Disability Rights Education & Defense Fund

DREDF

November 20, 2013 **Submitted electronically to www.regulations.gov**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket ID No. FDA-2013-N-0745, Comments on FDASIA Section 907 Report: "Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products"

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) August 2013 report, *Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products*. The undersigned organizations strongly support the need for the development and public availability of data about how new drugs and devices work in people with disabilities, women, minorities, and older Americans that have traditionally been subject to exclusion. Many of us had the opportunity to sign on to recommendations outlined in earlier comments developed by the American Heart Association, and in this letter we further focus on the critical need to encourage, develop and disseminate demographic subgroup data that fully includes people with disabilities in FDA-reviewed clinical trials, research and analysis. If the Action Plan that the FDA must produce by July 2014 fails to acknowledge women, minorities, older adults, and people with disabilities, as well as the reality that these are categories that overlap in ways that raise genetic and/or biologic implications, the FDA will be sanctioning a status quo in which medical products can fail to serve the very populations that most depend on them.

The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) that underlies both the FDA report and the Action Plan explicitly mentions sex, age, racial, and ethnic subgroup characteristics, but the use of language like "including" and "such as" in Section 907 of the act clearly indicates that the FDA was not given an exhaustive list to consider when assessing the extent to which clinical trial preparation and safety and effectiveness data take demographic subgroups into account. As such, the FDA's lack of consideration of disability in its recent report is a choice, and it is not a choice that can go unremarked.

Absence of Assessment or Analysis of Disability Subgroup Representation

It is difficult to assess or critique the report's analysis of disability as a demographic subgroup since disability was essentially ignored as a demographic characteristic.[1] This

[1] Page 53 of the report does cite to the Americans with Disabilities Act of 1990 and Section 508 of the Rehabilitation Act of 1973 in the context of FDA-wide posting and disclosure policies, apparently referring

is unfortunately in keeping with how information concerning disability is routinely excluded from clinical research in general. Scientific evidence is lacking about effective treatments for people with disabilities, especially those who develop common conditions of aging (e.g., cancer, heart disease, diabetes) because they are routinely excluded from clinical trials, and creating comparative effectiveness research that incorporates people with disabilities presents complex challenges.[2] Healthcare professionals therefore have access to limited comparative treatment information and evidence about therapeutic options. It consequently becomes very difficult to discuss or refute the often unexpressed bias that poorer health, shorter lifespans, and a lesser quality of life are inherent features of living with a disability, regardless of the functional impairment or clinical condition in question, and without respect to whether or not healthcare facilities are accessible and legally required accommodations have been provided. People with disabilities must be included in research activities, especially when much of this research is intended, implicitly or explicitly, to help establish standards for evidence-based treatment and prescription standards. The development of clinical research that does not involve people with disabilities will lead to treatment standards that ignore the needs of people with disabilities.[3]

Many studies on specific medical research exclude people with any form of disability as participants, and this exclusion is also common when research is done on general health topics such as sex or aging or the impact of certain treatments. People with disabilities may in fact take part in a study, but since identifying demographic questions are not asked, the data cannot be analyzed with an understanding of disability as a treatment or health factor. The failure to include or even identify people with disabilities when providers and health care delivery systems are increasingly held to "evidence-based medicine" standards means that individuals with disabilities face procedural delays and barriers because there are few scientifically validated or administratively "pre-authorized" treatments for people with disabilities. More broadly, people with disabilities simply disappear from the national health agenda. There is a dearth of scientifically validated information about how people with various disabilities respond to common, leading, or cutting edge treatments, whether they are medical, mental or behavioral health, or preventive programs for smoking cessation or weight loss. The costs of this will become increasingly clear as the American population ages and the prevalence of different types of disabilities increases.

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to technical accessibility requirements that apply to the FDA's product labels and website documents. While it is reassuring that the FDA acknowledges its obligation to, for example, provide a visually impaired individual with product information in an alternative format such as Braille or large print, it would be equally reassuring for that individual to know that his or her underlying chronic condition was appropriately taken into account when the product in question underwent clinical trials.

[2] *Identifying effective health care services for adults with disabilities: Why study designs and outcome measures matter*. (2011). Presentation at the Mathematica Policy Research Center on Health Care Effectiveness (CHCE) Issue Forum. Retrieved from http://www.mathematica-mpr.com/CHCE/forum_archives/July_2011/powerpoint.pdf.

[3] *See* Zulman D.M. *et al*. (2011) Examining the Evidence: A Systematic Review of the Inclusion and Analysis of Older Adults in Randomized Controlled Trials, *Journal of General Internal Medicine*, 26(7), 783-790; Chronic Disease Prevention and Control Research Center at Baylor College of Medicine. Major Deficiencies in the Design and Funding of Clinical Trials: A Report to the Nation Improving on How Human Studies Are Conducted (April 2008).

As federally conducted or federally funded health programs or activities, *all* government supported research activity must encourage addressing disability-related issues and health disparities research in funded studies. Similarly all government support research activity, whether initiated under the Affordable Care Act (ACA) or not, must require including people with disabilities within the study populations in the same way that members of other medically vulnerable or underserved groups, such as women or racial minorities, are required for inclusion, and the inclusion of all demographic subgroups must be incentivized, monitored and implemented. Research proposals that explicitly, or by design, fail to address the recruitment of people with disabilities must explain the rationale or medical value of such an exclusion.[4]

The FDA report concludes with concern that the "broad self-identified demographic categories used today may not relate to the complex genetic and biological factors that are the basis for differences in response to medical products, although they may be useful in generating hypotheses that may drive additional studies or product development in the future." While full inclusion of people with disabilities in clinical research and trials will benefit the disability community as a whole, as well as the general population, we are not necessarily insisting that every project must include people that have every possible kind of disability and chronic condition. Historically researchers have had substantial difficulty with incorporating people with disabilities in clinical trials and safety and effectiveness data, at least in part because of a failure to draw a distinction between disability as a diagnosis and disability as a functional limitation.

On the one hand, an individual's functional limitations such as hearing or mobility impairments may have very little impact on the operation of a medical product, but the fact of the limitation could require physical accessibility and reasonable policy modifications such as assistive listening devices or telephone relay services for verbal communication, or the use of height-adjustable examination equipment. These external factors can result in the unjustified exclusion of people with disabilities from clinical research and trials. On the other hand, an individual's underlying chronic condition could have substantial physiological and genetic implications for the effectiveness of a medical product. For example, a common underlying cause of vision loss could be a genetic condition that may influence how a proposed blood pressure drug works. There is an established correlation between blindness and a greater propensity to obesity, hypertension and heart disease.[5] At the same time, people who are Hispanic have

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[4] *Developing Quality of Care Measures for People with Disabilities: Summary of Expert Meeting*. AHRQ Publication No. 10-0103, September 2010. Rockville, MD: Agency for Healthcare Research and Quality, *available online* at: http://www.ahrq.gov/populations/devqmdis/ ("In recent years, the National Institutes of Health (NIH) and AHRQ have required investigators submitting grant applications to explicitly address the inclusion of persons by sex and race and ethnicity. Both NIH and AHRQ grant applicants must justify the exclusion of people by sex, race, and ethnicity. NIH applicants must also address the inclusion of children and justify their exclusion. Beyond women and racial and ethnic minorities, AHRQ requires grant applicants to consider including the following "priority populations": inner-city residents; rural residents; low income persons; children; elderly people; and those with special health care needs, including individuals with disabilities and those who need chronic care or end-of-life health care.")

[5] Michele Capella-McDonnall, "The Need for Health Promotion for Adults Who Are Visually Impaired," Journal of Visual Impairment and Blindness 101, no. 3 (March 2007).

higher rates of visual impairments than people who are African American, and both groups have higher rates of vision impairment than people who are white.[6] Ignoring those links and failing to recruit people who are blind in research for blood pressure drugs and biologics will lead to incomplete research results and serves no one.

There is certainly room for stakeholders to work together to develop and refine a workable definition of demographic characteristics that will have an impact on clinical research and findings, including a framework for when the presence of disability should be taken into account and how. This is critical work that will never be done as long as the failure to explicitly address and incorporate people with disabilities is taken for granted as an acceptable way to conduct medical research.

Recommendations

Our first recommendation is that the FDA must recognize and include people with disabilities as a target under-served population in future studies and data collection on demographic subgroups. Such inclusion is consistent both with the ACA's identification of disability as a health disparity population, and with the anti-discrimination provisions of Section 1557 that acknowledge how people with disabilities encounter myriad barriers to receiving equally effective treatment *and* research consideration. Currently people with various functional limitations are commonly excluded from clinical trials because of irrelevant external factors such as the use of inaccessible medical equipment or communication methods in data gathering, and at the same time relevant and biologic factors inherent in people with specific conditions and disabilities are equally excluded when trials are designed. The FDA's acknowledgement of people with disabilities is a key tool to breaking these patterns of exclusion.

Additional specific recommendations follow.

- FDA should issue regulations that require new drugs, biologics, and device applications and investigational device exemption reports to present safety and effectiveness data relevant to disability. FDA should also issue guidance for disability-specific analysis within product research and trials.

- FDA regulations, guidance, and actions should clearly indicate that lack of inclusion of required demographic subgroup data will result in withholding of product approval until such data is provided.

- FDA regulations should require the separate collection and reporting of information for people with disabilities so that future analysis can determine whether people with specific disabilities such as communication, mobility or cognitive limitations are underrepresented in research. The disability identification questions used in the American Community Survey should be used as a starting point for identifying people with functional limitations.

[6] C. Kirchner & E. Schmeidler, "Life Chances and Ways of Life: Statistics on Race, Ethnicity, and Visual Impairment," Journal of Visual Impairment and Blindness, 93 (1999) at 5.

- FDA should require that representative proportions of people with disabilities be included in clinical trials, consistent with the investigated disease's prevalence and impact in the underlying population, as the NIH required 20 years ago. Adequate representation of those patient subgroups that will ultimately be using the drug or device is critical to ensuring safety and efficacy for all people.

- Study sponsors should be required to develop a plan to enroll sufficient proportions of people with disabilities in all phases of clinical research. There are proven strategies to ensure outreach to and bolster participation of people with disabilities. These strategies need to be actively disseminated and their adoption encouraged.

- FDA should establish an FDA Advisory Group for groups underrepresented in clinical research studies to make recommendations to improve participation rates and ensure that people with various disabilities are included in the Advisory Group.

- FDA should require that appropriate disability demographic information is a required section in all medical product labeling, as is the case for pediatrics and geriatrics information, even if subgroup-specific analyses suggest no difference in outcomes or has not yet been undertaken.

- If the proportion of subgroup members participating in product studies is not sufficient to evaluate whether differences exist, we recommend that FDA require this be stated on the label.

- FDA should develop standard label content requirements for medical devices.

- Demographic subgroup information should be readily available and fully accessible to people with disabilities, including information for how information in alternate formats such as Braille, large font print, accessible CD or sign-language videos can be requested and received.

- FDA should implement procedures to routinely monitor, publicly report compliance with, and implement these recommendations.

Thank you again for considering our comments. All of the undersigned groups would appreciate the opportunity to work with FDA to fully recognize disability as both a demographic group and as a subgroup that requires investigation, analysis, and transparent reporting, thereby ensuring full and appropriate inclusion of people with disabilities in clinical research and trials for medical products requiring FDA approval. Please feel free to contact Silvia Yee at DREDF with any questions or concerns on the above.

Yours Truly

Access Living

Adapt Montana

American Association on Health and Disability

Association of University Centers on Disabilities

Autistic Self Advocacy Network

Breast Cancer Action

California Center for Rural Policy, Humboldt State University

Center for Independence of the Disabled of New York

Coalition for Disability Health Equity

Community Access National Network

Community Action Partnership

Dignity Health

Directors of Health Promotion and Education

Disability Rights Education and Defense Fund

Disability Section of the American Public Health Association

HealthHIV

National Center for Lesbian Rights

National Fibromyalgia and Chronic Pain Association

New York Lawyers for the Public Interest

New Yorkers for Accessible Health Coverage

Senior Moments

United Spinal Association