

REPORT

THE MULTI-TRILLION DOLLAR OPPORTUNITY IN REFORMING THE FDA

UNLEASH PROSPERITY NOW

Date :

MAY 2026

Prepared by :

UNLEASH PROSPERITY NOW
STEPHEN MOORE
TOMAS PHILIPSON

The Multi-Trillion Dollar Opportunity

in Reforming the FDA

Executive Summary

Before a new medical product can be marketed in the United States, Congress has ruled that the Food and Drug Administration (FDA) must ensure that it is both safe and effective. This administration has successfully addressed permitting delays in many industries, such as infrastructure and real estate development, but such delays are even more damaging for drug development.

This paper reports on the economic value of faster medical innovation by FDA shortening delays due to effectiveness approvals and provides a set of recommendations to unleash that value. We report that reducing development times for FDA-approved medical products (small molecule drugs, biologics, and medical devices) has been found to generate $4 to $61 trillion in combined value to consumers and producers of drugs for shortening of FDA effectiveness determination by 1 to 6 years. The undiscounted foregone value of a one-year delay in market access due to FDA is the benefit to producers and consumers measuring consumers and producer surplus in a conventional way capturing the value in health beyond the price paid for and the earnings obtained by innovators. It is calculated through multiplying sales, about $676 billion in aggregate in the US in 2024, by what the existing evidence base suggests is the multiple of sales that make up benefits to consumers in terms of consumer surplus (a multiple of about 15) and producers in terms of earnings (a multiple of about 0.8) affecting innovation incentives.

In addition to FDA delays generating large losses in value to patients, the long FDA delays are hurting the US competitive position versus China, which has a faster and cheaper approval process. China has dramatically shortened the path from lab discovery to first-in-human trials – they are 50-70 percent faster than in the rest of the world.[1] And clinical trials are 50-60 percent cheaper than in the United States.[2]

Given both of these dimensions, shortening FDA regulatory timelines for effectiveness is of first-order importance. This paper includes a set of recommendations that will help to achieve this objective as well as other objectives that enhance FDA's ability to serve US patients effectively:

Recommendations

- The FDA should issue final, disease-specific guidance on the use of externally controlled trials and synthetic control arms, including qualified registries and natural-history data sources.

- The White House should establish a Cancer Warp Speed Office with line-of-sight to FDA, NIH, NCI, CMS, and DoD/VA, led by a director reporting to the President, HHS Secretary, and the FDA Commissioner.

- The Prescription Drug User Fee Act should fund a dedicated hiring commitment for the Oncology Center of Excellence, Center for Biologics Evaluation and Research gene therapy

[1] https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future

[2] https://www.clinicaltrialsarena.com/news/oct-west-coast-chinas-clinical-trial-infrastructure-delivers-upto-60-cost-savings/

review, and rare-disease review teams, with measurable performance goals tied to complex-product filing volumes.

- FDA's Title 42 authority for specialized scientific and medical officers should be expanded, bringing pay flexibility in line with NIH and FDA Critical Pay.

- Project Orbis-style concurrent review should be extended beyond oncology products to all serious and life-threatening conditions, including rare pediatric disease, neurodegeneration, and high-unmet-need infectious disease.

- FDA and CMS should jointly publish a coordinated evidence and coverage framework for Multi-Cancer Early Detection, defining the endpoints (mortality, stage-shift, resolution of positive signals) and populations on which approval and coverage decisions will be based.

- Substitute pre-market effectiveness approval with post-market approval of safe products through better incentivized post-market obligations on manufacturers.

- FDA should have a greater reliance on AI for both initial drug approval and to support ongoing assessment of effectiveness and safety throughout a product's lifecycle with appropriate transparency and safe-guards in terms of human scientific oversight.

- FDA should utilize AI more for post-market surveillance to quicker determine ineffective but safe drugs used in real-world settings that need to be pulled from the market or not reimbursed by public payers.

- The existing "right to try" regulations should be altered to enable more widespread use, building on the law passed during President Trump's first term.

- More authority over early-stage trial approvals should be shifted to local institutional review boards for Phase 1 trials and faster initiation of first-in-human studies should be allowed. The FDA should expand the use of adaptive trial designs and allow rolling data submissions.

Section 1: Background

Before a new medical product can be marketed in the United States, Congress has ruled that it must demonstrate both safety and efficacy through clinical trials. Requiring evidence of not only safety but also product quality in terms of efficacy prior to market entry is a distinctive feature of pharmaceutical regulation. Historically, pharmaceutical regulation focused primarily on preventing harm from unsafe products, and requirements for demonstrating therapeutic efficacy were introduced later, most notably following the 1962 Kefauver–Harris Amendments (Ritter, 2008).

This is an added regulatory layer for medical product in addition to existing product liability and false advertising regulations. Even after safety has been established relatively quickly for a product, it may remain unavailable for a decade or more while additional trials are conducted to demonstrate product quality or efficacy. Because consumers can benefit from a medical innovation only after it receives regulatory approval, and producers can generate returns only once a product is marketed, these regulatory delays in development directly cuts both gains in patient health and innovation incentives.

Determining effectiveness in the private sector could potentially be done much more widely, efficiently, and quickly as demonstrated by how the private sector already determines it for off-label uses of drugs that does not require FDA approval. This raises the question of why, after safety has been established, it should take a decade or more for FDA to establish effectiveness for *one particular use* of the drug, while the private market establishes it better and faster for many other off-label uses afterwards.

The economic value of a medical product can be understood as the combined value to both sides of the market, in terms of consumer- and producer surplus. This paper first provides a quantitative framework to capture this combined value lost due to FDA delays and apply it

separately to small molecules, biologics, and medical devices. In 2024, sales across all three product categories amounted to about $676 billion, which reflect post-rebate transaction prices rather than list prices. We use disaggregated sales data to calculate multiples of the sales levels that the existing evidence base suggests correspond to consumer and producer surplus, a total multiple of about 16. Under various assumptions, we find that accelerating development by one year generates between $4.1 to $10.2 trillion in combined social value to consumers and producers. These gains reflect contributions from all three categories with small molecules accounting for 36.7%, biologics for 42.7%, and devices for 20.6% of the total value.

In addition to unleashing a greater value stemming from medical innovation, reduced FDA delays will position US in a better position in regulatory competition internationally, in particular with adversaries such as China, where clinical trials are performed faster and cheaper. Early discovery-to-IND (investigational new drug) timelines are 50-70 percent faster than in the rest of the world, points out McKinsey.[3] And the cost of clinical trials are 50-60 percent lower than in the United States.[4]

[3] https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future

[4] https://www.clinicaltrialsarena.com/news/oct-west-coast-chinas-clinical-trial-infrastructure-delivers-upto-60-cost-savings/?cf-view

Section 2: Need for Faster Effectiveness Determination

The Food and Drug Administration plays a critical role in building confidence in the safety of pharmaceuticals sold in the United States. That confidence has made the FDA the gold standard in drug regulation. And it's contributed to the United States being a global leader in the development of new drugs. Today, the U.S. share of health-sciences output is higher than the next 10 leading countries combined.[5]

But that pre-eminent position is not guaranteed. The FDA, like all regulators, must adjust to the modern era of more rapid biomedical innovation abroad, particularly in China. That means adapting its tools in ways that maintain safety while also accelerating patient access to lifesaving therapies by speeding up lengthy effectiveness determinations.

Patient access is curtailed by the high cost and slow pace of the FDA's drug approval process. A 2024 study found that the estimated mean cost of developing a new drug, during the 2000-2018 period, was nearly $880 million (inclusive of the costs of failures and capital were included). But for oncology and ophthalmology drugs, the costs were about $1.2 billion. Notably, 90 percent of clinical drug development fails. And development typically takes 10-15 years. Innovation suffers greatly when many potential wonder drugs developed by small biomedical firms are shelved when that process' exorbitant costs and delays drain their capital.

Section 3: Valuing the Benefits of Faster Effectiveness Determination

[5] https://www.nature.com/articles/d41586-024-00755-9

This section reports on a University of Chicago study conducted of one of the authors that provides a framework for valuing faster FDA effectiveness approval (Philipson et al (2026)). It provides our framework for valuing faster FDA effectiveness approval. A valuable medical innovation enters the market at patent-protected prices for the duration of the patent and then at lower, competitive prices after the patent expires. Consumer surplus, which is the value patients derive from the technology beyond what they pay in premiums or copays, is therefore lower during the patent period and higher thereafter. Accelerating development shifts the entire stream of benefits forward in time, allowing patients to access the innovation sooner and for a longer share of their lifetimes.

To calculate the social surplus of a medical innovation, let's consider a technology that requires F years to clear the FDA under a patent with a statutory life of T years, so that the medical innovation is marketed for $T - F$ years under patent protection. During the patent period, the medical innovation generates a per-period social surplus s, which reflects returns to both consumers and the innovating producers. After expiration, surplus rises to S as generic competition lowers prices closer to manufacturing costs. The present value of total social surplus is therefore given by

$$V(F) = \sum_{t=F}^{T} f^t \cdot s + \sum_{t=T+1}^{\infty} f^t \cdot S,$$

where f < 1 is a discount factor. If regulatory reform reduces the FDA review period from F to F' years, the welfare gain is

$$V(F') - V(F) = \sum_{t=F'}^{F} f^t \cdot s,$$

which is the discounted value of social surplus during the additional years of marketing and access under the patent period. When discounting is modest (f close to 1), this simplifies to approximately

$(F - F') \cdot s$, which is the number of years saved multiplied by the per-period surplus during those years.

We calculate both undiscounted values obtained immediately and discounted values applied from the start of FDA regulatory review, while social surplus accrues only after market entry.

Section 3.1: Data and Calibration

A critical input for the welfare calculation is the baseline development time F, which determines how long patients must wait before accessing the quality of a safe innovation. Small molecules, biologics, and medical devices differ substantially in their regulatory pathways and typical development durations for effectiveness evidence, where medical devices have substantially shorter development cycles (3-7 years) than small molecules (12 years) or biologics (10-12 years) (Van Norman, 2016). In our analysis, we set the maximum year accelerated (n) at 6 years for all categories.

Social Surplus as a Multiplier of Observed Sales

To translate faster market entry into welfare gains, we calculate the relationship between observed net sales and total social value using evidence from Hult and Philipson (2023) on the social surplus multiplier of sales. The paper draws on more than 9,000 cost-effectiveness analyses from the Tufts CEA Registry and finds that the median share of value appropriated by the supply side for pharmaceutical interventions is approximately 6 percent and declined at 0.1 percent per year between 1997 and 2019. For nonpharmaceutical interventions, the median share is 9 percent, declining at 0.3 percent per year. These estimates are upper bounds on profit estimations because they reflect revenue shares before deducting R&D and manufacturing costs and rebates. If innovators appropriate 6 percent of total surplus through observed revenue, total surplus equals revenue divided by 0.06, or approximately 16.67 times net transaction sales. Decomposing this, producer surplus corresponds to 0.80 times sales given that not all revenue represents profit after

manufacturing and distribution costs while consumer surplus accounts for the remaining 15.87 times sales. Letting S denote observed annual net transaction sales, the total social surplus is expressed as

$$(15.9 + 0.8)S=16.7 * S$$

To calculate the net present value, we use 2024 net transaction prices from IQVIA (2025). U.S. pharmaceutical net transaction sales totaled approximately $487 billion, where $225 billion was for small molecules and $262 billion was for biologics. For medical devices, we apply a device-specific appropriation share of 9 percent, yielding a surplus multiplier of approximately 11.11 times sales, based on estimated U.S. net device revenues of $189 billion (Fortune Business Insights, 2026). Total net sales across all three categories amount to approximately $676 billion.

Calculating the combined annual social surplus across all categories yields a combined output of approximately $10.22T. Small molecules account for 36.7%, biologics for 42.7%, and devices for 20.6% of the total surplus.

We compute the welfare gain V(F') − V(F) for each category using its own baseline development time F. Each year saved n=F-F' and the discounted surplus is computed over the newly accessible years. All three categories are capped at 6 years of acceleration in the analysis.

Table 1: Welfare Gains without discounting (f = 1.00) ($ in Trillions)

Years Accelerated (n)	Small Molecules (F=12)	Biologics (F=11)	Devices (F=5)	Combined
1	3.75	4.37	2.10	10.22
2	7.50	8.74	4.20	20.44
3	11.25	13.10	6.30	30.65
4	15.00	17.47	8.40	40.87

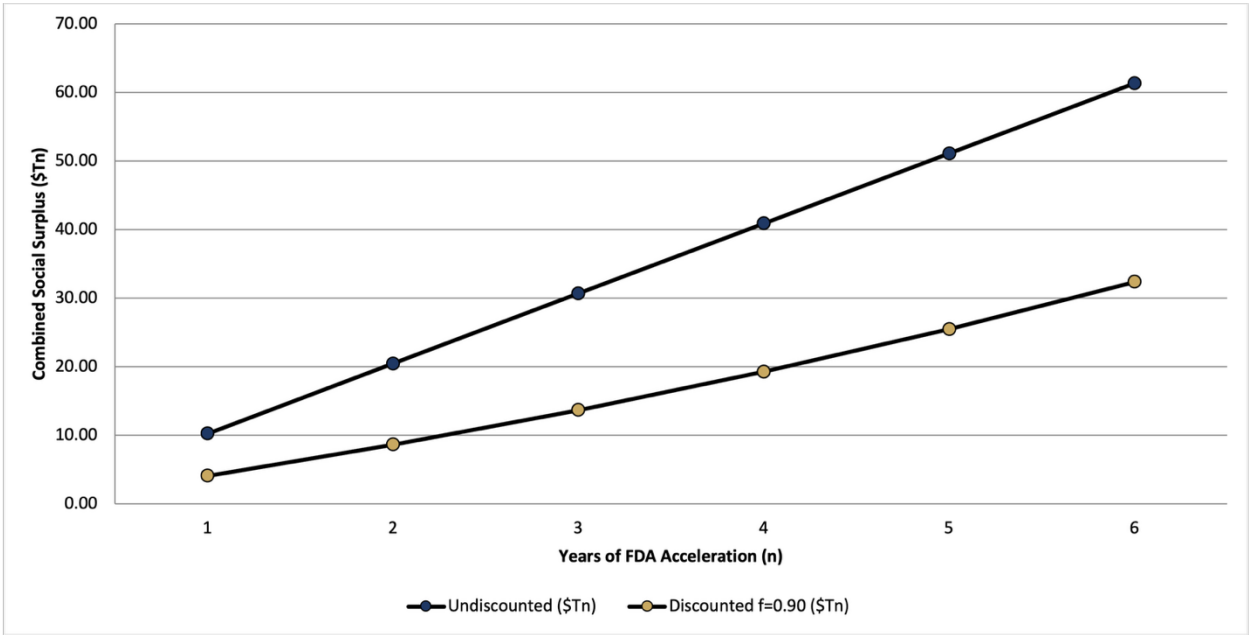
5	18.75	21.84	10.50	51.09
6	22.50	26.21	12.60	61.31

Table 2: Welfare Gains with discount (f = 0.90) ($ in Trillions)

Years Accelerated (n)	Small Molecules (F=12)	Biologics (F=11)	Devices (F=5)	Combined
1	1.18	1.52	1.38	4.08
2	2.48	3.21	2.91	8.61
3	3.94	5.10	4.61	13.64
4	5.55	7.18	6.50	19.24
5	7.35	9.51	8.60	25.45
6	9.34	12.08	10.93	32.36

Figure 1 visualizes the combined social value of FDA acceleration across different values of years of acceleration (n). The figure compares estimates with and without discounting applied at the start of the FAD review period.

Figure 1: Combined Social Value of Acceleration with and without Discounting



These calibrations suggest very large gains from speeding up effectiveness approval, conditional on effective products. Clearly, there may be value in ruling out safe products that are not effective, but payers and patients are able to do that for off-label uses of safe products at costs that seem swamped by these benefits. **Section 4: The**

Section 4: The Competitive Regulatory Landscape to Attract Medical Innovation

China's emergence as a center of pharmaceutical innovation and development poses a competitive threat to companies in the United States and should be a catalyst for reforms to the FDA's drug review and approval process.

China has rapidly transformed itself from a "fast follower" in pharmaceuticals into a global leader in pre-clinical research and early-stage (Phase 1) drug development. In 2015, about 48 percent of early-stage programs originated in the U.S. and 8 percent in China. By 2024, the U.S. share was down to 37 percent, while China's share exceeded 32 percent.[6]

[6] https://medicalxpress.com/news/2026-03-decade-early-stage-drug-shifted.html

China's system is particularly optimized for early-stage trials. Roughly 64 percent of domestic trials in China are Phase 1, indicating a strong focus on early human testing.[7] Investigator-initiated trials allow rapid experimentation without the same bureaucratic hurdles seen in the U.S. This structure creates a high-throughput environment for testing new drug candidates.

A critical bottleneck in U.S.-based Phase 1 trials – finding patients – is far less severe in China. McKinsey points out that recruitment can be 2-5 times faster than in the U.S. or EU.[8] And high patient density near major hospitals and centralized healthcare systems streamline enrollment. Speed directly translates into earlier data and lower costs.

In 2024, China was home to more than 2,500 new clinical trials for innovative drugs,[9] which exceeded U.S. levels.[10] The current FDA commissioner, Marty Makary, has pointed to hospital contracting, as well as ethical reviews and approvals, as contributing to the slowdown in the United States. He has called them "clunky processes that take too long and are leaving us noncompetitive with the countries that are moving a lot faster."[11]

China's clinical trial volume and innovation pipelines are also expanding rapidly, attracting global pharma partnerships. Increasingly, U.S. and European firms are licensing Phase 1 and 2 assets from China, effectively outsourcing early innovation.

The center of gravity in drug development is shifting toward early-stage data generation. That's where scientific hypotheses are validated, capital allocation decisions are made, and intellectual property value is created. If Phase 1 work migrates abroad, the U.S. risks losing innovation leadership, investment flows, and domestic biotech ecosystems. There is already evidence

[7] https://www.globaldata.com/store/report/china-drug-development-clinical-trials-theme-analysis/
[8] https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future
[9] https://www.lexology.com/library/detail.aspx?g=c4b6dcbb-ad2b-4fc2-a43d-4e020f2ed081
[10] https://www.cnbc.com/2026/02/18/fda-chief-warns-us-is-losing-ground-to-china-in-early-drug-trials.html
[11] https://www.cnbc.com/2026/02/18/fda-chief-warns-us-is-losing-ground-to-china-in-early-drug-trials.html

that a growing share of drug candidates originates in China, with Western firms increasingly dependent on those pipelines.

Section 5: A Policy Agenda for Reforming FDA

Reducing development times for FDA-approved medical products (small molecule drugs, biologics, and medical devices) can generate $4-$10 trillion in combined value to consumers and producers of drugs. Adopting the following measures will help advance this objective, while also strengthening the FDA's ability to enable the pharmaceutical remedies that will benefit the American people

Adapt trials to precision oncology, rare disease, and pediatric populations

The FDA should issue final, disease-specific guidance on the use of externally controlled trials and synthetic control arms, including qualified registries and natural-history data sources. Along the same lines, the FDA should accelerate its Drug Development Tools qualification process for biomarker-based surrogates (MRD in hematologic malignancies, pCR in early breast cancer, ctDNA dynamics, tumor-informed assays) so sponsors have predictable, reusable endpoints. There should also be greater federal support for precompetitive master protocols — especially pediatric basket trials and rare-tumor platforms — so that second-in-class sponsors can plug into existing infrastructure rather than rebuild from scratch.

Establish a White House office coordinating the federal government's anti-cancer efforts

The White House should establish a Cancer Warp Speed Office (ten-year authorization) with line-of-sight to FDA, NIH, NCI, CMS, and DoD/VA, led by a director reporting to the White House, the HHS Secretary and the FDA Commissioner. This office should have the authority and funding to run regulatory review, Phase III-scale manufacturing preparation, and payer coverage

determinations, concurrently rather than sequentially for designated high-priority programs. The office should also be able to authorize milestone-based advance market commitments and prize mechanisms for specific, high-value targets, such as early detection of the ten most lethal cancers and durable cures for pancreatic, glioblastoma, and metastatic triple-negative breast cancer.

Rebuild FDA review capacity for serious illness products

The Prescription Drug User Fee Act (PDUFA) VIII should fund a dedicated hiring commitment for the Oncology Center of Excellence, Center for Biologics Evaluation and Research gene therapy review, and rare-disease review teams, with measurable performance goals tied to complex-product filing volumes. And to ensure that that patient access is not affected by annual budget politics, there should be a non-user-fee appropriations floor so FDA is not destabilized by shutdowns, continuing resolutions, or filing-volume fluctuations. PDUFA VII investments in electronic submissions, real-world evidence data platforms, and structured product labeling should be continued, with explicit milestones published annually.

Give the FDA the tools to recruit and retain the scientists it needs

FDA's Title 42 authority for specialized scientific and medical officers, bringing pay flexibility in line with NIH and FDA Critical Pay, should be expanded. Similarly, permanent direct-hire authority for reviewers in advanced therapeutics should be implemented, along with AI-enabled device review, and complex biologics. Taking these steps will reduce time-to-hire from 12-18 months to under 90 days. The FDA should also fund a formal industry-exchange fellowship (modeled on the Secretary of Defense Corporate Fellows Program) that allows FDA scientists to

spend 6-12 months embedded in sponsor development programs, and vice versa, with appropriate conflict-of-interest safeguards.

Formalize and extend Project Orbis beyond oncology

Project Orbis-style concurrent review should be extended beyond oncology products to all serious and life-threatening conditions, including rare pediatric disease, neurodegeneration, and high-unmet-need infectious disease. To further help save lives, the FDA should be authorized to rely on specified components of trusted foreign regulators' reviews (CMC, clinical pharmacology, pharmacovigilance) when the product is identical — with clear transparency to U.S. patients and providers. That means working through ICH and FDA/EMA channels to align Risk Evaluation and Mitigation Strategies (REMS), confirmatory trial milestones, and pharmacovigilance so sponsors run one trusted global program rather than parallel duplicative ones.

Build the real-world evidence and MCED framework cures will depend on

FDA and CMS should jointly publish a coordinated evidence and coverage framework for Multi-Cancer Early Detection (MCED), defining the endpoints (mortality, stage-shift, resolution of positive signals) and populations on which approval and coverage decisions will be based. There should also be a dedicated Medicare coverage pathway for MCED and similar high-value prevention tools — coverage with evidence development where warranted, but with predictable decisional criteria. Also important is investing in standards-based real-world data infrastructure (electronic health records, cancer registries, claims linkage) as a public good, so that post-market verification can be completed faster, cheaper, and more credibly than dedicated confirmatory trials alone.

Create public-private competition in effectiveness labeling

The FDA should permit differential labeling of drugs, based on whether or not they have been evaluated as part of effectiveness trials. (This would be subject to the drugs having already been certified as safe.) As part of this reform, private sector entities should be allowed to compete with the FDA to generate the evidence to upgrade the label to the drug having been certified for effectiveness. The labeling would include the name of the entity doing the certification, giving these entities the incentive to be extremely rigorous in their certifications and facing standard product liability and false advertising regulations. Having these entities making certifications would provide a market test of whether consumers would pay less (or more) for drugs evaluated by the private sector versus drugs being evaluated by the FDA.

Drug approvals and post-market surveillance

The FDA should shift to a dynamic lifecycle approach, where initial market entry is just the beginning of a continuous process of evidence generation. Under such a framework, regulators would allow earlier access to promising therapies based on strong but not exhaustive evidence, while creating better incentivized post-market obligations on manufacturers to monitor safety and effectiveness in real-world settings.

Expand use of AI

There are also opportunities linked to the integration of artificial intelligence and advanced data tools with the evaluation of drug treatment safety and effectiveness. To realize the full benefits of AI, the FDA should be actively deploying it to speed up market access. That means investing in internal AI capabilities to analyze real-world data at scale. And rather than treating drug approval as a one-time decision, the FDA could use AI to support ongoing assessment of effectiveness and safety throughout a product's lifecycle, to more quickly determine whether drugs that are safe but

ineffective need to be pulled from the market or not reimbursed by public payers. The FDA should also encourage the use of AI-generated evidence, provided it meets clearly defined criteria for reliability and interpretability.

FDA should create permanent expert advisory committee to determine a strategy and timeline for how FDA can incorporate such innovations efficiently. The committee shall be focused on how FDA can generate greater reliance on AI for approval purposes as it will greatly speed up testing compared to human trial investigations and will reduce harm through less dependence on animal trials.

Expand "right to try"

The existing "right to try" regulations should be altered to enable more widespread use, building on the law passed during President Trump's first term. This should include right to try for individual treatments, which are easier to develop thanks to innovations in genetic sequencing. This will benefit people with rare illnesses who have no other options. "The current clinical trial evaluation is based on treatments for large population, not an individual patient which were not a reality when the system was created more than a half-century ago," points out the Goldwater Institute. The result is that patients are being deprived of potentially life-saving medications.[12]

Accelerating trials

To address delays and cost inflation in the U.S. system of early-stage trial approvals, more authority needs to be shifted to local institutional review boards for Phase 1 trials. Similarly, faster initiation of first-in-human studies should be allowed, similar to China's decentralized model.

[12] https://www.goldwaterinstitute.org/right-to-try-for-individualized-treatments-right-to-try-2-0/

China's advantage comes partly from running multiple experimental pathways simultaneously. The United States should expand the use of adaptive trial designs and allow rolling data submissions.

References

Fortune Business Insights. (2026). U.S. medical devices market size, share & industry analysis. Retrieved April 10, 2026, from https://www.fortunebusinessinsights.com/u-s-medical-devices-market-107009

IQVIA Institute for Human Data Science. (2022). *The use of medicines in the U.S. 2022: Usage and spending trends and outlook to 2026*. IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2022

IQVIA Institute for Human Data Science. (2023). Use of medicines in the U.S. continued to grow in 2022 while patient out-of-pocket costs remain low, says IQVIA Institute [Press release]. IQVIA. https://www.iqvia.com/newsroom/2023/05/use-of-medicines-in-the-us-continued-to-grow-in-2022-while-patient-out-of-pocket-costs-remain-low-sa

IQVIA Institute for Human Data Science. (2023). *The use of medicines in the U.S. 2023: Usage and spending trends and outlook to 2027*. IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023

IQVIA Institute for Human Data Science. (2024, May 14). U.S. medicines spending grew in 2023 as greater access offset COVID-19-related decline, says IQVIA Institute [Press release]. IQVIA. https://www.iqvia.com/newsroom/2024/05/us-medicines-spending-grew-in-2023-as-greater-access-offset

IQVIA Institute for Human Data Science. (2024). *The use of medicines in the U.S. 2024: Usage and spending trends and outlook to 2028*. IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

IQVIA. (2025, October). U.S. life sciences industry thrives with robust growth and innovation [Blog post]. IQVIA. https://www.iqvia.com/locations/united-states/blogs/2025/10/us-life-sciences-industry-thrives-with-robust-growth-and-innovation

Hult, K. J., & Philipson, T. J. (2023). The value of medical innovation versus industry rewards. Value in Health, 26(3), 320–327. https://doi.org/10.1016/j.jval.2022.12.001

Philipson et al (2026), "The Social Value of Faster FDA Approval", Initiative on Choice and Competition in Health Care, The Department of Economics, The University of Chicago.

Precedence Research. (2024, December 16). Medical devices market size to hit USD 1,146.95 bn by 2034 [Press release]. BioSpace. https://www.biospace.com/press-releases/medical-devices-market-size-to-hit-usd-1-146-95-bn-by-2034

Precedence Research. (2023, December 4). Medical devices market size estimated to reach USD 996.93 billion by 2032 [Press release]. Yahoo Finance. https://finance.yahoo.com/news/medical-devices-market-size-estimated-151500895.html

Ross, J. S., Dzara, K., & Downing, N. S. (2015). Efficacy and safety concerns are important reasons why the FDA requires multiple reviews before approval of new drugs. Health Affairs, 34(4), 681–688. https://doi.org/10.1377/hlthaff.2014.1160

Ritter, J. M. (2008). Drug regulation & therapeutic efficacy. British Journal of Clinical Pharmacology, 65(6), 801–802. https://doi.org/10.1111/j.1365-2125.2008.03208.x

Selker, H. P., Gorman, S., & Kaitin, K. I. (2018). Efficacy-to-effectiveness clinical trials. Transactions of the American Clinical and Climatological Association, 129, 279–300.

U.S. Food and Drug Administration. (2025). *Small business assistance: Frequently asked questions on the patent term restoration program*. FDA. https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program

U.S. Food and Drug Administration. (2018). *Step 3: Clinical research*. FDA. https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

Van Norman, G. A. (2016). Drugs, devices, and the FDA: Part 2: An overview of approval processes: FDA approval of medical devices. *JACC: Basic to Translational Science*, *1*(4), 277–287. https://doi.org/10.1016/j.jacbts.2016.03.009

Mitra-Majumdar, M., Gunter, S. J., Kesselheim, A. S., Brown, B. L., Joyce, K. W., Ross, M., Pham, C., Avorn, J., & Darrow, J. J. (2022). Analysis of supportive evidence for US Food and Drug

Administration approvals of novel drugs in 2020. JAMA Network Open, 5(5), e2212454.

https://doi.org/10.1001/jamanetworkopen.2022.12454