

THE WHITE HOUSE

July 5, 1994

CC's sent to Dr.
Janet Woodcock C DER
E Dr. Kathryn Zoon
C DER (D) FDA
7/8/94

The Honorable Peter W. Barca
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Barca:

Thank you for writing about your constituent's concerns regarding coverage of ozone therapy under the President's health care reform proposal. The information on ozone therapy was interesting and thought-provoking.

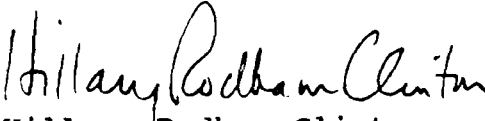
According to the summary attached to your letter, an application is currently pending with the Food and Drug Administration (FDA) for human clinical trials of the drug Medizone, an ozone therapy. Under the President's proposal, a health plan may choose to cover an investigational treatment for a life-threatening disease that is part of an FDA approved research trial. Further, routine care provided to an individual during an investigational treatment must be covered by the health plan.

I have forwarded your letter and the enclosed information to the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and

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Research at the FDA for further review. I
look forward to working with you in the
coming weeks.

Sincerely yours,


Hillary Rodham Clinton

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WASHINGTON

April 28, 1994

The Honorable Peter W. Barca
U.S. House of Representatives
Washington, D.C. 20515

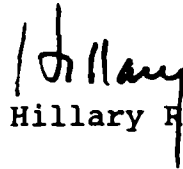
Dear Congressman Barca:

Thank you for your letter concerning Mr. Thomas Hapka, a constituent who contacted you about his difficulty obtaining specialty drugs.

Under the President's proposal for health care reform, the comprehensive benefit package guarantees coverage for outpatient prescription drugs. Medications, including specialty drugs, are covered if used as approved by the Food and Drug Administration. "Off-label" uses, or uses other than the FDA-approved use, are covered if the alternative use is supported by certain recognized drug compendia or peer reviewed literature.

Thank you again for writing. Thank you too for the hospitality you showed me on my recent trip to your district. I look forward to working with you in the coming weeks as Congress works toward passage of health care reform legislation.

Sincerely yours,



Hillary Rodham Clinton