

United States Senate

WASHINGTON, DC 20510

May 11, 2004

Elias A. Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

We are writing to request that you enlist the advice of Mr. Timothy Muris, Chairman of the Federal Trade Commission (FTC), as the Department of Health and Human Services (HHS) considers a request to open competition on the patent-protected drug Norvir. Specifically, we ask that you invite FTC Chairman Muris to be a presenter at the public meeting on Norvir being hosted by the National Institutes of Health on May 25.

Given the FTC's expertise in evaluating the effect of industry actions on consumers, and their history of identifying and taking enforcement actions against abusive practices in the pharmaceutical industry, we believe that the FTC's comments would greatly assist HHS in determining whether steps should be taken to open competition on Norvir.

As you know, in December 2003, Abbott Laboratories announced a 400 percent increase in the price of ritonavir, a drug for AIDS marketed under the brand name Norvir. Norvir is a protease inhibitor which can be taken by itself, or, much more commonly, as a "booster" to increase the efficacy of another protease inhibitor – either a non-Abbott drug or as part of Abbott's own combination product, Kaletra. It is our understanding that Abbott's own product, Kaletra, was insulated from this price increase and now costs less than every other Norvir-boosted protease inhibitor treatment. In January, a complaint was filed with the FTC alleging that Abbott's selective price increase was anticompetitive.

We believe the FTC's unique expertise would significantly assist HHS in evaluating the request of 200 organizations and individuals who have asked HHS to break Abbott Laboratories' monopoly on Norvir by exercising "March-In" rights provided to the federal government under the Bayh-Dole Act. Specifically, the FTC could help HHS to evaluate whether Norvir is being made available on "reasonable terms" under federal law; what effects Abbott's actions have had on the market for AIDS drugs, including potential anticompetitive effects; and what effect the opening of competition on ritonavir would have in the market.

As you may know, the FTC has evaluated a significant number of pharmaceutical licensing remedies in its merger enforcement program and has tremendous practical expertise, as demonstrated by the Bureau of Competition's "A Study of the Commission's Divestiture

Process." As HHS considers the March-In request, and especially in the event that HHS does decide to exercise the March-In rights and license ritonavir, the FTC's expertise could be applied to help HHS in establishing licensing terms and evaluating candidates for licenses.

Given the FTC's expertise in this area, and the importance to AIDS patients across the country of an objective and thorough hearing on this issue, we respectfully request that you invite Chairman Muris to present the FTC's perspective as part of the May 25th meeting. Thank you very much for your consideration and for your attention to this issue.

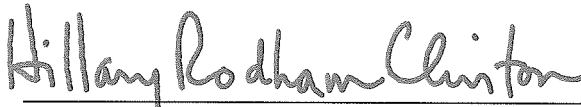
Sincerely,



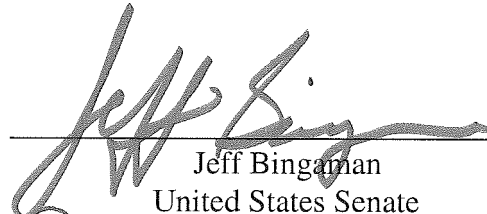
Charles E. Schumer
United States Senate



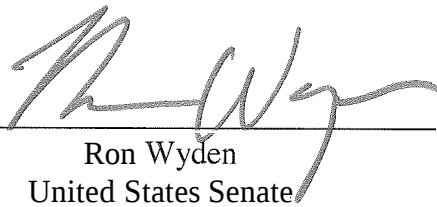
Mark Pryor
United States Senate



Hillary Rodham Clinton
United States Senate



Jeff Bingaman
United States Senate



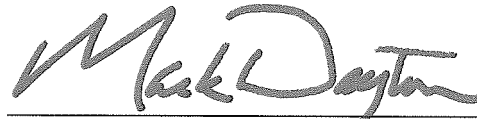
Ron Wyden
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Debbie Stabenow
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