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MEMORANDUM FOR THE PRESIDENT

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy

SUBJECT: New AIDS treatments

Protease Inhibitors.
There has been considerable press attention recently regarding the promise offered by a new class of AIDS drugs called protease inhibitors. Most of these drugs have been licensed by the FDA under accelerated approval policies, coming to market in record time -- as short as 43 days for one of the four protease inhibitors.

In short-term studies with small numbers of patients, these drugs have been shown to suppress the replication of HIV to extremely low or, in some cases, undetectable levels. If replication of HIV can be held in check, there is an expectation that HIV can soon be treated as a chronic manageable disease. The effect of these protease inhibitors is greatest when taken in combination with other drugs, such as AZT. It is believed that finding the right combination taken early enough in the HIV infection process might even result in eradication of the virus in some individuals or completely block transmission from mother to fetus, though this has not yet been proven.

New Research Questions.
It is hard to describe the sense of hope and optimism that has been restored among people living with HIV. This enthusiasm is also felt within the scientific community. But it is important to remember that this is based on *short-term* results. We do not yet know the *durability* of this effect, whether these early results are generalizable to all persons with HIV infection, and the actual impact of these drugs on reducing mortality among people with HIV. Nor do we know the answers to some very important clinical questions relating to the most effective use of these drugs -- such as when in the course of HIV infection is the best time to start therapy, how long individuals should be treated, what is the optimal combination of drugs, and when one might need to change therapies when resistance develops.

The NIH has committed to answering these clinical effectiveness questions as rapidly as possible. This capacity to respond to emerging scientific questions underscores the importance of our support for the enhanced programmatic and budget authority of the NIH Office of AIDS Research.

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Access to Treatments.

We are also committed to assuring that the benefits of our $1.4 billion annual investment in AIDS research are translated into access to care for people with AIDS. These new drugs are expensive; the cost of these new combination therapies can be as high as $10-12,000 a year. This highlights the importance of clinical effectiveness research into how best to use these new treatment regimens.

On the same day that the FDA approved the first protease inhibitor, you sent to Congress a $52 million FY 1996 budget amendment increasing funding for the AIDS Drug Assistance Program, bringing to $142 million the Federal commitment to this program. This was included in the final continuing resolution. On June 19, HCFA sent a letter to all state Medicaid directors informing them that treatment with protease inhibitors is now the standard of care, creating the expectation that states must include them in their formularies. (As you know, Medicaid covers nearly 50 percent of people with AIDS.) As it has become clearer that these drugs are going to be widely used, we are also working with OMB to try to identify still more funding in FY 1997 for the AIDS Drug Assistance Program.