

Is Flo expecting
more of an
answer ~~from~~
from me?

Yes - I spoke with her again
after giving you this. She would
like to submit a one-pager to
POTUS on the status of this issue.
She's not been able to get Kevin.

June 21, 1994

MEMORANDUM TO CAROL RASCO

FROM: Flo McAfee *(FM)* *file*

RE: OraSure *don't we have file started?*

Today, I received the attached letter relating to the ongoing concerns over the approval of OraSure. In addition over the last several weeks, the Americans for a Sound AIDS/HIV Policy and Rich Cizik of the National Association of Evangelicals have been earnestly lobbying Congress about approving OraSure.

What is a recommended response from the Administration to the concerns that: (a) the FDA is moving too slowly with regards to OraSure; and (b) the Administration is doing very little to seek approval of the product. Also, is it advisable to have a White House representative attend the FDA's June 22 public hearing?

Thank you for any assistance on this issue.

cc: Alexis Herman
Steve Hilton
Keith Boykin

*Carol—
Per my voice mail to you while
in NY. Kevin advised Flo on
the public hearing issue. She also
has his direct # for updates
per his request.
Roy*

A.S.A.P.

Americans for a Sound AIDS/HIV Policy

P.O. Box 17433 • Washington, D.C. 20041 • Telephone: 703/471-7350 • Fax: 703/471-8409

June 17, 1994

Flo McAfee
Office of Public Liaison
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

Dear Flo,

On Wednesday, June 22, the FDA is holding public hearings on over-the-counter HIV diagnostics as well as "novel sample collection devices." There will be a number of people present to speak for and against home testing as it is known. Additionally, there will be people speaking on behalf of approval of OraSure. That the FDA is even holding this meeting in respect to OraSure is very unfortunate, in that they seem to intentionally want to confuse it with home testing. Fortunately, they have at least divided the program into the morning session which is focused on novel devices and the afternoon on home testing.

I believe it is important, if at all possible, that the White House speak out forcefully for approval of OraSure at this time, either through its AIDS office, or the call for approval come directly from the President or his senior staff. I say this now fully a year-and-a-half into the Clinton presidency in that the response to the epidemic now will be viewed in the future as on his "watch". We have seen no significant effort in the last year-and-a-half to stem the spread of this disease in a meaningful way in communities of color, the center-point of the present HIV epidemic. Excuses regarding the Reagan and Bush administrations' lack of response to this epidemic won't "wash" in the future. Clearly, those administrations allocated significant resources to both prevention, education, and research, while their resolve to promote greater knowledge of infection was always stymied by AIDS activism. The attitudes opposing diagnosis are largely now gone in the AIDS community, so it should be clear sailing if we really want to promote more knowledge of HIV infection.

Flo, I have been intimately involved in this issue for eight years, and feel very strongly that the effects of this epidemic in communities of color, particularly in the African American community, will be potentially devastating. The OraSure product will help numerous individuals in underserved communities learn their HIV status, which in turn will allow many to not infect others. While home testing may benefit the "white, worried-well", as it has done with home pregnancy tests, those not being

Dedicated to limiting total suffering from AIDS/HIV.

able to afford the test, but at greatest risk, will be left defenseless without the OraSure product available to them. I do not believe that further delay will be viewed historically in any context other than sheer dereliction of responsibility to those most at risk. This simple device is perhaps the easiest way we have today to stem the spread of this disease.

When I heard the President speak on World AIDS Day last year, I was very moved by what I thought was a sincere commitment to help limit suffering. I am no longer convinced of that sincerity since I have seen a bureaucracy "sit on its hands" in respect to this product since he and his administration became aware of its need and the gravity of the present situation. I do not believe there are words that can express as strongly as I feel the tragedy this epidemic is bringing to the African American community and how totally unnecessary that tragedy is and will be. I know it is more complex than simply saying this test will end all problems. It will not. However, without it greater hardship and suffering will be brought to the underserved and disadvantaged within this country and throughout this country and the world.

This White House, more than any before it, has the ability and power today to make a difference. It is time now for the bureaucratic process to come to a screeching halt and allow meaningful protection to be offered to those most in need. I beseech you to please have this administration make a strong statement on Wednesday, June 22, in support of immediate approval of OraSure.

Thank you very much for your concern about people who suffer from this disease. I know it is very real and deeply felt.

Sincerely,

Shepherd

W. Shepherd Smith, Jr.
President