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Congress of the United States
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COMMITTEE:
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JOINT ECONOMIC COMMITTEE
CONGRESSIONAL HEALTH CARE CAUCUS,
CHAIRMAN

October 27, 2009

The Honorable Henry Waxman
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Waxman and Chairman Stupak:

The continued reports of insufficient quantities of the promised H1N1 vaccine to the American public troubles and alarms me. As Chairmen of the Committee(s) with jurisdiction over the U.S. Department of Health and Human Services as well as its two tangential agencies in charge of the vaccination process and production – the Centers of Disease Control (CDC) as well as the Food and Drug Administration (FDA) – I would request we immediately hold a hearing on the efficacy in procedure of the contractual process of this crop of vaccines; the rationales for holds-ups in the delivery of vaccines; and the disproportionately irrational logic for distribution of current vaccines in hand.

The substance of this hearing I am requesting could have been addressed in the September 15, 2009 Full Committee hearing entitled “Preparing for the 2009 Pandemic Flu”; however, the witness list, while eminently distinguished, was singular and short. The presence of Secretary Sebelius was a sign of confidence by the Obama Administration in her capacity as the top health official in President Obama’s cabinet, but the fullness of the topic matter would have been better addressed with the presence of numerous other individuals.

First, we should have had the presence of the CDC and the FDA. I would hope these two agencies will be present in my requested hearing. In July of this year, under the leadership of the World Health Organization, the CDC stopped the individual count of H1N1 outbreak with the seeming rationale that this was a full blown pandemic. Unfortunately, due to the newness of the H1N1 flu outbreak, this lack of scientific data makes it now extremely difficult to delineate which flu illnesses are H1N1 and which are seasonal. In fact, with the level of hysterical attention brought about by The White House Office of Science and Technology Report that

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90,000 Americans would die of H1N1, the fact that there is no longer an individual count of H1N1 illnesses in the United States should never had occurred. We should have continued the scientific research irrespective of the advice of the World Health Organization.

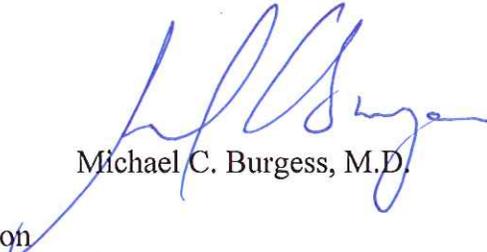
Second, nearly two billion dollars have currently been authorized and appropriated for approximately 150 million vaccines to combat H1N1. These contacts with five companies (Sanofi Pasteur, Novartis, MedImmune, Glaxo SmithKline and CSL) are little known. For instance, was the transfer of taxpayer dollars given at the front before delivery of the vaccine or was there a performance clause in the contract? We need to know if there are penalties for these five companies failing to deliver on the expectations they raised in the Obama Administration, and to the public, regarding the amount of H1N1 vaccine available during the height of flu season.

Third, this weekend President Obama declared H1N1 an emergency, thus allowing hospitals and the FDA to have greater power in combating this illness. For instance, with the emergency designation, the FDA can approve vaccines even if the science is not all-together there. I am deeply troubled by the FDA having the power to single-handedly determine the efficacy of a new vaccine without the scientific metrics in existence. The FDA is still doing clinical trials of the H1N1 vaccine on the high-risk groups, such as pregnant women, and with the H1N1 vaccine makers receiving 100% immunity from tortuous lawsuits once the FDA approves a drug, I would be sure and slow in informing the American public that an H1N1 drug is effective.

Finally, I am concerned about the distribution of the limited supply of H1N1 vaccine. As the representative from the district with the largest number of deaths as a direct result of H1N1, it is imperative for me to understand the rationale given by the CDC in their recently released distribution list of vaccines to combat H1N1. Despite our high concentration of high risk groups, as well as previous outbreaks of the H1N1 illness, my district should have received a large number of vaccines; instead, The Dallas Morning News reported today, Dallas County would only be receiving approximately 5,700 doses of the vaccine. Why?

The timeliness of a secondary hearing on the vaccine process at HHS is necessary. I look forward to working with you on finding answers to this difficult and frustrating situation.

With regards,



Michael C. Burgess, M.D.

cc: The Honorable Joe Barton
Ranking Member

The Honorable Greg Walden
Ranking Member