



Congress of Racial Equality

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Wednesday, February 19, 2003

Mark McClellan, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket # 98P-0610

Dear Commissioner:

On behalf of the members and leadership of Congress of Racial Equality (CORE), we are writing today to communicate our profound concerns about potential forced switches of prescription drugs to over-the-counter status, which the FDA is currently considering. Minority populations will be negatively impacted by these switches, and we trust that you will heed our concerns as your agency continues to deliberate on this issue.

The main issue is a petition by WellPoint Health Networks, requesting that the FDA switch newer non-sedating antihistamines to over-the-counter status. We understand that this 'switch' is typically done at the behest of drugmakers' themselves and not usually spurred by the wishes of a for-profit managed care company hoping to protect its bottom line. We hope that you will be concerned by the various ramifications implicit in FDA taking WellPoint's request under advisement.

It is well-established that minority populations in America are vastly underserved by the healthcare system; this condition exacerbates crippling disparities in the prevalence of certain preventable chronic illnesses such as diabetes, hypertension and asthma, all of which are widely found in these populations. In this case, FDA's complicity in deselecting certain necessary

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treatment options, such as prescription drugs for allergies and asthma, perpetuates a vicious cycle that will play out on the health of America's minority populations.

By removing the finite vehicle that motivates disadvantaged populations to visit a healthcare professional in the first place—the requirement of seeing a physician to obtain a prescription—HMOs, and the FDA if it allows such a move, will limit the opportunities these individuals have to obtain quality healthcare services; these limitations will trickle down to affect school and work performance, could cause premature death and will certainly continue to exacerbate the burgeoning crises impacting the nation's health care safety net.

FDA must rely on science and research to deny WellPoint's petition, as the research available to defend the continued prescription-only-status of non-sedating antihistamines is considerable. According to one study, 'morbidity from asthma disproportionately affects African Americans and women, and even among patients with health insurance, disparities in asthma care for African Americans compared with whites exist and may contribute to race disparities in outcomes.'¹ The Institute of Medicine reported that 'reduced access to medical care can lead to delays in diagnosis and treatment and contribute to well-documented disparities in minority health.'² Additionally, we know that continued use of these medications in children could significantly improve overall school performance and improved future health status.

Mr. Commissioner, we ask you to strongly consider the long-term health and economic implications that stem from limiting physician-supervised access to these vital medications. Vast gaps in the health security of African-Americans and other minorities will grow wider, which will contain to drain necessary resources from public health systems. The use of these drugs, under the supervision of a physician (which is inherently threatened by forced OTC switching), could vastly improve the chances of future success for underprivileged minority children. And despite protestations to the contrary by the petitioner and others, there is no guarantee that success in this effort would not breed further attempts to forcibly switch other therapeutic categories of prescription drugs.

¹ Arch Intern Med. 2001;161:1660-1668 -- <http://archinte.ama-assn.org/issues/v161n13/abs/loi00689.html>

² Ayanian, John Z., et al., "Unmet Health Needs of Uninsured Adults in the United States," *Journal of the American Medical Association*, Vol. 284, No. 16 (2000); Institute of Medicine, *Coverage Matters. Insurance and Health Care*. Washington: National Academy Press (2001)

Dr. McClellan, we trust that you will stridently consider our concerns as expressed here and deny WellPoint's petition to forcibly switch non-sedating antihistamines to over-the-counter status. Leave healthcare decisions in the hands of physicians and other clinicians, and do not allow the desires of one company further threaten the health of already disadvantaged Americans.

Sincerely,



Niger Innis
National Spokesman
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Cc:

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