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Clinical and Regulatory Tradeoffs for Innovation: Lessons from the FDA's Breakthrough Devices Program

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The US Food and Drug Administration (FDA) grapples with a fundamental question when regulating medical devices: can adopting more flexible authorization standards accelerate innovation without compromising patient safety or clinical benefit? Prior work has examined these regulatory tradeoffs for drugs,[1-3] but there is comparatively little empirical evidence on medical device development. However, there is consensus that FDA has historically achieved limited success stimulating innovation or expediting patient access via special regulatory programs.[4-6] Scholars have proposed that these failures may stem from added regulatory complexity that may deter first-movers, existence of less-regulated markets outside the U.S., and delayed clinical adoption due to the gap between market authorization and insurance coverage and reimbursement.[7-9]

In an effort to address these concerns, Congress established the Breakthrough Devices Program (BDP) under the 21st Century Cures Act of 2016. The BDP is intended to accelerate premarket development of devices with the potential provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions. To qualify for participation, manufacturers must additionally demonstrate that technologies meet at least one of the following criteria: (1) represent a "breakthrough" technology, (2) have no authorized alternatives, (3) provide significant advantage over existing technologies, or (4) be available in the best interest of patients. Manufacturers which receive breakthrough device designations are entitled to considerable regulatory benefits, such greater engagement from FDA staff during premarket

development, more flexible authorization standards, and prioritized FDA application review.[10] To promote the adoption of breakthrough-designated devices, the Centers for Medicare and Medicaid Service (CMS) has implemented to reforms Medicare's processes for coverage, coding, and payment, including streamlining eligibility for supplemental Medicare reimbursement (2020) and developing a voluntary pathway for transitional coverage (2024).[11,12]

Unlike preceding FDA programs to expedite device access, BDP has proven popular with device manufacturers. As of June 30, 2025, FDA has granted breakthrough designation to over 1,200 devices and authorized 160 breakthrough-designated devices for use.[13] Following intense lobbying from the device industry, both chambers of Congress are now considering bills with bipartisan support that would guarantee Medicare coverage for all breakthrough-designated devices following FDA authorization.[14] If passed, the proposed legislation could have substantial impacts on public health and healthcare financing. The Congressional Budget Office conservatively forecasts billions in additional Medicare spending on breakthrough-designated devices.[15]

Despite popularity with manufacturers and intense focus among policymakers, much remains unknown about BDP program outcomes. We therefore performed a comprehensive review of therapeutic devices authorized during the first ten years of the BDP (2016-2025). We focused on three key areas: (1) innovation (measured by product novelty and benefit); (2) speed (measured by clinical and regulatory review times); and (3) evidence (measured at the time of FDA authorization).

First, we sought to assess the intrinsic claim of the BDP: that "breakthrough"-designated technologies truly represent medical innovations. To this end, we analyzed therapeutic breakthrough-designated devices according to three metrics: device novelty (defined as first-in-

class product codes), device availability (defined as devices where the US was the market of first launch), and therapeutic benefit (based on international health technology assessment [HTA] organization ratings of clinical benefit). We found that 67.6% were first-in-class devices and 41.1% were first commercialized in the US.[15] However, most breakthrough-designated devices were not deemed clinically or economically important enough to undergo HTA rating. Among rated devices, less than 40% earned recommendations for adoption in routine clinical practice.[16]

Second, we sought to quantify the impact of breakthrough designations on (a) clinical development times and (b) regulatory review times. To estimate clinical development times, we manually extracted all start and completion dates for premarket studies listed within FDA documents and ClinicalTrials.gov. We found that clinical development times were similar between breakthrough-designated devices compared to non-breakthrough designated devices (4.66 years vs 4.18 years, P=0.7740). To calculate FDA review times, we extracted application and submission dates and authorization devices from the Devices@FDA database. We found that FDA review times were shorter for breakthrough-designated devices compared to non-breakthrough designated devices (0.57 vs 0.89, P=0.0245) and largely (57%) met shared FDA-industry review time goals, despite the novel scientific concepts associated with these devices.[17]

Third, we sought to characterize the clinical evidence supporting FDA authorization of breakthrough devices. To this end, we review FDA decision summaries to evaluated the rigor of premarket and FDA-required postmarket evidence for breakthrough-designated devices.[15] Among therapeutic devices, we found notable gaps in premarket evidence generation, including 1 in 10 devices lacking clinical testing, 1 in 3 devices using surrogate measures as primary end points, 1 in 8 devices lacking comparative effectiveness testing, and 1 in 7 devices failing to meet their primary effectiveness end point. An integral aspect of BDP's regulatory flexibility is

allowing manufacturers to shift the balance of evidence generation from the premarket to postmarket setting. However, FDA only required 40% of breakthrough-designated devices to undergo postmarket testing, and these studies were characterized by similar methodological weaknesses (e.g., lack of clinical endpoints or comparator groups) and high rates of delays (41.3%).

Taken together, these findings provide a comprehensive assessment of the clinical and regulatory outcomes of the BDP. Our investigation demonstrates that unlike predecessor programs, BDP has succeeded in expediting device development and patient access, but that these gains accrued via shortened regulatory review rather than accelerated clinical development time. Furthermore, our work provides quantifiable estimates of the magnitude of tradeoffs for regulatory incentives for medical device innovation, demonstrating that increasing permissibility among regulators for clinical uncertainty results in the authorization of devices with substantial evidence limitations and lower therapeutic benefit ratings. Taken together, these findings extend regulatory science literature for medical technology and suggest opportunity to reform the BDP in the service of patients and public health.

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