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Challenges and solutions to advancing health equity with medical devices

In October 2022, the US Food and Drug Administration (FDA) proposed updating its Breakthrough Devices Program (BDP) to reduce disparities in health and health care[1]. Created by Congress in 2016, the BDP is intended to expedite developing and authorizing devices that diagnose or treat life-threatening conditions and represent technologies that either lack approved alternatives or offer substantial advantages when compared to existing modalities[2]. Breakthrough designations are coveted by manufacturers, who receive special access to senior FDA staff during premarket development, priority review that shortens regulatory review time periods, and automatic eligibility for supplemental Medicare payments following authorization. Additionally, to enable expedited authorization of breakthrough devices, the FDA accepts greater uncertainty about device risks and benefits during premarket review, with the expectation that manufacturers collect further data in the postmarket setting after authorization. As of 31 December 2022, the FDA has granted 760 breakthrough designations and authorized 62 of these devices[3].

The FDA is now proposing to broaden eligibility for the BDP — and the program's associated regulatory and financial benefits to manufacturers — to include devices that could promote and advance health equity. The agency argues that such devices fulfill the BDP's statutory criteria of "provid[ing] for more effective treatment or diagnosis" by using design features that address factors causing health and health-care disparities (for example, phenotypic variation or geographic barriers to access)[1]. The proposal comes in wake of new directives by Congress and actions by the FDA to promote clinical trial diversity and reduce health disparities[4,5]. These disparities gained attention during the COVID-19 pandemic, which illustrated how differential access to certain medical devices (for example, ventilators) and variable performance of some technologies across race and ethnicity (for example, pulse oximeters) can contribute to worse outcomes for underserved populations[6,7]. While such disparities warrant action, the FDA's BDP proposal does not address the systemic factors underlying them (for example, device access and affordability). Furthermore, although policies to advance health equity for medical devices are needed, the FDA's proposal to expand expedited review of technologies with greater uncertainty about clinical benefits and risks does not guarantee that disparities-focused breakthrough devices will actually promote and advance health equity. In this Correspondence, we examine core equity considerations for medical device regulation and apply these insights to the proposed FDA reforms for breakthrough-designated medical devices.

Table 1 | Health equity considerations for medical device regulation

Health equity theme	Challenge	Example	Policy opportunity
Representation	Many underserved populations are inadequately represented in premarket testing of medical devices	Many devices used in pediatric care were authorized on the basis of data from studies that primarily enrolled adults	Apply new legal requirements for clinical trial diversity, which may improve representation
Performance variation	Use of some medical devices is associated with worse outcomes among some populations	Medical devices such as artificial hips and implantable cardioverter defibrillators have higher complication rates for women	Require postauthorization studies to verify clinical benefit and perform adequately powered, stratified analyses to assess outcomes across patient groups
Accessibility and affordability	Systemic factors ranging from clinical bias to geographic barriers to insurance coverage policies may limit patients' access to devices	Launch prices for breakthrough medical devices are increasing and may result in higher cost sharing for patients	Convene payers and manufacturers before FDA authorization to proactively address issues related to cost and coverage

Health equity considerations for medical device regulation

Disparities in access to medical devices and clinical outcomes of device use can manifest across multiple domains[1] (Table 1). First, premarket testing of medical devices often lacks adequate representation of certain populations, including racial and ethnic minorities, women, older adults, children, rural communities and low-income patients. Most medical devices are classified as having low or moderate risk by the FDA and therefore are not required to undergo premarket clinical testing, precluding any opportunity for detecting potential population-specific differences in performance[8]. High-risk devices undergo premarket testing, but manufacturers frequently do not report information about the race, ethnicity or sex of participants, and in some cases restrict enrollment to specific age groups[9]. Furthermore, even when such information is available, analyses by demographic subgroups are rarely performed or are performed without sufficient statistical power to generate clinically significant insights[10]. For instance, the labeling for pediatric devices often relies on evidence from trials that enrolled primarily adults[11,12].

Second, the same populations who are under-represented in premarket testing of medical devices may also experience worse outcomes when using such devices in the real world. For instance, research suggests that complication rates are higher for women receiving some implantable devices (such as artificial hips and implantable cardioverter defibrillators)[13,14]. Experts have hypothesized that differential performance for devices with standardized designs may be attributed to physiological differences between male and female anatomy[14].

Third, access to the benefits of medical devices may be impeded by factors including geography, insurance coverage restrictions, out-of-pocket costs, bias and structural racism. Consider the case of mechanical thrombectomy, which may be an appropriate intervention to improve neurological outcomes for the approximately 30% of strokes caused by large vessel occlusions if performed within 24 h of stroke onset[15]. Many clinically eligible patients who live far from hospitals equipped to perform mechanical thrombectomy do not receive timely endovascular treatment[16]. For other health conditions, the prohibitive cost of medical devices, due to insurance coverage restrictions or high out-of-pocket costs, can lead some patients to forgo treatment or seek care outside of the USA, as is often the case for artificial hip implants[17]. Families of children may also bear substantial financial burdens because payers may decline to cover devices developed for adults on the basis that use in pediatric patients is "off label"[18].

Expedited review could exacerbate medical disparities

The proposed policy by the FDA fails to address systemic factors responsible for disparities in health and health care and risks establishing regulatory precedents that may inadvertently exacerbate health inequities. Expediting the authorization of breakthrough devices, which may be (and have been) authorized without effectiveness endpoints, without randomization or control groups, despite substantial safety concerns[19], could lead to the authorization of devices without verified clinical benefit for conditions with proven standards of care.

Given that previous research has demonstrated higher recall rates among devices authorized under priority review[20], increased use of expedited review pathways claiming to advance equity could exacerbate disparities if underserved populations are marketed devices without verified clinical benefit and with potentially greater risk of safety issues that were never detected because of limited premarket clinical testing. A regulatory paradigm that prioritizes claims of equity over evidence of clinical benefit may cause persistent or irreversible harm if such devices are later shown to be ineffective or even harmful. The FDA and manufacturers often struggle to identify affected patients and resolve recalls in a timely fashion[21]. For example, Philips Respironics recalled millions of ventilators and positive airway pressure machines in 2021, and many patients are still awaiting replacements and refunds[22]. If such a scenario were to arise for a breakthrough device authorized with the intent of reducing disparities, it would further disadvantage already underserved populations and potentially erode trust in the FDA and healthcare providers.

Furthermore, the BDP has unique implications for both cost and access, which are critical dimensions for health equity. However, the FDA does not consider either in its proposed guidance updates or when deciding to authorize a medical device. Breakthrough-designated devices automatically qualify for supplemental Medicare payments, and manufacturers may leverage the designation to extract additional prices increases that could lead private insurers to implement restrictions[23,24]. These higher prices can also trickle down to both Medicare and privately insured patients in the form of increased out-of-pocket costs, which could discourage them from using devices or increase the financial burden of care. Breakthrough devices authorized on the basis of their potential to address health inequities could therefore risk replacing one access barrier with another.

Opportunities to maximize public health benefit

Inequities in access to new technologies are detrimental to public health, and the FDA's focus on improving access to medical devices is timely and welcome. However, the agency will need to ensure its proposals include adequate oversight, protections and enforcement mechanisms to avoid entrenching and exacerbating inequities that have long plagued the health-care system.

The FDA could consider modifying its proposed reforms to BDP to include expectations for premarket and postmarket testing. For such studies, the FDA could apply new legal requirements for clinical trial diversity to ensure enrollment is sufficiently representative to provide evidence of disparity reduction. The FDA could also condition equity-based approvals on the initiation of postapproval studies to confirm both clinical benefit and disparity reduction and could require manufacturers to submit proof that these devices are accessible to and used by their intended populations in real-world settings. Although the FDA does not regulate the cost of medical products, the agency could support improvements in access by convening public and private insurers to assess the potential impact of coverage policies for BDPs. Lastly, the FDA could develop protocols for rescinding breakthrough designations for devices that prove unsafe, prove ineffective or fail to improve health equity, including penalties for delayed confirmatory studies and initiation of mandatory recalls.

Addressing medical device disparities will also require action beyond the BDP to address the systemic drivers of inequity, including diversifying clinical trials, measuring outcomes across diverse populations and improving device access and affordability. By taking a broader view of disparities, the FDA will be better positioned to maximize the public health benefits of new medical technology.

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Competing interests

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