions of the Advisory Committee's report was its critical analysis of informed consent. Despite the vigor with which all parties embrace the informed consent process, little is

actually known about the effectiveness of this transaction between researcher and prospective subject. In response, the NIH and the Departments of Energy and Veterans Affairs are initiating research to develop new knowledge about the informed consent process. NIH put forth a solicitation for research proposals last Fall, with a closing date this month. Some 6 to 10 awards can be expected in Fiscal Year 1997 to support the best research in this area.

Q: Now that the National Bioethics Advisory Commission has been given a special assignment on cloning, does this mean that there will be a delay in addressing protection of human research subjects.

A: No. the National Bioethics Advisory Commission has already established an ambitious plan of work to address the current status of Federal protection for human research subjects. This work plan includes: interviews with Institutional Review Board members and Federal agencies responsible for ensuring protection of human subjects, soliciting background papers and remarks from outside experts, and reviewing and assessing existing documents and regulations for adequacy in protecting human subjects. This work will proceed in parallel with the special assignment on cloning.

NBAC is planning to issue a report to the President and to Congress in

October and hopes that little or no delay will be incurred as a result of the additional work.

ENVIRONMENTAL RELEASES OF RADIATION

Q: What is the relationship between human radiation experiments and environmental releases of radiation?

A: The Committee was charged to review any environmental releases in the past that were designed to test human health effects of ionizing radiation or the extent of human exposure, along with a number of specifically identified releases. The Committee report also discussed atomic veterans - veterans who participated in atomic test blasts, Marshall Islanders, and others who were affected by the nuclear weapons program.

Q: What steps is the government taking on environmental releases of radiation?

A: The Advisory Committee made several recommendations to ensure that secret environmental releases could not occur in the present without being appropriately approved and documented. EPA, in conjunction

with

Federal agencies conducting classified research, is taking steps to improve environmental oversight and enforcement capability over all classified activities. EPA will also establish and maintain a permanent file to document EPA's classified reviews under the National Environmental Policy Act (NEPA).

The Government is also taking a number of steps to improve its program for providing compensation and redress to certain groups of people who developed radiation-related diseases as a result of radiation exposure from the government's Cold War nuclear weapons program, including atomic veterans, uranium miners, and Marshall Islanders.

VETERANS ISSUES

Q: Is the government taking any steps to reform legislative relief measures for veterans?

A: The Department of Veterans Affairs (VA) is drafting legislation to make veterans exposed to nasopharyngeal radium irradiation during military service eligible for VA's Ionizing Radiation Program. This

includes eligibility for a screening exam and special eligibility for treatment of conditions recognized by VA by statute or regulation as being potentially radiogenic.

As recommended by the Advisory Committee, the VA is also updating the "epidemiological tables" to improve the scientific basis for veterans' compensation under the existing compensation system.

Q: What else is the government doing for atomic veterans?

A: The Administration has taken steps to make the VA claims process work better. For example, VA recently proposed to expand the list of diseases it recognizes as radiogenic by including all forms of cancer.

This means that a veteran with cancer will no longer have to establish that a specific cancer is radiogenic before VA can determine entitlement to benefits based on the estimated level of radiation that the veteran was exposed to while in the military.

In addition, the Administration has worked and will continue to work with the Veteran's Advisory Committee on Environmental Hazards, an independent panel that reviews scientific literature related to radiation-induced diseases, to determine whether other diseases should be added to VA's list of radiogenic diseases.

Q: Are the controversies surrounding radiation experiments and the Persian Gulf illnesses in any way similar or related?

A: Yes, there are some similarities regarding the Administration's response to public concerns about the two sets of events. President Clinton appointed advisory committees to thoroughly investigate both events and directed complete cooperation from all Federal agencies. Issues of secrecy in government recordkeeping have created a "credibility gap" with the participants and their advocates regarding both events.

The Administration's openness initiatives and related directives will help ensure the future welfare of our nation's military personnel and the American public. In addition, hundreds of thousands of pages of documents on these two events are now openly accessible via the Internet.

URANIUM MINERS

Q: What is the purpose of the proposed legislation to amend the Radiation Exposure Compensation Act (RECA)?

A: The legislation responds to the concern expressed by the Advisory Committee that the present RECA eligibility criteria relating to uranium miners do not provide compensation to all miners who

develop(ed) lung cancer as a result of their mining employment. The legislation would amend the RECA to incorporate new compensation criteria for lung cancer that reflect the latest scientific data, and better achieve the statutory goal of providing compassionate payments to individuals who suffer or have suffered from lung cancer as a result of their exposure to radiation in uranium mines. The legislation would also expand the existing list of compensable diseases for downwind and onsite participant claimants to reflect current scientific knowledge.

Q: Who will benefit from this legislation?

A: This legislation will principally benefit uranium miners who suffered or suffer from lung cancer. The legislation would incorporate new eligibility criteria for lung cancer, including defining eligibility for partial compensation. The new criteria would apply to uranium miners covered by the Act who presently suffer from or contract lung cancer in the future (prior to 2010 when the Program is scheduled to terminate), as well as all uranium miners with lung cancer who previously were denied compensation because they did not meet the present eligibility criteria. The Administration anticipates that most of the claimants who will benefit from this legislation reside in Arizona, Colorado, New Mexico, Utah or Wyoming, the states covered by the RECA.

Q: How many people will benefit from the legislation, and how much compensation will they receive?

A: The Administration estimates that over 500 uranium miners who do not presently qualify for compensation under the RECA would receive either full or partial compensation under the proposed amendments. The Administration estimates that these newly eligible miners would be paid approximately $45 million dollars in compensation: approximately 335 miners would be eligible for full compensation ($100,000 per miner), and approximately 240 miners would be eligible for partial compensation ($50,000).

Q: How will this legislation be financed?

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begin 666 qaasc.wpd========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IGS3RUSVS000UX4Y@PMDF.EOP.GOV> for drye_e@a1.eop.gov; Fri,
21 Mar 1997 22:25:07 -0500 (EST)
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by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01IGS3RSECF400B5NA@PMDF.EOP.GOV> for
drye_e@a1.eop.gov; Fri, 21 Mar 1997 22:25:03 -0500 (EST)
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id <01IGS3RG8Q1600004H@STORM.EOP.GOV> for drye_e@a1.eop.gov; Fri,
21 Mar 1997 22:24:49 -0500 (EST)
Received: from eh.doe.gov (146.138.16.206)
by spok.eh.doe.gov (EMWAC SMTPRS 0.81)
with SMTP id <B0000153011@spok.eh.doe.gov>; Fri, 21 Mar 1997 22:08:30 -0400
Received: from ccMail by eh.doe.gov (IMA Internet Exchange 2.1 Enterprise)
id 00014E66; Fri, 21 Mar 1997 22:25:08 -0500

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

FOIA Number: 2013-0365-F

Clinton Presidential Records Automated Records Management System [EMAIL]

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

Hex Dump file is not in a recognizable format, has been incorrectly decoded or is damaged.

File Name: qaasc.wpd

Attachment Number:

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: RACharo (racharo@facstaff.wisc.edu [UNKNOWN])

CREATION DATE/TIME:21-APR-1997 14:09:18.00

SUBJECT: harold's memo

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

TEXT:
applause applause applause.

and now for the nitpicking:

1. you suggest to the president that we continue the moratorium he announced; later you make it clear that when we say "cloning human beings" we mean making babies, not embryos. i feel the president's statement was not quite as clear as it could have been on this point, and so would suggest that when you say we should continue the "existing" moratorium that you also say "on making babies" or sme such thing.

2. i notice in your list of recommendations at the end that you never mention cloning cells that leads to embryos on which we do research. may i assume this is deliberate?

3. under "f" (were you checking to see that we got down that far?), your suggested titles for the report omits "Don't Clone for Me, Argentina" etc...

4. (still reading?) on a final nitpick, where you say moral

consensus will be "easy" to achieve, i wonder if we might soften it a bit -- in light of folks like roebrtson and macklin -- and simply say it is achievable.

otherwise, i am most happy to second your recommendations.

r. alta charo, j.d.
associate professor, law & medical ethics
university of wisconsin law school & medical school

u.w. law school 608.262.5015 (tel)
975 bascom mall 608.262.5485 (fax)
madison, wi 53706 racharo@facstaff.wisc.edu

u.w. program in medical ethics: 608.263.3414 (tel)
mdethics@macc.wisc.edu

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: acapron (acapron@law.usc.edu [UNKNOWN])

CREATION DATE/TIME:21-APR-1997 10:57:28.00

SUBJECT: Re: law & policy bucket may 1 vs. may 3

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

TEXT:
I agree with Alta that it would be desirable for us to consider meeting BOTH on the afternoon/evening of May 1 (to talk about how to use the tentaive conclusions from the ethics bucket) and after the May 2 Commission meeting to see what needs to be done to translate the whole group's conclusions into policies. As I said, I can make myself available on the afternoon and evening of May 1 and wait instructions from H2K or MQ about what the results of this polling are--ie are there sufficient numbers to make that session feasible, where will it be held, etc. As I also communicated, I will not be able to participate after the Commission meeting on May 2.

I also agree with what I take to be Alta's suggestion that a prime outcome of the ethics bucket this wednesday should be to work out (with whatever pro/con is necessary) the rationale for the rrstricting/not restricting cloning. Since the reasons for restrictions, if any, do not grow out of the sort of conventional risk-to-others that lies behind most exercise of the police powers (as was true for r-DNA), they must instead be supported by a well worked out balancing of the sorts of considerations that the ethics bucket (and to some extent, the whole Commission) discussed on the 12th and 13th of this month.

Alta also suggests that the ethics folks do what they can to articulate "how cloning is different." This is important. But it does not exhaust the question of constitutional limitations. I am not sure whether others think it would be appropriate to ask Lori Andrews to carry her analysis a little further, but I did not find she was as definitive on this as we may need. Here the question is in two parts, only one of which is dependent on the ethics-bucket analysis referred to in the preceeding paragraph.

The first question is: is cloning different enough as a method of "reproduction" that the state's authority to restrict it is determined by (or, cannot be fully predicted from) the Supreme Court's decisions in the "reproductive liberty" area? In answering this question, the reasoning from the ethics bucket (and others) will be enormously helpful.

The second questions is: do the Supreme Court's "reproductive liberty" decisions establish a positive right to unrestricted use of any assistance one needs in achieving one's reproductive goals, or merely a negative right not to have one's natural reproductive processes (to become pregnant or to avoid pregnancy through contraception or to avoid parenthood through abortion) interfered with by the state [assuming in either case that the relevant sphere of liberty is not absolute but could be restricted by the state for compelling reasons and provided that the state acted in the least restrictive fashion]. If the answer to the question is the latter, then per force reasonable restrictions on cloning would not run afoul of a protected liberty interest---meaning that the justifications for governmental limitations provided by the Commission would not have to be

so overwhelming.

I would appreciate reactions from other members of the policy/law bucket both on the substance and on whether need to have our contractor grapple more fully with the arguments put forward by Robertson and others that reproductive liberty creates a strong positive right to use any reproductive methods. I also look forwad to hearing about plans for our bucket in conjunction with the May 2 commission meeting, so I can adjust my arrival time accordingly!

Be well,

Alex

****

* Alexander M. Capron acapron@law.usc.edu *

* Henry W. Bruce Professor of Law (213) 740-2557 (voice) *

* University Professor of Law and Medicine (213) 740-5502 (fax) *

* University of Southern California (213) 740-0149 (fax) *

* Los Angeles, CA 90089-0071 *

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RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: RACharo (racharo@facstaff.wisc.edu [UNKNOWN])

CREATION DATE/TIME:21-APR-1997 13:22:39.00

SUBJECT: Alex's memo

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

TEXT:
first, logistics: the law/policy bucket will meet from 6:30 - 9:30 PM at

a conference room to be announced on BOTH the evening of may 1 AND the

evening of may 2

second, substance: Alex correctly notes that the procreative liberty

arguments have two components that must be addressed if we are to call for

a ban on baby making thru cloning. first: is there a constitutionally

protected right to pursue procreation by means other than sexual

intercourse? without even asking Lori Andrews to write more on this, I'd

suggest the answer is "unclear". as someone who has written often in the

reprotech area, i have yet to see a clear and definitive statement from

the Supreme Court on this issue. most work depends upon inference from

cases that have held that people have a constitutionally protected right

to be free of state efforts to sterilize them or otherwise interfere with

sexual intercourse leading to procreation. other inferences are drawn

from the wealth of cases on the right to avoid procreation thru the use of

contraceptives and abortion.

nonetheless, to be conservative, one can *assume*, for the sake of

argument, that the Supreme Court would uphold a claim of a right to

procreate using reproductive technologies, and then progress to see

whether the basis on which they would uphold it would apply equally well here.

i think the extensive writing done on this topic already, and which i am happy to provide to members or to kathi, will probably suffice for the commission.

on another note, an LLM student at UW has just handed in a draft of her thesis on property rights in human tissue. since this has bearing on the rights of the individual or third parties over the use of an individual's tissue for the purpose of cloning research, i wonder if members or kathi would like to have a copy of the draft.

r. alta charo, j.d.
associate professor, law & medical ethics
university of wisconsin law school & medical school

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u.w. program in medical ethics: 608.263.3414 (tel)
mdethics@macc.wisc.edu

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: rosemenz (rosemenz@arachne.Princeton.EDU [UNKNOWN])

CREATION DATE/TIME:21-APR-1997 14:27:54.00

SUBJECT: Draft Material from Dr. Harold T. Shapiro

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

TEXT:
Princeton University Office of the President

April 21, 1997

To: NBAC Commissioners

From: Harold T. Shapiro

Re: Proposed Recommendation

==========

We are now well into writing various sections of the report, and it is clearer than ever to me that it would be useful to have some general notion of the recommendations we will make. As a result, I have taken the liberty of drafting a proposed transmittal letter to President Clinton (to provide some general context) and a set of recommendations, which I derived from my own meeting notes--etc. and which I believe might achieve consensus among Commissioners. Needless to say, I would appreciate your detailed reaction and in particular objections that you might have to these recommendations as

well as any additional recommendations you might propose.

Please also look carefully at the transmittal letter since the letter and the recommendations taken together would tell us a good deal about the nature of the report that we are now writing.

==========

DRAFT Transmittal Letter

Dear President Clinton:

The attached report is submitted in response to your request that NBAC report to you, within ninety days, regarding the legal and ethical . . .

In this short interval, we have made every effort to consult with ethicists, theologians, scientists, physicians, and other citizens with interests and concerns in this area. Moreover, we have invited inputs for the Commission's consideration from as broad a cross-section of the community as time allowed. Further, recognizing that science and medicine are international activities with outstanding investigators and facilities in many nations, we have

attempted, therefore, to review relevant policies and proposals with respect to human cloning in other countries. However, we do not view it as essential to follow others in this area unless we find their proposals compelling. Likewise, the policies America chooses to adopt in these areas may or may not be followed by others. Once again, however, we do not find this potential asymmetry troubling, although it might have implications for U.S. participation and leadership in certain developments.

Not surprisingly, we have discovered that the potential ability to clone human beings by nuclear transfer raises a whole host of complex and difficult legal and ethical issues -- both new and old. It seems clear to all of us, however, given the current stage of science in this area that any attempt to clone human beings via adult nuclear transfer is uncertain in its prospects, is dangerous and morally unacceptable. At present, therefore, moral consensus on this issue should be easily achieved. While we have been able to agree on this and certain other recommended actions, we feel quite strongly that most of the legal and moral issues raised can only be resolved, even temporarily, by a great deal more widespread deliberation and education. This is especially true because in our pluralistic society there is no universally accepted ethical theory; because Americans hold various religious perspectives on these issues; because while Americans differ on the importance and meaning of particular traditions, tolerance (agreeing to disagree) governs wide areas of our national life; and because of our historical tradition to leave to the individual conscience, if we can, acts that are

private, do not harm others and on which there is no moral consensus.

As a result, while our specific recommendations include a continuation of the moratorium you announced in February of this year, the report also includes important sections outlining the scientific, religious, legal and ethical issues that are raised by these new scientific developments.

It is our hope that these materials, by clarifying certain issues and highlighting others, will form a useful initial basis for the ongoing deliberations and educational dialogues that we believe are so essential.

Finally, it is critically important that we try to understand the widespread public concern that has been generated by these recent developments. Some of the reaction can be explained by an inadequate understanding of the issues--even confusing science and science fiction--but this can be addressed over time through public education. Some concerns, however, run much deeper than this and range from the implications for particular faith commitments, to views regarding the appropriate sphere for human action, to concerns regarding the future of the family, to cumulative apprehensions about the real net benefit of our rapidly advancing technology that some believe is too aggressively pushing aside important social and moral values. As we move ahead to the next stage of our national discussion, all these--and other--issues need to continue to be thoughtfully addressed.

I would like to take this opportunity to thank all the Commissioners and our very dedicated staff for the intensity and depth of their commitment to the task that you assigned to us.

Sincerely,

Harold T. Shapiro

==========

DRAFT - NBAC Recommendations

NBAC unanimously recommends that:

a. The current moratorium on the cloning of human beings (i.e., the transfer to a uterus of a human embryo developed from the nucleus of an adult somatic cell) should be continued for some time, perhaps indefinitely.

b. At this time, we believe it is morally unacceptable for anyone, in the public or private sector whether in a research or clinical setting, to attempt the cloning of human beings. Nevertheless, private sector compliance with the intent of the federal moratorium should first be sought through the voluntary adherence of the

relevant community of firms, clinicians, investigators, and professional societies.

c. Research on cloning by nuclear transfer using animals should continue to be permitted, subject to existing regulations regarding the humane use of animals and subject to existing regulations by institution-based animal protection committees.

d. Cloning of DNA sequences and cell lines should continue, subject to existing regulations and standards.

e. Since the different ethical theories and the various religious traditions are not of one mind on many of the important ethical issues that surround the cloning of human beings, it is critical to encourage widespread and continuing deliberation and education on these issues.

f. That the title of our report should be "One of Each Is Enough...Quite Enough,"or more succinctly "One Is Enough!".

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: RACharo (racharo@facstaff.wisc.edu [UNKNOWN])

CREATION DATE/TIME:22-APR-1997 11:10:22.00

SUBJECT: steve holtzman's memo

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

TEXT:
steve -- i agree with you that it is desirable to highlight the distinction between cell cloning that creates, inter alia, embryos for research and cell cloning that is done in conjunction with transfer to a uterus. i also think it is valuable to highlight the scientific gains to be made with research on embryos derived thru cloning, and to highlight the current limitations on public funding for this research. i'm not sure that you are advocating we go the next step, though, and make recommendations regarding the situation on public funding. if we do, we enter the morass that swallowed the embryo panel. would it be enough to merely highlight the research goals and the obstacles that are posed by the absence of public, federal funding?

regarding larry's note that it is "premature" to do such embryo research before animal cell work has een done, fyi, this merely re-iterates one of the embryo panel's recommendations, i.e., that human embryos be used as sparingly as possible, which in turn led to the recommendation that avenues of research be exhausted on animal embryos before moving on to human embryos.

finally, on the "research protocol" versus "clinical experiment" setting and the potential constitutional challenges -- you are right, these are

not necessary distinctions when it comes to the constitutional challenges. my only purpose in highlighting the two settings for baby making efforts was, as you suspected, to highlight the different avenues for legal intervention offered by them for the purpose of controlling the development of the technique -- in the research protocol setting, the avenue for intervention is primarily thru prospective review by an IRB, assuming te research takes place in a setting subject to IRB requirements. in the clinical experiment setting, the avenue for intervention is control of clinical practice, achieved thru state law governing medical practice (whether via legislative rules or indirectly thru medical malpractice) or thru the use of nih consensus development conferences and other professional society consensus statements (to influence practice prospe ctively and to be used

finally, on the source of oocytes -- here, i recall bernie lo being the most eloquent of all of us on the embryo panel. our recommendation was that oocytes be retrieved ONLY from women already undergoing a procedure for their own benefit (e.g. someone obtaining oocytes for her own use in an IVF attempt). thus, while it would necessitate using living donors, we attempted to ensure that these donors underwent no marginal increase in physical risk due to the oocyte donation decision.

r. alta charo, j.d.
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mdethics@macc.wisc.edu

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: holtzman (holtzman@mpi.com [UNKNOWN])

CREATION DATE/TIME:22-APR-1997 00:12:51.00

SUBJECT: More E-Mail

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

TEXT:
The following are some thoughts I started writing shortly after our last meeting. To some extent they have been superseded by Commission Members faster to the "Send e-mail button" than I. Apologies in advance for the length of what follows.

When we were last in Washington, the "policy bucket" set forth a framework in which the major divide was set up between: Activity (A): nuclear transfer
of an adult, somatic cell nucleus to an oocyte (or other enuncleated pre-embryonic or embryonic cell) wherein there exist the intent and actions (re: implantation in a uterus with gestation to term) requisite to create a new individual whose genetic make-up is (essentially) identical to an existing (or previously existing) human being; VS. Activity (B): nuclear transfer of an adult, somatic cell nucleus to an oocyte (or other enuncleated pre-embryonic or embryonic cell) wherein there exist no such intent and no such actions. For reasons noted below, I continue to believe this is the right approach and that the Commission should elucidate the distinction and develop recommendations with respect to both (from both an ethical as well as policy perspective).

Since our meeting, Larry and Harold have sent out memos which, at least to

me, are striking in what they share, but also in how they (implicitly) differ with respect to whether the basic framework of Activity A vs. Activity B should be adopted as a cornerstone of our analysis. In particular, their key recommendations, by my reading, are as follows:

Larry?s Letter: suggests a three year prohibition/moratorium on Activity A; suggests we tackle head on the issue of the embryo research necessarily entailed in undertaking Activity B as this is an opportunity to clarify the (negative) results of the current prohibition of federal funding for embryo research; suggests that we recommend that while Activity B can and is likely to have significant benefits associated with it, (i) it is premature, or at least pending a case-by-case analysis of the proposed research activity, is premature until such time as relevant work in animals is performed, and, (ii) should take place only when appropriate criteria (and a mechanism to determine whether the criteria have been met) have been established and human subjects safeguards are implemented; suggests, without getting into the legal niceties, that whether Activity A is undertaken in a "research" or "clinical" mode is irrelevant and should be treated the same (i.e., prohibition/moratorium).

Harold?s Transmittal Letter & Draft Recommendations: endorses animal cloning research and basic rDNA/cell biology cloning research; recommends an indefinite moratorium on Activity A; is silent on Activity B (or at least I read harold to be silent on this); recommends that whether Activity A is to undertaken in a "research" or "clinical" mode is irrelevant and should be treated the same (i.e., moratorium).

So, here are some thoughts, again perhaps now outdated, on why we should adopt the basic framework and on why I believe we can?t avoid a position on Activity B (and, hence, on embryo research).

1. Activity A is the principal issue we have been asked to address by the President, namely how should we, as a nation, view/regulate/etc. the prospect of bringing into existence individuals whose genetic make-up is (essentially) identical to an existing (or previously existing) human being.

2. Having drawn the major distinction between Activity A and Activity B, at the least we will then be to say the following kinds of things with respect to Activity B (nuclear transplantation w/o intent or actions to achieve implantation with gestation to term):- that its motivations and ends can be wholly distinct from the creation of new people- enumerate what those goals may be (e.g., understanding developmental regulation of genes, development of cell lines for transplantation) and the potential value to be derived from the success of such research- state that, for the foreseeable future, pursuit of these goals involves a research program that: (a) must employ oocytes as recipients of the transferred nuclei; (b) that, inter alia, this will create preimplantation embryos; and, (c) that these preimplantation embryos will not be implanted to be brought to term but, rather, will be used for the creation of cell lines, i.e., will involve the creation and "destruction" of research purpose embryos.

3. It follows from having drawn the major distinction and having made CLEAR the points under (2), that how one feels about Activity B is NOT a function of one?s beliefs about Activity (A); rather, beliefs about Activity (B) <hence, public policies to effectuate those beliefs> are entirely derivative of one beliefs about <the policies governing> embryo research.

Most succinctly, and a point I think NBAC should drive home with force: Activity (B) is a species of the genus "embryo research for non therapeutic purposes" (i.e., not intended for the benefit of the person the embryo would have/could have matured into); Activity (B) is NOT a species of the genus "cloning human beings" in the relevant sense of Activity A..

4. Now, the foregoing, particularly the last point # 3 may seem patently obvious (actually, it is patently obvious). But perhaps one of the greatest EDUCATIONAL functions NBAC can serve on this issue is to draw attention to this patently obvious distinction. The heat/emotion/ethical concerns stimulated by Dolly arise from the prospect of Activity A (babymaking), not Activity B. For me, this is strikingly similar to the heat/emotion/and eugenics-related ethical concerns that arose in 1980/81 about the prospect for human gene therapy that really were directed to germ line gene therapy, not somatic gene/cell therapy. I would argue that perhaps the greatest educational/public policy end served by the President? s Commission in "Splicing Life" was to elucidate the "patently obvious" germ line vs. somatic gene therapy distinction. Having done so, it paved the (conceptual) road along which medical progress on somatic gene/cell

therapy could progress.

I would argue that the response that we have heard from the biomedical research community and the biotechnology industry is a screaming plea for us to make this kind of distinction loud and clear so that legislation, moratoria, and public discourse do not throw away Activity B along with Activity A (whether that throwing away is the inadvertent result of poorly drafted laws/regulations or the result of an intentional effort by those who oppose Activity B because it is a species of the genus "embryo research").

5. I do not think we should, or necessarily even CAN, be simply agnostic with respect to the current embryo research situation. With Larry, I think it worthwhile to draw out the implications of the current situation of a
moratorium on federal funds (re: unregulated research goes on in non fed-funded arena; differential and confusing state-to-state situation). This could (should?) provide us with a reason for recommending a uniform, nationwide policy governing embryo research.

It is important to note that, given the state of the art, it is not possible to "compromise" by saying that it would be ok to pursue Activity B, provided only "spare" oocytes are used. State of the art technology does not allow for the freezing of oocytes; consequently "spare oocytes will not be generally available. Thus, the source must be either: (a) a live donor intentionally induced to produce the oocytes for explicit use in the experimentation, or (b) a cadaver (who presumably, prior to her death, consented to the use of her ovary for such experimental purposes). (Note: aspirating oocytes from slaughterhouse ovaries is common practice

in sheep and bovine research; not yet reduced to practice, to my knowledge in pigs or humans. Interestingly, there are issued US Patents covering methods for keeping ovaries "alive" in culture so that they can be kept around to produce, in theory, 1000?s of oocytes; however, to my knowledge, the

technology has not been successfully practiced.)

I am less comfortable than Larry, however, in jumping to the conclusion that the early state of the research implies that it would be premature for any work in connection with Activity B-type research activities to commence with human oocytes. (Carol and David should feel free to jump all over what I am about to say).

What Wilmut teaches is the importance of "arresting" the cell cycle of the donor cell to enable the transferred nucleus to be in a state such that it can "take" in the oocyte. A key outstanding question is whether species differences in the rate of cell division (and the control of this process) in the early embryo will make it possible in some species, but not others, for the transferred nucleus to "take". I don?t see how one can address this question, i.e., whether early embryonic development in the human is an environment conducive to arrested somatic cell nuclei "taking", apart from moving to human cells. ?In other words, we shouldn?t confuse the early stage of the research with respect to trying to make babies (bring embryos with transferred somatic cell nuclei to term), with the state of the research with respect to Activity B-type research activities. I think that the latter are already quite advanced and, for many imaginable, scientifically sound experiments, using human nuclei and oocytes would not be an unreasonable next step.

Orkin?s presentation, Rossant?s paper, and observations by many others

(e.g., conversation with Carol Greider) point to the fact that the goal of transplantable cell lines can be pursued w/o somatic cell nuclear transplantation, re: by culturing pluripotent cell lines derived from embryonal stem (ES) cells. But this alternative only constitutes an argument against the permissability of Activity B-type research if you find the following two differences morally important: (i) ES cell research can be conducted on "spare" embryos while, given the state of the art, somatic cell nuclear transplantation into oocytes cannot; and, (ii) while Activity B research is not directed to babymaking (Activity A), its practice and development inter alia will perfect techniques necessary for (hence, will bring closer to reality) Activity A in a way that research on human ES cells will not. ?I personally am unpersuaded by these arguments. I am also less sanguine than, say, Rossant that we will be able to understand immunological rejection sufficiently well so as to be able to create (by knocking out the appropriate genes) universal donor cell lines from ES cells; the prospects for successful autologous cell line transfers (i.e., my receiving cell lines created from an embryo made via the transplantation of a nucleus from one of MY cells) seem to me much closer to hand.

In summary: as much as I would like NBAC not to have to become embroiled in the embryo research debate, I find all my own intellectual attempts to avoid it disingenuous. We can?t in the same breath acknowledge and support the potential basic science and medical benefits of Activity B-type research, and then turn around and be either supportive of, or silent on, the ban on embryo research. And, worst of all (from a political perspective), that acknowledgment and support is of a type of research which, given the current state of the art in oocyte freezing, can?

t be undertaken with "spare" embryos and, therefore, requires the creation (and destruction/non-implantation) of embryos. Furthermore, I don?t see how we can "duck" the issue by saying that it would be premature to undertake any and all Activity B research using human material at this time; I think this
statement quite simply to be false. Bottom line: support for Activity B-type research requires support for the recommendations of the Embryo Research Panel (or similar recommendations).

6. At the last meeting, when discussing Activity A (babymaking), much was made of the difference between non-profit (typically federally funded) activities vs. privately funded activities. I think that this is not the critical distinction. Rather, as pointed to by Larry and Harold, historically the critical distinction has been between activities viewed as involving human subject research in a research protocol setting vs. activities construed as the practice of clinical medicine (however experimental). It has been under the guise of the practice of clinical medicine that the IVF clinics have been undertaking what most of us would regard as human subject research?and that includes not-for-profit hospital-based IVF clinics. Thus, with Larry and Harold, I suggest we take the position that these activities are all human subject research (not clinical medicine).
Alta?s note of 4/16 seems to imply that we need to maintain the distinction between Activity A in a clinical setting vs. in a research protocol setting (she would extend human research subjects protection to the latter as the safeguard while having NBAC issue a statement about the risks of Activity A thereby bringing into play professional

standards/malpractice liability to police the former).

Alta?s argument (for having to maintain the distinction)seems to be that in the clinical setting a procreative right is in play in a manner in which it would not be in a research protocol setting. ?I?m not sure I see this. In other words, how does what we call the setting affect whether or not the procreative right (if it exists, or to the extent that it exists) is in play? If we stipulate that all practices of Activity A are in a research protocol setting (i.e., may only be undertaken in a research protocol setting), it seems to me the distinction simply evaporates?and we deal with whether there is (or to what extent there is) a procreative right in play and whether it trumps in the research protocol setting. I don?t find such a stipulation any more intellectually tenuous then the maintenance of the clinical setting vs. research protocol setting distinction. I think here of Phase II/Phase III FDA trials of experimental drugs. These are undertaken in a research protocol setting. Some patient advocate groups have argued (from, as it were, a right to access the [potentially] best available health care) for early access to such experimental drugs?hence the origins of accelerated approvals and compassionate use sales. But the force of those arguments has not required (to my knowledge) a distinction between use of an experimental drug in a clinical setting vs. a research protocol setting. (Is it just because "babymaking" is a "procedure", as opposed to a "drug" that we feel that the distinction needs to be maintained? Did we feel the need to maintain the distinction in the case of gene therapy, which is essentially a procedure?)

Steven H. Holtzman

Chief Business Officer

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RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: eiseman (eiseman@rand.org [UNKNOWN])

CREATION DATE/TIME:22-APR-1997 13:37:11.00

SUBJECT: cloning questionnaire

TO: levinson (levinson [UNKNOWN])
READ:UNKNOWN

TEXT:
Dear Rachel,

Just thought I would give you an update on where we are with the responses to the questions sent to the scientific societies/associations. So far we have received 19 responses. (BIO and PHRMA did send letters saying that they would be sending their response this week, but I have not received them yet. So that would bring us up to 24 responses). Seven have not responded to questions 1-6 -- 3 had no position (American College of Obstetricians and Gynecologists, American Board of Medical Genetics, and Society for Research in Child Development), while 4 provided comments, but did not directly address the questions (American Psychological Association, Genetics Society of America, Public Responsibility in Medicine and Research, and AAAS). There have only been 12 responses to questions 1-6 -- 8 are official responses of some kind while 4 are personal. So far the answers to questions 1-6 are setting an interesting trend -- the majority of responders want to prohibit the cloning of human beings for reproductive purposes (questions 5&6), but do not want to inhibit the use of nuclear transfer cloning using human donor nuclei for basic research (questions 1-4). Here are the numbers:

Question #1: prohibit entirely - 3/12

allowed in limited circumstances - 1/12

allow freely - 8/12

Question #2: prohibit entirely - 3/12

allowed in limited circumstances - 1/12

allow freely - 8/12

Question #3: prohibit entirely - 2/12

allowed in limited circumstances - 3/12

allow freely - 7/12

Question #4: prohibit entirely - 3/12

allowed in limited circumstances - 3/12

allow freely - 6/12

Question #5: prohibit entirely - 8/12

allowed in limited circumstances - 1/12

allow freely - 3/12

Question #6: prohibit entirely - 9/12

allowed in limited circumstances - 1/12

allow freely - 2/12

The comments provided by the societies that responded have been extremely interesting and rich in content. I have tried to capture all of the points raised and catagorized them into 7 different areas: 1) knowledge

gained and potential uses; 2) potential risks; 3) embryonic vs. adult human donar nuclei; 4) limited circumstances/restrictions; 5) regulations or legislation; 6) ethical and religious issues; and 7) general comments.

I updated Carol Greider on Friday (at that time we had 11 responses to questions 1-6). I think we are off to a good start, but it would be nice if we could get some more societies to respond. As of yesterday, Monday, April 21, I have been calling the societies/associations to try to track down what has happened to the original letter sent by NBAC and to try to convince them to send in their responses. Unfortunately, quite a few letters were sent to the wrong address or to people who are no longer with the society. I'll keep plugging away, and if you have any suggestions on how to expedite the situation, let me know.

Thanks, Elisa

Elisa Eiseman, Ph.D.
RAND Critical Technologies Institute
1333 H Street, NW
Washington, D. C. 20005-4707
phone: (202) 296-5000, x 5829
fax: (202) 296-7960
http://www.rand.org/centers/cti/

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: eemanuel (eemanuel@NIH.gov [UNKNOWN])

CREATION DATE/TIME:22-APR-1997 14:33:57.00

SUBJECT:

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

TEXT:
I agree with Steve's thoughtful email. It is my view that distinguishing different types of cloning is a useful exercise. I also think personally that it is very important to distinguish the moral arguments about each. In particular, the reasons that make me very hesitant--opposed--to cloning human beings are 1) objectificiation, 2) threats to individual identity, and 3) disruption of social understandings related to generational order. These arguments have nothing to do with cloning for cell therapies. And, of equal importance, pursuing cloning technologies for cell therapies have added advantages--curing or ameliorating debilitating diseases--that are not present with cloning for human beings. Therefore the threats to values and the advantages are much different between the two types of cloning.

And I agree with Steve that a clear message on the scientific and ethical differences--with the differences for policy--would be very helpful.

zeke emanuel

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: SkirbolL (SkirbolL@od1tm1.od.nih.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:29-MAY-1997 17:01:00.00

SUBJECT: Re: Here it is again as text of message

TO: Elizabeth Drye (Elizabeth Drye@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Our comments have gone to the Department and they are on a fast track.

You

should hear shortly. Thanks for the opportunity to have a look at it!

lana

From: Elizabeth_Drye@oa.eop.gov

To: Lana_Skirboll@nih.gov

Subject: Here it is again as text of message

Date: Thursday, May 29, 1997 12:09PM

Message Creation Date was at 29-MAY-1997 11:09:00

CLOSE HOLD

May 28, 1997

MEMORANDUM FOR: Toby Donenfeld, Office of the Vice President

Nancy Ann Min, Office of Management and Budget

Bill Corr, Dept. of Health and Human Services

Greg Frasier, Dept. of Agriculture

Elgie Holstein, Dept. of Energy

FROM: Elizabeth Drye, Domestic Policy Council

Rachel Levinson, Office of Science and Technology Policy

SUBJECT: Paragraph on Cloning for Denver Summit

The French have proposed a paragraph on cloning for inclusion in the Summit of the Eight joint communique. We need your comments on the text -- and on our proposed revised text -- by 5:00 pm Thursday, May 29. Please fax your Department's comments to Elizabeth Drye at 456-7431. In reviewing the texts, please keep the following in mind:

1) The National Bioethics Advisory Commission is scheduled to complete its report the week of June 9th. We will ask our negotiators to reserve the right to modify the U.S. position pending the completion and our review of this report. We expect, however, that NBAC will recommend a legislative ban.

2) We will recommend to our negotiators that the U.S. not actively advocate including a paragraph on cloning, and that the U.S. oppose including the

paragraph if it remains broadly drawn.

3) Three other countries have stated their reactions to the French proposal.
The German's support it. The Canadians want to delete the final sentence regarding a "universal ban" (note that we suggest modifying the last sentence
to read "universal moratorium"). The Japanese are not yet prepared to comment
without further technical review.

If you have any questions, please contact Rachael (202-456-6137) or Elizabeth
(202-456-5573). Thanks in advance for your review.

Attachment

cc: Sherman Boone, National Economic Council

FRENCH PROPOSAL

Human cloning:

We have taken note with great concern of recent scientific experiments which

could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.

OUR PROPOSED REDRAFT

We are hopeful that the recently reported breakthrough in entire animal cloning will yield enormous medical and agricultural benefits. We have also taken note with great concern that this scientific advance could open the way to using this technology (by which we mean somatic cell nuclear transfer technology) to create a child. We agree on the need for appropriate domestic legislation and close international cooperation to prohibit the use of somatic cell nuclear

transfer to create a child while countries explore ethical and scientific

implications in greater depth. We are encouraged by the reflections

already

underway within national ethics committees as well as in various regional

and

international fora. We are determined to give a strong impetus to their

work

with a view to arriving as soon as possible at a universal moratorium on

the

use of somatic cell nuclear transfer to create a child.

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IJG8PCAKOW0066L4@PMDF.EOP.GOV> for "Elizabeth Drye"@oa.eop.gov; Thu,
29 May 1997 18:01:54 -0500 (EST)
Received: from gatekeeper.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IJG8PAQ1LC006LPB@PMDF.EOP.GOV> for Elizabeth_Drye@oa.eop.gov; Thu,
29 May 1997 18:01:52 -0500 (EST)
Received: from imc.nih.gov by gatekeeper.eop.gov;
(5.65v3.2/1.1.8.2/17Oct95-0424PM) id AA25806; Thu, 29 May 1997 18:01:49 -0400

Received: by imc.nih.gov with SMTP
(Microsoft Exchange Server Internet Mail Connector Version 4.0.995.52)
id <01BC6C5A.5D5CCAB0@imc.nih.gov>; Thu, 29 May 1997 18:01:42 -0400
X-Mailer: Microsoft Exchange Server Internet Mail Connector Version 4.0.995.52

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

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: Robert J. Pellicci (Robert J. Pellicci@EOP@LNGTWY@LNGTWY [UNKNOWN])

CREATION DATE/TIME: 5-JUN-1997 17:22:00.00

SUBJECT: Presidential draft bill on cloning

TO: Christopher C. Jennings (Christopher C. Jennings@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Message Creation Date was at 5-JUN-1997 17:22:00

Spoke to jennifer and Sarah about the need for your views by 10 a.m.

tomorrow.

Thanks.

---------- Forwarded by Robert J. Pellicci/OMB/EOP on 06/05/97

05:21 PM ----------

Robert J. Pellicci

06/05/97 05:07:26 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Janet R. Forsgren/OMB/EOP, James C. Murr/OMB/EOP

Subject: Presidential draft bill on cloning

Earlier today I circulated for your review and signoff a White House

prepared

draft bill on legislation that would make it unlawful for any person to create or attempt to create a child using somatic cell nuclear transfer, a form of cloning. The President is scheduled to announce and transmitt the legislation on Monday, June 9th. In order for all the needed materials to be finalized in time for the White House event I need to know no later than 10 a.m. tomorrow if you have any comments. If I don't hear from you by 10 a.m tomorrow, I will assume your concurrence. Thanks.

Thus far DOD, NASA, NSF, OSTP, and VA have signed off on the legislation.

Message Sent

To:_____

William P. Marshall/WHO/EOP

Robert G. Damus/OMB/EOP

Barry T. Clendenin/OMB/EOP

Richard J. Turman/OMB/EOP

Bruce D. Long/OMB/EOP

Toni S. Hustead/OMB/EOP

Gary L. Bennethum/OMB/EOP

Jack D. Fellows/OMB/EOP

Mark A. Weatherly/OMB/EOP

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: damon_t (damon_t@hotmail.com@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME: 6-JUN-1997 20:44:00.00

SUBJECT: cloning Qs and As

TO: Christa Robinson (christa robinson@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
i've attached the q's and a's incorporating the comments from general

counsel, white house,ophs, and assistant sec-pub. affairs.

Get Your *Web-Based* Free Email at http://www.hotmail.com

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IJRMT6JB9S0006CS@PMDF.EOP.GOV> for "christa robinson"@oa.eop.gov; Fri,
06 Jun 1997 21:44:35 -0500 (EST)
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id <01IJRMT41668000XMK@PMDF.EOP.GOV> for christa_robinson@oa.eop.gov; Fri,
06 Jun 1997 21:44:32 -0500 (EST)
Received: from F55.hotmail.com by gatekeeper.eop.gov;
(5.65v3.2/1.1.8.2/17Oct95-0424PM) id AA32451; Fri, 06 Jun 1997 21:44:27 -0400

Received: (from root@localhost) by f55.hotmail.com (8.8.5/8.8.5)
id SAA18058; Fri, 06 Jun 1997 18:44:18 -0700 (PDT)
Received: from 158.72.20.132 by www.hotmail.com with HTTP; Fri,
06 Jun 1997 18:44:18 -0700 (PDT)
X-Originating-Ip: [158.72.20.132]
========== END ATTACHMENT 1 ==========

========== ATTACHMENT 2 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
Unable to convert ARMS_EXT:[ATTACH.D96]ARMSZZ0008ICO.001 to ASCII,
The following is a HEX DUMP:
========== END ATTACHMENT 2 ==========

Qs and As on NBAC's Report on Cloning

Q. 1 How would you summarize the Commission's recommendations?

A. The Commission supports a continuation of the current moratorium on federal funding of any attempt to create a child by cloning, using the somatic cell nuclear transfer technique, the same technology that made possible the creation of "Dolly". NBAC is also asking the private sector for voluntary compliance with this moratorium. Furthermore, the Commission recommends enactment of legislation to prohibit anyone in either the public or private sector from attempting to create a child, using this technology, in either a research or clinical setting. Such legislation must include a "sunset" provision to ensure that this issue is reviewed by Congress after a specified time period to determine whether there is a continuing need for this prohibition.

Because there are various ethical and religious perspectives on the cloning of humans, NBAC also recommended that the Federal Government and other appropriate organizations encourage widespread and continuing public dialogue on these issues to further understand the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding the use of this technology.

Q. 2 Why is there need for a "sunset" provision?

A. Our base of scientific knowledge expands over time and public attitudes and concerns often shift to reflect these changes. A sunset provision takes this into account and ensures that, at a specified point in time prior to the expiration of the legislation, an appropriate advisory body will evaluate and report on the status of somatic cell nuclear transfer technology and on the ethical and social implications of its use with human beings in the context of public attitudes at that time.

Q. 3 Why ban the cloning of humans?

A. The Commission finds it morally unacceptable for anyone in either the public or private sector to attempt this type of cloning on the grounds that there is no information on the safety and effectiveness of this method in humans. Knowing that "Dolly" was the only successful case in 277 attempts, there is no doubt that there would be substantial risk to the potential child and birth mother. In addition to the safety concerns, there are other serious ethical considerations raised by the possibilities that we could replicate ourselves that require broader and more thoughtful public deliberation.

Q. 4 Why not ban all cloning? What are the potential benefits of cloning research?

A. There are legitimate and beneficial applications of cloning cells, DNA, tissues, and animals: in animal husbandry to create herds with desirable traits; to develop animal models for biomedical research, to the production of important drugs in the milk of

animals, and to further our knowledge about developmental biology that may one day lead to such advances as regeneration of tissue in severe burns and spinal cord injuries.

Q. 5 Why is any additional legislation necessary? Why not extend the President's moratorium?

A. The President's moratorium covers only federally funded activities. In March, President Clinton called for a voluntary ban on privately funded activities. Legislation is necessary, however, to ensure that the privately funded research and clinical centers comply with the proposed prohibition on cloning of humans using the somatic cell nuclear transfer technique.

Q. 6 Would the NBAC recommendations, if followed, stop anyone from producing another "Dolly" or a cloned human being? If we prohibit cloning of humans in the U.S., will it not be done somewhere else?

A. There is no intention to prohibit anyone from cloning animals as long as such practices are subject to existing regulations regarding the humane use of animals. However, NBAC's recommendations, if implemented, will make it a violation of federal law for anyone to attempt to clone a human being using somatic cell nuclear transfer technology. Most countries in Europe have already placed a ban on such cloning.

Q. 7 Does the President agree with all the Commission's recommendations? Could there be instances in which cloning of humans would be acceptable?

A. Yes, the President endorses all of NBAC's recommendations. At this time neither the safety considerations nor the state of the science can justify any attempt to use this cloning technique for creating human beings. Furthermore, even if safety concerns were to be met someday, any serious consideration of applying this technology to create humans must be preceded by extensive public debate on the various ethical concerns associated with this issue. As a nation, we need to understand the ethical and social implications of this technology before it is ever used to create human beings.

Q. 8 With the proposed legislation, are we interfering with people's reproductive freedom?

A. Currently we do not have the science base to create a child by somatic cell nuclear transfer. Thus, what is being prohibited is currently not possible to do. Yes, the proposed legislation does restrict the reproductive freedom of individuals but in only limited ways. This narrow curb on reproductive freedom is necessary because we do not have the science to ensure that the risks to the resulting baby can be either eliminated or reduced to an acceptable level.

Q. 9 Since the "Dolly" experiment has not been replicated yet, are we overreacting? It took over 270 tries to produce "Dolly."

A. The fact that 276 attempts to clone a sheep failed and that the experiment has been successful so far only in sheep are

precisely the reasons to continue the moratorium, and to make it even stronger.

Q. 10 How will the recommendations and legislation affect research?

A. NBAC found that a ban on human cloning will not impede any important research at this time. Basic research in such areas as animal husbandry and drug development will continue. Similarly, basic research using somatic cell nuclear transfer technology to study, for instance, the potential for regenerating tissues and organs will continue. However, under current federal restrictions, human embryo research using federal funds will remain prohibited.

Q. 11 Why would you support a total ban on cloning people, but not on creating embryos using cloning technology for research?

A. The proposed ban on creating children using somatic cell nuclear transfer rests primarily on the fact that no information is available regarding the safety and effectiveness of this method in humans. Indeed, the technique clearly has many imperfections and uncertainties insofar as animal husbandry uses are concerned. As reported by the scientists in Scotland, out of 277 nuclear transfers involving cells from adult sheep, only one led to a live birth (Dolly).

Creation of human embryos for research through in vitro fertilization or somatic cell nuclear transfer is a separate question. NBAC did not speak to this issue, but the President has already acted on it. In 1994, the President imposed a prohibition on creating embryos for research; and the Congress included similarly restrictive provisions in the appropriations statutes for the Department of Health and Human Services for Fiscal Years 1996 and 1997. The prohibition applies irrespective of the technology used to create the human embryos.

Neither the President nor the Congress heretofore has placed restrictions on privately funded activities that involve creation of human embryos, whether for assisted reproduction or research.

Q. 12 If human embryo research is bad, why not ban it in the private sector as well? If human embryo research is good, why prohibit federally funded investigators from doing it?

A. Americans hold a range of views with respect to human embryo research, in vitro fertilization, or other methods of assisted human reproduction. Both the President and the Congress have determined that such activities are not appropriate uses for federal funds. Private sector restrictions raise difficult questions. They could impede, for example, in vitro fertilization as a method of assisted human reproduction for infertile couples who desire children that are genetically related to them. The Administration opposed addresssing the issue through legislation.

Q. 13 How does the Federal Government oversee privately funded research with human embryos? If a privately funded program were to use somatic cell nuclear transfer

technology to create human embryos for research purposes, what regulatory oversight would that research receive?

A. Privately funded research with human embryos is subject to regulation the FDA. If it is part of an effort to develop a drug, biologic, or medical device, the research is subject to regulation by the Food and Drug Administration. Otherwise, it is unregulated. However, many research institutions also voluntarily subject all privately funded research projects to the same human subjects protections that they are required to apply to federally funded research.

Q. 14 Pro-life groups are opposed to the use of human embryos for research. How do you explain the (Commission's position) (legislative proposal) to them?

A. Neither the Commission's report nor the President's legislative proposal alters the nature or the scope of current restrictions on research with human embryos. NBAC's recommendations do not address this area of research because the commission chose to focus on issues raised by creating a child, and did not speak to the issue of embryos..

Q. 15 What happens to human embryos created for research? If they are not implanted, isn't that tantamount to abortion, or even murder?

A. Creation of human embryos for research is a prohibited use of federal funds. The extent of such research under private sponsorship is unknown; therefore, we have no reliable information on the fate of human embryos used in this way.

Q. 16 How will this affect childless couples who see cloning as their only chance to have genetically related offspring?

A. Continuing the President's moratorium and strengthening it with penalties will have little practical effect on such couples. Currently neither the science base nor safety considerations make it possible to produce a child by somatic cell nuclear transfer.

Q. 17 Is the United States acting unilaterally on this issue? Are we treating this issue any differently than other countries?

A. Some European countries have already established legal prohibitions on the cloning of humans. To the extent that there are common aspects to our respective policies, we will certainly cooperate with these nations regarding enforcement.

Clinton Presidential Records
Automated Records Management System
[EMAIL] and Tape Restoration Project [Email]

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

This marker identifies a responsive email, already made available within another collection.

Collection: Elena Kagan Systematic

Bucket: Default

Creation Date: 1997-06-06

Subject: Re: Cloning

Creator: Elizabeth Drye

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: nobody (nobody@www2.whitehouse.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:17-SEP-1997 14:01:00.00

SUBJECT: Guest_Book_WH_WWW_MAIL

TO: guestbook (guestbook@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Remote host: 164.58.71.24

Remote IP address: 164.58.71.24

BROWSER: Mozilla/2.0 (compatible; MSIE 3.01; Windows 95)

[Sender information]

PERSONAL-NAME: Jake Rhinehart

[Message information]

SUBJECT: Cloning

[Message content follows]

I think it is moraly wrong to clone a person or any living thing. I think

all testing of it should be terminated because if some terorist knows how

he can clone different people and then we wouldn't know who the real one

is. Example: He could make anot

her president and teach it to act just like the real one.========== ATTACHMENT 1
==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01INR2RSKNHS00FMEU@PMDF.EOP.GOV> for guestbook@oa.eop.gov; Wed,
17 Sep 1997 14:04:52 -0400 (EDT)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01INR2RM3AN400C5SH@PMDF.EOP.GOV> for
guestbook@oa.eop.gov; Wed, 17 Sep 1997 14:04:49 -0400 (EDT)
Received: from www2.whitehouse.gov ([198.137.240.92])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01INR2REAWV2004119@STORM.EOP.GOV> for guestbook@oa.eop.gov; Wed,

17 Sep 1997 14:04:36 -0400 (EDT)
Received: by www2.whitehouse.gov (951211.SGI.8.6.12.PATCH1042/940406.SGI.AUTO)

for guestbook@oa.eop.gov id OAA03870; Wed, 17 Sep 1997 14:01:37 -0400
Apparently-to: guestbook@oa.eop.gov
Keywords: WWW-Correspondence; Guest_Book
Comments: Forwarded from White House WWW.
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: nobody (nobody@www1.whitehouse.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:27-SEP-1997 16:34:00.00

SUBJECT: Guest_Book_WH_WWW_MAIL

TO: guestbook (guestbook@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Remote host: ww-tp01.proxy.aol.com

Remote IP address: 152.163.204.135

BROWSER: Mozilla/2.0 (compatible; MSIE 2.1; AOL 3.0; Mac_PPC)

[Sender information]

PERSONAL-NAME: Mike Matthews

[Message information]

SUBJECT: Cloning

[Message content follows]

Why does the Federal Goverment not allow cloning. Instead, why doesn't

the Federal Government create a new commity to over-see all cloning in the

U S? Than you for your time.

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IO5749QZHS00K8MZ@PMDF.EOP.GOV> for guestbook@oa.eop.gov; Sat,

27 Sep 1997 16:40:32 -0400 (EDT)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01IO5747YF1C00ITRU@PMDF.EOP.GOV> for
guestbook@oa.eop.gov; Sat, 27 Sep 1997 16:40:30 -0400 (EDT)
Received: from www1.whitehouse.gov ([198.137.240.91])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01IO573IZ0BW005TPY@STORM.EOP.GOV> for guestbook@oa.eop.gov; Sat,

27 Sep 1997 16:39:57 -0400 (EDT)
Received: by www1.whitehouse.gov (951211.SGI.8.6.12.PATCH1042/940406.SGI.AUTO)

for guestbook@oa.eop.gov id QAA16445; Sat, 27 Sep 1997 16:34:42 -0400
Apparently-to: guestbook@oa.eop.gov
Keywords: WWW-Correspondence; Guest_Book
Comments: Forwarded from White House WWW.
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: nobody (nobody@www2.whitehouse.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:26-OCT-1997 20:08:00.00

SUBJECT: Guest_Book_WH_WWW_MAIL

TO: guestbook (guestbook@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Remote host: ww-tj65.proxy.aol.com

Remote IP address: 152.163.213.248

BROWSER: Mozilla/2.0 (compatible; MSIE 3.0; AOL 3.0; Windows

95)

[Sender information]

PERSONAL-NAME:

[Message information]

SUBJECT: cloning

[Message content follows]

In my point of view cloning is the second best way to help the hungry========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IP9WY9Z1MO00QWWZ@PMDF.EOP.GOV> for guestbook@oa.eop.gov; Sun,
26 Oct 1997 20:11:54 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01IP9WY71HHC00TGEG@PMDF.EOP.GOV> for

guestbook@oa.eop.gov; Sun, 26 Oct 1997 20:11:50 -0500 (EST)
Received: from www2.whitehouse.gov ([198.137.240.92])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01IP9WXRK968001UE6@STORM.EOP.GOV> for guestbook@oa.eop.gov; Sun,

26 Oct 1997 20:11:27 -0500 (EST)
Received: by www2.whitehouse.gov (951211.SGI.8.6.12.PATCH1042/940406.SGI.AUTO)

for guestbook@oa.eop.gov id UAA13560; Sun, 26 Oct 1997 20:08:14 -0500
Apparently-to: guestbook@oa.eop.gov
Keywords: WWW-Correspondence; Guest_Book
Comments: Forwarded from White House WWW.
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: david-fiala (david-fiala@sandhills.com@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:13-NOV-1997 10:36:00.00

SUBJECT: Re: New dork at work

TO: Philip C. Droege (Philip C. Droege@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Do me (and all) a favor and stay out of the lab.

From: Philip_C._Droege@oa.eop.gov[SMTP:Philip_C._Droege@oa.eop.gov]

Sent: Thursday, November 13, 1997 9:34 AM

To: david-fiala

Subject: Re: New dork at work

Message Creation Date was at 13-NOV-1997 10:34:00

There has been a lot of cloning lately========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01IPYI8E7D3400USMZ@PMDF.EOP.GOV> for "Philip C. Droege"@oa.eop.gov; Thu,
13 Nov 1997 10:39:56 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01IPYI88GJ3K00RMFJ@PMDF.EOP.GOV> for
Philip_C._Droege@oa.eop.gov; Thu, 13 Nov 1997 10:39:48 -0500 (EST)
Received: from mail.sandhills.com ([204.96.107.6])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01IPYI7J3BH20016AY@STORM.EOP.GOV> for
Philip_C._Droege@oa.eop.gov; Thu, 13 Nov 1997 10:39:15 -0500 (EST)
Received: by mail.sandhills.com with SMTP
(Microsoft Exchange Server Internet Mail Connector Version 4.0.995.52)
id <01BCF017.A5FC4A20@mail.sandhills.com>; Thu, 13 Nov 1997 09:36:41 -0600
X-Mailer: Microsoft Exchange Server Internet Mail Connector Version 4.0.995.52

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

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: vzonana (vzonana@os.dhhs.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:12-JAN-1998 13:20:00.00

SUBJECT: Crossfire/Tuesday/Shalala

TO: Mark D. Neschis (Mark D. Neschis@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Secretary Shalala has accepted an invitation to appear on

Crossfire as

a solo guest tomorrow (Tuesday), live, at 7:30 p.m.

I'm the staff contact and will staff her. Nancy Segerdahl at CNN

is

the contact for the show. She's at 898-7655.

We need to arrive at 7:15 p.m. or so for make-up at CNN studio:

820

First St., NW, 11th Floor.

I'll brief her. Interviewers are John Sununu and Bill Press.

Subjects: Medicare, childcare, cloning.========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ISAHJMXV5S008ZCS@PMDF.EOP.GOV> for Neschis_M@a1.eop.gov; Mon,
12 Jan 1998 13:27:18 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ISAHJKZO5C004YQV@PMDF.EOP.GOV> for
Neschis_M@a1.eop.gov; Mon, 12 Jan 1998 13:27:15 -0500 (EST)
Received: from B11WDC-OV08B.os.dhhs.gov ([158.70.254.1])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01ISAHJBEMDY00158J@STORM.EOP.GOV> for Neschis_M@a1.eop.gov; Mon,

12 Jan 1998 13:27:03 -0500 (EST)
Received: by B11WDC-OV08B.os.dhhs.gov; Mon, 12 Jan 1998 13:27:26 -0500 (EST)
X-Priority: 3 (Normal)
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: vzonana (vzonana@os.dhhs.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:12-JAN-1998 10:57:00.00

SUBJECT: Crossfire: Tuesday night?

TO: Mark D. Neschis (Mark D. Neschis@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Sec. Shalala has been invited onto Crossfire as a solo guest to

talk

about PoTUS's family friendly agenda(Medicare, childcare) and cloning.

Tormentors would be Sununu and Press. Tomorrow-- Tuesday, is their

preference, tho they could take her Wednesday.

Show is at 7:30 live, though they could if pressed pretape.

Thoughts?

Marty, is either day preferable sked-wise? ========== ATTACHMENT 1
==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ISACKFSMK0008OBX@PMDF.EOP.GOV> for Neschis_M@a1.eop.gov; Mon,
12 Jan 1998 11:04:24 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ISACKEIT8W003J9M@PMDF.EOP.GOV> for
Neschis_M@a1.eop.gov; Mon, 12 Jan 1998 11:04:21 -0500 (EST)
Received: from B11WDC-OV08B.os.dhhs.gov ([158.70.254.1])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01ISACJPT06I00158E@STORM.EOP.GOV> for Neschis_M@a1.eop.gov; Mon,

12 Jan 1998 11:03:49 -0500 (EST)
Received: by B11WDC-OV08B.os.dhhs.gov; Mon, 12 Jan 1998 11:03:58 -0500 (EST)
X-Priority: 3 (Normal)
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: vzonana (vzonana@os.dhhs.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:15-JAN-1998 09:43:00.00

SUBJECT: mclaughlin one on one

TO: Mark D. Neschis (Mark D. Neschis@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
donna's been invited to tape mclaughlin one on one on our big issues_

medicare, childcare, cloning. we're inclined to do it. tapes tomorrow at

11 a.m., airs over the wkd========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ISEGQHNL1S009T0T@PMDF.EOP.GOV> for Neschis_M@a1.eop.gov; Thu,
15 Jan 1998 09:46:58 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ISEGQF2M7K00NHF8@PMDF.EOP.GOV> for
Neschis_M@a1.eop.gov; Thu, 15 Jan 1998 09:46:54 -0500 (EST)
Received: from B11WDC-OV08B.os.dhhs.gov ([158.70.254.1])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01ISEGPPYGZW001KUM@STORM.EOP.GOV> for Neschis_M@a1.eop.gov; Thu,

15 Jan 1998 09:46:21 -0500 (EST)
Received: by B11WDC-OV08B.os.dhhs.gov; Thu, 15 Jan 1998 09:46:09 -0500 (EST)
X-Priority: 3 (Normal)
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: Bill_Dauster (Bill_Dauster@labor.senate.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:20-JAN-1998 19:12:00.00

SUBJECT: Re: Committee Agenda

TO: Barbara Chow (Barbara Chow@eop [UNKNOWN])
READ:UNKNOWN

TEXT:

F.Y.I., here are the bills that Jeffords' staff director Mark

Powden tells us they are planning to address in the committee:

_____ Forward Header

_____

Subject: Re: Committee Agenda

Author: Mark Powden at Labor

Date: 1/20/98 5:59 PM

still correct, voc rehab and workforce get married, and HIPAA stock

is

down, not sure whether lack of consensus or urgency. will worry

about

public health bills when i see the whites of their eyes...

_____ Reply Separator

_____

Subject: Committee Agenda

Author: Bill Dauster at Labor

Date: 1/20/98 5:38 PM

Mark,

Based on our discussion before the holidays, we got the impression

that you wanted to move the follwoing bills, in roughly this order.

Has your view changed, or is this still roughly right?

voc-rehab

workforce

Kassebaum-Kennedy technicals

tobacco

higher ed

confidentiality

health quality

Other pieces? NIH? cloning? SAMHSA? other health reauthorizations?

Thanks for your advice.

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ISLY1YDK6O0049H4@PMDF.EOP.GOV> for chow_b@a1.eop.gov; Tue,
20 Jan 1998 18:18:19 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ISLY1PYT9C0050ZK@PMDF.EOP.GOV> for
chow_b@a1.eop.gov; Tue, 20 Jan 1998 18:18:05 -0500 (EST)
Received: from mailsys.senate.gov ([198.78.181.132])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with ESMTP id <01ISLY1DPS3Q0025UR@STORM.EOP.GOV> for chow_b@a1.eop.gov; Tue,
20 Jan 1998 18:17:40 -0500 (EST)
Received: from mailexch.senate.gov by mailsys.senate.gov; (8.8.5/SCO5)
id SAA00083; Tue, 20 Jan 1998 18:18:06 -0500 (EST)
Received: from ccMail by mailexch.senate.gov
(IMA Internet Exchange 2.11 Enterprise) id 003B3E0E; Tue,
20 Jan 1998 18:14:11 -0500
Content-description: cc:Mail note part
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: Bill_Dauster (Bill_Dauster@labor.senate.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:20-JAN-1998 19:12:00.00

SUBJECT: Re: Committee Agenda

TO: Cynthia A. Rice (Cynthia A. Rice@eop [UNKNOWN])
READ:UNKNOWN

TEXT:

F.Y.I., here are the bills that Jeffords' staff director Mark

Powden tells us they are planning to address in the committee:

_____ Forward Header

_____

Subject: Re: Committee Agenda

Author: Mark Powden at Labor

Date: 1/20/98 5:59 PM

still correct, voc rehab and workforce get married, and HIPAA stock

is

down, not sure whether lack of consensus or urgency. will worry

about

public health bills when i see the whites of their eyes...

_____ Reply Separator

_____

Subject: Committee Agenda

Author: Bill Dauster at Labor

Date: 1/20/98 5:38 PM

Mark,

Based on our discussion before the holidays, we got the impression

that you wanted to move the follwoing bills, in roughly this order.

Has your view changed, or is this still roughly right?

voc-rehab

workforce

Kassebaum-Kennedy technicals

tobacco

higher ed

confidentiality

health quality

Other pieces? NIH? cloning? SAMHSA? other health reauthorizations?

Thanks for your advice.

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ISLY21U54W00WACQ@PMDF.EOP.GOV> for rice_c@a1.eop.gov; Tue,
20 Jan 1998 18:18:23 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)

by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ISLY1PYT9C0050ZK@PMDF.EOP.GOV> for
rice_c@a1.eop.gov; Tue, 20 Jan 1998 18:18:10 -0500 (EST)
Received: from mailsys.senate.gov ([198.78.181.132])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with ESMTP id <01ISLY1EN03G0025UR@STORM.EOP.GOV> for rice_c@a1.eop.gov; Tue,
20 Jan 1998 18:17:41 -0500 (EST)
Received: from mailexch.senate.gov by mailsys.senate.gov; (8.8.5/SCO5)
id SAA00089; Tue, 20 Jan 1998 18:18:06 -0500 (EST)
Received: from ccMail by mailexch.senate.gov
(IMA Internet Exchange 2.11 Enterprise) id 003B3E10; Tue,
20 Jan 1998 18:14:12 -0500
Content-description: cc:Mail note part
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: vzonana (vzonana@os.dhhs.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:20-JAN-1998 11:36:00.00

SUBJECT: Medicare TP's

TO: Joshua Silverman (Joshua Silverman@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Please send over any TP's Chris Jennings generates on today's

Rob't

Pear Medicare story.

You should have already received 1) old cloning TP's, still

current

2) Trent Lott transcript on Satcher and 3) release on Deadbeat Docs.

-- Victor

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ISLI7WM84W0077NF@PMDF.EOP.GOV> for Silverman_J@a1.eop.gov; Tue,
20 Jan 1998 10:44:47 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ISLI7SS8XC002L73@PMDF.EOP.GOV> for
Silverman_J@a1.eop.gov; Tue, 20 Jan 1998 10:44:42 -0500 (EST)
Received: from B11WDC-OV08B.os.dhhs.gov ([158.70.254.1])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01ISLI7MOJJK0029M4@STORM.EOP.GOV> for Silverman_J@a1.eop.gov;
Tue, 20 Jan 1998 10:44:37 -0500 (EST)
Received: by B11WDC-OV08B.os.dhhs.gov; Tue, 20 Jan 1998 10:42:37 -0500 (EST)
X-Priority: 3 (Normal)
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

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

CREATION DATE/TIME: 2-FEB-1998 16:40:10.00

SUBJECT: Re: Your response to Alta's comments

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

TEXT:
Alexander Capron wrote:

>

> On Tue, 13 Jan 1998, kramer wrote:

>

> > alta: it was not the foundation of my vote either and i distinctly

> > recall clarifying at the last session that such was the case for the

> > commission report. i wonder if steve was misquoted. bette

> >

>

> Bette:

>

> Good to see you last week. As I communicated on an earlier e-mail, I

> agree with Alta that the cloning report was not driven SOLELY by moral/

> ethical concerns other than safety but I don't take that to be what

Steve > was saying in the article that quoted him. Instead, I took the

gist to be

> simply that we didn't duck the ethical/social issues and rest our

> recommendation SOLELY on safety either. Indeed, the notion of the

> recommendation resting on two legs seems undeniable from the text of the

> NBAC report (as well as from my memory of the Commission's

deliberations, > but I don't expect the latter to be persuasive with

anyone). For example,

> we stated that in light of the unresolved "ethical and social concerns"

> about which debate was not yet resolved, we "therefore concluded that

> there should be imposed a period of time in which no attempt is made to

> create a child using somatic cell nuclear transfer" (Executive Summaryy,

> at p. iii of report) and "in addition to safety concerns, many other

> serious ethical concerns have been identified, which REQUIRE much more

> widespread and careful public deliberation before this technology MAY BE

> USED" (Conclusions and Recommendations #I, also p. iii; EMPHASIS mine).

>

> Of course, these kinds of conflicts are what keep historians employed!

> Alex

>

> **********

> * Alexander Morgan Capron *

> * University Professor of Law and Medicine *

> * Co-Director, Pacific Center for acapron@law.usc.edu *

> * Health Policy and Ethics (213) 740-2557 (voice) *

> * University of Southern California (213) 740-5502 (fax) *

> * Los Angeles, CA 90089-0071 (213) 740-0149 (fax)

* *

> **********

My memory of the deliberations is slightly different. I thought that

our "consensus concern" was the safety issue. And that concern was so

great that we called not only for the extension of the ban on federal

funding but also called for legislation both to regulate in the private

sector and to forestall multiple and differing state laws. Although not

reported in the paper, my recollection is that there were many on the Commission who had grave concerns about proposing legislation and did so reluctantly for the above reasons. I also thought that re. the other issues, we were calling attention to the multiple issues that had been brought to our attention, and the varying reactions to them from all peoples including the Comm members, and that we were unable and unwilling to come to any conclusions based on any of those issues feeling that society, ourselves included, needed more time to ponder and that the five year moratorium would provide that opportunity. I guess the difference between my memory and Steve/Alex is that I thought we were quite clear IN OUR CONVERSATIONS that there was no consensus for making any decisions based on the other issues. Bette

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: marilyn.yager (marilyn.yager@mcmail.vanderbilt.edu@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME: 9-FEB-1998 12:10:00.00

SUBJECT: two items

TO: Barbara D. Woolley (Barbara D. Woolley@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Do you know if Varmus made a statement on the cloning legislation yet?

And, I understand that HHS has sent the Organ Transplant regulations

to OMB. Can you check with OMB to find out how soon they are likely

to sign off on the regulations?

Thanks.

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ITDJ5SCKRK00D90U@PMDF.EOP.GOV> for woolley_b@a1.eop.gov; Mon,
09 Feb 1998 12:14:19 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ITDJ5NGTLS00S2HQ@PMDF.EOP.GOV> for
woolley_b@a1.eop.gov; Mon, 09 Feb 1998 12:14:15 -0500 (EST)
Received: from mcmail.vanderbilt.edu ([160.129.40.3])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with SMTP id <01ITDJ5EIC4I001PRM@STORM.EOP.GOV> for woolley_b@a1.eop.gov; Mon,

09 Feb 1998 12:13:59 -0500 (EST)
Received: from in2.mcmail.vanderbilt.edu by mcmail.vanderbilt.edu
(SMI-8.6/SMI-SVR4) id LAA04637; Mon, 09 Feb 1998 11:12:36 -0600
Received: from ccMail by in2.mcmail.vanderbilt.edu (SMTPLINK V2.11)
id AA887051223; Mon, 09 Feb 1998 11:10:25 -0600 (CST)
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: Carol_Pertowski (Carol_Pertowski@labor.senate.gov@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME: 9-FEB-1998 12:11:00.00

SUBJECT: Re: 2/10

TO: Jonathan T. Weber (Jonathan T. Weber@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:

Thanks for offering to come here. So far, it looks good for me to be able to leave on time tomorrow. The big issue on the floor tomorrow will be cloning, and I'm not directly involved in that, so I shouldn't be held up.

I just checked with the guards on where you should come. On C street, a very short walk from the corner of 1st and C is an employee/Federal worker entrance that is open til 6 pm. If you have some type of federal ID, they are supposed to let you in. Before I got my Senate ID, I occasionally had trouble with that entrance. So if that doesn't work, a very short walk further down C street will bring you to the public entrance. That closes at 7 pm, so there shouldn't be a problem.

I'll plan to be down near the first entrance at six pm. If you arrive and I'm not already there - the phone number in the office is
224-7139. That's a general number, but the office is small and you shouldn't have a problem getting to me. My phone was supposed to have been installed on Friday, but I still

don't have a direct line. If I get one before tomorrow,

I'll EMAIL it to you.

I'll check on restaurants near here. I've only been to a

couple and they were Ok

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

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ITDK6FX6KG00FCY3@PMDF.EOP.GOV> for "Jonathan T. Weber"@oa.eop.gov; Mon,

09 Feb 1998 12:43:04 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ITDK6CUJ5C00AX6I@PMDF.EOP.GOV> for
Jonathan_T._Weber@oa.eop.gov; Mon, 09 Feb 1998 12:43:01 -0500 (EST)
Received: from mailsys.senate.gov ([198.78.181.132])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with ESMTP id <01ITDK60FQDA001M0T@STORM.EOP.GOV> for
Jonathan_T._Weber@oa.eop.gov; Mon, 09 Feb 1998 12:42:43 -0500 (EST)
Received: from mailexch.senate.gov by mailsys.senate.gov; (8.8.5/SCO5)
id MAA24606; Mon, 09 Feb 1998 12:43:00 -0500 (EST)
Received: from ccMail by mailexch.senate.gov
(IMA Internet Exchange 2.11 Enterprise) id 0040D552; Mon,
09 Feb 1998 12:06:13 -0500
Content-description: cc:Mail note part
========== END ATTACHMENT 1 ==========

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: James C. Murr (James C. Murr@EOP@LNGTWY@LNGTWY [UNKNOWN])

CREATION DATE/TIME:11-FEB-1998 11:39:00.00

SUBJECT: Re: Varmus Cloning Testimony

CC: Elena Kagan (Elena Kagan@eop [UNKNOWN])
READ:UNKNOWN

TEXT:
Message Creation Date was at 11-FEB-1998 11:39:00

Thanks for the update (below). In clearing this statement, please

remember the

longstanding guidance for the review of scientific testimony - - i.e.,

in

part, "[i]n no instance should OMB staff alter a witness's statements

reporting

his or her own scientific research." Thanks.

Robert J. Pellicci

02/11/98 11:00:03 AM

Record Type: Record

To: KAGAN_E@A1 @ CD @ LNGTWY, Joshua Gotbaum/OMB/EOP@EOP, Jerold R.

Mande/OSTP/EOP@EOP, Rachel E. Levinson/OSTP/EOP@EOP

cc: See the distribution list at the bottom of this message

Subject: Varmus Cloning Testimony

HEADS UP --

Varmus will be testifying tomorrow before the House Commerce Committee on cloning ban legislation. According to HHS staff, his statement will concentrate on the science and will not break new ground. The testimony should arrive for clearance around 1:00 p.m. -- I'm planning to put a 4:00 p.m. deadline for views.

Message Copied

To:_____

Barry T. Clendenin/OMB/EOP@EOP

Richard J. Turman/OMB/EOP@EOP

Jill M. Pizzuto/OMB/EOP@EOP

James C. Murr/OMB/EOP@EOP

RECORD TYPE: FEDERAL (TRP NOTES MAIL)

CREATOR: Davis.Lori (Davis.Lori@mgh.harvard.edu@INET@LNGTWY [UNKNOWN])

CREATION DATE/TIME:11-FEB-1998 11:36:00.00

SUBJECT: - no subject (01ITGAN84KC200EPTE) -

TO: Katherine Hubbard (Katherine Hubbard@EOP [UNKNOWN])
READ:UNKNOWN

TEXT:
Hey -- do you have a copy of the POTUS's statement from yesterday re:

cloning? Muchas grassy-ass.========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
RFC-822-headers:
Received: from conversion.pmdf.eop.gov by PMDF.EOP.GOV (PMDF V5.0-4 #6879)
id <01ITGAN11RVK00EPTE@PMDF.EOP.GOV> for "Katherine Hubbard"@oa.eop.gov; Wed,

11 Feb 1998 11:42:29 -0500 (EST)
Received: from storm.eop.gov (storm.eop.gov)
by PMDF.EOP.GOV (PMDF V5.0-4 #6879) id <01ITGAMYXF1C00X9OK@PMDF.EOP.GOV> for
Katherine_Hubbard@oa.eop.gov; Wed, 11 Feb 1998 11:42:26 -0500 (EST)
Received: from phsexchico.partners.org ([132.183.126.50])
by STORM.EOP.GOV (PMDF V5.1-7 #6879)
with ESMTP id <01ITGAM5H4Z4001M0T@STORM.EOP.GOV> for
Katherine_Hubbard@oa.eop.gov; Wed, 11 Feb 1998 11:41:46 -0500 (EST)
Received: by phsexchico.mgh.harvard.edu with Internet Mail Service
(5.0.1458.49) id <D5MX5RK3>; Wed, 11 Feb 1998 11:41:36 -0500
X-Mailer: Internet Mail Service (5.0.1458.49)
X-Priority: 3
========== END ATTACHMENT 1 ==========