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## Racing Forward: The Genomics and Personalized Medicine Act

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In 2006, then–U.S. Senator Barack Obama introduced the Genomics and Personalized Medicine Act (GPMA) as S.3822 (1) and again, with the cosponsorship of U.S. Senator Richard Burr (R–North Carolina), in 2007 as S.976 (2). Broad in scope, the bill outlines measures that bolster governmental oversight and create economic incentives to catalyze translation of research into clinical care. However, in the transition from S.3822 to S.976, there were omissions that decouple consideration of the implications of human genetic diversity from legislation aimed at building the infrastructure for genomic medicine. This represents a missed opportunity to engage critical issues with deep scientific, social, and ethical implications.

Pharmacogenomic testing of individuals may prevent adverse drug reactions and save both lives and money. However, personalized medicine remains in its nascency, and populations identified by race and ethnicity, rather than individuals, remain the focus of current pharmacogenomic research despite the dominant view in anthropological genetics that race is a poor predictor of genotype. A central question in pharmacogenomics is which populations have greater frequencies of alleles associated with drug-metabolizing enzymes, drug transporters, or drug targets. Although scientists suggest that “race” in the context of genetic research will be rendered obsolete once genetic markers for the relevant phenotypes are found, recent developments reflect growing use of racial categories in efforts to translate basic research into clinical practice (3,4).

In 2005, the U.S. Food and Drug Administration (FDA) approved BiDil as an antihypertensive combination therapy for use in “self-identified Blacks” (5). Scholars have challenged the scientific justification (6,7) of setting a precedent for race-specific drugs, cautioning that conflation of genes, race, and drugs undermines what many scientists insist—that the sociopolitical concepts of race and ethnicity are not genetic (8,9) This nuance is quickly lost in clinical translation and market segmentation when race becomes a “category of convenience” (10). The roughly 700 drugs in the development pipeline aimed at African Americans (11) signal an emerging landscape of race-based therapeutics and underline the risk of prematurely jumping from genotype to phenotype.

A strength of S.3822 was its direct engagement with the issue of genetic variation and the rationale for using racial and ethnic categories in pharmacogenomic research. In a dedicated section entitled, “Race, Genomics, and Health,” the bill mandated that within 1 year of its passage, a newly formed Genetics and Personalized Medicine Interagency Working Group (IWG) would be charged with (i) determining appropriate definitions and use of categories of race and ethnicity, (ii) determining ways to increase access to pharmacogenomic and related clinical genetic services for minority populations, (iii) providing research opportunities and funding support in the area of race and genomics, (iv) enhancing integration of federal wide effort and activities, and (v) recommending privacy protection of genetic information.

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A key section was eliminated from a bill supporting research and development in pharmacogenomics.

The IWG was charged with leading a national discussion that would have addressed fundamental questions including the following: What constitutes racial and ethnic difference in the context of human genetic variation research? How are individuals designated as members of a racial and ethnic group? What should be the standards for evaluating claims of race-based therapeutics? Perhaps most important, how will guidelines regarding use of racial and ethnic categories affect health disparities among minority populations?

However, when S.3822 was revised and reintroduced to Congress in 2008 as S.976, the entire section of “Race, Genomics, and Health” and its provisions were deleted from the bill. In S. 976, there is no mention of “race,” “ethnicity,” or “diversity,” and “minority” is mentioned only once.

Many of the measures addressing genetic variation and population diversity outlined in S.3822 were added to the current version of Minority Health Improvement and Health Disparity Elimination Act S.1576 (12), an overarching bill to enhance efforts to eliminate health disparities. Race and ethnicity are clearly defined in S.1576 by the census categories of the Office of Budget and Management, but the appropriateness of these categories in the context of pharmacogenomics remains a key question for the field. In building an infrastructure for personalized medicine, such questions are best addressed in the context of the GPMA.

A feature outlined in S.3822 and S.976 is the National DNA Biobanking Research Initiative, which would facilitate collection and integration of genomic data with environmental and clinical health information. A mandate in S.3822 was aimed at ensuring diverse representation of the individuals included, which would allow analysis of population subgroups. In S.976, this provision has been dropped. This has implications for pharmacogenomics, where population stratification issues and challenges to recruitment of minority populations persist.

An opportunity to provide clarity and leadership on critical issues of human genetic variation from “bench” to “bedside” is lost in the current GPMA. Direct engagement on these problems within the context of specific legislation on pharmacogenomics is necessary in setting a scientifically valid and ethically responsible agenda for personalized medicine.

## References and Notes

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