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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

February 16, 2012

George Doyle III
President and Chief Operating Officer
Ben Venue Laboratories
c/o Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

Dear Mr. Doyle,

We are deeply troubled by recent reports of the acute and prevalent shortages of Methotrexate as well as other lifesaving drugs for patients across the country.

As you know, Methotrexate is a generic product that is used by millions of Americans to treat pediatric leukemia as well as severe autoimmune conditions. Recent reports, including an article this weekend in the *New York Times*, have indicated that Ben Venue Laboratories -- one of the nation's largest suppliers of injectable preservative-free Methotrexate -- voluntarily suspended operations at its Bedford, Ohio, plant in November because of "significant manufacturing and quality concerns."

Of even greater concern, these same reports also indicated that the publicly available supply of these drugs may be exhausted within the next few weeks. While Ben Venue has publicly stated that supplies of Methotrexate will become available in stages and that certain portions of its plant will return to production in the first quarter of 2012, no timeline has been given to patients and providers with specific information as to when production of Methotrexate will fully resume, and how much product will be available in the meantime.

Given the nature of this shortage, the serious health impacts it is having at the state and national levels, as well as Congress' ongoing efforts to address such drug shortages, we would request that you please provide the following information by February 24, 2012:

1. The specific "significant manufacturing and quality concerns" that led your company to suspend production, including what preventative maintenance and re-qualifications of equipment were overdue as noted in your Dec. 23, 2011 press release;
2. Copies of any inspection findings regarding your facility by FDA, EMEA and/or any other global agencies as referenced in your Dec. 23, 2011 press release;

3. The date on which Company management learned of these concerns and how they were brought to your attention;
4. The relationship among Boehringer Ingelheim, Bedford Laboratories and Ben Venue Laboratories as it relates to production and distribution of Methotrexate, and the factors that led Bedford to suspend the distribution of all Ben Venue products;
5. The date on which your company first reported the need to suspend production of Methotrexate to the Food and Drug Administration and what actions your company has subsequently taken to work with the Food and Drug Administration to mitigate the adverse consequences of this suspension;
6. A description of what other actions your company has taken to address the identified "significant manufacturing and quality concerns;"
7. Your company's timeline for restoring full manufacturing capacity for Methotrexate, including whether it can be manufactured other than in the North facility (described in your December 2011 press release as being unavailable until fourth quarter 2012), and how your company intends to allocate available stock until prior capacity is restored; and
8. Whether you believe that reimbursements for Methotrexate played a factor in the current overall shortage. As part of your answer please provide the quarterly reported Average Sales Prices (ASP), total annual revenues, total annual sales, and production costs for the previous two years associated with your sales of Methotrexate.

We appreciate Ben Venue's efforts to mitigate the adverse consequences of the Methotrexate shortage thus far. We look forward to hearing what further actions you will take to ensure that patients have access to safe, quality drugs upon which they rely.

Please contact Rachel Pryor at (202) 224-2823, Jenelle Krishnamoorthy at (202) 224-7675 or Chuck Clapton at (202) 224-6770, with any questions you may have regarding this request.

Sincerely,



Senator Tom Harkin



Senator Michael B. Enzi

Richard Blumenthal

Senator Richard Blumenthal

Lamar Alexander

Senator Lamar Alexander

Bob Casey, Jr.

Senator Robert P. Casey, Jr.