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Case file Number(s): 428500-430999
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Last Updated: 04/19/2023

WITHDRAWAL SHEET
Ronald Reagan Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
1. note	from T.G. to Pat re: AIDS (1p)	6/23/86	~~P-5~~ MOB 12/14/00
COLLECTION: WHORM: Subject File			ggc
FILE FOLDER: HE001 (430274)			3/21/96

RESTRICTION CODES

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

- P-1 National security classified information [(a)(1) of the PRA].
- P-2 Relating to appointment to Federal office [(a)(2) of the PRA].
- P-3 Release would violate a Federal statute [(a)(3) of the PRA].
- P-4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA].
- P-5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA.
- P-6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA].

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

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

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

ID# 428721

THE WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET

INCOMING

HE001

DATE RECEIVED: OCTOBER 06, 1986

NAME OF CORRESPONDENT: THE HONORABLE EDWARD P. BOLAND

SUBJECT: WRITES ON BEHALF OF 9-YEAR OLD RICHARD J. METCALF OF CHICOPEE, MASSACHUSETTS WHO IS IN DESPERATE NEED OF A LIVER TRANSPLANT AND REQUESTS ASSISTANCE AS HIS PARENTS INSURANCE*

ROUTE TO: OFFICE/AGENCY (STAFF NAME)	ACTION CODE	ACTION DATE YY/MM/DD	DISPOSITION TYPE RESP	DISPOSITION C	DISPOSITION COMPLETED YY/MM/DD
WILLIAM BALL	ORG	86/10/06	WBA	8	86/10/07
REFERRAL NOTE:					
REFERRAL NOTE:					
REFERRAL NOTE: FYI					
REFERRAL NOTE:					
REFERRAL NOTE:					

COMMENTS: * WILL NOT COVER THE TRANSPLANT

ADDITIONAL CORRESPONDENTS: MEDIA:L INDIVIDUAL CODES: 1230 ____ ____

__ MAIL USER CODES: (A)_____ (B)_____ (C)_____

*ACTION CODES:	*DISPOSITION	*OUTGOING CORRESPONDENCE:
*A-APPROPRIATE ACTION	*A-ANSWERED	*TYPE RESP=INITIALS OF SIGNER
*C-COMMENT/RECOM	*B-NON-SPEC-REFERRAL	* CODE = A
*D-DRAFT RESPONSE	*C-COMPLETED	*COMPLETED = DATE OF OUTGOING
*F-FURNISH FACT SHEET	*S-SUSPENDED	
I-INFO COPY/NO ACT NEC		
*R-DIRECT REPLY W/COPY *		
*S-FOR-SIGNATURE *		
*X-INTERIM REPLY *		

REFER QUESTIONS AND ROUTING UPDATES TO CENTRAL REFERENCE (ROOM 75,OEOB) EXT-2590
KEEP THIS WORKSHEET ATTACHED TO THE ORIGINAL INCOMING LETTER AT ALL TIMES AND SEND COMPLETED RECORD TO RECORDS MANAGEMENT.

TELEPHONE REPORT

Page 1 of 1

NAME (AS SHOWN OR TO BE SHOWN ON CONTROL SHEET)			NAME OF CONGRESSMAN/THIRD PARTY
LAST: Metcalf	FIRST: Richard	MIDDLE: J.	Edward P. Boland
SOCIAL SECURITY NUMBER: —	DATE OF CALL: 10/30/86	STAFF MEMBER: Ellen Thilbin	EXTENSION: (112) 225-5601 HOME ☐ D.C. ☐
BENEFICIARY'S ADDRESS: 219 Wildemere Street Chicopee, Massachusetts		TELEPHONE NO.: (413) 592-3240	SUBJ. MAT. CODE: 101

☑ Call to or ☐ Call from (Check as applicable)

☑ Congressman's Office ☐ Congressional Liaison Office ☐ Other

☐ Member of Public ☐ Regional Office _____

REPORT OR REQUEST INFORMATION:

I telephoned Ms. Thilbin to inform her that I had spoken to Mrs. Metcalf in response to her letter to the President. I explained that she told me the family is now awaiting a decision from the Tri-State Insurance Company's Board of Trustees as to whether Richard's operation can be covered. I told her that until this decision has been rendered, there is no action we can take to assist the Metcalfs. Ms. Thilbin also explained how Congressman Boland had contacted officials from Tri-State and was advised that there is a limited fund available to its members and Richard's operation could deplete the fund and set a precedent for other policy holders who are seeking similar services. We then discussed the need for the Metcalfs to contact the Consumer Action Center, and the Commissioner of Insurance if the redetermination is not favorable.

FT

ACTIONS REQUIRED:

COPIES ROUTED TO:

HCFA/OS
File
White House
Writer

☐ PREPARE CONTROL SHEET ☐ ACKNOWLEDGEMENT

☑ FINAL ☐ SUBSTANTIVE INTERIM ☐ REFER TO _____

PREPARED BY: A. Weatherbee

EXTENSION: 4-9028

FORM HCFA-83 (12-78)

8610150062

RECEIVED

1986 I I 4 PM 3:49

OFFICE OF THE SECRETARY
COMMUNICATIONS
CONTROL CENTER

THE WHITE HOUSE OF FICE

REFERRAL

OCTOBER 15, 1986

TO: DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN: LARRY DENARDIS

ACTION REQUESTED:
DIRECT REPLY, FURNISH INFO COPY

DESCRIPTION OF INCOMING:

ID: 428721

MEDIA: LETTER, DATED OCTOBER 3, 1986

TO: PRESIDENT REAGAN

FROM: THE HONORABLE EDWARD P. BOLAND
U.S. HOUSE OF REPRESENTATIVES

WASHINGTON DC 20515

SUBJECT: WRITES ON BEHALF OF 9 YEAR OLD RICHARD J. METCALF OF CHICOPEE, MASSACHUSETTS WHO IS IN DESPERATE NEED OF A LIVER TRANSPLANT AND REQUESTS ASSISTANCE AS HIS PARENTS INSURANCE WILL NOT COVER THE TRANSPLANT

CORRESPONDENCE 86 OCT 22 P4:45

PROMPT ACTION IS ESSENTIAL -- IF REQUIRED ACTION HAS NOT BEEN TAKEN WITHIN 9 WORKING DAYS OF RECEIPT, PLEASE TELEPHONE THE UNDERSIGNED AT 456-7486.

RETURN CORRESPONDENCE, WORKSHEET AND COPY OF RESPONSE (OR DRAFT) TO:
AGENCY LIAISON, ROOM 91, THE WHITE HOUSE, 20500

SALLY KELLEY
DIRECTOR OF AGENCY LIAISON
PRESIDENTIAL CORRESPONDENCE

October 7, 1986

Dear Mr. Boland:

Thank you for your October 3 letter to the President on behalf of Richard J. Metcalf, who is in need of a liver transplant.

Your interest in bringing this case to our attention is appreciated. I will be pleased to ask the appropriate Administration officials to look into this situation and do whatever is possible to assist Richard.

With best wishes,

Sincerely,

William L. Ball, III
Assistant to the President

The Honorable Edward P. Boland
House of Representatives
Washington, D.C. 20515

WLB:KRJ:MDB:mdb

cc: w/copy of inc to Larry DeNardis, Legis Affairs, HHS
- for DIRECT response
WH RECORDS MANAGEMENT HAS RETAINED ORIGINAL INCOMING

919
541-5952

October 7, 1986

Dear Mr. Boland:

Thank you for your October 3 letter to the President on behalf of Richard J. Metcalf, who is in need of a liver transplant.

Your interest in bringing this case to our attention is appreciated. I will be pleased to ask the appropriate Administration officials to look into this situation and do whatever is possible to assist Richard.

With best wishes,

Sincerely,

William L. Ball, III
Assistant to the President

The Honorable Edward P. Boland
House of Representatives
Washington, D.C. 20515

WLB:KRJ:MDB:mdb

cc: w/copy of inc to Larry DeNardis, Legis Affairs, HHS
- for DIRECT response
WH RECORDS MANAGEMENT HAS RETAINED ORIGINAL INCOMING

4287?1

EDWARD P. BOLAND
SECOND DISTRICT, MASSACHUSETTS

COMMITTEE
APPROPRIATIONS

Congress of the United States
House of Representatives
Washington, D. C.

October 3, 1986

The President
White House
Washington, D.C.

Dear Mr. President:

I am writing to you on behalf of a constituent of mine, nine year old Richard J. Metcalf of 219 Wildemere Street Chicopee, Massachusetts, who is in desperate need of a liver transplant.

Richard was born with a malfunctioning liver. At birth, his doctors performed an operation to temporarily correct the malfunction and decided to delay performing a transplant operation until Richard was older. The time has come for Richard to have a transplant and according to Richard's physician, Dr. Jeffrey Hayms of Hartford Hospital in Hartford, Connecticut, Richard needs this operation in order to survive. As you know, the cost of such an operation is extremely high, and without insurance coverage very few people can afford the operation. The problem facing Richard is that his parent's insurance fund, the Teamsters Union Local 404 Tri-State Insurance Fund in Bridgeport, Connecticut, will not cover the transplant because the Fund considers this procedure to be "experimental". Without insurance coverage, the Metcalf's cannot possibly afford to pay for the transplant.

I have contacted the National Institutes of Health, the Department of Health and Human Services' Health Care Financing Adminstration, and the American Liver Association in an attempt to find funds for the operation. Richard does not qualify for Medicare or Medicaid, and the Liver Association does not provide funding for transplant operations. Knowing of your interest in such cases, I am asking that you provide whatever assistance you can to this young boy. We both know the importance of helping those most in need, and I cannot stress enough to you how much the Mectcalf's need your help. The assistance you and Mrs. Reagan have provided in similar cases in the past has made a tremendous difference in the lives of several children. I am asking for that same type of assistance for Richard.

Thanking you in advance for your help, I am

Sincerely,

Edward P. Boland

EDWARD P. BOLAND
Member of Congress

EPB/ekp

ID# 429420

HE 001

THE WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET

INCOMING

DATE RECEIVED: OCTOBER 15, 1986

NAME OF CORRESPONDENT: MR. ROBERT ROSS

SUBJECT: ENCLOSES RELEASE ANNOUNCING THE MAJOR RESEARCH BREAKTHROUGH, DISCOVERY OF THE GENE FOR DUCHENNE MUSCULAR DYSTROPHY

ROUTE TO: OFFICE/AGENCY (STAFF NAME)	ACTION ACT CODE	ACTION DATE YY/MM/DD	DISPOSITION TYPE RESP	DISPOSITION C D	DISPOSITION COMPLETED YY/MM/DD
MILDRED WEBBER	ORG	86/10/15		C	86/10/24
REFERRAL NOTE:					
HHS	R	86/10/24			
REFERRAL NOTE:					
REFERRAL NOTE:					
REFERRAL NOTE:					
REFERRAL NOTE:					

COMMENTS: _____

ADDITIONAL CORRESPONDENTS: MEDIA:L INDIVIDUAL CODES: ____ ____ ____

PL MAIL USER CODES: (A)_____ (B)_____ (C)_____

*ACTION CODES:	*DISPOSITION	*OUTGOING CORRESPONDENCE:
*A-APPROPRIATE ACTION	*A-ANSWERED	*TYPE RESP=INITIALS OF SIGNER
*C-COMMENT/RECOM	*B-NON-SPEC-REFERRAL	* CODE = A
*D-DRAFT RESPONSE	*C-COMPLETED	*COMPLETED = DATE OF OUTGOING
*F-FURNISH FACT SHEET	*S-SUSPENDED	
*I-INFO COPY/NO ACT NEC		
*R-DIRECT REPLY W/COPY		
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*X-INTERIM REPLY		

REFER QUESTIONS AND ROUTING UPDATES TO CENTRAL REFERENCE (ROOM 75,OEOB) EXT-2590
KEEP THIS WORKSHEET ATTACHED TO THE ORIGINAL INCOMING LETTER AT ALL TIMES AND SEND COMPLETED RECORD TO RECORDS MANAGEMENT.

31
8A52
9746

November 7, 1986

Mr. Robert Ross
Vice President & Executive Director
Muscular Dystrophy Association
810 Seventh Avenue
New York, New York 10019

Dear Mr. Ross:

Your letter to President Reagan announcing the recent major advance in research on Duchenne muscular dystrophy has been referred to the National Institute of Neurological and Communicative Disorders and Stroke for reply. We certainly share your excitement--the achievement of Dr. Louis Kunkel and his associates in locating the gene for Duchenne muscular dystrophy is a cause of celebration for all of us.

The Institute is pleased to join with you in supporting Dr. Kunkel and other prominent scientists as they continue to investigate the abnormalities involved in Duchenne muscular dystrophy and similar devastating conditions. Best wishes for your future success.

Sincerely yours,

Murray Goldstein, D.O., M.P.H.
Director

Prepared by: NIH/NINCDS/OSHR/JMuller:1st 496-5751
Official file located in NINCDS files

8610280032

T H E W H I T E H O U S E O F F I C E

REFERRAL

OCTOBER 28, 1986

TO: DEPARTMENT OF HEALTH AND HUMAN SERVICES

ACTION REQUESTED:
DIRECT REPLY, FURNISH INFO COPY

DESCRIPTION OF INCOMING:

ID: 429420

MEDIA: LETTER, DATED OCTOBER 10, 1986

TO: PRESIDENT AND MRS. REAGAN

FROM: MR. ROBERT ROSS
VICE PRESIDENT & EXECUTIVE OFFICER
MUSCULAR DYSTROPHY ASSOCIATION
NATIONAL OFFICE
810 SEVENTH AVENUE
NEW YORK NY 10019

SUBJECT: ENCLOSES RELEASE ANNOUNCING THE MAJOR RESEARCH BREAKTHROUGH, DISCOVERY OF THE GENE FOR DUCHENNE MUSCULAR DYSTROPHY

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1986 I 27 PM 5:28
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RETURN CORRESPONDENCE, WORKSHEET AND COPY OF RESPONSE (OR DRAFT) TO:
AGENCY LIAISON, ROOM 91, THE WHITE HOUSE, 20500

SALLY KELLEY
DIRECTOR OF AGENCY LIAISON
PRESIDENTIAL CORRESPONDENCE

78305
TRACER

429420

MDA

MUSCULAR DYSTROPHY ASSOCIATION
Fighting 40 Neuromuscular Diseases
Active Member, National Health Council

M Webber

October 10, 1986

President and Mrs. Ronald Reagan
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D. C. 20005

Dear President and Mrs. Reagan:

Because of the tremendous support both of you have always given to MDA, I wanted you to be among the first to know about the good news reported in the attached advance copy of a press release we'll be issuing next week. As you'll see, the release announces the major research breakthrough in MDA history: discovery of the gene for Duchenne muscular dystrophy -- the most severe form of the disease. I'm sure you'll especially appreciate the fact that this achievement is a result of voluntary effort of the private sector.

I know I speak for Jerry Lewis and all of us involved in the work of MDA, as well as the patients and families of patients whom we serve, when I say that the two of you have been a source of great inspiration and motivation to all of us.

Many thanks for your help, and with warm good wishes...

Sincerely,

Robert Ross
Vice President & Executive Director

RR/jf
Attachment
cc/Jerry Lewis

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Cincinnati, Ohio

NEWS FROM MDA

MUSCULAR DYSTROPHY ASSOCIATION
810 Seventh Avenue, New York, N.Y. 10019
(212) 586-0808

FOR IMMEDIATE RELEASE

MDA-SUPPORTED RESEARCHERS FIND DUCHENNE MUSCULAR DYSTROPHY GENE

New York, October 16 -- A Muscular Dystrophy Association (MDA)-supported research team has discovered the hereditary unit, or gene, which, when defective, causes Duchenne muscular dystrophy -- the most severe form of the disease.

MDA National Chairman Jerry Lewis, the world leader of the fight against muscular dystrophy and related disorders, hailed the discovery as "a landmark event that opens a new era in our effort to find a cure for this vicious killer." The discovery of the gene was made by an MDA-supported investigative team at Children's Hospital in Boston and is reported in today's issue of the prestigious international scientific journal Nature.

Louis M. Kunkel Ph.D., who headed the successful research team, emphasized that discovering the gene for Duchenne muscular dystrophy is not the same as finding a cure for the disease. Stated Dr. Kunkel, "Much work remains to be done. With the discovery of the Duchenne gene, we move on to the next step -- to determine how the defective gene brings about the devastation of apparently healthy muscle." MDA-supported researchers have already uncovered important clues to understanding this destructive process.

- more -

The Duchenne muscular dystrophy gene, like all genes, contains the instructions for making a protein. All cells, including muscle cells, need many different proteins to survive and function. Faulty instructions resulting from a gene defect could cause a nonfunctioning or even harmful protein to be made. Or the instructions could be scrambled enough that no protein is produced.

"The discovery of the Duchenne gene," explained MDA President S. Mouchly Small, M.D., "brings us to the brink of identifying the affected protein and understanding in detail how an abnormality in the protein causes the disease."

Duchenne muscular dystrophy is the most common form of the disease, as well as the most common disease caused by a gene on the X chromosome, one of the two chromosomes that determine sex. The disorder, which strikes boys almost exclusively, is marked by a relentless progressive destruction of the muscles. Most patients are confined to wheelchairs by age 12, and few survive beyond their early twenties. While measures have been developed to improve the quality of life and prolong the survival of people with Duchenne muscular dystrophy, as yet there is no specific treatment for the disease.

MDA is a national voluntary health agency dedicated to seeking treatments and cures for 40 neuromuscular diseases, including Duchenne and other types of muscular dystrophy, myasthenia gra-

vis and amyotrophic lateral sclerosis. The Association currently supports some 500 individual research projects worldwide, as well as a network of 240 hospital-affiliated clinics where people with disorders covered by MDA's program receive medical care, orthopedic aids, and counseling.

###

CONTACT: Donald S. Wood, Ph.D.
Associate Director of Research
Muscular Dystrophy Association
(212) 586-0808

Craig H. Wood
Director, Public Health Education
Muscular Dystrophy Association
(212) 586-0808

Re: AIDS 430274

Pat,

HE001

FYI There is a serious inter-agency dispute brewing here; Justice & HHS. Cabinet Affairs will likely side w/ HHS. HHS fears that we a restating our AIDS/contagion position. PY

The DOJ opinion is not very clear.

TG.

6/23/86

AIDS

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(complete writethru _ department opinion)

WASHINGTON (UPI) _ AIDS victims may be fired or excluded from federal programs if public health officials and employers believe such acts will prevent spreading the fatal disease, a Justice Department ruling said today.

A copy of the Justice Department legal opinion, applicable to federal offices and others receiving federal aid, was obtained by United Press International after details were published by the New York Times.

The opinion stemmed from the debate over whether AIDS is a handicap under federal law. The ruling could be superseded by judicial decisions if the issue is taken to court.

The Justice Department emphasized its opinion is limited to section 504 of the Rehabilitation Act of 1973. "We have not examined any other federal, state or local laws that may extend broader protections in this field."

The opinion stated that "discrimination based on the disabling effects of AIDS on its victims may violate section 504, but that the statute does not restrict measures taken to prevent the spread of the disease."

The 49-page opinion, with 107 footnotes, was signed Friday by Assistant Attorney General Charles Cooper. It was done at the request of Ronald Robertson, general counsel of the Health and Human Services Department.

While acknowledging AIDS victims have some protection under federal civil rights laws, the opinion said: "It is imperative to recognize the distinction between the disabling effects of AIDS on its victims and the ability to spread the condition to others."

A person's dismissal from a job or exclusion from a federal program, solely because that person suffers from the effects of AIDS, would be illegal discrimination if the person is otherwise qualified for the job or program, the opinion said.

But it would not be necessarily illegal _ in fact, generally would be legal _ to dismiss that same person out of concern that he or she could spread AIDS, if the authority's fear of contagion was not merely "a pretext for discrimination on account of handicap," the department's opinion said.

Despite scientists' claims that AIDS is not spread through mere casual contact, the ruling said, "The risk of medical uncertainty must be borne" by the person alleging discrimination.

Those making such allegations, the decision said, bear the burden of showing that the risk they pose to the health of others "can be calculated with a high degree of medical certainty and is low enough" to be safely disregarded.

The department's intrepretation of existing federal law has implications for employers, schools, hospitals and other entities that receive federal money.

Federal agencies and recipients of federal aid may not legally discriminate against handicapped people who are "otherwise qualified" for a particular job, service or benefit.

Such institutions, under the staff lawyers' earlier recommendation, would have been restricted for the most part from taking action against AIDS victims.

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United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510

July 14, 1986

Mr. John Svahn
Assistant to the President
for Policy Development
The White House
Washington, D.C. 20500

Dear Jack:

Dr. Jonas Salk has asked me to forward to you a revised draft of the proposal for a Franco-American agreement to settle the litigation over the AIDS diagnostic test kit. This draft, which provides more detail on the proposed disposition of the patent dispute, supersedes the version that I sent to you prior to the meeting between Presidents Reagan and Mitterand earlier this month.

It appears that through Dr. Salk's efforts there has been significant progress toward a constructive resolution of this dispute. If Senator Mathias or the subcommittee staff can contribute further to this process, I hope you will not hesitate to call on us.

Sincerely,

Steven J. Metalitz
Chief Counsel and Staff Director

SJM:sd

Enclosure

STEVEN J. METALITZ
Chief Counsel and Staff Director

Subcommittee on
Patents, Copyrights and Trademarks
Committee on the Judiciary
United States Senate

Washington, D. C. 20510
(202) 224-5617

07-14-86
REVISED

AIDS
Proposal for
A Franco-American Agreement

Due to an unfortunate concatenation of circumstances, misunderstandings have arisen among teams of scientists in France and the United States as to the antecedents with respect to the discovery of the causes of AIDS. Nevertheless, the convergent efforts of these scientists have led to the development in both countries of blood tests for the diagnosis of AIDS virus infection which now permit the implementation of strategies for the avoidance of transfusion-transmitted infection. There is a continuing need for additional means to contain the viruses of AIDS.

The scientists of both countries acknowledge the important contributions that have been made in each country, and in a conciliatory spirit their respective institutions, the Institut Pasteur ("IP") and the National Institutes of Health/National Cancer Institute ("NIH/NCI"), have agreed to integrate their rights or claims to royalties from patents for sero-diagnostic kits. In the same spirit, they have agreed to place these royalties into a foundation to be established for furthering research in prevention and treatment of AIDS. This foundation will be called the Franco-American AIDS Foundation ("FAAF"), the Board of which will include equal numbers of French and American directors.

The basic principles have been agreed upon, and the details of the plans and programs will in due course be announced with respect to:

1. Satisfactory resolution of rights or claims to patents,
2. Creation of a joint fund with royalties,
3. Establishment of a foundation,
4. Utilization of foundation funds.

The principles that have been agreed upon are:

A. The parties have recognized that under the 1883 Paris Convention for the Protection of Industrial Property and the U.S. patent laws neither the NIH nor IP patent is prior art against the other and therefore, assuming PTO agreement, both patents can issue and coexist; the FAAF will own both patents.

B. The IP and the NIH/NCI will each receive annually from the FAAF, for continued support of research, an amount equal to one-third of the royalties received, the remaining one-third to be used for collaborative research on AIDS control and prevention, primarily directed to the specific needs of the developing countries.

C. A scientific advisory committee will be created by the Board of FAAF to consider and suggest collaborative research strategies supplementary to efforts which are supported from other sources, as well as to advise the Board on the allocation of the remaining one-third of the royalties.

D. This committee will also encourage the expansion of financial resources, from the private as well as the public sector, destined to encourage collaborative research toward the development of vaccines against AIDS.

FOR SETTLEMENT PURPOSES ONLY -
WITHOUT PREJUDICE TO EITHER
SIDE'S RAISING ANY AND ALL
ARGUMENTS IN THE INTERFERENCE

Coexistence of U.S. Patents to Gallo et al. and Montagnier et al.

Currently, an interference proceeding has been initiated in the United States Patent and Trademark Office (PTO) between U.S. Patent No. 4,520,113 of Gallo et al. (the "Gallo patent") and U.S. Patent Application Serial No. 785, 638 of Montagnier et al. (the "Montagnier application") to determine priority of the invention. A settlement proposal has been proffered which provides, in part, for the continued existence of the Gallo patent and the issuance of a United States Patent to Montagnier et al. (the "Montagnier patent"). The settlement proposal includes common ownership of these patents by a foundation, the Franco-American AIDS Foundation (FAAF). The FAAF would be empowered according to this scheme to take actions necessary to obtain and maintain both patents. The legal bases for the coexistence of the Gallo patent and the Montagnier patent according to this scheme are set forth below.

As a preliminary matter, the PTO has determined that the Montagnier application was patentable over all relevant prior art except for the activities of Dr. Gallo. Dr. Gallo's activities could be prior art against the Montagnier application only under 35 U.S.C. §102(a) or §102(g).[1/] However, the Montagnier application is entitled under the Paris Convention of 1883 to an effective U.S. filing date of September 15, 1983 (the filing date of

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1/ See Exhibit 1 for a copy of 35 U.S.C. 102.

the British counterpart application), which, in the absence of other evidence, establishes that date as a presumptive date of invention. Since the work of Dr. Gallo was not publicly known prior to September 15, 1983, it cannot be prior art against the Montagnier application under §102(a). In re Katz, 687 F.2d 450, 215 U.S.P.Q. 14 (C.C.P.A. 1982). Additionally, if Dr. Gallo's date of invention is after September 15, 1983, the activities of Dr. Gallo are not prior art under §102(g) against the Montagnier application.

If the Montagnier application were to issue today as a patent, it would become prior art under 35 U.S.C. §102 (e) against the invention claimed in the Gallo patent. However, the Montagnier patent could be removed as a reference against the Gallo claims if Dr. Gallo were to prove a date of invention prior to the December 5, 1983 U.S. filing date of the Montagnier application. According to the U.S. Court of Customs and Patent Appeals (now the Court of Appeals for the Federal Circuit) in In re Hilmer (Hilmer I), 359 F 2d. 859, 149 U.S.P.Q. 480 (CCPA 1966), the "date of application for patent" referred to in §102(e) is the date of application in the United States. A foreign priority filing date claimed by a U.S. patent application under 35 U.S.C. §119 may not be used as the applicable date of a §102(e) reference. Hilmer I at 876-7, 149 U.S.P.Q. at 494-5.

Initially, the application which gave rise to the Gallo patent was examined and deemed presumptively patentable over the prior art cited to the PTO. 35 U.S.C. §282. This included the

May 20, 1982 Science publication by Barre et al. It is plausible that the Barre article and the presentation by Dr. Montagnier at Cold Spring Harbor on September 15, 1983 would not be patent defeating prior art against the invention claimed in the Gallo patent if they are deemed to be non-enabling. See, e.g., In re LeGrice, 301 F.2d 929, 133 U.S.P.Q. 365 (C.C.P.A. 1962) (to amount to a statutory bar, a reference must place a skilled artisan in possession of the invention). It is arguable that, in order to provide an enabling disclosure, these references required public availability of the LAV virus. See In re Arqoudelis, 434 F.2d 1390, 168 U.S.P.Q. 99 (C.C.P.A. 1970). It could be contended that the LAV virus was not publicly available prior to the effective filing date of the Montagnier application.

Because the date of invention provided by Montagnier's British priority application is not based on activity in the U.S., the Montagnier invention appears not to be prior art against the Gallo patent under 35 U.S.C. §102(g). See In re Hilmer (Hilmer II), 424 F.2d 1108, 165 U.S.P.Q. 255 (C.C.P.A. 1970). Thus, if Dr. Gallo's legally cognizable date of invention is between September 15 and December 5, 1983, *neither* Gallo's invention nor the Montagnier application constitute prior art against the other and the only remaining impediment to the issuance of the Montagnier application as a U.S. patent is the pending interference.

Therefore, except for the interference, both the Gallo patent and the Montagnier patent could co-exist. The PTO rules

provide that, unless good cause is shown, interferences shall not be continued between applications and unexpired patents owned by a single party. 37 C.F.R. §1.602. Thus, if both the Montagnier application and the Gallo patent were commonly owned, i.e., by FAAF, the PTO should discontinue the interference.

The Manual of Patenting Examining Procedure (MPEP) in §2302 discusses the method for ending interferences when an application and a patent in an interference become commonly-owned after the interference has been declared. This discussion is intended to supplement the new interference rules which took effect on February 11, 1985. The MPEP commentary on Rule 602 (37 C.F.R. §1.602) states that interferences are to be terminated upon common ownership of the application and patent involved in the interference by judgement entered against one party or the other, citing Chillas v. Weisberg, 1928 CD 24 (Comm'r Pat. 1928).

However, these rules were promulgated prior to the decision by the Court of Appeals for the Federal Circuit in In re Longi, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). In Longi, contrary to prior PTO policy, the Court approved the coexistence of two patents in the names of different inventive entities, even though the claimed subject matter of the two patents was patentably indistinct, where neither case was prior art against the other (except under 35 U.S.C. §102(g)), provided that (1) precisely the same subject matter was not claimed in each case, (2) the patents were commonly-owned, and (3) a terminal disclaimer was filed so that both patents expire on the same date. The PTO

has acquiesced in the practice sanctioned by the Federal Circuit in Longi in 056 OG 316 by the abandonment of its prior procedure under which it would not accept terminal disclaimers in the case of commonly-assigned applications naming different inventive entities. Because the commentary in MPEP §2302 is apparently predicated on the incorrect, prior PTO policy, which was abrogated in Longi and in the 1985 changes in 37 C.F.R. §1.78(d) necessitated by the Patent Law Amendments Act of 1985 (Pub. L. 97-247), it should be possible to dissolve an interference when (1) the interfering cases become commonly-owned and (2) the interfering subject matter of the parties is patentably indistinct but not identical,[2/] by abandoning the interference and filing a terminal disclaimer, thus obtaining issuance of both patents in spite of the difference in inventive entities.

2/ In this regard, it should be noted that the subject matter claimed in the Montagnier application is not identical to that claimed in the Gallo. For example, the subject matter differs at least in the scope of the descriptions of the immuno diagnostic assays which are used.

/ENTIONS AND GRANT OF
5

TY OF INVENTIONS

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ous subject matter.

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only the patentee to whom
successors in title to the

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or any new and useful
t therefor, subject to the

§ 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other (Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; November 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691.)

§ 103. Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this ti-

STEPS

1. SET UP FAAF.

2. HAVE THE NIH PATENT AND THE IP APPLICATION TRANSFERRED TO FAAF WITH A STATEMENT THAT SEPTEMBER 15, 1983 - DECEMBER 5, 1983 WAS THE LEGAL DATE OF INVENTION (PATENTABLE STAGE) AND WITH THE AGREEMENT BY FAAF TO APPLY FOR IP PATENT. [PATENT GOES TO FAAF UPON GRANTING]

   AND

   IP WILL FILE A TERMINAL DISCLAIMER (SO PATENT WILL NOT EXTEND BEYOND ORIGINAL 17 YEAR LIMIT)

   AND

   NIH WILL TRANSFER APPLICATION OR PATENT OR LICENSE FOR CELL LINE TO FAAF.

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02-07-86/Bis

AIDS
Proposal for
A Franco-American Agreement

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B. A scientific advisory committee will be created by the Board of FAAF to consider and suggest collaborative research strategies supplementary to efforts which are supported from other sources, as well as to advise the Board on the allocation of the remaining one-third of the royalties.

C. This committee will also encourage the expansion of financial resources, from the private as well as the public sector, destined to encourage collaborative research toward the development of vaccines against AIDS.

Jack Svahn —
Per our conversation.
— Steve Metalitz

STEVEN J. METALITZ
Legislative Director

Senator Charles McC. Mathias, Jr.
387 Russell Senate Office Building
Washington, D. C. 20510

Washington, D. C. 20510
(202) 224-5617

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Thank you

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

June 23, 1986

CJ

Mrs. Ronald Reagan
The White House
Washington, D.C. 20500

Dear Mrs. Reagan:

Thank you for sending me the letter to Mrs. William Buckley from Dr. Mathilde Krim, American Foundation for Aids Research, regarding release of experimental drugs for Aids patients.

We also have been concerned about these issues and are committed to accelerating the drug evaluation process in any way consistent with sound scientific principles.

I have extended an invitation to Dr. Krim and members of the Foundation to meet with me to discuss these issues.

Sincerely,

Otis R. Bowen, M.D.
Secretary

HAND DELIVERED