Federal Support for Development and Adoption of FDA Breakthrough-Designated Devices

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Word Count

2,883

Abstract

Importance: Federal policymakers have sought to accelerate the development and adoption of innovative medical technologies. However, the extent to which manufacturers of breakthrough devices rely on federal support for premarket discovery and postmarket adoption remains poorly understood.

Objective: To characterize manufacturers of FDA-authorized breakthrough-designated devices and assess federal support for their research, development, and commercialization.

Design, Setting, and Participants: This cross-sectional study analyzed 144 firms marketing 182 FDA-authorized breakthrough-designated devices between 2016 and 2025.

Main Outcomes and Measures: Firm characteristics, NIH funding through firm-level and founder/executive-level grants, and eligibility for supplemental Medicare payment through the New Technology Add-On Payment (NTAP) and Transitional Pass-Through (TPT) programs.

Results: Most firms were small (84%), U.S.-based (70%), and privately held (76%). Nearly 40% of U.S.-based small firms received NIH funding totaling $250 million through firm-level Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants and founder/executive-level grants to individual investigators. Approximately 35% of manufacturers qualified for supplemental Medicare payment through the NTAP and TPT programs.

Conclusions and Relevance: In this cross-sectional study, small U.S. firms played an outsized role in breakthrough medical device innovation. Federal support spanned both premarket development and postmarket adoption. Congress and CMS should consider targeted policies to sustain these firms' research, development, and commercialization efforts.

Introduction

In 2016, the U.S. Congress established the Food and Drug Administration (FDA) Breakthrough Devices Program (BDP) to expedite the development and review of medical devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions. Manufacturers may request breakthrough designation at any point during premarket development and are entitled to several regulatory benefits following designation, such as prioritized FDA review and study design flexibility (*1*). Eligible devices must meet one of the following criteria: (1) represents a breakthrough technology, (2) has no authorized alternatives, (3) offers substantial improvement over existing therapies, or (4) be available in the best interest of patients (*1*). The BDP has attracted substantial manufacturer participation; as of December 31st, 2025, FDA had granted 1,246 breakthrough device designations and 185 devices had subsequently received authorization (*1*).

Prior work has demonstrated that the BDP shortened FDA review times for innovative devices and often qualifies new products for generous Medicare subsidies that incentivize adoption (*2*, *3*). However, there are concerns that federal policies remain inadequate to help small firms traverse the "valley of death" between discovery and successful commercialization (*4*). These small firms face substantial challenges, including limited capital to fund premarket device development (*5*) and an uncertain path to coverage following FDA authorization (*6*).

The U.S. Congress and current presidential administration are now reconsidering the federal government's role in supporting premarket development and postmarket adoption of innovative devices. In April 2026, Congress reauthorized the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs following a six-month funding lapse. In August 2026, the Centers for Medicare & Medicaid Services (CMS) narrowed supplemental reimbursement eligibility for breakthrough-designated medical devices.

To understand the impact of these policies, we investigated the extent to which the federal government has supported the research, development, and commercialization of FDA breakthrough-designated devices before and after authorization. We asked three questions: (1) what types of firms have received FDA authorization for breakthrough-designated devices?; (2) to what extent does the federal government fund their research and development?; and (3) to what extent is the market for these devices sustained by Medicare subsidies?

Linking Innovative Firms to Federal Support

We performed a cross-sectional analysis of firms receiving FDA authorization for breakthrough designated devices between July 11th, 2016, (first breakthrough authorization) and December 31st, 2025. We identified firms using the FDA's publicly available website. For each firm, we extracted the following organizational characteristics from Pitchbook, a private market financial database: year founded, location of headquarters (U.S./outside U.S.), ownership status (privately held/publicly traded), firm status (going concern/acquired/bankrupt), and size (small/large). We classified firm size based on headcount; firms with <500 employees were considered small in accordance with federal regulations. We additionally extracted the following financial characteristics (as available): annual revenue, receipt (yes/no) and amount of venture capital (VC) investment (yes/no), and most recent VC funding (pre-seed or seed/series A/series B/series C or later).

Federal Funding

We assessed two types of NIH support for breakthrough device development: (1) research funding awarded to individual founders and firm executives; and (2) small business

innovation funding awarded to firms through the SBIR and STTR programs. Most NIH funding is awarded to investigators affiliated with nonprofit organizations (e.g., health systems) seeking to advance generalizable scientific knowledge. To commercialize discoveries arising from NIH-funded research, investigators and sponsoring institutions may obtain intellectual property rights or form spin-out companies.

In contrast, SBIR and STTR are specifically intended to support early-stage R&D and commercialization of innovative technologies. These programs provide small, U.S.-based, for-profit firms with non-dilutive seed capital; unlike venture capital firms, the SBIR and STTR programs do not require firms to exchange equity for funding. SBIR (founded in 1982) supports business-led research and development, and STTR (founded in 1992) supports formal collaborations between small businesses and nonprofit research institutions such as academic medical centers. By law, NIH must set aside 3.65% of the extramural research budget for the SBIR (3.2%) and STTR (0.45%) programs, which translates to approximately $1.3 billion in annual funding.

To identify relevant federal research funding, we queried the NIH RePORTER database for founder/executive and firm names; we identified founder/executive names on firm websites. We focused our analysis on individuals in four specific positions relevant to scientific discovery: founders, chief executive officers, chief medical offers, and chief scientific officers. We binarily categorized funding type based on NIH research activity codes as firm-level (SBIR or STTR) or founder/executive-level (independent research grant, training and career development grant, or cooperative and program grants; activity codes listed in **Table S1**). We reviewed project summaries for founder/executive-level awards to determine whether funding was relevant to the FDA-authorized, breakthrough-designated device(s) marketed by their affiliated firm. We

considered awards focused on the same technology type or disease area to be relevant; we excluded all other founder/executive-level awards from analysis.

Supplemental Medicare Payment

We assessed federal support for the adoption of FDA breakthrough-designated devices through two Medicare programs: the New Technology Add-On Payment (NTAP) and Transitional Pass-Through (TPT) payment programs. These programs are intended to facilitate utilization of promising, but expensive technologies following FDA authorization by providing hospitals with supplemental payment for reimbursement in excess of standard inpatient (the NTAP program) and outpatient (the TPT payment program) facility fees for a maximum of 3 years. CMS anticipates that recalibration of cost-based payment methodologies or establishment of new procedural codes facilitate adequate hospital reimbursement for device use after the expiration of supplemental reimbursement.

To qualify for supplemental Medicare payment, CMS typically requires that devices meet three criteria: (1) authorized by FDA within 3 years; (2) cost sufficiently exceeding standard reimbursement rates; and (3) evidence of substantial clinical improvement versus existing alternatives. In 2020, CMS began waiving the substantial clinical improvement criterion for breakthrough-designated devices to further promote adoption. We identified breakthrough devices using codes in CMS Hospital Outpatient Prospective Payment System (HOPPS) and Inpatient Prospective Payment System (IPPS) final rules (2020-2024), and estimated NTAP/TPT eligibility using HOPPS and Medicare Provider Analysis and Review (MEDPAR) files from the same period.

Statistical Analysis

We characterized firms and devices using descriptive statistics. We focused analysis of financial characteristics and NIH funding on U.S. based, small firms because these firms (1) typically require outside capital to fund premarket research and development and sustain operations before achieving profitability or undergoing acquisition and (2) are eligible for SBIR and STTR funding. We adjusted all dollar amounts for inflation to 2026 USD using the Biomedical Research and Price Development Index. We performed all statistical analyses in R (version 4.5.0). All results on firm characteristics and NIH funding were current as of March 25th, 2026. This study utilized publicly available, non-clinical data and therefore did not require institutional review board exemption or approval at The Ohio State University College of Medicine.

Small Firms, Public Dollars

Firm Characteristics

Between 2016-2025, FDA authorized 182 breakthrough-designated devices marketed by 144 unique firms (**Table 1**). Most firms marketed therapeutic devices (n=90/144; 62.5%). Roughly half were founded between 2010 and 2019 (n=70/144; 48.6%). Approximately 70% were U.S. based (n=101/144; 70.1%); most non-U.S. firms were based in Israel (n=10/144; 6.9%). More than three-quarters of firms were privately held (n=110/144; 76.4%). Over 80% of firms were small (n=121/144; 84.0%), with a median (interquartile range [IQR]) headcount of 67 employees (IQR: 29-251 employees). Most firms were going concerns (114/144; 79.2%); an additional 28 (19.4%) had been acquired and two (1.4%) had declared bankruptcy.

U.S.-Based Small Firm Characteristics

Nearly 60% of firms were both U.S-based and small (n=85/144, 59.0%). Among these firms, 80% raised venture capital funding (n=68/85; 80.0%), including nearly 90% of all privately held firms (n=68/76; 89.5%). The median venture capital investment was $81.1M (IQR: $22.8M – $177.2M). Nearly 10% of VC-financed firms had most recently received pre-seed/seed funding (n=7/68; 10.3%), approximately 20% had progressed to series A (n=14/68; 20.6%) and series B (n=14/68; 20.6%), and nearly half had received series C or later funding (n=33/68; 48.5%). Among U.S. based, small firms with publicly available financial data (n=24/68; 35.3%), the median annual revenue was $20.8M (IQR: $2.8M – $76.4M).

Federal Funding to U.S.-Based Small Firms

Nearly 40% of U.S. based, small firms received some type of federal NIH funding at the founder/executive or firm level (n=33/85; 38.8%). Ten (n=10/85; 11.8%) firms received only founder/executive-level NIH funding, seventeen received only firm-level funding (n=17/85; 20.0%), and six (n=6/85; 7.1%) received both founder/executive-level and firm-level funding. Total federal funding awarded to U.S.-based small firms was $250.0M, including $121.0M (48.4%) of founder/executive-level funding and $129.0M (51.6%) of firm-level funding. Among funded firms, the median NIH funding amount was $6.2M (IQR: $2.6M – $10.6M). Median founder/executive-level funding and firm-level funding amounts were $5.2M (IQR: $3.4M – $11.1M) and $4.9M (IQR: $2.0M – $7.0M), respectively. Among firms receiving founder/executive-level NIH funding, the most common award type was independent research grants (n=15/16; 93.8%), which accounted for 94.1% ($113.9M of $121.0M) of all founder/executive-level funding totals.

NIH allocated nearly all firm-level funding through the SBIR program (n=22 of 23 firms, 95.7%; $123.8M of $129.0M, 95.9%). The median (IQR) amount and duration of SBIR funding per firm was $4.3M (IQR: $2.0M – $6.7M) and 6 years (IQR: 3 – 9 years), respectively. Six NIH institutes accounted for the majority of firms receiving SBIR awards (n=19/22; 86.4%): the National Cancer Institute (NCI) (n=5/22; 22.7%), National Institute of Child Health and Human Development (NICHD) (n=4/22; 18.2%), National Institute on Drug Abuse (NIDA) (n=4/22; 18.2%), National Heart, Lung, and Blood Institute (NHLBI) (n=3/22; 13.6%), National Institute of Allergy and Infectious Diseases (NIAID) (n=3/22; 13.6%), and National Institute of Neurological Disorders and Stroke (NINDS) (n=3/22; 13.6%). NIDA provided the largest amount ($17.8M of $123.8M; 14.3%) of SBIR funding. NIH awarded three firms STTR funding (n=3/85; 3.5%), with a median funding amount of $0.2M (IQR: $0.2M – $2.5M).

Comparing SBIR/STTR Awardees to Non-Awardees

Compared to firms that did not receive SBIR/STTR funding, a greater proportion of firms receiving SBIR/STTR funding marketed 510(k) devices (SBIR/STTR: n=20/23, 87.0%; non-SBIR/STTR: n=43/62, 69.4%), were privately held (SBIR/STTR: n=22/23, 95.7%; non-SBIR/STTR: n=54/62, 87.1%), and raised venture capital funding (SBIR/STTR: n=22/23, 95.7%; non-SBIR/STTR: n=48/62, 77.4%) (**Table S2**). However, among VC-backed firms, SBIR/STTR-funded firms raised substantially less venture capital (SBIR/STTR: median $26.2M [IQR: $4.7M – $153.8M]; non-SBIR/STTR: median $94.9M [IQR: $40.5M – $191.3M]).

Supplemental Medicare Payment

Between fiscal years 2020-2026, fifty-one firms (35.4%) qualified for supplemental Medicare payment for 63 unique breakthrough-designated devices. CMS budgeted a total of $2.3 billion in supplemental payment for these devices, including $1.3 billion for NTAP (inpatient) and $1.0 billion in TPT (outpatient) payments. The annual level of projected spending and number of qualifying devices increased substantially during this period, from $56.5M for 2 NTAP devices in 2020 to $704.4M for 42 NTAP/TPT devices (34 NTAP, 8 TPT) in 2026. The median budgeted amount per device over the 6-year period was $11.4M (IQR: $2.9M – $45.8M) overall. Thirty (20.8%) firms only qualified for NTAP supplemental payments (median [IQR] budgeted amount per device: $7.8M [$2.9M – $18.9M]), five (3.5%) only qualified for TPT supplemental payments (median [IQR] budgeted amount per device: $2.0M [$1.6M – $2.9M]), and 14 (9.7%) qualified for both NTAP and TPT supplemental payments (median [IQR] budgeted amount per device: $95.4M [$59.6M – $161.0M]).

Optimizing Federal Investment in Device Innovation

In this cross-sectional analysis of firms marketing FDA-authorized, breakthrough-designated devices, we found that most were manufactured by small, U.S.-based, and privately held with venture capital backing. Our results suggest that the U.S. federal government has played a substantial role supporting the premarket development and postmarket adoption of breakthrough-designated devices. Nearly 40% of U.S. based small firms were supported by NIH funding, including 25% that received SBIR funding designated for small, for-profit firms. Approximately 35% of all manufacturers qualified for supplemental Medicare payment, with a 12.5-fold projected spending increase on breakthrough-designated devices from 2020 to 2026 (projected spending >$700 million).

We empirically demonstrate that small U.S. firms drive the development of innovative devices. Though large firms possess greater resources, their efforts towards innovation may be hindered by protracted, formalized decision-making processes and risk aversion. Large firms therefore often seek to acquire small firms with novel technologies in late stage clinical development or early commercialization, but without the human (e.g., salesforce) and financial (e.g., for international market expansion) capital necessary to maximize revenue potential. Our results underscore the central importance of federal policy in fostering a robust U.S. device innovation system; small U.S. firms are necessary to catalyze discovery and pioneer proof-of-concept, but are the most vulnerable to economic and regulatory uncertainty (*7*).

Our findings show that the NIH has provided substantial funding to support research and development for breakthrough-designated devices. This work complements prior research illustrating the importance of NIH-funded research in drug discovery (*8*, *9*). Recent analysis estimates that SBIR/STTR funding supported the development of 16% of FDA-approved drugs granted priority review for the potential to advance public health beyond existing treatments (*10*). SBIR/STTR funding may be particularly meaningful to small device firms because development costs are lower for devices than drugs. The large majority of firms receiving SBIR/STTR funding (median amount per firm: over $4 million) marketed their devices through the 510(k) pathway, which requires $31 million (direct cost) to bring a product from concept to clearance according to industry estimates (*11*); in contrast, capitalized research and development costs for new drugs typically approach $1 billion. These economics may additionally explain why firms without SBIR/STTR funding marketed devices through more capital-intensive regulatory pathways (estimated cost for Premarket Approval Pathway: $54 million direct cost,

$522 million capitalized cost) (*5*), more frequently accessed public equity markets, and raised greater sums of venture capital.

The 2026 reauthorization of the SBIR and STTR programs restores this critical funding source for small, innovative device firms. The Small Business Innovation and Economic Security Act of 2026 extended both programs at current set-aside rates (SBIR: 3.2%, STTR: 0.45%) through fiscal year 2031 and added a funding mechanism to bring commercialization within reach: Strategic Breakthrough Awards of up to $30 million – conditional on firms securing matching funding from outside sources – to support product production and development (*12*). Our findings suggest that firms developing breakthrough-designated devices will readily meet this requirement; nearly all SBIR/STTR-funded firms had raised venture capital funding, with a median amount of $26 million. Nonetheless, NIH budget cuts recently proposed by the current presidential administration to Congress may diminish the overall magnitude of SBIR/STTR support for small firms. The fiscal year 2027 President's Budget calls for a $2.8 billion reduction in NIH research project funding, including $143 million (relative reduction vs. fiscal year 2026: 11.2%) in SBIR/STTR cuts (*13*).

Federal support is under reconsideration at both ends of the device life cycle. As Congress weighs reductions in premarket research funding, CMS has reinstated more rigorous standards for Medicare subsidies facilitating postmarket clinical adoption. We found that the number of firms qualifying for supplemental Medicare payment through the NTAP/TPT programs expanded rapidly following CMS's waiver of the "substantial clinical improvement" criterion for breakthrough-designated devices in 2020. CMS' decision to reinstate this criterion is supported by empirical work demonstrating that breakthrough-designated devices are often authorized based on limited clinical evidence or without premarket clinical testing (*2*), which has

led international health technology assessment organizations to frequently recommend against coverage (*14*). However, meeting the bar for "substantial clinical improvement" demands scientific expertise and capital reserves that small firms are less likely to possess. For example, trials assessing clinical endpoints typically require more participants and longer follow-up than trials relying on surrogate endpoints, thereby increasing study costs and prolonging time to revenue generation.

This study has several limitations. First, financial data was not publicly available for all firms, and it is unclear how missingness might bias our results; for example, firms with lower revenue may be less likely to report financial information. Second, attribution of founder/executive-level funding required investigator judgment about whether the research was related to technology or disease area of breakthrough-designated devices. We therefore may have over- or under-estimated the amount of relevant NIH funding. Third, our cross-sectional analysis was based on 2026 firm data and may not accurately reflect firm characteristics or leadership at the time NIH funding was awarded. For instance, some firms (e.g., Intuitive Surgical) that received SBIR/STTR awards were excluded from our analysis of NIH funding because they are now large and publicly traded. Fourth, our study focuses on NIH SBIR/STTR funding and does not capture support from the National Science Foundation, Department of Defense, or other federal agencies; we may therefore underestimate overall government support for breakthrough-designated device development.

Our findings reveal that small, U.S.-based firms have propelled the growth of the FDA breakthrough devices program, and the federal government has been instrumental in supporting these firms during both premarket development and postmarket commercialization. Policymakers now face a choice whether to divest from this pipeline. We believe such action

would be unwise, and Congress should reject the proposed NIH funding cuts. Congress could instead strengthen the SBIR/STTR innovation pipeline by enacting reforms to increase set-aside rates, harmonize grant review processes among NIH institutes, and engage grant reviewers with complementary technical and commercial expertise (*10*). To level the playing field for reimbursement, FDA and CMS could consider prioritizing inclusion of small firms in inter-agency programs that facilitate device coverage by providing scientific guidance and coordinating regulatory review (*15*). Whether the U.S. device ecosystem produces transformative technologies depends not only on the quality of science performed by small firms, but also on the federal policies that enable them.

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List of Supplementary Materials

Table S1. NIH Activity Codes by Funding Level

Table S2. Characteristics of U.S.-Based Small Firms Receiving FDA Authorization for Breakthrough-Designated Devices, Stratified by Receipt of NIH SBIR/STTR Funding

Tables and Figures

Table 1. Characteristics of Firms Receiving FDA Authorization for Breakthrough-Designated Devices

Characteristic	
All firms, No. (%)	144 (100)
Organizational	
Breakthrough device indication, No. (%)	
Therapeutic	90 (62.5)
Diagnostic	54 (37.5)
Year founded, No. (%)	
Before 2000	34 (23.6)
2000-2009	36 (25.0)
2010-2019	70 (48.6)
2020 or later	4 (2.8)
Location, No. (%)	
U.S.	101 (70.1)
Outside U.S.	43 (29.9)
Ownership status, No. (%)	
Private	110 (76.4)
Public	34 (23.6)
Firm status, No. (%)	
Going concern	114 (79.2)
Acquired	28 (19.4)
Bankruptcy	2 (1.4)
Firm size, No. (%)	
Small (< 500) [1]	121 (84.0)
Medium or large (≥ 500)	23 (16.0)
No. employees, median (IQR)	67 (29 – 251)
Medicare Supplemental Payments	
Projected spending 2020-26, $	$2,313,920,826
New Technology Add-On Payment (inpatient), $	$1,315,984,435
Transitional Pass-Through Payment (outpatient), $	$1,039,765,462
Unique devices granted, No.	63
Firm breakdown by pathway, No. (%)	
NTAP only	30 (20.8)
TPT only	5 (3.5)
NTAP and TPT	14 (9.7)
Median overall per device (IQR), $	$11,449,510 ($2,921,849 – $45,826,431)
U.S.-based small firms, No. (%)	85 (100)
NIH Federal Funding	
Funding type, No. (%)	
Overall	33 (38.8)
Founder/executive-level only [2]	10 (11.8)
Firm-level only	17 (20.0)
Both founder/executive- and firm-level	6 (7.1)
Funding amount, $	
Total	$250,037,841
Founder/executive-level	$121,022,380
Firm-level	$129,015,461
Median per funded firm (IQR), $	$6,245,271 ($2,611,267 – $10,648,592)
Founder/executive-level funding	16 (18.8)

Independent research grants, No. (%)	15 (17.6)
Training and career development grants, No. (%)	4 (4.7)
Cooperative and program grants, No. (%)	2 (2.4)
Median per funded firm (IQR), $	$5,207,714 ($3,397,187 – $11,120,756)
Firm-level funding	23 (27.1)
Small Business Innovation Research (SBIR) program, No. (%)	22 (25.9)
Small Business Technology Transfer (STTR) program, No. (%)	3 (3.5)
Median per funded firm (IQR), $	$4,854,939 ($1,951,406 – $6,985,231)
Financial Metrics	
Annual revenue, median (IQR), $ [3]	$20,829,000 ($2,818,500 – $76,419,500)
Venture capital raised	
Overall, No. (%)	68 (80.0)
Median (IQR), $	$81,086,785 ($22,845,615 – $177,216,552)
Most recent VC equity financing, No. (%) [4]	
Pre-seed or seed	7 (10.3)
A	14 (20.6)
B	14 (20.6)
C or later	33 (48.5)

Abbreviations: FDA, Food and Drug Administration; BDP, Breakthrough Devices Program; U.S., United States; IQR, interquartile range; NTAP, New Technology Add-On Payment; TPT, Transitional Pass-Through Payment; NIH, National Institutes of Health; SBIR, Small Business Innovation Research program; STTR, Small Business Technology Transfer program; VC, venture capital.

All dollar amounts (excluding venture capital funding; financing year not consistently reported) adjusted for inflation to 2026 USD using the Biomedical Research and Price Development Index.

Sources: US Food and Drug Administration, NIH RePORTER, Pitchbook. Data current as of March 25th, 2026.

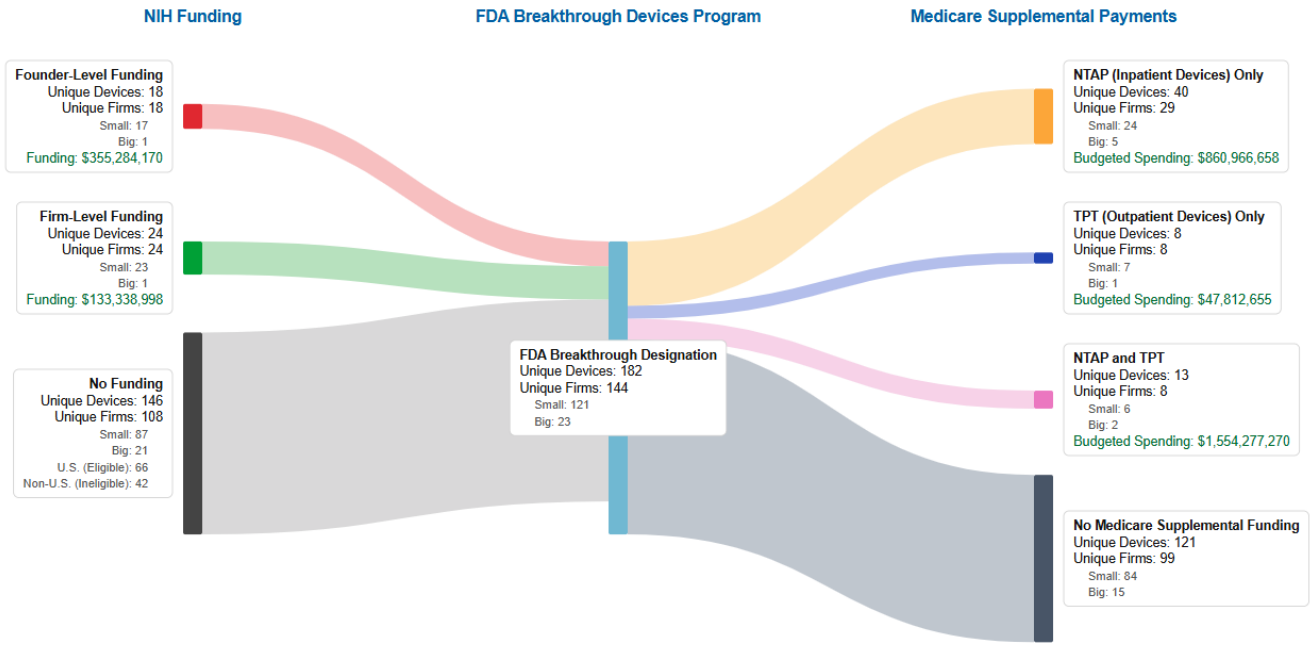
[1] Defined as <500 employees per 13 CFR Part 121.

[2] Founder/executive-level funding reflect NIH awards to individuals who served as founder, chief executive officer, chief scientific officer, or chief medical officer for work salient to the FDA breakthrough device, its underlying technology, or target disease/pathophysiology. Award level categorization (firm-level vs. founder/executive-level) was mutually exclusive.

[3] Analysis of most recently reported revenue for U.S.-based small firms with publicly available data (n=24).

[4] Analysis was performed in the subset of firms who received VC funding (n=68). If a firm was acquired or filed for bankruptcy, we reported the latest round of VC financing pre-acquisition or pre-bankruptcy.

Figure 1. NIH Funding and Enhanced Medicare Payments for FDA Breakthrough-Designated Devices Receiving Authorization Between 2016-2025



Abbreviations: FDA, Food and Drug Administration; BDP, Breakthrough Devices Program; NIH, National Institutes of Health; NTAP, New Technology Add-On Payment; TPT, Transitional Pass-Through Payment.
Source: Made with https://www.sankeyart.com/ and modified with Claude Sonnet 4.6.
Description: NIH funding and Medicare supplemental payment dollar amounts adjusted for inflation to 2026 U.S. dollars using the Biomedical Research and Development Price Index. Budgeted Medicare supplemental payment amounts derived from CMS inpatient and outpatient prospective payment system final rules (fiscal years 2020-2026).

Figure Captions and Legends

Figure 1. NIH Funding and Enhanced Medicare Payments for FDA Breakthrough-Designated Devices Receiving Authorization Between 2016-2025

Caption:

Abbreviations: FDA, Food and Drug Administration; BDP, Breakthrough Devices Program; NIH, National Institutes of Health; NTAP, New Technology Add-On Payment; TPT, Transitional Pass-Through Payment.

NIH funding and Medicare supplemental payment dollar amounts adjusted for inflation to 2026 U.S. dollars using the Biomedical Research and Development Price Index. Budgeted Medicare supplemental payment amounts derived from CMS inpatient and outpatient prospective payment system final rules (fiscal years 2020-2026).