

Press Conference: Secretary Margaret Heckler

United States. Dept. of Health and Human Services

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UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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PRESS CONFERENCE
SECRETARY MARGARET HECKLER

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Hubert H. Humphrey Building
First Floor Auditorium
200 Independence Avenue
Washington, D. C.

Monday, April 23, 1984
1:15 p.m.



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P R O C E E D I N G S

1
2 MS. DE REAL: Sitting up here on the platform with
3 Secretary Heckler will be Dr. Ed Brandt, Assistant Secretary
4 for Health; Dr. Robert Gallo, Jr., he's the Chief of Laboratory
5 Tumor Cell Biology at NCI; Dr. James Mason, Director of CDC;
6 Dr. Vincent Devita, Director of the National Cancer Institute;
7 Dr. James Weingarten, Director of NIH; and Dr. Peter Fissinger,
8 who is Associate Director of the National Cancer Institute.

9 The Secretary will make a statement, and then the
10 panel on the Secretary will take questions.

11 STATEMENT OF MARGARET M. HECKLER, SECRETARY OF
12 HEALTH AND HUMAN SERVICES

13 SECRETARY HECKLER: Good afternoon.

14 As I believe you anticipate, this press conference
15 will be devoted to the subject of AIDS, in which area there is,
16 of course, important news. But, unfortunately, we have not
17 made similar breakthroughs in the field of laryngitis. So I
18 apologize for the state of my voice today.

19 On June 14th of last year, about 10 months ago, I
20 traveled to Denver to tell the United States Conference of
21 Mayors that I had designated the conquest of AIDS as the
22 federal government's number one health priority. I told the
23 Mayors and the American people that this awesome medical
24 problem was a disease of two names. One was AIDS, Acquired
25 Immune Deficiency Syndrome; the other was Fear.

1 In the intervening months, public education and
2 public understanding have reduced the incidence of fear; the
3 panic which was beginning to spread to the American people has
4 been quieted.

5 Today, I am pleased to...whisper that...

6 (Laughter.)

7 ...the arrow of funds, medical expertise, research
8 and experimentation with the Department of Health and Human
9 Services, and its allies around the world, have aimed and
10 fired at the disease AIDS, and has hit the target only two or
11 three rings away from the bullseye itself.

12 Here are the specifics:

13 First, the probable cause of AIDS has been found --
14 a variant of a known human cancer virus, called HTLV-III.

15 Second, not only has the agent been identified, but
16 a new process has been developed to mass produce this virus.
17 This discovery is crucial because it enables us for the first
18 time to characterize the agent in detail and to understand its
19 behavior.

20 Thirdly, with discovery of both the virus and this
21 new process, we now have a blood test for AIDS which we hope
22 can be widely available within about six months. We have
23 applied for the patent on this process today.

24 With the blood test, we can identify AIDS victims
25 with essentially 100 percent certainty. Thus, we should be

1 able to ensure that blood for tranfusion^s is free from AIDS.

2 We should be able to prevent transfusion-related AIDS cases,
3 as well as those which might appear in hemophiliacs.

4 We'll also be able to promptly and easily diagnose
5 people ^{who've been} infected by the virus, and perhaps develop ways to
6 prevent the full syndrome from occurring.

7 Finally, we also believe that the new process will
8 enable us to develop a vaccine to prevent AIDS in the future.
9 We hope to have such a vaccine ready for testing in approxi-
10 mately two years.

11 The credit for these discoveries belongs to many.
12 Under leadership of the Public Health Service, many scientists,
13 both inside and outside of the government, have given their
14 time and their dedication, and their genius, to solving this
15 problem.

16 In particular, credit must go to our eminent Dr.
17 Robert Gallo, chief of the National Cancer Institute Laboratory
18 of Tumor Cell Biology, who directed the research that produced
19 this discovery; and to Dr. Edward Brandt, the Assistant
20 Secretary for Health, who has led the Public Health Service
21 effort in the fight against AIDS since its inception; and Dr.
22 Vicent DeVita, very eminent Director of the National Cancer
23 Institute; Dr. James Mason and Dr. James Curran of the Centers
24 for Disease Control, and to their scientific teams.

25 I would like to turn now to the eminent scientist who

1 has made the breakthrough which prompts the conference today,
 2 to call upon Dr. Robert Gallo, with applause and appreciation,
 3 the Secretary of Health and Human Services and the apprecia-
 4 tion of the American people. And I'd like to ask Dr. Gallo
 5 to come forward to make a brief statement, to respond to your
 6 questions; and to be accompanied by Dr. Brandt, who has led
 7 this fight, and who, from within the Department, has been a
 8 very essential part of the team. --

9 Dr. Gallo...

10 STATEMENT OF DR. ROBERT GALLO, CHIEF OF THE NCI
 11 LABORATORY OF TUMOR CELL BIOLOGY, RE: AIDS

12 DR. GALLO: Thank you, Madam Secretary.

13 I should start and be brief by first saying that there
 14 are obviously other major contributors. And, in our own group,
 15 I have to mention someone who came to us from Czechoslovakia,
 16 who has been on rather a permanent stay with us. Dr. Mikulas
 17 Popovic, who played a very major role in some of the growth of
 18 cells that would be permissive for the large-scale production
 19 of the virus. Also, a post-doctoral from Switzerland, Dr.
 20 Jorg Schupbach; Dr. Sarngadaran, a colleague of mine for many
 21 years, who is a protean chemist; and a technician, who did a
 22 lot of work with, I think, a reasonable amount of risk, Betsy
 23 Reed.

24 These were some of the major people in the early part
 25 of this work that has just been described, from our laboratory.

1 Obviously, a lot of this could not have been initiated without
2 the epidemiological studies that have been carried out, the
3 provision of tissues, and the collaborations with many people,
4 including CDC.

5 Also, a lot of this could not have been done in this
6 period of time without the previous support from the Cancer
7 Institute on the earlier HTLV isolates. These viruses, as
8 this audience is aware, I'm sure, are called retro-viruses.
9 And they were isolated in the first time in human beings by
10 my colleagues and myself in the late 1970's in aggressive forms
11 of human T-cell cancers.

12 We found other variants of that original virus in
13 ensuing years. But, the dominant type, we called HTLV-1, is
14 linked to a form of aggressive cancer of T-lymphocytes. With
15 that background, we focused on AIDS with the idea that a
16 similar, but probably ultimately different retro-virus, but
17 belonging to the same family, might infect the same kind of
18 cell, a T-cell. And, instead of making it grow as a cancer
19 would lead to its rapid death.

20 There was precedent for that. Many of you know that
21 precedent. In cat leukemia, a virus that causes leukemia,
22 the same family of virus, the retro-virus, but different than
23 the HTLV family, can cause leukemia of T-cells, but a minor
24 variant can cause an AIDS-like disease.

25 There was also important work that I have to mention

3
that

1 from Max Essex at Harvard, and his colleagues. He has had his
2 neck out for sometime, sometimes with criticisms for using an
3 assay for antibodies in the serum of patients with AIDS or pre-
4 AIDS that was not always completely 100 percent certain; but
5 an assay that he believed was giving him important leads.

6 We now can state that that assay, for the most part --
7 there might be some false positives -- but for the most part
8 is able to detect viruses of the whole HTLV family, including
9 the new virus that we call HTLV-III.

10 It's not as specific. It is certainly not going to
11 be as good as the assays that will come out of having mass-
12 produced the exact right virus. But, the fundamental data
13 published by him and in collaboration with CDC in part, I
14 believe to be correct.

15 Many of you, or all of you, have seen discussions
16 about work in Paris. There was. There is not. There has
17 never been any fights or controversies between us and a group
18 in France. I came back from a meeting astounded to see this
19 kind of discussion.

20 The Laboratory at the Pastuer Institute and my
21 Laboratory have been friends for about 15 years. We, in fact,
22 are collaborating. There were some miscommunications while I
23 was away, and some misunderstandings.

24 We have active collaboration in the coming month if
25 what they identified in science a year ago is the same as what

1 we now have produced more than 50 isolates of and in mass
2 production, and in detailed characterization. If it turns out
3 to be the same, I certainly will say so, and I will say so
4 with them in the collaboration.

5 But, it is obvious that that paper one year ago did
6 not tell you that the ediology of AIDS is fairly clear now.
7 It is obviously the fact that there are four papers that are
8 going to be published in Science that have added to this
9 interpretation. And we think the two laboratories are very
10 likely to come together, although I cannot say at this point
11 whether the viruses are identical.

12 QUESTION: Dr. Gallo, what does this discovery that
13 you and your colleagues have made mean for the thousands of
14 AIDS victims who have the disease now, and are dying from it?

15 DR. BRANDT: Let me just explain to you what we will
16 be doing now, and I think that's the real answer to the question.

17 In the first place, as you know, one of the papers
18 describes a process whereby we can test for the presence of
19 the virus in blood. That will allow us to do two things.

20 One, it will allow us to screen for transfusions;
21 and, second, it will allow us to begin to define the early
22 course of this disease, with the hopes that by some form of
23 early intervention we can prevent it from taking its full toll.

24 The second is that we should be able to develop a
25 vaccine over the next few years. It's not something that's

1 going to happen right away.

2 Finally, it may give us a lead, although, at the
3 moment, we haven't seen it, towards some more definitive
4 treatment.

5 So what we have at the moment is not particularly
6 of great benefit to people with the disease right now -- that
7 is, immediately -- but it hopefully will be in a short while.

8 QUESTION: Could I ask a question about the cause
9 of this? It looks to me like it's more very strong circumstan-
10 tial evidence than hard facts proof.

11 Have you been able to take this agent, inject it
12 into animals, or expose animals to it, and have an AIDS-like
13 syndrome produced?

14 DR. GALLO: Yes...do you have more question on it...?

15 I'll repeat it, if you like.

16 ^{RIMPLE}
Judy Rimple, isn't it? Has asked me is it hard and
17 fast proof, or is it a very strong lead? Have we been able to
18 reproduce the disease in animals as the, I suppose, hard and
19 fast proof that she would like?

20 QUESTION: Well, I mean, that is classic test for
21 ^{an infectious agent}
it, is it not?

22 DR. GALLO: Yes, that you can produce a disease in
23 an animal. Yes and no, Judy. It's a very complex issue, but
24 I'll give you the best explanation I can.

25 Yes, it's being inoculated in animals now. No,

1 there hasn't been anywhere near enough time to look for a
2 disease.

3 But let me give you a problem both ways with that
4 kind of an experiment, which was not always fulfilled by
5 Robert Kock, by the way; and he still had been able to draw
6 intelligent ^{etiological} devialogical conclusions at a time you didn't have ^{he}
7 today's technology.

8 But, first of all, I'll give you an example:

9 Give an AIDS leukemia virus a vorectoral (ph.)
10 virus, which produces leukemias in the gibbon ape, when
11 innoculated into other monkeys, produces nothing; when innoculat-
12 ed into the Gibbon, produces leukemia.

13 Conversely, a herpes ^{saracoid} scenarid virus in a certain
14 species of marmasets that carries the virus produces nothing
15 in the marmaset, that is its natural host. Innoculating into
16 other primates, it causes cancer.

17 What's the conclusion from the animal study?

18 I think we have something potentially better than
19 that. In collaboration with the CDC, Jim ^{Curran} Kearn and I, and
20 other members of the CDC and members of my Laboratory, have
21 been doing prospective studies -- people who donate blood in
22 blood banks, who then are recipients, develop AIDS, as a
23 consequence of that blood transfusion, might be akin to having
24 the animal innoculation done in human beings, by accident.

25 SECRETARY HECKLER: Excuse me just a minute. I'd

1 like to have Dr. Kearn respond as well. He's not here?

2 Dr. Mason, how about you? Would you like to make a
3 comment for CDC?

4 DR. MASON: How about letting Dr. Gallo complete his
5 statement?

6 QUESTION: I'm sorry, please let Dr. Gallo.

7 SECRETARY HECKLER: Yes.

8 QUESTION: I appreciate you wanting to --

9 DR. GALLO: I think what she wanted to do is to
10 show you that they have these blood donors, and they have the
11 serum samples. And we have been testing them and broke the
12 code with Jim Kearn, who belongs to the CDC. And it was an
13 appropriate for an interruption.

14 In any case, let me say that, obviously, with the
15 collections that knowledge this, with the blood transfusion
16 donors and recipients, material is available to test.

17 With a good assay to this virus, an assay that is
18 definitive because we have learned how to master this virus.
19 Our problem in the past has been that we've had large numbers
20 of detection of this virus. And I haven't been able to speak
21 about it because I wasn't sure exactly what it was.

22 But when we learned how to -- you see, that virus,
23 when it infects a human T-cell from a patient's blood in the
24 laboratory, will kill that cell.

25 So we couldn't keep the virus going. We couldn't

1 analyze what we had and we were frustrated.

2 And a lot of people, some of you probably here,
3 were asking me, you know, "Why are you holding this?" Or,
4 "Why don't you say more about that?" Because we had to under-
5 stand what the heck we were doing. We had to know what this
6 virus was in detail before we would talk about it.

7 When we learned how to mass produce, we were able
8 to develop reagents, antibodies, nucleic acid probes. We
9 could then go back to the other isolates and know what we
10 had, again. Okay?

11 And, now, in collaboration with the CDC, when
12 prospective studies of blood transfusion victims and donors,
13 it's like having a human being inoculated with the virus
14 experimentally, isn't it?

15 So that data is becoming available in the collabora-
16 tive study that involves CDC and us. And, also, it will
17 involve the Pasteur Institute. And so things will come
18 together. And I suspect the next few months are going to be
19 also exciting times.

20 Does that answer your question? I think the agent
21 is at hand that produces the disease.

22 *Michael*
Martin
Chase QUESTION: Dr. Gallo, how many patients have you
23 looked at? What percentage have shown response to the anti-
24 bodies?

25 DR. GALLO: Yes, okay, what we are publishing in a

1 few days' times is approximately 90 percent of the people with
2 AIDS have detectable antibodies in their serum that react
3 specifically with this particular virus.

4 Patients with pre-AIDS -- you know, the at risk
5 groups and the people with lymphadenopathy -- it's about 80
6 percent. And normal heterosexuals, healthy heterosexuals,
7 it's less than a half -- it's less than one percent, about a
8 half of one percent.

9 The homosexual population, we haven't done a large
10 survey yet, but what we have done is the people who have come
11 to a clinic, so it's a selected group.

12 And there's a substantial percent that have anti-
13 bodies right now, but I can't give you the final data on that.

14 Now, more recently, in collaboration with Jerome
15 ^{Grupman} Grupman, in Boston, New England (Beaconist) and ^{Bijan Safai} Dijun Saphais
16 at Sloane-Kettering, and their sera that they sent to us
17 blind, we scored in a hundred percent of AIDS cases.

18 That work has not yet been gathered for publication.

19 QUESTION: Are you testing the Haitian population?

20 DR. GALLO: Yes, we're testing the Haitian population.
21 I don't have enough statistics to say what percentage, but
22 it's clear that there are Haitians who have antibodies to this
23 virus.

24 QUESTION: Dr. Gallo, if this does turn out to be
25 the virus, realistically, how many years will it be before

1 there is a marketable vaccine, based on past experience?

2 DR. GALLO: I think Dr. Brandt already made a comment,
3 which I would agree with.

4 DR. BRANDT: Yes, we're estimating a minimum of two
5 years, probably more like three years. In two years, we think
6 it's possible to begin to start human trials. But I think
7 we have a -- one of the first steps that has to be accomplished
8 is to mass produce this virus in sufficient quantity to
9 accomplish that.

10 So I think we're talking about probably three years.

11 QUESTION: Excuse me, the French told me this ^{We're going to}
_{hurry}
12 morning that they would predict at least five years. And
13 Lou Montagnier said he thought it might be five to 10 years.

14 Why are you more optimistic than the French are?

15 DR. BRANDT: I'm just more optimistic, I guess. I
16 don't know. I'm more optimistic. Except that I believe it
17 can be done, that's all.

18 QUESTION: It is my understanding that there is no
19 virus presently available for any retrovirus.

20 DR. BRANDT: No vaccine.

21 QUESTION: Any vaccine for any retrovirus.

22 DR. BRANDT: That's correct.

23 QUESTION: You've got a situation where you have got
24 a number of viruses that have been known for as long as two
25 decades and they haven't been able to produce vaccines.

1 Why are you confident that you can get one for AIDS
2 in two years?

3 DR. GALLO: I believe that the reason that there's
4 a wide difference in what time it takes, you know, it obvious-
5 ly is not in the interest of the scientist to give a fast
6 prediction. You'll only press us all, say, "Remember what you
7 said eight months ago, four months ago?" You'll be giving
8 us a clockwatch.

9 I can only say that we have the problem of mass
10 production solved. I think most of you are aware there's
11 nothing in the literature from any laboratory that says they
12 have an ediological agent that they can mass-produce.

13 I haven't seen anything published from France, or
14 anywhere else, that if these two viruses are the same, that
15 they even have it continually grown in the laboratory; only
16 that it's tranqently transmitted to T-cells. I haven't seen
17 any publication that says they have a line that's permissive
18 that mass produces.

19 That's one of the significances of what we are
20 telling you today. Therefore, we can develop reagents, and we
21 will develop those reagents rapidly. And it will be less than
22 two years that those reagents will be available.

23 Now, your question gets tricky. How do you know
24 you'll have one that really works in AIDS patients?

25 Of course, the prediction for that is impossible.

1 You have no hundred percent proof that it will be two years,
2 a hundred years, or it may never come from vaccination. It
3 depends on subtleties of biology. But, the principles are
4 there. The likelihood -- the best we can say in Science --
5 with the technology available, we should have things ready
6 to be able to be tried by then.

7 And although I said yes to Dr. Brandt that
8 there is no vaccine for any retrovirus, there is work going on
9 in Scotland, William Jarret, who is coming to NIH as a
10 Fogerty Scholar, and he's done a lot of work in vaccination^S
11 with cats.

12 Talking to him last week leads me to believe he does
13 have data that is of interest in the vaccination of cats with
14 leukemia, the ^{for} prevention of leukemia. I don't know all that
15 data yet.

16 There's also a group at Ohio State. And there are
17 also people --

18 QUESTION: How long before exposure until symptoms
19 occur?

20 DR. GALLO: How long before exposure to the virus do
21 people get symptoms? I don't have the answer to that yet.

22 In ^{to} perspective, long-term studies, and collaborations with
23 people at CDC, and with clinicians, we should have that answer.

24 But, from epidemiological grounds, Jim Kearn already
25 estimated that from the blood transfusion studies to be some-

1 where from -- I think it's two to eight years. And it was
2 a mediant (ph.) of five-six years...

3 From other work, Jim Kearn at CDC, I believe he
4 told me at a meeting we were at together that from these
5 blood transfusions, his estimate -- I'm sorry I gave you the
6 wrong answer. They're telling me nine months.

7 QUESTION: Dr. Gallo, what would you tell to a
8 ^{fo}perspective high risk candidate for AIDS, in nonmedical terms,
9 about the significance of today's announcement, the prospect
10 for developing it? In as basic English as possible.

11 DR. GALLO: I think the most immediate simple -- I
12 can conceive a lot of applications of this, all right? But
13 you want something fairly simple and fairly quick. It's
14 obvious, the blood bank assay, the transfusion cases, the at
15 risk populations can be detected. That should be of some
16 immediate use. That's a simple one. I'd like to back off with
17 that.

18 QUESTION: Dr. Gallo, may I follow up on that, if
19 I may?

20 If you had as a patient in private practice one of
21 the 2,300 currently diagnosed AIDS victims in this country,
22 what would you tell him that this discovery means, if anything,
23 to him?

24 DR. GALLO: Can somebody else answer that?

25 DR. BRANDT: I think what we would try to tell that

1 person is that this discovery may not be of direct benefit to
2 them in the immediate future, but it opens up, for the first
3 time, I think, the real possibility that we may be able to
4 develop an intervention system, that we haven't so far.

5 QUESTION: But, you're in time to save him?

6 DR. BRANDT: Well, it depends on how long he lives.

7 QUESTION: Well, what is the expectation now on the
8 average AIDS victim?

9 DR. BRANDT: For what? For their lifespan?

10 QUESTION: Yes, sir.

11 DR. BRANDT: Slightly over three years.

12 QUESTION: They have a chance then?

13 DR. BRANDT: They might.

14 MS. DEL REAL: Excuse me.

15 Ladies and gentlemen, the Secretary has to leave now,
16 but I'm sure that a few of the scientists will stay for a few
17 more questions.

18 Thank you.

19 QUESTION: De. Brandt, a question about the test.

20 Will the test be able to determine a person that
21 creates symptoms? How will the test be applied? Will it be
22 a blood test from a person? They'll take a sample of blood
23 and they'll be able to tell if they have AIDS, or pre-AIDS?
24 And will that test solve the problem of hemophylliacs and
25 blood transfusion?

1 DR. BRANDT: It should solve the problem of both
2 blood transfusions and for hemiphiliacs in the sense that when
3 this test becomes commercially available, then, of course, we
4 will be able to screen blood.

5 And, by the way, we're talking about real volume.
6 You know, there are over three million blood transfusions
7 given every year. We figure we have to have 23 million tests
8 annually in order to --

9 QUESTION: Dr. Brandt, they're commercially available
10 to what?

11 DR. BRANDT: "Commercially available" means that we
12 will have a large enough volume that we can get out to the
13 1,700 or so blood banks and use it.

14 Let me finish this question first, if I could.

15 The second thing is that it should be possible to
16 detect AIDS in the presymptomatic patient so that we can begin
17 to understand the course of this disease. In response to the
18 earlier question about treatment, our hope would be that if we
19 can detect this virus early on, then we might be able to inter-
20 vene with simpler steps than somebody who already has a
21 suppressed or depressed immune system.

22 QUESTION: Are you saying then that the presence of
23 HTLV or the presence of antibodies to HTLV indicates that in
24 nine months, or some period of time, this person is definitely
25 going to have AIDS?

1 DR. BRANDT: We do not know whether or not there is
2 a carrier state for this disease at the present time. So the
3 answer is no, you can't be certain that the presence of the
4 virus would indicate that fullblown AIDS would develop.

5 Dr. Gallo...

6 DR. GALLO: Yes, before you keep saying HTLV, say
7 "HTLV-III", and say that it may in time be the same as what has
8 been called LAV in a couple of publications. ..

9 And, also, related to therapy, we're collaborating --
10 in fact, I'm supposed to go tomorrow afternoon to Wistar
11 Institute in Philadelphia for a discussion with Hillary
12 ^{Kapowski} Grapowski, the Director of that Institute there. And Dr.
13 Danny Bolonaise of Duke University, and a few other people,
14 my colleague, Dr. Fissinger, to discuss ideas for therapy.

15 We're trying to put our heads together. And one idea
16 that Dr. Grapowski has been discussing with us is the direct
17 therapy of someone with the disease if you catch them early
18 enough, as Dr. Brandt has said, it's by making an antibody to
19 antibody. That antibody to an antibody looks like an antigen,
20 a more effective antigen. It might produce the type of an
21 immune response that eliminates the virus.

22 And if this disease, if we learn that the pathogenesis
23 of this disease is something like this -- a group of T-cells
24 are infected. They're dying. Virus is released. Other T-4-
25 cells get infected. They die. Eventually, since the T-4 cell

1 makes the growth factor, the T-cell growth factor, that led
2 us to first isolate HTLV-I, and since T-cell growth factor
3 ^{interleukin-2} makes all the other T-cells grow, in the end you don't have any
4 T-cells at all in AIDS.

5 But, if, early on, you can knock out the virus with
6 a proper immunological approach, it's possible that somebody
7 with the disease, or with the preliminary aspect of the dis-
8 ease, could be greatly benefited.

9 But we can't say that with certainty. That therapy
10 in practical aspects are now in the first set of an experiment-
11 al phase, at least for people with the disease.

12 QUESTION: Dr. Brandt, how much will this test cost,
13 and how much will it add to the cost of blood transfusions?

14 DR. BRANDT: In the first place, we don't know how
15 much it will cost when we make it commercially available,
16 clearly, since it is commercially available. So I don't know
17 the answer to your question.

18 QUESTION: Dr. Brandt, when will it become commer-
19 cially available?

20 DR. BRANDT: As soon as the entire techniques are
21 worked out. We're anticipating now six months.

22 QUESTION: You would test everybody who donates
23 blood? Is that how it would work?

24 DR. BRANDT: I'm sorry?

25 QUESTION: You'd test everybody who donates?

1 DR. BRANDT: I'm not sure whether we would test
2 everybody that donates, or whether we would test the blood
3 before it's transfused. Most likely, we would test everybody
4 before it's donated.

5 QUESTION: Doctor, do you know yet why the groups
6 like Haitians get AIDS as opposed to other ethnic groups?

7 DR. BRANDT: Not really, no. We -- no.

8 (Laughter.)

9 QUESTION: A couple of days ago, the comments about
10 a possible AIDS virus were very tentative and very carefully
11 qualified. And, today, we're getting a very bold statement.

12 What accounts for the abrupt change of posture?

13 DR. BRANDT: Well, this is the first time you've
14 heard from us.

15 (Laughter.)

16 What the news media has been writing, I can't be
17 accountable for.

18 QUESTION: I'm talking about people from the NCI as
19 well as the CDC in Atlanta. Very cautiously guarded statements
20 just a couple of days ^{ago} and...

21 DR. BRANDT: Most of those people were not familiar
22 with all the details on the work. That's the explanation for
23 that, as I see it.

24 QUESTION: Dr. Brandt, in talking about approval of
25 a vaccine, aren't you sort of blithely leaping over what could

1 be a very difficult, ethical problem, namely, the testing of
2 this for safety and efficacy on healthy individuals?

3 DR. BRANDT: Absolutely not. I mean, we would
4 certainly test any vaccine. That's why I said earlier that we
5 would go through the whole period of human testing first before
6 we ever put a vaccine on the market, for sure.

7 QUESTION: Dr. Brandt, could you comment on the
8 difficulty of testing such a vaccine when it concerns a dis-
9 ease with such a fatality rate? Maybe Dr. Gallo would...

10 DR. BRANDT: I'm not sure I understand the question.
11 I mean...

12 QUESTION: AIDS has a very high fatality rate. Can
13 you comment on the difficulty of human clinical trial of such
14 a vaccine? ^{Would} Won't you be using a live virus, or ^{a killed} kill virus?

15 DR. BRANDT: Well, we're going to develop the vaccine
16 first. Then we'll be able -- it depends entirely on what kind
17 of vaccine comes out of it. So we certainly are not going to
18 test in humans any vaccine that would put those people at risk
19 of ^{the} disease.

20 QUESTION: Dr. Brandt, I don't believe that you
21 answered my earlier question on that very point, which was:

22 If this is a vaccine to prevent the disease, you're
23 going to have to test it on people who haven't got the disease,
24 and then possibly expose them to the disease to see whether or
25 not it will work.

1 DR. BRANDT: Yes, but you're making the assumption
2 that that's the only kind of vaccine there is, the one that
3 exposes people to disease. That's not true, so that that's
4 not the way -- I mean, you're presupposing the kind of vaccine.

5 QUESTION: I'm not presupposing anything. One, it's
6 a vaccine that will prevent a disease if somebody is exposed
7 to it.

8 DR. BRANDT: Right. --

9 QUESTION: Are there other kinds?

10 DR. BRANDT: We don't have a vaccine at the moment.
11 And we would certainly take all --

12 QUESTION: You're talking about having one in a
13 couple of years.

14 DR. BRANDT: We will take all the necessary steps
15 to be sure that that vaccine is safe. And we will not expose
16 anybody to this disease, through a vaccine or any other way.

17 QUESTION: So how are you going to go through your
18 trials on healthy volunteers?

19 DR. BRANDT: Well, as soon as we see the vaccine,
20 then I'll be able to answer that question.

21 QUESTION: Dr. Mason talked about these antibody
22 tests that Dr. Gallo has told us about a little bit. I mean,
23 that went by very quickly. Maybe the CDC could tell us a
24 little bit more about that?

25 DR. MASON: Just a word about it. I think you have

1 heard a most magnificent report today from Secretary Heckler
2 and Dr. Brandt and Dr. Gallo. And we are just in the beginning
3 stages of what we can actually do to build on these discoveries

4 We've described AIDS as a fatal disease with certain
5 characteristics. Now, with the kind of tests that Dr. Gallo
6 has developed, we can begin to look at AIDS as a whole
7 spectrum of disease, a disease that starts probably with an
8 initial infection. It probably has presymptomatic phases.
9 It probably then gets into a lymphanopathy phase. And we have
10 not even completely described the disease yet, because we
11 haven't had the tests available to do so.

12 And building upon these things that ~~have~~ been reported
13 today, we can begin to test populations of people to see who
14 has antibodies, who does not have antibodies, when do those
15 antibodies after exposure to such things as blood transfusions
16 where we can trace back to the donor?

17 It just begins a whole series of miracles that can
18 occur as a result of these very basic reports that you've
19 heard here today. We would hope that within a year or two as
20 we meet with you again that we are going to have much, much
21 information that will enable us to control and prevent this
22 horrible disease.

23 QUESTION: Dr. Gallo cited your data — that's not
24 a good answer, I'm sorry.

25 DR. BRANDT: What's the question?

1 QUESTION: The question is: Dr. Gallo cited some
2 perspective antibody tests that were done at CDC as --

3 DR. GALLO: I said they were going to collect -- the
4 reason they were CDC, they were done in our lab. They may be
5 independently done recently in CDC. There was serum provided
6 by CDC from blood donors, blood recipients, a variety of other
7 perspective --

8 QUESTION: Would you go over that data for us a
9 little bit?

10 DR. GALLO: Well, I would rather have it collected
11 completely and have it in the form where I could present it to
12 you properly. I'll just give you the general statement. I'm
13 not going to give you the details on that now, so the answer
14 is no, I won't.

15 What I'll tell you is that ^{vo}perspective studies mean
16 blood bank donors and recipients, and those people who were
17 followed who eventually got AIDS.

18 Let's say the collaboration with CDC in that respect
19 with our laboratory is producing fruitful results. The
20 specifics will come later. And that's as far as I ^{I'd} go.

21 I'll get back to -- you wanted to get back to that
22 question?

23 You keep asking about the vaccine, when it comes up,
24 what's going to be available in two years. As best as a
25 scientist can calculate. We can't predict anything 100 percent.

1 But you've got to give some answers.

2 We have the proteans available in large amounts from
3 these viruses by recognity ^{recombinant DNA} (ph.) and a technology. You're not
4 going to vaccinate with a live virus, in my view. In my view,
5 you'd vaccinate perhaps with the envelop protean of the virus.
6 We'll go to recognity in any technology, we are doing that now.

7 And we will produce the protean that way. That
8 protean, I would certainly be willing to take if I were a
9 high risk person, and I'd do it voluntarily. I don't know
10 how many people that entails.

11 That's the direction we're kind of thinking about.
12 Earlier, I was asked and didn't have a chance to answer, when
13 was HTLV-III first found by this...and I said the answer to
14 that, there's no one day I can tell you, only that we have
15 large numbers of isolates that were openly discussed at NCI
16 in meetings that involved 30-40 people in our lab, and many
17 outside people, including members of CDC. That we could not say
18 what they were because we couldn't get them to grow, but we
19 believed firmly for many reasons they were in the HTLV family.

20 But, because we couldn't get the cells to grow, we
21 were stuck in saying what they were. And we didn't want to
22 report on it because we didn't know the significance of it.

23 But, when we got -- and I believe this is the only
24 one that exists right now -- a permissive cell, that is, a
25 cell that will grow forever and not be hurt by infection with

the virus, that will mass-produce the virus--when we can do that reproducibly, we now can characterize that virus in detail, make what we call reagents against the mass-produced virus, its proteans, get its nucleic acids, go back to all the earlier isolates, and have the answer.

The first time we saw what wasn't HTLV-I and II, I don't know exactly when. It was certainly over a year ago, a year and a half ago. I don't know.

DR. BRANDT: Let me introduce the other people on the stage. Down here at the far right is Dr. Vince DeVita, who is Director of the National Cancer Institute. Next to him is Dr. James Weinberg, the Director of NIH; and Dr. Peter Fisinger also, from the NCI.

We'll take only one more question and then we'll have to leave. And it's going to be Chris Russell, who has been waving her hands there for a long time.

MS. RUSSELL: It's a couple of questions on the same point.

One, are you going to be proceeding ahead with the blood tests and all of these other clinical things before this whole question of whether we've got the same virus, and so on, is resolved?

DR. BRANDT: Yes.

MS. RUSSELL: Second of all, Dr. Gallo, could you describe how you will work with the French to figure out if they

1 have got the same virus? And, also, why hasn't that been done
2 already?

3 DR. BRANDT: Well, let me -- Chris, that's going to
4 take a long time to describe that in any detail. And I think
5 that --

6 MS. RUSSELL: We have been waiting for the science
7 to be presented, and this is the opportunity that many of us
8 have. *And we have a lot of science writers here who would like to get*
9 *fine information.*

10 DR. BRANDT: I understand.

11 MS. RUSSELL: We the Science Register would like to
12 get the information.

13 DR. BRANDT: All right, it will be described in some
14 detail. If Dr. Gallo wants to take a quick, easy shot at it,
15 why that's fine.

16 Do you want to try it?

17 DR. GALLO: It should not be terribly difficult,
18 having enough reagents sent to us to analyze. Our problem has
19 been this. Originally, one of the French co-workers Francois
20 Sin Sevari (ph.), came to our lab to learn the techniques to
21 grow T-cells. That was two years ago.

22 We provided them with reagents of HTLV-I and HTLV-II.
23 In other words, in fact, they started out by learning the
24 techniques to grow T-cells in obtaining T-cell growth factor
25 from our laboratory.

There's been a collaboration from day one, in short.

1 Now what they originally sent us and believed not to be related
2 to the HTLV family did not react with the reagents we had.
3 And that was not clear, what was going on.

4 In retrospect, if the viruses are the same as what
5 we now have in numbers, we already know they clearly do belong
6 to the HTLV family. It's probably because they really didn't
7 have enough material.

8 They didn't have enough material to send to us.
9 That's what's been the delay. They don't have a mass producer.
10 As of a few weeks ago, they didn't have it successful in a
11 cell line.

12 I talked to with Chermon and Montagnier today and
13 two weeks ago. They believe they're getting it into a cell
14 line just now.

15 When you see the papers published in Science, you
16 will see that we've been mass-producing it for six months.
17 Okay? So we've had it in the cell line for a long time. I
18 was developing reagents over that period of time to go back
19 and do the analyses.

20 Now what they are sending us are what we call plates
21 with some of the virul proteans that they have obtained put
22 on the plates to see if they react with antibodies. We've
23 made, because we've been able to mass produce virus. Other-
24 wise, you can't get enough virus to make antibodies in a rabbit
25 or a goat.

1 We will test what they send us now in that way.
2 Also, they will send us DNA from cells infected with their
3 virus. And we will see if there is relationship with the genes
4 we are cloning now from HTLV-III.

5 Thirdly, one of my co-workers, Dr. Sargar Dar, will
6 go over there in the last week of April, which is very soon, I
7 guess, or the beginning of May, and we will work on protean
8 comparisons directly with them.

9 I'm not sure they have enough quantity to do every-
10 thing I'd like to do. But I feel confident that in a matter
11 of a month's time or less, we should be able to have a more
12 definitive answer.

13 The problem before is there could not be a definitive
14 answer from lack of amount of material that was sent to us.

15 *Levy Atman* QUESTION: Dr. Gallo, I have sort of a political
16 question. And that is if, in fact, your -- the virus you
17 discovered and the French ^{discovery} are the same, it sounds like both
18 you and the French believe, isn't this announcement sort of
19 stealing a little bit of the thunder from the French?

20 I mean, everybody says, "Well, we think the French
21 have been doing great work, but we've..." I mean, it seems
22 somewhere we're taking the credit where the French should share
23 it.

24 DR. BRANDT: Well, I think Dr. Gallo said in his
25 opening statement that if this turns out to be the same virus,

1 he's readily going to give them the credit for reporting it
2 first. I don't think that's a problem. I mean, the point is
3 that we've come to this point. We've isolated it. We've
4 mass produced it. He has, I should say, not "we". And it's
5 now available.

6 DR. GALLO: I could have presented an electron
7 micrograph and reversed ^{transcriptase} transcript activity of a variant a
8 long time ago.

9 What I'm telling you is there are 50 isolates.
10 They are characterized. Test is available for blood banks.
11 The reagents are available to characterize anything now and
12 a method is available to isolate this virus routinely.

13 If I held that back from you, you would be mad at
14 me for other reasons.

15 (Laughter.)

16 DR. BRANDT: Well, thank you all very much.

17 (Whereupon, at 2:00 o'clock, p.m., the press confer-
18 ence was concluded.)
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REPORTER'S CERTIFICATE

This is to certify that the attached proceedings
before The Department of Health & Human Services
in the matter of:

The Press Conference of
Secretary Margaret Heckler

Monday, April 23, 1984

were held as herein appears and that this is the original
transcript thereof for the file of the Department
or Commission.



Official Reporter

DATE: April 24, 1984.