



**National Black Nurses Association, Inc.**

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**Before the  
Food and Drug Administration  
U.S. Department of Health and Human Services**

**"FDA Modernization Act"**

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**My name is Millicent Gorham, Executive Director of the National Black Nurses Association and a member of the FDA Consumer Consortium.**

**The National Black Nurses Association is pleased to submit testimony before the Food and Drug Administration regarding the FDA Modernization Act. The National Black Nurses Association is a professional organization of registered nurses/ licensed vocational/practical nurses and nursing students. Our mission is to "investigate, define and determine the health care needs of African Americans and to implement changes to make available health care commensurate with that of the larger society." Our Association represents over 150,000 African American nurses and has 27 years of commitment and dedication to quality health care for all Americans. On behalf of our membership and all those we represent, NBNA thanks the Food and Drug Administration for providing us with the opportunity to state our position on issues under its jurisdiction.**

**NBNA applauds the work of the Congress and FDA for pushing through legislation that would allow FDA to approve drugs in a speedy manner, yet be able to maintain the safety and efficacy of the consumer's health. The African American community continues to strive for positive health outcomes, with the understanding that access to the appropriate drugs and new technology will help to change the downward spiral health indices. While cancer morbidity and mortality rates may be on the downswing overall, breast cancer rates and prostate cancer rates in the African American**

community remains high. HIV/AIDS rates in African American women are now at near epidemic proportion. And, cardiovascular disease remains the number one killer for all African Americans. Speedy access to new, safe and effective drugs and technology may make the difference in the quality of life for our communities.

Access to health care services, particularly making sure that the appropriate pharmaceuticals are accessible in managed care facility formularies, is germane to improving the health of African Americans and the underserved. It is believed that managed care organizations in underserved communities have not always provided access to premiere pharmaceuticals that would enhance the health care of consumers. Too often more advanced drugs are not a part of the managed care formulary, making it difficult for the health care provider to manage a patient's health, particularly a patient with multiple chronic health care needs.

It is evident that our nation must be able to bring safe drugs to the market place and our nation must offer to all consumers appropriate, culturally sensitive information about those drugs.

Critical to bringing a drug application for FDA approval is the need for appropriate clinical trials. Research has shown that drugs react very differently between the sexes and the races. More research must be conducted by culturally competent research scientists within the ethnic minority community to ensure that the drugs that FDA approves will result in positive health outcomes for African Americans.

Access to the most up to date health care technology is key to improving the health care status in the African American community. One new technology recently approved by FDA to better detect cervical cancer, may help to improve the overall survival rates for African American women. This technology, the next generation Pap smear, offers genuine hope to all women to better evaluate cervical cells in a more efficacious manner.

While we find that FDA does its job by providing thorough scientific review to approve drugs and new technology, there appears to be a gap between the FDA approval process and the HCFA coverage process. HCFA has suggested that it no longer wants to accept FDA-approval of drugs as its primary coverage criteria. This will slow down substantially the dissemination of new drug therapies. Moreover, in some cases, the Health Care Financing Administration reimbursement rates for new technologies are so low that it places barriers to women being able to access technologically advanced health care services. NBNA recommends that FDA and HCFA work hand in hand to make sure that FDA approved drugs and technology are covered and have appropriate reimbursement levels so the American consumer may have access to these health care services in a timely manner.

**The consumer community applauds the FDA and its Office of Consumer Affairs for excellent performance in the area of public participation, considering their staff and resource limitations. It is time that the Agency re-evaluates how it conducts its public participation business.**

**As a member of the FDA Consumer Consortium that recommends consumer representatives to the Agency's 16 panels and 32 advisory committees, there needs to be more funding provided to adequately staff and manage the public participation process. It is quite an involved process to recruit and maintain a data base of consumer representatives to serve on the FDA panels and advisory committees; to provide the necessary training and support so that the consumer representative is comfortable with the FDA review process; and to manage the public participation process.**

**NBNA recommends that FDA dedicate adequate staffing and resources to manage the FDA Consumer Consortium process and support of consumer representatives and public members who serve on the FDA Advisory Committees and Panels. We need to make sure that the consumer voice is heard during the public policy deliberations on new drugs and new technology. Perhaps a public hearing to solicit public comment is in order for this issue. We stand ready to lend our suggestions and ideas.**

**On behalf of the National Black Nurses Association, I  
thank you for listening to our issues relating to the FDA  
Modernization Act.**