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COMMENT
FDA GUIDANCE FOR INDUSTRY
COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS

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The National Center for Policy Research for Women and Families is committed to the fundamental scientific principle that clinical trials evaluating the safety of and effectiveness of medical products should reflect the diversity of the population, including race and ethnicity criteria, which will use the medical product.

The FDA Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials is a critical step forward in the identification of differences in physiological response among racial and ethnic subgroups during the evaluation of the safety and effectiveness of FDA regulated products. However, the FDA Guidance merely encourages that the data be identified according to race and ethnicity. The Guidance fails to require the inclusion of racial and ethnic groups in the study population, or to even encourage the use of subsamples of adequate size to ensure that subgroup analysis can provide meaningful data about safety and effectiveness for those subpopulations.

The Guidance reflects the policy of the U.S. Department of Health and Human Services, which is designed to "determine that Federal funds are being used in a nondiscriminatory manner" and to "promote the availability of standard racial and ethnic data across various agencies to facilitate HHS responses to major health and human services issues." These goals should apply to all medical products, including drugs, biologics, and medical devices. It is deeply disturbing that the Center for Devices and Radiologic Health does not require or even recommend that racial or ethnic groups be represented in studies submitted for the PMA applications for medical devices. For example, when there is reason to believe that variation among racial or ethnic groups may influence the safety or effectiveness of a medical device, then the burden should shift to the manufacturer to include all relevant racial or ethnic groups. It is critical that racial and ethnic subpopulations be adequately represented in clinical trials in order to ensure that the tested product is safe and effective for all the subpopulations that are likely to use that product

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It is the policy of the National Institute of Health that women and members of minority groups must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling justification establishes that inclusion of these groups would be inappropriate with respect to the health of the human subjects or the purpose of the research. This mandatory requirement in clinical research seeks to match the human study trial demographics with the demographics of those individuals that are likely to be served.

The lack of similar requirements by the FDA puts consumers at risk. For example, Artecoll was reviewed by the FDA Advisory Committee on General and Plastic Surgery Devices on February 28, 2003. This cosmetic injectable device, if approved, is likely to be demanded by men and women of all racial and ethnic groups. However, the research findings suggesting a 16% chance of an adverse reaction in the first year following permanent implantation in facial wrinkles can only be extrapolated to the white and Hispanic populations that were tested. Adverse reaction rates for African Americans and Asian Americans could be even higher. Indeed, the Executive Clinical Summary for Artecoll noted the exclusion of subjects with known susceptibility to keloids and to subjects presenting with a history of autoimmune disease. Those exclusion criteria would exclude many, but not all, African Americans and Asian Americans; nevertheless, it is essential that these populations be studied before any decision is made about approving the product, unless the product is labeled as being for whites only.

Differences in response to medical products have been documented in racially and ethnically distinct subgroups of the U.S. population. For example, African Americans with facial acne are more likely than their white counterparts to develop post inflammatory hyperpigmentation changes when using a topical medication. It is also known that laser treatments for resurfacing procedures in the African American population will result in more hypopigmentation, which persists indefinitely. It is furthermore known that keloiding following an incision is more likely among African Americans and Asian Americans than whites. The Japanese population is noted to have more sensitivity to ethanol compared to whites. Those are just a few examples of why racial and ethnic diversity is essential in study populations when cosmetic devices are considered for approval. [1] [2] [3] [4]

Similarly, prescription drugs sometimes reference race and ethnicity factors for their indications and usage. For example, the P.D.R. labeling on the prescription drug Lexxel, used in the treatment of hypertension, states that "It should be noted that black patients

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[1] Fanous,Nabil "A New Patient Classification for Laser Resurfacing and Peels: Predicting Responses, Risks and Results", Aesthetic Plastic Surgery , 2002 Mar-Apr 26 (2) 99-104

[2] Sattler ME "Folliculitis keloidis nuchae" WMJ (Official Publication of the State Medical Society of Wisconsin) 2001; 100(1) 37-8

[3] Weber WW "Populations and genetic polymorphisms" Molecular Diagnosis 1999 December; 4(4) 299-307

[4] Jacyk WK "Adapalene in the treatment of African patients" Journal of European Academy of Dermatology and Venereology 2001: 15 Suppl 3:37-42

receiving ACE inhibitors have been reported to have a higher incidence of angioedema compared to non blacks." Physicians are cautioned to consider the possibility that the antimalarial drug Aralen may induce hemolysis in G-6-PD deficient individuals, and the glucose 6 phosphate dehydrogenase deficiency is known to be more prevalent in the African American population and those of Asian and Mediterranean ethnicity/race.

The design of human study trials for medical products, including medical devices, must be consistent with sound scientific principles. A scientifically valid research design incorporates racial and ethnic diversity sampling, as part of a heterogenous study group, in clinical trials. Our nation is a melting pot of all races and ethnic groupings and our government is charged with responsibly overseeing the safety and efficacy of medical products intended for the use of all Americans.

The Guidance states that "Collecting race and ethnicity data using standardized categories will enhance the early identification of differences in physiological response among racial and ethnic subgroups during the evaluation of safety and effectiveness of FDA-regulated products." We agree; however, identification of these differences will only be enhanced if a substantial number of human subjects representing racial and ethnic subgroups are included in the research.

We agree with former FDA Commissioner Jane Henney, who said "It is only through participation of the many populations that will ultimately receive a new product that we can ensure that the medical products we approve are appropriate, safe and effective for all Americans, and not just a narrow cut of our country's population."[5] In our view, the FDA should require that all studies involving human subjects upon which FDA approval are based should demonstrate that the human subjects are representative of the target population intended to be treated by the medical product, including devices. The only exception to this mandatory requirement should be when the manufacturer presents compelling scientific evidence for the exclusion of a racial or ethnic population based on legitimate safety concerns, and agrees to label the product as contraindicated for that population.

[5] Remarks of Dr. Jane E. Henney, Commissioner of Food and Drugs, U.S. Food and Drug Administration, to the National Medical Association 2000 Annual Convention and Scientific Assembly, Washington D.C. http://www.fda.gov/oc/speeches/2000/nationalmedicalassoc.html