ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

December 3, 2004

Kathleen Coelingh
Senior Director for Regulatory and
Scientific Affairs
MedImmune, Inc.
One MedImmune Way
Gaithersburg, MD 20878

Dear Dr. Coelingh:

On November 18, 2004, you testified before the Subcommittee on Health and Subcommittee on Oversight and Investigations in a joint hearing entitled "Flu Vaccine: Protecting High-Risk Individuals and Strengthening the Market." I now request your response to several additional questions (attached).

Because I wish to include the questions and responses in the printed record of this hearing, please respond no later than Friday, December 17, 2004. Please fax and e-mail the responses. The faxed response should be directed to Eugenia Edwards, Committee on Energy and Commerce majority staff, at (202) 226-2447, and Voncille Hines, Committee on Energy and Commerce minority staff, at (202) 225-5288. The e-mail copy of the response should be in MS Word format and directed to Eugenia Edwards (Eugenia.Edwards@mail.house.gov) and Voncille Hines (Voncille.Hines@mail.house.gov). Due to the uncertainties of postal deliveries on Capitol Hill, your response should not be sent through the postal service.

If you have any questions, please contact John Ford, Minority Counsel with the Committee on Energy and Commerce, at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

Attachment

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health

The Honorable Sherrod Brown, Ranking Member
Subcommittee on Health

The Honorable Greg Walden, Vice Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

Questions for Dr. Kathleen Coelingh
Senior Director for Regulatory and Scientific Affairs
MedImmune, Inc.
from the Honorable John D. Dingell
Committee on Energy and Commerce
regarding the November 18, 2004, Subcommittee on Health and Subcommittee on Oversight and Investigations
Hearing entitled "Flu Vaccine: Protecting High-Risk Individuals and Strengthening the Market"

1. One suggestion for a government-supported surplus vaccine buy back program is for the government to provide an end-of-season, below market price, buy back of surplus doses of flu vaccine up to some prearranged limit. Do you agree with this suggestion? If so, please provide details on how you think a buy back program should work. If not, what alternative programs do you recommend?

2. It is clear that much of the distribution and reallocation that takes place during a shortage happens from the goodwill of persons who could refuse to comply with requests to give up supplies that they own. Please comment on whether you believe states have adequate authority to require redistribution in a shortage. The state of Michigan, for example, is operating under a public health order, but many states either do not have this authority or are not exercising it. What criteria should apply to such authority? For example, should this only be triggered upon declaration of a public health emergency? What limits in scope and duration should apply to such authority? Finally, what penalties should apply to violation of an order? Please also answer this question from the perspective of federal authority. Does the Federal Government need more authority to deal with severe vaccine shortages? If so, or if not, please explain.

3. Some believe that the current GMPs (FDA's good manufacturing practice standards for how to run a vaccine production facility) may not be adequate to protect public health. Others believe that one reason we have so few participants in the flu vaccine business is the GMPs are unduly burdensome and that less burdensome alternatives could be adopted. Please indicate which view you hold and explain with some specific examples how the GMPs should be altered.

4. Are there elements of FDA's pre-market review of vaccines that you think need to be changed in order to obtain an adequate and reliable supply of safe and effective flu vaccines? Please be specific.

5. Do you believe that inclusion of the flu vaccine in the Vaccine Injury Compensation Program is adequate to alleviate any reasonable liability concerns? If not, please explain what else you think needs to be done.