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United States Senate

COMMITTEE ON LABOR AND
HUMAN RESOURCES

WASHINGTON, DC 20510-6300

January 9, 1991

Thomas J. Borody, M.D.
144 Great North Road
Five Dock, NSW2046
Sydney, Australia
St. Vincents Hospital

Dear Dr. Borody:

I am writing to ask your opinion about the possible role of bacteria in peptic ulcer disease and its implications for treating the disease. I am interested in the possibility that elimination of the bacterium, *Helicobacter pylori* by use of combinations of antibiotics and bismuth preparations can prevent ulcer recurrence and reduce the high cost of long term treatment for many Americans. However, I am concerned that treatments for this bacterium which are unlikely to have a commercial sponsor may not be adequately or expeditiously studied in the United States.

I would invite your answers to the following questions:

1. Is it necessary to do a multi-center randomized double-blind study of the safety and efficacy of treatment of *H. pylori* in peptic ulcer disease to determine if this treatment should be used in general practice?
2. Is published data on treatment of *H. pylori* in peptic ulcer disease sufficiently promising to warrant a multi-center study? Is the data sufficient to enable planning of a definitive study or are more preliminary basic or clinical studies necessary?
3. If a multi-center study is indicated should the NIH plan and support this study or is it more appropriate for others to undertake this task?
4. If treatment of *H. pylori* can prevent ulcer relapse could you estimate the effect its use would have on annual health care costs in the U.S.?

I would welcome any other comments you may have on this important matter.

Sincerely,



Edward M. Kennedy
Chairman, Labor and Human
Resources Committee
United States Senate