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# The FDA's Diverse and Dynamic Activities in the Social and Behavioral Sciences: Advancing and Supporting Health Equity

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**Abstract**

The U.S. encompasses a heterogenous mix of people and health disparities exist for various subpopulations, such as minorities, women, people with limited English proficiency, those with low socioeconomic status, and other underserved groups. Differences in health outcomes arise in part due to inequalities and injustices rooted in biological, social, and structural factors. Because the origins of health disparities are multifactorial, the approaches to reduce, or even eliminate them, must be multifactorial as well. The social and behavioral sciences are well poised to address the myriad and complex factors that affect health outcomes, including those at the individual level (eg, individuals' behaviors, attitudes, and beliefs), the neighborhood level (eg, housing), the community level (eg, cultural values and norms), and the policy level (eg, public policies that influence healthcare funding and access to healthcare resources and educational materials). In addition, the social and behavioral sciences (1) help equip government agencies with the perspectives and tools needed to promote health equity and (2) contribute to rigorous, evidence-based solutions for public health issues, such as disparities found in childhood vaccination rates, childhood obesity, tobacco use, and access to health information technology. The FDA, in particular, actively conducts social and behavioral sciences research to guide the Agency's efforts to advance and support health equity.

**Keywords**

behavioral health, community health, disease management, focus groups, health literacy, health outcomes, health promotion, mixed methods, qualitative methods

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Health equity is broadly defined as the elimination of health disparities and the attainment of the highest level of health for all people, meaning no one is denied the possibility of being healthy for belonging to a historically disadvantaged group.[1] However, a one-size-fits-all approach to health equity in the U.S. is unlikely to succeed as it assumes a monolithic population. In reality, the U.S. encompasses a heterogenous mix of people and health disparities exist for various subpopulations, such as minorities, women, people with limited English proficiency, those with low socioeconomic status, and other underserved groups.[2] Differences in health outcomes arise in part due to inequalities and injustices rooted in biological, social, and structural factors.[3] Because the origins of health disparities are multifactorial, the approaches to reduce, or even eliminate them, must be multifactorial as well.

The social and behavioral sciences are well poised to address the myriad and complex factors that affect health outcomes, including those at the individual level (eg, individuals' behaviors, attitudes, and beliefs), the neighborhood level (eg, housing), the community level (eg, cultural

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values and norms), and the policy level (eg, public policies that influence healthcare funding and access to healthcare resources and educational materials).[4-7] In addition, the social and behavioral sciences (1) help equip government agencies with the perspectives and tools needed to promote health equity and (2) contribute to rigorous, evidence-based solutions for public health issues, such as disparities found in childhood vaccination rates, childhood obesity, tobacco use, and access to health information technology. The FDA Office of Minority Health and Health Equity (OMHHE), established in 2010, provides leadership and policy direction on minority health, health disparity, and health equity matters for the Agency. OMMHE works to advance health equity-focused research, education, and scientific exchange with public and private sector stakeholders and FDA Centers, Offices, and including FDA's Social and Behavioral Science Working Group (SBSWG). The SBSWG consists of representation from FDA's Centers and provides advice and guidance to FDA and center leadership on planning, reporting, programs, policies, and communication, as well as emerging issues, related to social and behavioral science. The FDA, in particular, actively conducts social and behavioral sciences research to guide the Agency's efforts to advance and support health equity. These efforts are described in detail below.

## Using Research and Evidence-Based Approaches to Reach Diverse Populations

The Office of Minority Health and Health Equity (OMHHE), in FDA's Office of the Commissioner, is dedicated to providing leadership and policy direction for the Agency on issues related to the health of racial and ethnic minority, underrepresented, and underserved populations. The mission of OMHHE is to promote and protect the health of diverse populations through research and communication that addresses health disparities to ultimately, make health equity a reality for all. To achieve this goal, the office works across the FDA and with a broad range of public and private stakeholders to strengthen FDA's ability to respond to minority health concerns, advance minority health and health equity focused research, improve FDA communication with diverse populations, and advocate for the inclusion of racial and ethnic minority populations in clinical trials. One study funded by OMHHE used social media and unstructured data from sources like Facebook, Twitter, and transcripts of meetings of the FDA's Diabetes Advisory Committee to further understand patients' perspectives on diabetes. The Agency gleaned valuable information on best practices for communicating with minority patients and their caregivers about diabetes. This study prompted further studies to be conducted for additional diseases that disproportionately affect minority populations.

The FDA's Office of Women's Health (OWH) serves as the principal advisor to key Agency officials on scientific, ethical, and policy issues related to women's health. To achieve its mission of protecting and promoting women's health, the Office engages in 3 program areas: (1) scientific research, (2) education, and (3) outreach and communications. OWH funds social and behavioral sciences research both inside and outside of the FDA that generally focuses on patient preferences and health communications. Current projects are exploring how patients decide to use medical devices; how clinicians can better understand and communicate lactation-related health information to breastfeeding women; how to assess possible clinician biases that may affect referrals for clinical trials; and how to tailor health communications to diverse groups of older women about medications, vaccines, nutrition, and cosmetics.

## Including Diverse Stakeholder Perspectives

FDA involves patients during the overall process for development and review of medical products. Hearing directly from patients and caregivers about their perspectives on issues such as disease and treatment burden, daily impacts of a disease or condition, and patient priorities for managing symptoms informs the Agency's regulatory decision-making. The Patient Affairs Staff (PAS) in the Office of the Commissioner leads, coordinates, and supports patient engagement activities across the FDA medical product centers. Specifically, PAS programs and initiatives are a resource for the Agency staff to engage with patients and their advocates and provide patient communities with opportunities to share their unique experiences living with a disease or condition.

The Center for Devices and Radiological Health (CDRH) routinely leverages the social and behavioral sciences to promote its mission and vision to ensure patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. The Center proactively integrates the social and behavioral sciences with other aspects of regulatory science. CDRH's evaluation of medical devices and monitoring of their safety is complemented by the feedback that patients provide, such as their views about and experiences with a particular device, their experience living with their condition, and their overall well-being. CDRH incorporates patients' perspectives into regulatory decisions including considering patient-reported outcomes and patient preference information. CDRH is also exploring how patient-generated health data can be used as a source of real-world data and is piloting efforts in collaboration with the Yale-Mayo Center of Excellence in Regulatory Science and Innovation (CERSI) and the Medical Device Innovation Consortium (MDIC) the National Evaluation System for Health Technology (NESTcc).

## Providing Information to Diverse Communities to Inform their Health Decision-Making

The Consumer Studies Branch at FDA's Center for Food Safety and Applied Nutrition (CFSAN) has a multidisciplinary team of social and behavioral scientists who design and conduct research to (1) inform the Center's deliberations about policies and regulations to promote public health and safety; (2) guide the content and dissemination of public information and education to help consumers make better informed decisions about food and cosmetic products regulated by FDA; and (3) make CFSAN science more understandable and accessible to the public, industry, and other stakeholders. Findings from these studies provide CFSAN with an in-depth understanding of consumers' awareness, knowledge, beliefs, attitudes, feelings, and motivations related to food labeling, food safety, nutrition, cosmetics, and dietary supplements. This research also can provide empirical data about the accuracy of consumers' judgments in response to labeling statements and claims that appear on food and cosmetic products, and the effectiveness of disclosures and disclaimers intended to remedy possible consumer misperceptions and confusion. Since the 1980s CFSAN's social and behavioral scientists have conducted periodic national surveys that provide population estimates for consumers' understanding of labels for food and cosmetic products and dietary supplements; knowledge about nutrition, specifically the relationship between diet and certain diseases; and self-reported behaviors related to food safety in the home, including safe handling of pet food. The data from these surveys help CFSAN set priorities for additional research, education, and communications to consumers and stakeholders.

Social and behavioral scientists in the FDA's Center for Drug Evaluation and Research's (CDER's) Office of Nonprescription Drugs (ONPD) play a key role in drug approvals when a company wants to switch a drug from prescription to over-the-counter status. Companies often conduct consumer behavior studies to assess if consumers (1) understand the drug label (label comprehension studies), (2) appropriately self-diagnose their condition (self-selection studies), (3) appropriately decide to take the drug given their personal medical histories and concomitant medication use (self-selection studies), and (4) use the drug correctly (actual use studies). As members of the clinical review team, ONPD social and behavioral scientists are responsible for reviewing most aspects of these consumer behavior studies. ONPD social and behavioral scientists seek to ensure that limited literacy subgroups are adequately represented in all types of consumer studies and that other key subgroups, such as caregivers, adolescents, and/or current sufferers of a condition, are appropriately represented. ONPD social and behavioral scientists are also in the forefront of experimenting with how to implement and assess innovative digital tools to help diverse subpopulations of consumers appropriately decide to use an over-the-counter drug.

CDER's Office of Communications (OCOMM) conducts diverse social and behavioral sciences research to inform the Agency's outreach communications and regulatory and policy decisions regarding drug safety issues. The goal is to raise awareness about drug safety issues among healthcare professionals, patients, and the public, leading to better decision-making. OCOMM conducts research to (1) gather information before it communicates to help the Office develop information and materials, and (2) assess how consumers, including the most vulnerable, understand and act on the information once it's disseminated. These types of formative and evaluative qualitative and quantitative mixed-method studies enhance the Agency's understanding of its diverse audiences' knowledge, perceptions, needs, decision-making processes, experiences, and behaviors related to a variety of topics, including prescription opioids and medical countermeasure drugs that may be used in terrorist attacks or other public health emergencies.

As part of CDER's more traditional proactive pharmacovigilance efforts, several years ago OCOMM social scientists began monitoring and analyzing the vast amount of unstructured data in discussions on social media and other online platforms. These studies allow the FDA to quickly collect a breadth of information across multiple platforms from large, heterogeneous, and geographically diverse groups. Such studies have been key in providing the human and social contexts surrounding a variety of drug-related topics, such as the national opioid epidemic. This can help identify trends in the use and abuse of new or emerging substances before they become public health threats.

The Center for Tobacco Products (CTP) social scientists play key roles in the development of culturally sensitive and tailored educational content. Campaigns aimed at preventing and reducing tobacco use across diverse target populations include FDA's *Fresh Empire* campaign, the first tobacco public education campaign designed to reach African American, Hispanic, and/or Asian American/Pacific Islander youth ages 12 to 17 years who identify with the Hip Hop crowd[8,9]; *This Free Life* campaign designed to prevent and reduce tobacco use among LGBT young adults who use tobacco occasionally[10]; and "The Real Cost" Smokeless Tobacco prevention campaign that seeks to educate rural male teenagers about the health risks of using smokeless tobacco products.[11]

## Helping to Ensure that Prescription Drug Information is Truthful and Non-misleading

The Office of Prescription Drug Promotion (OPDP) within the Office of Medical Policy at CDER protects public health by helping to ensure that prescription drug promotional

material is truthful, balanced, and accurately communicated. OPDP's Social Science Research Team has an extensive research agenda that focuses on exploring diverse groups of consumers' and healthcare providers' understanding of, perceptions of, and attitudes toward promotional material for prescription drugs. The team examines (1) how different audiences may understand the risks and benefits of prescription drugs differently, (2) how elements in promotional material, such as graphics, format, and descriptions of the disease and product, impact how patients and healthcare providers understand these risks and benefits, and 3) how to maximize the quality of our data through analytical methodology development and investigation of sampling and response issues. OPDP frequently publishes research articles that focus on consumer-directed prescription drug promotional material, including articles about (1) ways to better communicate the drug's risks in the major statement of television ads,[12,13] (2) ways to effectively communicate quantitative information about the drug's efficacy and its risks,[14-19] (3) ways to investigate the effectiveness of communicating the drug's risks and benefits on consumer-directed websites,[18,20] and (4) the impact of comparative claims,[21,22] marketing claims,[19,20,23,24] promotional offers,[25] and composite scores[26,27] on the perceptions of both consumers and healthcare providers regarding the drug's risks and benefits.

## Examining Consumer Beliefs, Attitudes, and Cultural Factors to Inform Tobacco Product Regulatory Decisions

The 2009 Family Smoking Prevention and Tobacco Control Act created the Center for Tobacco Products (CTP) and established a new standard for the FDA to regulate tobacco products according to their effects on overall population health, which differs from traditional FDA safety and efficacy standards.[28] This population health standard means that FDA considers the risks and benefits about tobacco use on the population as a whole, and depending on the decision or policy, relevant subpopulations. Social and behavioral scientists who review applications for tobacco products consider the myriad implications of introducing new tobacco products into the market and the effects on users of potential modified risk claims for tobacco products (claims that the products have a reduced harm or risk). For each application, CTP social and behavioral scientists evaluate the potential uptake and initiation among nonusers, including youth and other vulnerable populations, and consider the potential transition to a potentially less harmful product or cessation among current adult users. CTP social and behavioral scientists also contribute to science-based tobacco regulatory policy by considering the potential differential impact of such policy on various vulnerable populations,[29] and conduct research to examine tobacco-relevant beliefs and perceptions held by subgroups (eg, foreign-born populations) to inform communication strategies.[30]

## Language Access

FDA's multilingual resources span across various Centers/Offices, an example of a language access program include CVM efforts. The FDA's Center for Veterinary Medicine (CVM) has a mission to protect both human and animal health. Clear and effective communication to all stakeholders is a cornerstone of this mission. For some of the Center's stakeholders, Spanish is their first language and they may have limited proficiency in English. For these stakeholders, it may be difficult to read and understand the content on CVM's website. To this end, CVM recently started an outreach effort to connect more with Spanish speakers. With support from the FDA's Office of Minority Health and Health Equity, the Center has begun translating selected website content into Spanish for pet owners, animal producers, veterinarians, and other groups in the animal health industry. Although the number of translated webpages is limited thus far, this outreach effort will continue to expand in 2020 and 2021. To further advance the Center's mission, CVM hopes to break down the barriers to effective communication caused by limited English proficiency.

## Conclusion

Given its responsibility to regulate a variety of products—including food, drugs, and medical devices for both people and animals as well as cosmetics and tobacco products—the FDA is well positioned to address health equity implications for the diverse populations who use these products. The social and behavioral sciences are embedded within each Center's and Office's activities and currently used to help the Agency achieve its mission of protecting public health. There are also existing efforts to connect social and behavioral scientists throughout the Agency, most notably through the Social and Behavioral Sciences Working Group (SBSWG). Supported by the FDA's Office of the Chief Scientist, the working group coordinates projects focused on social and behavioral sciences research and advises the Agency's leadership on issues related to the social and behavioral sciences.

The current efforts help inform future endeavors addressing health disparities as we continue to support research, outreach, and education programs for address health equity. By continuing to elevate the perspectives and needs of diverse populations through social and behavioral sciences research and by encouraging social and behavioral scientists to share resources, expertise, and ideas through the SBSWG and other avenues, the FDA can serve as an example for how

government agencies can take a proactive approach to advance and support health equity.

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