CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Phillip L. Swagel, Director

July 18, 2025

Honorable Jeffrey A. Merkley
Ranking Member
Committee on the Budget
United States Senate
Washington, DC 20510

Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Honorable Brendan F. Boyle
Ranking Member
Committee on the Budget
U.S. House of Representatives
Washington, DC 20515

Re: How Changes to Funding for the NIH and Changes in the FDA's Review Times Would Affect the Development of New Drugs

Dear Ranking Member Merkley, Ranking Member Sanders, Ranking Member Pallone, and Ranking Member Boyle:

As you requested, this letter provides information about how changes to funding for the National Institutes of Health (NIH) and changes in the Food and Drug Administration's (FDA's) review times would affect the development of new drugs. In particular, you asked the Congressional Budget Office to assess two hypothetical scenarios:

- A permanent 10 percent reduction in the amount of funding that the government provides to the NIH, and
- A nine-month increase in the time it takes the FDA to review new drug applications (NDAs).

To assess the effects of the hypothetical reduction in NIH funding, CBO focused on how the reduction would affect external preclinical research—that is, research conducted before clinical trials begin by organizations that receive money from the NIH. CBO estimated that a reduction in the NIH's funding of external preclinical research would ultimately decrease the

number of new drugs coming to market by roughly 4.5 percent, or about 2 drugs per year.[1] That result would not be immediate; rather, the impact of the reduction in funding would grow over a 30-year period and would take full effect in the third decade after the reduction began. A reduction in other components of the NIH's budget would further decrease the number of new drugs coming to market; CBO has not assessed the magnitude of that effect.

A nine-month increase in FDA review times for NDAs would reduce the number of FDA-approved drugs in the first year following the increase because all but three months' worth of drug approvals would shift to the next year. In addition to that initial delay, the increase in review times would reduce the number of such approvals by raising the cost to develop new drugs. The number of drug approvals deterred by the increase in development costs would grow over time and would reach its full effect of a 2 percent reduction—amounting to about one less new drug—each year in the second decade after the increase in review times began.

You also asked CBO to analyze the implications of reducing NIH funding by 35 percent to 38 percent. CBO has not yet assessed whether historical evidence can be generalized and reliably used to estimate the effects of a reduction in funding of that magnitude.

Background on the Drug Development Process

The process for developing new drugs consists of several stages. Scientific research is followed by an initial application to the FDA, clinical trials, and, finally, an application for FDA approval to bring a drug to market.[2]

The process begins with preclinical research, which seeks a better understanding of biological mechanisms that may later inform the development of new drugs. The research also initially tests the effectiveness of potential new drugs in treating diseases and medical conditions.

Once a drug candidate has been identified as a potential treatment for a disease or condition, the sponsor—often a pharmaceutical company wanting to develop the drug for commercialization—submits an initial Investigational New Drug application to the FDA to conduct clinical trials of the drug in humans. That application includes results from preclinical studies and a

[1] CBO expects that under current law, about 44 drugs will be approved per year, amounting to about 1,300 newly approved drugs over the next 30 years.

[2] For more information about the drug development process and related FDA activities, see Food and Drug Administration, "The Drug Development Process" (January 4, 2018), https://tinyurl.com/r4drh2em.

proposed set of protocols for conducting the trials. The FDA reviews the application and determines whether the drug candidate can advance to clinical trials in humans.

Clinical trials start with smaller-scale trials to demonstrate that a drug is safe. Larger-scale trials follow to show the efficacy of a drug in treating a particular disease or condition.

Once human clinical trials are complete, the sponsor may apply to the FDA for approval to market the drug candidate in the United States to treat a particular disease or condition. The FDA evaluates that application on the basis of the drug's safety and efficacy. New chemically synthesized drugs—including small-molecule drugs and some complex products (for example, large synthetic peptides)—are submitted for review through NDAs. Biologic products, which are derived from living organisms, are submitted for review through biologics license applications (BLAs).

In addition to regular NDAs and BLAs, the FDA reviews supplemental NDAs and abbreviated NDAs. Supplemental NDAs request changes to an already approved NDA. Those changes include approving the drug for treating an additional disease, changing the dosage, adding a new method of administering the drug, and approving the drug's use among a new population (such as children). Abbreviated NDAs are requests to approve a generic version of a previously approved brand-name drug and do not require new clinical trials; rather, the applicant must demonstrate that the generic version being considered performs in the same way as the corresponding brand-name drug.

The development of new drugs is supported by private- and public-sector funding. For-profit businesses—such as pharmaceutical companies—spent $116 billion on pharmaceutical research and development in calendar year 2022. About two-thirds of that amount ($76 billion) was allocated to clinical trials and other activities related to producing new drugs; about one-third ($40 billion) was allocated to preclinical research.[3] In calendar year 2020, the NIH spent $43 billion on research and development. About 80 percent of that amount was spent on preclinical research; about 15 percent was spent on

[3] National Center for Science and Engineering Statistics, "Business Enterprise Research and Development (BERD) Survey: 2022" (accessed June 24, 2025), https://tinyurl.com/32ekp4cs. The BERD Survey separates funding for research and development into the categories "basic research," "applied research," and "development." (For more information about the definitions of those categories, see the survey documentation.) In this letter, CBO categorizes combined spending on basic research and applied research as spending on "preclinical research" and reports spending on development as spending on "clinical trials and other activities related to producing new drugs."

clinical trials and related activities. About 4 percent directly supported training and career development, not including training funded by grants for basic, preclinical, and clinical research.[4] In that year, about 80 percent of the $43 billion obligated by the NIH for research and development supported external researchers—largely those at universities and colleges—whereas about 20 percent of the obligated amount supported internal research and development activities at the NIH.[5]

Background on CBO's Model of Drug Development

CBO uses its simulation model of new drug development to analyze the potential effects of legislative proposals on the drug development process.[6] The model provides information about drug development that supplements the agency's estimates of the budgetary effects of legislation. Specifically, the model is designed to analyze how the number and timing of new drugs entering the market would be affected by the following factors:

- The revenues that pharmaceutical companies expect to earn from a new drug;
- The costs of development, in terms of time and money, that companies expect to be associated with bringing a new drug to market; and
- The number of drugs eligible for each phase of development.

Various policies influence those factors. For instance, expected revenues may shift because of negotiated prices of certain prescription drugs covered under Medicare. Development costs are affected by the duration of the FDA's approval process and the resources needed to navigate it. Changes in how research and development are taxed also affect the costs of development. And the number of drugs eligible for each phase of development is affected by NIH funding levels and other changes within the NIH. Changes in economic factors, such as the cost of capital, can also affect

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[4] Government Accountability Office, *National Institutes of Health: Better Data Will Improve Understanding of Federal Contributions to Drug Development*, GAO-23-105656 (April 2023), www.gao.gov/products/gao-23-105656.

[5] National Center for Science and Engineering Statistics, "Survey of Federal Funds for Research and Development: 2020–2021" (accessed July 11, 2025), https://tinyurl.com/75m6natx.

[6] Christopher P. Adams, *CBO's Simulation Model of New Drug Development*, Working Paper 2021-09 (Congressional Budget Office, August 2021), www.cbo.gov/publication/57010. In the context of CBO's model, "new drugs" include any new chemically made drugs or biologic products. The model does not estimate supplementary uses for which an existing drug may be approved (such as uses for treating new diseases or conditions), nor does it consider the safety or value of new drugs.

expected revenues and costs. To assess how such policy and economic changes would affect the number and timing of new drugs entering the market, CBO draws on its drug development model, as well as multiple data sources and evidence from the research literature.

Effects of a Permanent 10 Percent Reduction in NIH Funding

In its analysis of the effects of a permanent 10 percent reduction in funding for the NIH, CBO considered the different ways that the NIH uses its funding. The different uses of the funding affect drug development through different channels.

CBO's analysis focused on the effect of a permanent 10 percent reduction in the NIH's funding of external preclinical research and provides a *quantitative* estimate of that effect. Such funding tends to affect drug development through one channel—namely, the number of drug candidates available to test in clinical trials. CBO also analyzed the impact of a reduction in internal and external support of clinical trials and provides a *qualitative* assessment of that impact. Such a reduction affects drug development through another channel—by influencing the number of clinical trials that will be performed.

The remaining elements of NIH funding of research and development—for internal research activities (other than clinical trial support) and workforce development—may also affect drug development through one of those channels, but CBO has not assessed the implications of reducing those elements of NIH funding. CBO has also not assessed the behavioral responses of other stakeholders, such as pharmaceutical companies, to a change in NIH funding.

Effects of Reduced Funding for External Preclinical Research. CBO estimates that a 10 percent reduction in the NIH's funding of external preclinical research would reduce the number of drug candidates available for phase 1 clinical trials by 4.5 percent and that it would take 12 years for that change to take full effect. The agency developed that assessment on the basis of research that examined links between external funding provided by

the NIH, drug-related patents, and clinical trials.[7] Using that research, CBO tested several approaches for estimating the relationship between changes in the NIH's funding of preclinical research and the availability of drugs to start clinical trials. CBO found that estimates were generally consistent among the various approaches. Over time, reductions in such funding eventually decrease the number of drug candidates available for subsequent development phases and entry into the market. (On average, a drug takes about seven years to advance from a phase 1 clinical trial to approval.)[8]

Applying that framework, CBO estimates that a permanent 10 percent reduction in the NIH's funding of external preclinical research would reduce the number of new drugs introduced by 1 drug in the first decade after the initial reduction occurred. That effect would grow to 9 fewer new drugs introduced in the second decade after the reduction and 20 fewer in the third decade and in subsequent decades. All told, the number of new chemically made drugs and biologic products entering the market would be reduced by roughly 4.5 percent after the policy had taken full effect in the third decade after the reduction in funding occurred.[9]

Effects of Reduced Funding for Clinical Trials. A 10 percent reduction in NIH funding would also decrease that agency's support for clinical trials. A

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[7] Pierre Azoulay and others, "Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules," *Review of Economic Studies*, vol. 86, no. 1 (January 2019), pp. 117–152, https://doi.org/10.1093/restud/rdy034; Margaret E. Blume-Kohout, "Does Targeted, Disease-Specific Public Research Funding Influence Pharmaceutical Innovation?" *Journal of Policy Analysis and Management*, vol. 31, no. 3 (Summer 2012), pp. 641–660, http://doi.org/10.1002/pam.21640; Amy Finkelstein, "Static and Dynamic Effects of Health Policy: Evidence From the Vaccine Industry," *Quarterly Journal of Economics*, vol. 119, no. 2 (May 2004), pp. 527–564, https://doi.org/10.1162/0033553041382166; Edward Kong and Olivia Zhao, *Market Incentives and the Drug Development Pipeline: Evidence From Antibiotics* (SSRN, June 18, 2025), https://tinyurl.com/uy6ney5m; and Danielle Li, Pierre Azoulay, and Bhaven N. Sampat, "The Applied Value of Public Investments in Biomedical Research," *Science*, vol. 356, no. 6333 (April 2017), pp. 78–81, https://doi.org/10.1126/science.aal0010.

[8] Aylin Sertkaya and others, "Costs of Drug Development and Research and Development Intensity in the U.S., 2000–2018," *JAMA Network Open*, vol. 7, no. 6 (June 2024), e2415445, https://doi.org/10.1001/jamanetworkopen.2024.15445.

[9] In 2022, CBO estimated the effects of changes to the NIH's appropriations that were included in the Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong. In that case, the policy examined was a temporary 1 percent increase in the NIH's budget. See Chris Adams, Health Analysis Division, Congressional Budget Office, "CBO's Model of New Drug Development" (presentation to the Dartmouth Institute for Health Policy & Clinical Practice, January 13, 2022), www.cbo.gov/publication/57450. In the current analysis (as in that 2022 estimate), CBO assumes that a given change in the NIH's appropriations would result in an equivalent change in its outlays for research. In the context of the analysis, it makes no difference whether a spending change stems from a change in appropriations or a change in the amount of the NIH's appropriations that it spends to fund research.

subset of those clinical trials involves the development of drugs that require FDA approval. Other NIH-funded clinical trials support broader research activities, such as behavioral interventions, that do not require FDA approval. For drugs approved by the FDA from 2010 to 2019, most NIH funding for phased clinical trials supported phase 2 and phase 3 trials.[10] Reduced funding for those later-stage trials would be expected to reduce the number of new drugs entering the market sooner than the effect of a reduction in basic research funding would be realized. CBO has not yet assessed the magnitude of that effect.

Uncertainty in CBO's Analysis. An important source of uncertainty in CBO's analysis is whether the research projects that would not be funded because of the policy change would be more likely or less likely to result in drug approvals than would an average research project. Which projects were affected would depend on how the reductions in NIH funding were implemented.

Implications of Larger Reductions in NIH Funding

It is unclear whether existing evidence for the effects on drug development of previous changes in NIH funding can be generalized to estimate the effects of large reductions in such funding. From fiscal year 1998 to fiscal year 2003, the NIH's budget nearly doubled. In fiscal year 2013, the NIH experienced the largest nominal decline in its budget in recent history, a 5 percent decrease.[11] The magnitude and direction of changes in funding would be fundamentally important in assessing their effects, but so, too, would be the way the changes were implemented—such as whether they were part of a broader policy. CBO has not yet assessed whether existing evidence can be generalized and applied to estimate the expected effects of even larger reductions to NIH funding—in this case, a reduction of 35 percent to 38 percent.

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[10] Edward W. Zhou, Matthew J. Jackson, and Fred D. Ledley, "Spending on Phased Clinical Development of Approved Drugs by the U.S. National Institutes of Health Compared With Industry," *JAMA Health Forum*, vol. 4, no. 7 (July 2023), e231921, https://doi.org/10.1001/jamahealthforum.2023.1921.

[11] Kavya Sekar, *National Institutes of Health (NIH) Funding: FY1996–FY2025*, Report R43341 (Congressional Research Service, June 25, 2024), www.congress.gov/crs-product/R43341. For information about historical funding for the NIH, see National Institutes of Health, Office of Budget, "Appropriations History by Institute/Center (1938 to Present)" (accessed on July 17, 2025), https://officeofbudget.od.nih.gov/approp_hist.html.

Effects of a Nine-Month Increase in FDA Review Times of New Drug Applications

In CBO's assessment, a nine-month increase in FDA review times of NDAs would have several effects, two of which CBO has quantified. First, it would automatically delay drug approvals and thus entries into the market from earlier years to later years. Second, it would increase the cost of developing new drugs.

Effect of Automatically Delaying Drug Approvals. Any delay in FDA review times would directly translate to a delay in drug approvals. Therefore, the first effect of a nine-month increase in the time it takes the FDA to review NDAs (from a drug's finishing clinical trials to its entry into the market) would be to push approval dates nine months into the future, thus delaying the introduction of new drugs in the first year. But after that first year, the number of drugs newly entering the market would remain the same as before the delay because approvals would equalize—in other words, in any given year, the decrease in the number of approvals caused by the delay would be offset by the increase from approvals pushed forward from the previous year.

That effect extends to other review activities that the FDA conducts, such as approving new uses for drugs already on the market and approving generic drugs. In the first year in which the delay occurred, approvals of supplemental NDAs and abbreviated NDAs would be pushed nine months into the future. In calendar year 2024, the FDA's Center for Drug Evaluation and Research approved 50 new drugs under NDAs or BLAs, along with 144 supplemental NDAs and about 720 abbreviated NDAs.[12]

Effect of Increasing Drug Development Costs. To estimate the second effect, CBO modeled the change in capitalized costs that would result from the delay in drugs entering the market. In the agency's model, expenditures in the three phases of clinical trials in humans are capitalized on the basis of

[12] For a count of approved NDAs and BLAs, see Food and Drug Administration, "Novel Drug Approvals for 2024" (July 14, 2025), https://tinyurl.com/4ena4kfs; for a count of approved abbreviated NDAs, see Food and Drug Administration, "Drugs@FDA: FDA-Approved Drugs" (July 15, 2025), www.accessdata.fda.gov/scripts/cder/daf. CBO calculated the number of supplemental NDAs using data from Food and Drug Administration, "Drugs@FDA Data Files" (July 8, 2025), https://tinyurl.com/3kmj9ekr. In that calculation, CBO counted only efficacy supplements because those supplemental NDAs require a clinical review by the FDA.

a weighted average cost of capital and the time taken to get the drug to market and realize returns on the investment.[13]

CBO estimates that a nine-month increase in FDA review times would boost the cost to develop new drugs, resulting in 3 fewer drugs entering the market in the first decade after the increase and 10 fewer drugs in both the second decade and the third decade. By the second decade, when the policy had taken full effect, the increase in FDA review times would be associated with a 2 percent decrease in the number of new chemically made drugs and biologic products coming to market.[14] CBO also expects that the FDA would issue fewer supplemental approvals for drugs already on the market because of the increase in costs, since approving new uses follows a regulatory process that is similar to that for new drugs.

Effects That CBO Did Not Assess. Delays in the FDA's reviews and approvals of new drugs would probably affect drug development in additional ways that CBO did not assess. Increases in FDA review times effectively reduce the period during which a drug manufacturer has exclusive rights to sell a drug, thereby lowering expected revenues.[15] CBO did not assess the effects of that decrease in expected revenues on new drug development. The agency also did not assess the effects of other changes in the behavior of pharmaceutical companies in response to longer review times, such as changes in the types of drugs selected for development. Finally, CBO's analysis does not account for any changes in processes or practices at the FDA that might result from increases in review times.

Forthcoming Updates to CBO's Drug Development Model

CBO is updating its drug development model to address the Congress's interest in additional policy outcomes. The updates will also incorporate

[13] For details, see Christopher Adams, Health Analysis Division, Congressional Budget Office, "CBO's Model of Drug Development: Ongoing Updates" (presentation at the Federal Reserve Bank of Boston, November 22, 2024), slide 17, www.cbo.gov/publication/60771.

[14] This analysis does not distinguish between review applications associated with NDAs and those associated with BLAs.

[15] Eric Budish, Benjamin N. Roin, and Heidi Williams, "Do Firms Underinvest in Long-Term Research? Evidence From Cancer Clinical Trials," *American Economic Review*, vol. 105, no. 7 (July 2015), pp. 2044–2085, https://doi.org/10.1257/aer.20131176.

responses to one of the agency's blog posts and other input, including feedback on presentations given at two recent conferences.[16]

CBO continues to seek input to enhance its analysis of factors that affect drug development, including federally funded research and the FDA's review process. The agency will continue to update that analysis to better account for the costs of drug development and for variation among different types of drugs (for example, chemically made drugs compared with biologic products).

I hope this information is useful to you. Please contact me directly if you have further questions.

Sincerely,

Phillip L. Swagel
Director

cc: Honorable Lindsey Graham
Chairman
Senate Committee on the Budget

Honorable Bill Cassidy
Chairman
Senate Committee on Health, Education,
Labor and Pensions

Honorable Brett Guthrie
Chairman
House Committee on Energy and Commerce

Honorable Jodey Arrington
Chairman
House Committee on the Budget

[16] For the blog post, see Phill Swagel, "A Call for New Research in the Area of New Drug Development," *CBO Blog* (December 20, 2023), www.cbo.gov/publication/59818. For the presentations, see Christopher Adams, Health Analysis Division, Congressional Budget Office, "CBO's Model of Drug Development: Ongoing Updates" (presentation at the Federal Reserve Bank of Boston, November 22, 2024), www.cbo.gov/publication/60771, and "CBO's Model of Drug Development: Ongoing Updates" (presentation at the American Enterprise Institute, April 4, 2025), www.cbo.gov/publication/61231.