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February 28, 2020

The Honorable Stephen Hahn, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20990

RE: Docket No. FDA-2019-N-4824, Office of Minority Health and Health Equity Strategic Priorities;  
Establishment of a Public Docket; Request for Comments

Dear Commissioner Hahn:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to share with you our three highly recommended focus areas to strategically advance the equity priorities of the U.S. Food and Drug Administration (FDA) Office of Minority Health and Health Equity (OMHHE). This request for input and comment is particularly timely for the AMA, as we have recently established our new Center for Health Equity to lead AMA efforts in this space. The Center for Health Equity's mission is to strengthen, amplify, and sustain the AMA's work to eliminate health inequities—improving health outcomes and closing disparity gaps—which are rooted in historical and contemporary injustices and discrimination. Therefore, the AMA strongly supports the FDA OMHHE's resolve to develop protocols to benefit medically underserved patients and the physicians who care for them.

In response to the FDA's call for input and comment on the establishment of strategic priorities for the FDA OMHHE, we recommend the FDA focus its equity strategies on the following three key areas:

- 1) Research & Innovation
- 2) Health Literacy Education & Communities Engagement
- 3) Public Health Workforce Development

## **Research & Innovation**

### *Research*

The current pace of medical research is extraordinary. Where once there was almost assured premature and painful death, advances in genomic therapeutics, genetic counseling, and nanotechnologies provide the potential to prolong and save lives. As populations of color in the United States increase, the data that informs new drug and medical applications development must reflect this transition. While data collection protocols in the U.S. Department of Health and Human Services have sought to improve collection and

use of racial and ethnic data to improve demographic diversity in clinical trials,<sup>1</sup> these efforts do not go far enough. **We recommend that the FDA OMHHE develop and diffuse annual surveillance of clinical trials protocols by race, gender, and age—with particular consideration of pediatric and elderly populations—to determine whether trials proportionately enroll, retain, and represent minoritized communities.** Clinical trials grounded in data gleaned from fully representative samples of diverse populations will enhance our understanding of how experiences punctuated by discrimination and other stressors associated with socially imbued markers impact health outcomes. Utilizing an equity framework in clinical trial design can help restore trustworthiness of institutions that have exacerbated social and medical harms in past medical studies and interventions. We therefore urge the FDA OMHHE to ensure that its research design and data collection efforts and protocols specifically incorporate mechanisms to strengthen racial and gender representation in clinical trials.

**We also recommend the FDA OMHHE clearly feature on its home webpage an updated version of the FDA's *Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data*.** Accompanying this publication should be interactive, detailed pull-out graphics on the prevalence of underrepresented groups in clinical trials due to lack of access, mistrust, and lack of patient awareness of clinical trials' health and health care benefits. **Furthermore, the public should be able to sort through all FDA clinical trials results by meaningful demographic categories, namely by race/ethnicity, gender, and age.** These details should also be readily accessible through the FDA OMHHE homepage.

### *Innovation*

Technological innovations such as precision medicine, augmented intelligence (AI), and the burgeoning use of big data in clinical settings have the potential to transform how physicians practice medicine. These exciting advancements also influence the ways in which FDA brings new products to market. Regulation of clinical decision-making tools and medical devices must be based on not only intended and reasonably expected product use, evidence of safety and efficiency, but also on equity and metrics addressing bias in product systems-design.

**In this way, equity should be considered a life-saving innovation, prompting new, or new uses of, technologies to evaluate deep systemic barriers to optimal health.** Without such tools, entities cannot understand clinical, social, or political determinants of health, and will be unable to identify the best pathways to bring about equity in health outcomes. Grounding data collection efforts in an equity framework that is integrative and persistent throughout the design process may not only inculcate better science, but it also roots out biases that may otherwise be threaded within the mechanics of machine learning algorithms. Care must be given to how such data sets are compiled and the potential for bias in AI and machine learning systems must be acknowledged and addressed. **We recommend the FDA adopt a sustainable and standardized health equity measurement framework by which to evaluate all FDA investigational and new drug applications, biologics licenses, and medical device applications.** This framework should include evaluation metrics on diversity and representativeness of research participants and should explicitly identify steps to address bias and avoid introducing or exacerbating health care inequities. This framework should evaluate the extent to which prescription drug and device manufacturers consider the effect of personal bias on applications design from start of data collection, through device testing, to device deployment. The framework should also consider the differential impact of the product or application on communities with historically divergent health outcomes experiences, and

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<sup>1</sup> Improving the Collection and Use of Racial and Ethnic Data in HHS (December 1, 1999), available at <https://aspe.hhs.gov/report/improving-collection-and-use-racial-and-ethnic-data-hhs>.

how such differences may bear on product efficacy, patient safety, and patient empowerment.<sup>2</sup> While physicians swear an oath to “do no harm,” the drug products, medical devices, and clinical enhancement tools the FDA approves should be designed with the same level of consciousness and conviction.

The creation and diffusion of new health therapies often falls along lines of affordability, which creates disparate medical drug and device access between communities that are historically well-resourced and networked compared to those communities historically under-resourced or distrusting of the health care system. Income inequality is a detrimental life determinant. For many families, the ability to afford necessary, prescribed medications is veritably a life-and-death scenario. While the FDA is not directly involved in the prescription drug pricing process, there are other ways it can influence the cost of critical drugs. **The significance of continuously refining equitable pathways for high-quality, low-cost generic drugs—whether maintenance, prevention or innovator drugs—into the marketplace cannot be overstated.** The AMA supports a competitive marketplace, but not one that galvanizes inequities in accessibility to lifesaving and quality of life-enhancing products.

## **Health Literacy Education & Communities Engagement**

### *Health Literacy Education*

Health literacy concerns are a canary in the coal mine of all the structural and individual health challenges facing vulnerable populations. Health literacy is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”<sup>3</sup> It is a prerequisite to determining drug accessibility and uptake among patients in need. Compared to Whites, racially minoritized people are more likely to possess lower health literacy levels, and are vulnerable to making dosage and adherence mistakes, which carries significant implications for wellness.<sup>4</sup> The AMA views this as an unacceptable phenomenon.

The AMA is working to bring greater accountability about health literacy in health care delivery settings between our physicians and our patients. Our work in health literacy harkens back to our 2003 case study titled, *Health Literacy: A Manual for Clinicians*.<sup>5</sup> In this case study, the authors identify the dangers of a mismatch of patients’ understanding with what physicians have communicated, including medication use instructions. This misalignment has both direct health as well as health care cost impacts, with exacerbated implications for historically medically underserved communities, such as the elderly, low-income, and/or minoritized. Health outcomes cannot be improved if health literacy is not improved.

Under the Congressional directives laid out in the 2012 Safety and Innovation Act, the FDA has made notable strides in considering the health literacy of patient-consumers as an issue of patient safety. By prioritizing development and use of meaningful, plain language, and through instituting other streamlining strategies, the agency has shifted the standardization culture around medical drug labeling, even stratified by racial/ethnic demographics, as demonstrated in the FDA 2016 Office of Minority

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<sup>2</sup> J. Wiens et al. 2019. “Do No Harm: A Roadmap for Responsible Machine Learning for Health Care.” *Nature Medicine*, 25, 1337–1340.

<sup>3</sup> U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. “National Action Plan to Improve Health Literacy.” Washington, (DC): Author; 2010.

<sup>4</sup> National Commission on Adult Literacy. 2008. “Reach Higher, America. Overcoming Crisis in the U.S. Workforce: Report on the National Commission on Adult Literacy.”, available at <https://files.eric.ed.gov/fulltext/ED506605.pdf>.

<sup>5</sup> Barry D. Weiss. *Health Literacy: A Manual for Clinicians* (2003), American Medical Association Foundation and American Medical Association, available at <http://lib.ncfh.org/pdfs/6617.pdf>.

Health Progress Update.<sup>6</sup> However, as we move into a new century, our population demographics change, the way we receive and process information has expanded, and our nation faces increasingly more complex medical challenges. There is much opportunity for the FDA OMHHE to impact issues associated with health literacy, beginning with an updated OMHHE report that emphasizes health literacy interventions. **We also recommend simplified food and drug labels that are made available in different languages for those whose English proficiency is limited. Finally, we suggest including information on food and drug labels potentially relevant to those whose nutritional and dietary intake is shaped by their culture or religion (e.g., vegetarian/vegan, Kosher, and Halal).**

#### *Historically Minoritized Communities Engagement*

There are additional benefits to using a health equity framework to evaluate access barriers to health care and to determine the quality of care delivered. Aside from the moral imperative that such a lens emphasizes, there are cost containment and savings advantages,<sup>7</sup> workplace implications,<sup>8</sup> and quality improvements associated with elevating health equity in research.<sup>9</sup> To leverage these benefits, **we recommend the FDA OMHHE develop community programs and support frameworks to raise patient/consumer clinical trials awareness and engagement.** More specifically, we recommend the following:

- Increase fiscal support for community outreach programs, such as culturally relevant community education, community leaders' support, and community-wide town-halls and listening sessions;
- Increase outreach to female physicians to encourage recruitment of patients who are also women into clinical trials (including transwomen and those who identify as female);
- Increase outreach to physicians who treat patients who have a disability/disabilities to encourage recruitment into clinical trials;
- Continue racial/ethnic and gender minority physician education and meaningful engagement on clinical trials, subject recruitment, and subject safety;
- Actively support involvement of minoritized physicians in the development of partnerships between minoritized communities and research institutions (e.g., serving on Institutional Review Boards); and
- Fiscally support minoritized patients' clinical trials accessibility by addressing socially determinant factors, such as transportation and childcare needs, and other forms of impactful reimbursement.

We are also attuned to the inequitable distribution of drug marketing and information between medically underserved communities. The history of racialized medicine, wherein some drugs have been specifically approved and marketed out to singular racial groups, such as BiDil among the African-American community in the late 1990s, has had misleading and potentially harmful consequences that erringly perpetuates race as a scientifically-founded biological factor in health outcomes.<sup>10</sup> Ensuring that future

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<sup>6</sup> Jonca Bull. *Office of Minority Health Progress Update* (2016), available at <https://www.fda.gov/media/96619/download>.

<sup>7</sup> Thomas LaVeist et al. 2011. "Estimating the Economic Burden of Racial Health Inequalities in the United States." *International Journal of Health Services*. 41(2):231-238.

<sup>8</sup> J.C. McCullough et al. 2012. "A Health Dividend for America." *American Journal of Preventive Medicine*. 43:650-654.

<sup>9</sup> Institute of Medicine (US) Forum on the Science of Health Care Quality Improvement and Implementation; Institute of Medicine (US) Roundtable on Health Disparities; Institute of Medicine (US) Roundtable on Health Literacy. *Toward Health Equity and Patient-Centeredness: Integrating Health Literacy, Disparities Reduction, and Quality Improvement: Workshop Summary*. Washington (DC): National Academies Press (US); 2009. 2, Opportunity at the Intersection of Quality Improvement, Disparities Reduction, and Health Literacy, available at <https://www.ncbi.nlm.nih.gov/books/NBK37527/>.

<sup>10</sup> Howard Brody and Linda M. Hunt. 2006. "BiDil: Assessing a Race-Based Pharmaceutical." *Annals of Family Medicine*, 4:556-560.

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drugs and products in the FDA pipeline are marketed strictly based on its cure or treatment efficacy is imperative for instilling trust among the patients most in need of life-saving medications designed to remedy conditions that may disproportionately impact some communities over others. **The AMA urges the FDA OMHHE to work with physician organizations to develop innovative risk communication approaches and data collection tools that capture new drug impact after an extensive marketing period and delineate funding to implement an improved FDA post-marketing prescription drug surveillance process.**

### **Public Health Workforce Development**

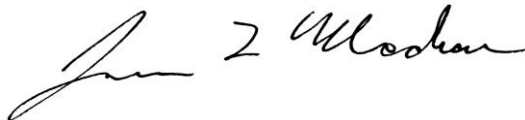
The AMA shares the FDA OMHHE's commitment to diversifying the health science and research workforce. Increasingly, clinical research and data analytics skills are necessary to reach actionable and safe solutions to our world's health and wellness challenges. **We urge the FDA OMHHE to continue its uptake of minoritized physician-scholars along the science, technology, engineering, and medicine continuum**, including from early career investigation opportunities the FDA sponsors, such as the Oak Ridge Institute for Science and Education "ORISE" Fellowship, to supports for mid-career scientists interested in pursuing health equity research. We also invite discussions about potential future programming and areas of collaboration between our institutions.

### **Conclusion**

The AMA is strongly committed to working with external partners to maximize and normalize the embeddedness of equity in health policy development, health care delivery, and health product design, toward the betterment of public health. Creating systems of equity will take great commitment and cooperation between our nation's institutions to diffuse systems-wide health equity frameworks. Without real commitment to achieving health equity through equity-embedded systems-building and firm partnerships, we run the great risk of deepening disease burden divides, thwarting life potential for disadvantaged communities, and diminishing opportunities for us to benefit from a society wherein all of our lives are well-lived. We view this Request for Comment as a firm step forward in advancing the health equity agenda of the FDA OMHHE.

We look forward to building and deepening a partnering relationship with your office as we also systemically deepen and demonstrate our commitment to equity in health outcomes and health care delivery. Should you have questions or wish to discuss our recommendations, please contact Shannon Curtis, Assistant Director of Federal Affairs, at [Shannon.Curtis@ama-assn.org](mailto:Shannon.Curtis@ama-assn.org), or 202-789-8510.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD