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**Folder Title:**  
Meeting with Direct Access 1/13/94

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December 16, 1993

MEMORANDUM

TO: Kristine M. Gebbie  
FROM: W. Steve Lee *W. Steve Lee*  
SUBJECT: Direct Access Diagnostics

You (and Carlos) are scheduled to meet with Elliott Millenson of Direct Access Diagnostics to discuss the FDA approval of their home access testing and counseling service. The meeting is scheduled for January 13, 1994 at 4:30 p.m. Direct Access Diagnostics is represented by Bruce Fried of The Wexler Group, who asked for the meeting.

Their November 24 letter made reference to an earlier briefing for Dr. David Satcher. According to Dr. Satcher's staff, the briefing amounted to a short chat following a speech at a conference. There is a briefing scheduled with Dr. Satcher for January 28. Consequently, there are no advance comments from CDC available as you requested.

Please advise me (or Carlos) if and how to approach FDA on this sort of issue. Or will you simply provide the advance for Dr. Satcher.

cc: Carlos Velez

*Let FDA know in meeting  
to them  
purpose of mtg is for me to  
listen & be informed  
of their work  
no commitments, comments, etc.*

THE WHITE HOUSE  
WASHINGTON

December 16, 1993

Bruce M. Fried  
The Wexler Group  
1317 F Street, N.W., Suite 600  
Washington, D.C. 20004

Dear Mr. Fried:

This letter confirms your meeting with Kristine M. Gebbie, National AIDS Policy Coordinator, on Thursday, January 13, 1994. The 30 minute meeting begins at 4:30 p.m. and will be held in her office at, 750 17th Street, N.W., Suite 1060 in Washington, DC.

If you have questions or need further clarification, please call me at (202) 632-1090.

Sincerely,

W. Steve Lee, Executive Assistant  
and Scheduler to  
National AIDS Policy Coordinator

Shall I?...

1/13 c130 (30)

NOV 24 1993 THE WEXLER GROUP

1317 F Street, N.W.  
Suite 600  
Washington, D.C. 20004  
202-638-2121  
202-638-7045 Telecopy

November 24, 1993

Dr. Kristine M. Gebbie  
National Aids Policy Coordinator  
750 17th Street, NW  
Suite 1060  
Washington, Dc 20503

Bruce M. Fried  
Executive Vice President

*fine to set up  
get comments from  
CDC in advance  
Carlos should set up*

Dear Dr. Gebbie:

I am writing on behalf of my client, Johnson & Johnson and its Direct Access Diagnostics subsidiary, to request a meeting with you.

The purpose of the requested meeting would be to familiarize you with a new effort to fight HIV and its transmission. I think you will find this new program to be an incredibly exciting development, as we have.

Direct Access Diagnostics is in the process of securing FDA approval for its Home Access HIV Testing and Counseling Service (it is currently in the final phase of clinical trials and is expected to proceed from there on an expedited basis.) A one-page summary of the program is attached. I think that even this short summary demonstrates how intelligently, thoroughly, and sensitively this testing and counseling service has been conceptualized and developed. As it is envisioned, this service would be available over-the-counter, by mail order and through public health programs.

Direct Access Diagnostics' President and CEO, Elliott Millenson, has met with and briefed Dr. David Satcher, Director of the Centers for Disease Control, leaders of the major AIDS organizations and others. The responses have been very enthusiastic.

We hope that you will be available for 15 to 30 minutes so that Mr. Millenson can brief you on this exciting development. We want to accommodate your busy schedule and are willing to meet at your convenience anytime during the week of December sixth.

Thank you for your consideration. I look forward to seeing you in the near future.

Sincerely yours,



Bruce M. Fried

cc: Elliott Millenson  
Jack McGrann

## DESCRIPTION

The proposed home access testing and counseling service has four major components: pre-test counseling and information booklet written by former Surgeon General C. Everett Koop; test kit containing instructions and materials to obtain and mail a fingerstick dry blood spot sample; HIV testing performed by a national clinical reference laboratory; Test Results and Counseling Center accessed via toll-free 800 number.

A client would obtain the test kit and pre-test counseling booklet through a variety of potential distribution points (such as college health center or pharmacy). The pre-test counseling booklet contains information on HIV transmission, prevention, and general information about AIDS and HIV. The kit instructions provide detailed information on how to obtain a fingerstick blood sample. The kit includes the Becton Dickinson MICROTAINER® Brand Safety Flow Lancet with an auto-retracting blade ( the same lancet used in the recently FDA approved home cholesterol kit).

The blood sample is placed on 903 filter paper encased within a "test card". The test card contains a unique identification number. This number is the only way in which the sample is identified, thereby maintaining total anonymity. The dry blood spot is sent via a pre-paid mailer to a national reference laboratory. The sample is tested initially by ELISA. Reactive samples are tested by repeat ELISA and then by confirmatory assay.

The client calls the counseling center via a toll-free number to obtain test results, counseling, and referrals to HIV related resources. The referral database has been provided through a cooperative relationship with the Centers for Disease Control and Prevention. Counselors undergo an intensive training program which was developed jointly by the American Social Health Association (which runs the National AIDS Hotline) and Cicatelli Associates (which conducts counselor training programs for the New York State Public Health Department).

THE WHITE HOUSE

WASHINGTON

December 23, 1993

MEMORANDUM

TO: Randy Wykoff, Director, Office of AIDS and Special  
Health Issues, Food and Drug Administration

FROM: Kristine M. Gebbie, R.N., M.N. *W Steve Lee for*  
National AIDS Policy Coordinator

SUBJECT: Meeting with Direct Access Diagnostics

Please note that I will be meeting with Elliott Millenson of Direct Access Diagnostics about their home testing and counseling service (description attached). The product is pending FDA approval. It is not my intention to offer any commitments or comments on the product, but simply to gather information. I also understand that Mr. Millenson will meet with Dr. Satcher in late-January. Please let me know if you have any questions or information that would be helpful.

Attachment

M E M O R A N D U M

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration

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DATE : January 3, 1993

FROM : Randolph F. Wykoff, MD, MPH & TM *Randolph Wykoff*  
Associate Commissioner for AIDS  
and Special Health Issues

SUBJECT : Meeting with Direct Access Diagnostics

TO : W. Steve Lee  
Office of the National AIDS Policy Coordinator

Thank you for your recent note about Ms. Gebbie's up-coming meeting with representatives of Direct Access Diagnostics. We appreciate knowing about such meetings.

Please let me know if you would like any relevant background materials prior to this meeting, or if you, or Ms. Gebbie, have any questions after the meeting.

RECEIVED

JAN - 7 1994