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Congress of the United States
House of Representatives
Washington, DC 20515-1002

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November 3, 2003

Mark McClellan, MD
Commissioner, US Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner McClellan:

After a recent conversation with a representative of the National Organization of African-Americans in Housing, I have concerns about the proposed move to force over-the-counter switching of prescription drugs, as your agency has been petitioned to do by WellPoint Health Networks (docket # 02P-0163). The impact of this proposed switch on the underserved and communities of color could be potentially devastating.

According to a 2002 report by the CDC, Georgia's self-reported asthma rates are nine percent. As you are most certainly aware, asthma and allergies are very frequently co-morbid conditions, especially in African-Americans. And due to the unfortunate rate of uninsurance found among the country's populations of color, many residents gain access to medical services through public health authorities, which often provide prescription drugs as part of comprehensive benefits.

In a letter to your office earlier this year, NOAAH made very clear its position on this matter, and we share their concern. NOAAH wrote: "NOAAH believes that the ramifications of a forced OTC switch of non-drowsy allergy drugs would be severely felt in America's minority and low-income communities. These populations, already vulnerable to unhealthy disparities, will acutely bear the brunt of the added cost burden and the long-term effects of being further distanced from the health-care system."

In the case of allergies and asthma, even in light of the rapid advances in drug therapies available for these conditions, it is still crucial that patient care be managed by a trained professional. This process serves as a bulwark against the further deterioration of a patient's status or the development of life-threatening adverse reactions to the drug. The role of the practitioner in managing these conditions is even more acute in elderly, people of color and low-income populations. For example, these patient groups are often in need of more immediate medical management or require adjustments of recommended dosages of medications specific to ethnic or racial backgrounds.

02P-0163

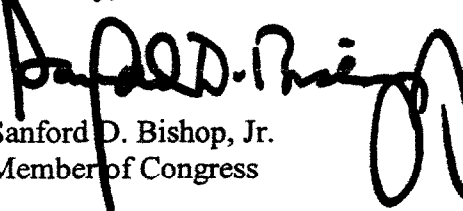
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Commissioner McClellan, we hope that you will respond to our concerns and update our office on the status of these OTC switch petitions. We also hope that you will take this opportunity to respond to NOAAH's concerns on this matter. We look forward to your response.

With warmest regards, I remain

Sincerely,

A handwritten signature in black ink, appearing to read "Sanford D. Bishop, Jr.", with a large, stylized flourish at the end.

Sanford D. Bishop, Jr.
Member of Congress

CC: FDA/Dockets Management Branch
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