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Respecting, Rather than Reacting to, Race in Biomedical Research: A Response to Professors Caulfield and Mwaria

Michael J. Malinowski
Louisiana State University Law Center, mjmalin@lsu.edu

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Commentary

*1489 RESPECTING, RATHER THAN REACTING TO, RACE IN BASIC BIOMEDICAL RESEARCH: A RESPONSE TO PROFESSORS CAULFIELD AND MWARIA

Michael J. **Malinowski** [FNa1]

I step back into this Article and the surrounding debate just weeks after a return trip to Taipei, Taiwan and Academia Sinica (AS), the Taiwan government's research arm. [FN1] While I was hosted by Institutum Jurisprudentia (AS's law institute) on this trip, [FN2] I also had an opportunity to spend time with one of my former hosts and to catch up on the progress of the Taiwan Biobank ("TBio")--a project that I was introduced to in August 2007. [FN3] The plan for TBio is to collect 15,000 blood samples from the Chiayi, Hualien, and Miaoli counties and to cover the country's four core ethnic groups--Minnan, Hakka, Han immigrants who moved to Taiwan after 1949, and indigenous peoples. [FN4] Though well funded, the project was stalled for several years before my first visit and *1490 has been since due to concerns over privacy, confidentiality, and fair usage of information. [FN5] Still, AS researchers have been building and using the TBio internally; it has enabled their faculty to enter into collaborations with the organizers of other biobanks, and they have generated significant science results. The most recent is a sophisticated, race-sensitive reference algorithm for Warfarin, an anticoagulant used to prevent heart attacks, strokes, and blood clots. This accomplishment is the subject of a forthcoming article that will appear in the February 19, 2009 issue of the New England Journal of Medicine. [FN6] Previously, the team identified a gene that exists only in South Asian populations that is associated with Stevens-Johnson Syndrome, an adverse drug reaction that causes skin devastation and is potentially fatal. [FN7] TBio is one illustration: race and ethnicity-based genetics research are making human health contributions and benefiting the groups under study.

I accepted the Houston Law Review's invitation to publish my article, Dealing with the Realities of Race and Ethnicity: A Bioethics-Centered Argument in Favor of Race-Based Genetics Research, [FN8] on the condition that we solicited responses from colleagues who disagree. [FN9] The goal was to maximize the contribution to the surrounding debate--to jolt it forward to the fullest extent possible. I embrace this opportunity to highlight and clarify a few core points in Dealing and, more generally, to engage in this dialogue with Professors Caulfield and Mwaria.

Professors Caulfield and Mwaria both emphasize the importance of definitional precision. [FN10] In fact, that is the core of *1491 Professor Caulfield's comments, which I generally accept and incorporate by reference. I did not embark upon a discussion of definitional conviction directly in Dealing largely because the context focus is human subject recruitment for basic ("bench") research in population genetics--a stage generally preliminary to media reporting on discoveries, biopharmaceutical marketing, and prescribing of derived human health products. My focus was on communicating with subjects-- respect for how people self identify. The general thrust of the Article is to promote bench research in population genetics that will enable more meaningful definitional certainty, deepen understanding at the interface of genetics and environment, and improve human health. My use of "responsible research" throughout Dealing suggests care with definitions to the fullest extent practicable. [FN11] Moreover, the last sentence in my article before the conclusion, the closing statement, is "Fortunately, those

who dare engage in race- and ethnicity-based research trigger suspicion and scrutiny that necessitates extreme clarity and precision to maintain credibility." [FN12] I continue to support recognition of and responsiveness to social and cultural definitions of race and ethnicity--how people actually relate and function--in subject recruitment to promote communication, reflection on group impact, and the informed consent process.
Professor Caulfield observes, "[I]t is my impression that almost everyone, regardless of disciplinary background, recognizes the value of race as a research variable . . . ." [FN13] Not Professor Mwaria. She recognizes just one use, and it is outside of genetic science: "There is, however, one area [just one!] in which so-called race based medical research is valid. That is in research relating to access to health care or health care disparities." [FN14]
1492 While we are 99.9% the same genetically and generally homogenous as Professor Mwaria reminds us, the human health differences among us are immense, including our diverse responses to prescription medications. We use crude genetic classifications all the time, including many common disease classifications such as "breast cancer," [FN15] because genetics is so subtle, environment matters so much, and our science is still so limited. Medicine is an art, even guesswork, rather than predictable science. [FN16]
As observed by Professor Pilar Ossorio,
. . . there are legitimate reasons to use race as a variable in answering some research questions or in making some medical decisions. Race variables may generate data that point towards new medical interventions or cures, or towards better understandings of the causes of health problems. At times, race may be a proxy for some cause that we cannot yet measure or have not figured out that we should measure. Race variables may also be useful in assessing the effects of racism and institutional inequalities in access to health care or other health-promoting goods in society. Finally, race variables may capture aspects of a person's cumulative life experience, effects that are difficult or impossible to disaggregrate into separate variables; the same could be true for gender and class variables. [FN17]
My appreciation to Professors Caulfiled and Mwaria for enriching this debate, and to the Houston Law Review.

[FNa1]. Ernest R. and Iris M. Eldred Professor of Law, Paul M. Herbert Law Center, Louisiana State University. JD Yale Law School; BA, summa cum laude, Tufts University.

[FN1]. For information about AS, visit their official internet site at http://www.sinica.edu.tw/main_e.shtml (last visited Feb. 6, 2009).

[FN2]. The purpose of this trip was to give a keynote address at the 2nd Conference on Law, Science, and Technology, entitled "Science Regulation, Freedom of Research, and Pluralist Democracy," hosted by AS's Institutum Jurisprudentia, and to participate in a panel discussion at the National University of Taiwan. Michael J. Malinowski, Keynote Address at the 2nd Conference on Law, Science, and Technology: A Law-Policy Proposal to Promote the Public Nature of Science in an Era of Academia-Industry Integration, Dec. 21, 2008 (written presentation on file with the author).

[FN3]. I was invited by the National Genotyping Center to present at a public meeting to launch the Taiwan Biobank held in Taipei, Taiwan, August 12- 14, 2007.

[FN4]. Sara Chuang, Dilemmas of Research, Taiwan Rev., Jan. 7, 2006, available at http://taiwanreview.nat.gov.tw/site/Tr/ct.asp? xItem=22901&ctNode=119 (last visited Feb. 6, 2009).

[FN5]. Chia-Hao Ou & Chen-Yang Shen, The Taiwan Biobank Project: For the Health of Future Generation, E-news (Academia Sinica, Taipei, Taiwan), Apr. 19, 2007, available at http://newsletter.sinica.edu.tw/en/file/file/1/125.pdf (last visited Feb. 6, 2009).

[FN6]. This latest discovery is part of a broader body of the team's work identifying ethnic differences in Warfarin sensitivity. See H.Y. Yuan, J.J. Chen, M.T. Lee, J.C. Wung, Y.F. Chen, M.J. Charng, M.J. Lu, C.R. Hung, C.Y. Wei, C.H. Chen, J.Y. Wu & Y.T. Chen, A Novel Functional VKORC1 Promoter Polymorphism Is Associated With Inter-Individual and Inter-Ethnic Differences in Warfarin Sensitivity, 14 Hum. Molecular Genetics 1745-51 (2005).

[FN7]. W.H. Chung, S.I. Hong, H.S. Hong, M.S. Hsih, L.C. Yang, H.C. Ho, J.Y. Wu & Y.T. Chen, Medical Genetics: A Marker for Stevens-Johnson Syndrome, 428 Nature 486 (2004).

[FN8]. Michael J. Malinowski, Dealing With the Realities of Race and Ethnicity: A Bioethics-Centered Argument in Favor of Race-Based Genetics Research, 45 Hous. L. Rev. 1415 (2009).

[FN9]. I had anticipated more division between Professor Caulfield and I but, apparently, the evolution of our positions and the debate itself have drawn us closer together on this topic.

[FN10]. See generally Timothy Caulfield, Defining Race as the Defining Problem, 45 Hous. L. Rev. 1475 (2009); Cheryl Mwaria, Rejecting Race as a Critical Marker of Human Biomedical Difference, 45 Hous. L. Rev. 1483 (2009). Professor Duster, a sociologist and leading critic of race and ethnicity-based genetics research, also demands definitional certainty, and I often agree with him on this point as well. See infra note 13 (quoting Professor Duster). See also Malinowski, supra note 8, at 1434-5 (summarizing Professor Duster's position).

[FN11]. See, e.g., Malinowski, supra note 8, at 1421. There is danger of muddling communication between researchers and human subjects, perhaps chilling participation, through excessive definitional detail with too many layers of scientific terminology, especially at the bench-research level and in the population genetics context--the very beginning of the discovery process.

[FN12]. Malinowski, supra note 8, at 1471.

[FN13]. Caulfield, supra note 10, at 1476.

[FN14]. Mwaria, supra note 10, at 1486. Consider that even Professor Duster, mentioned in supra note 10, has a broader vision. See generally Troy Duster, Race and Reification in Science, 307 Science 1050 (2008). Professor Duster recognizes that "The ability to use genomic knowledge to deliver effective pharmaceuticals more safely to special subpopulations that have some functional genetic markers holds promise." Id. at 1051. He demands definitional certainly as that becomes possible, as the science is done and alleles are identified, and a warning before:
[W]hen the phenotype distinguishing these populations is race, the likelihood of committing the fallacy of misplaced concreteness, in science, is nearly overwhelming. For this reason, when geneticists report population data, they should always attach a caveat or warning label that could read something like this, "allelic frequencies vary between and selected human groups--to assume that those variations reflect 'racial categories' is unwarranted."
Id. Unlike Professor Mwaria, Professor Duster does not propose to wholly abandon this genetic science at a potentially significant cost to human health.

[FN15]. Consider that identification of a portfolio of genetic variations associated with breast cancer, including BRCA1, BRCA2, and Her2-neu, has made the corral of "breast cancer" genetically forced at best.

[FN16]. See generally John Carey, Medical Guesswork: From Heart Surgery to Prostate Care, The Health Industry Knows Little About Which Common Treatments Really Work, 3989 Bus. Week 72 (2006). We want to think of medicine as a science, rather than an art, but, unfortunately, medicine is much, much cruder than we would like it to be--especially when pharmaceuticals are involved. For decades, we have relied upon a portfolio of pharmaceuticals of 2,000-3,000, derived from less than 500 compounds, to treat all human health ailments. See Michael J. Malinowski, Law, Policy, and Market Implications of Genetic Profiling in Drug Development, 2 Hous. J. Health L. & Pol'y 31, 33 n.10 (2002), citing Pharmaceutical Industry Profile 2001: A Century of Progress 14 (2001).

[FN17]. Pilar Ossorio, Race, Genetic Variation, and the Haplotype Mapping Project, 66 La. L. Rev. 131, 139 (2005).
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