Congressional Budget Office
Nonpartisan Analysis for the U.S. Congress

CBO's Recent Appeals for New Research on Health-Related Topics

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For information about No Patient Left Behind, see www.nopatientleftbehind.org/.

A Brief Introduction to the Congressional Budget Office

CBO's Role

The agency was established under the Congressional Budget and Impoundment Control Act of 1974 (often called the Budget Act) to provide:

- Objective, nonpartisan, and timely analysis to assist the Congress in making decisions that affect the federal budget and the economy; and
- Information and cost estimates required as part of the Congressional budget process.

CBO offers an alternative to information provided by the Office of Management and Budget (OMB) in the executive branch. The agency is strictly nonpartisan and does not make policy recommendations.

CBO's chief responsibility under the Budget Act is to help the Budget Committees with the matters under their jurisdiction. CBO follows processes that are specified in statute or that it has developed in concert with those committees and Congressional leadership.

CBO’s Organization

The agency’s Director is appointed jointly by the Speaker of the House and the President pro tempore of the Senate and has a four-year term.

CBO has about 270 employees. They are hired solely on the basis of professional competence, without regard to political affiliation. Most have advanced degrees.

CBO’s organization consists of the Office of the Director and nine divisions:

- Budget Analysis
- Financial Analysis
- Health Analysis
- Labor, Income Security, and Long-Term Analysis
- Macroeconomic Analysis
- Management, Business, and Information Services
- Microeconomic Studies
- National Security
- Tax Analysis

How CBO Uses Research

Research Informs All Aspects of CBO's Work

The agency uses research to develop its:

- Baseline budget projections and economic forecasts,
- Estimates of the effects of legislative proposals,
- Reports requested by Members of Congress, and
- Modeling methods.

CBO conducts several types of research:

- Empirical research (including descriptive analyses),
- Consultations with stakeholders and experts, and
- Syntheses of academic literature.

Example: Determining the Offsetting Effects of Prescription Drug Use on Medicare Spending

The use of prescription drugs affects people's health and their need for medical services. As a result, policies that affect Medicare beneficiaries' use of prescription drugs probably affect federal spending on their medical services.

Before 2012, CBO found insufficient evidence of "offsetting" effects of prescription drug use on spending for medical services. For example, the agency did not include such effects when it estimated the budgetary effect of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which established Medicare's Part D prescription drug benefit.

As more analyses demonstrated a link between changes in prescription drug use and changes in the use of and spending on medical services, CBO synthesized that research and estimated the size of that spillover effect for the Medicare population.

CBO estimated that a 1 percent increase in prescription drug use by Medicare enrollees would cause their medical spending to fall by roughly one-fifth of 1 percent and that a 1 percent decrease in prescription drug use would increase medical spending by roughly one-fifth of 1 percent.

For more information, see Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), www.cbo.gov/publication/43741.

CBO’s Recent Appeals for New Research on Health-Related Topics

CBO Recently Published Three Blog Posts Calling for New Research in the Area of Health

The blog posts called for research on four topics:

- How health care providers would respond to shocks to revenues or costs,
- How changes in Medicaid's benefit for long-term services and supports would affect the federal budget,
- How federal policies related to pricing drugs would affect innovation in the pharmaceutical industry, and
- How Medicare's coverage of anti-obesity medications would affect the federal budget.

(The remainder of this presentation focuses on the last two topics.)

For more information, see Chapin White, "A Call for New Research in the Area of Health," *CBO Blog* (July 19, 2023), www.cbo.gov/publication/59295; Phill Swagel, "A Call for New Research in the Area of Obesity," *CBO Blog* (October 5, 2023), www.cbo.gov/publication/59590; and Phill Swagel, "A Call for New Research in the Area of New Drug Development," *CBO Blog* (December 20, 2023), www.cbo.gov/publication/59818.

Modeling Approach: How Federal Policies Related to Pricing Drugs Would Affect Innovation in the Pharmaceutical Industry

CBO developed a simulation model that is based on a stylized representation of the pharmaceutical decisionmaking process. For each drug candidate, CBO models four decision points: phase 0 (pre-clinical), phase I, phase II, and phase III.

At each decision point, the pharmaceutical company observes the net present value of expected costs and expected revenues for its candidate drug. If expected revenues are greater than expected costs, the company chooses to enter the development stage.

The model draws a large number of simulated drugs from the joint distribution of expected returns and expected costs. The distribution is constructed using an estimation procedure; CBO estimates that expected revenues and expected development costs are positively correlated.

The distribution of lifetime revenues is estimated using data on net revenues from Medicare Part D, discounted using the weighted average cost of capital. The distribution of development costs is estimated using survey data from research literature.

For more information on the simulation model, see 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. For a summary of updates to the model, see Christopher P. Adams, "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. For a description of the data on development costs, see Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics*, vol. 47 (May 2016), pp. 20–33, https://doi.org/10.1016/j.jhealeco.2016.01.012.

Estimating Effects: How Federal Policies Related to Pricing Drugs Would Affect Innovation in the Pharmaceutical Industry

CBO estimated the effects that the 2022 reconciliation act (Public Law 117-169) would have on innovation in the pharmaceutical industry. The law includes these provisions:

- The Secretary of Health and Human Services is required to negotiate drug prices for Medicare.
  - Prices of 10 drugs with highest Medicare spending would be negotiated first.
  - Small-molecule drugs are not eligible for negotiated prices until they have been on the market for 9 years; biologic drugs for 13 years.
- Drug manufacturers owe inflation rebates when a drug's price exceeds an inflation-adjusted benchmark.
- The Medicare Part D benefit structure was redesigned, in part to limit out-of-pocket costs.

CBO estimated that global revenues from sales of new drugs would decrease by 1 percent to 3 percent, and that over the next 30 years, 13 fewer drugs (of 1,300 estimated new drugs) would come to market as a result of the law.

For more information, see Congressional Budget Office, letter to the Honorable Jodey Arrington and the Honorable Michael C. Burgess regarding additional information about drug price negotiation and CBO's simulation model of drug development (December 21, 2023), www.cbo.gov/publication/59792.

A Call for New Research: How Federal Policies Related to Pricing Drugs Would Affect Innovation in the Pharmaceutical Industry

CBO continues to refine its modeling and will keep abreast of new information about the drug development process as it prepares analyses for the Congress.

The agency is particularly interested in the following questions:

- How do changes in pharmaceutical companies' expected future profits affect the development of drugs with differing characteristics, such as:
  - Small- or large-molecule drugs,
  - Drugs that target certain diseases, or
  - Drugs that target certain patient populations?
- How do different policies, such as price negotiation or accelerated approvals, affect companies' decisions about which indications to target for approval by the Food and Drug Administration?
- How do changes in the number of new drugs affect health outcomes?

For more information, 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.

Background: Budgetary Effects of Allowing Medicare to Cover Anti-obesity Medications

New anti-obesity medications (AOMs) belong to a class of drugs called glucagon-like peptide-1 (GLP-1) agonists, which were originally developed to treat diabetes. Under current law, Medicare is statutorily prohibited from covering medications to treat obesity. Policymakers are interested in the effects of removing that restriction.

CBO's analysis focuses on two components:

- The direct cost of the medications, and
- Potential offsetting budgetary savings associated with improved health outcomes.

Both components are a function of the medications' use:

- The current price for a four-week supply of an AOM that is a GLP-1 agonist ranges from about $1,100 to $1,300, minus discounts paid to insurance plans and payments made by other payers.
- Health improvements occur over time after sustained weight loss, requiring continued use of medications.

A Call for New Research: Budgetary Effects of Allowing Medicare to Cover Anti-obesity Medications

CBO continues to monitor trends in the use of AOMs, along with their prices, effects on health, and coverage by insurance plans.

Research on the following topics could be especially valuable:

- Factors affecting the use of AOMs, such as take-up rates and patients' adherence to drugs currently on the market; and
- Expectations about the prices and effectiveness of AOMs that are being developed.

Research on near- and long-term clinical impacts of AOMs (including health benefits or complications) and their effects on patients' use of, and spending on, other medical services would also be of particular interest.

For more information, see Phill Swagel, "A Call for New Research in the Area of Obesity," *CBO Blog* (October 5, 2023), www.cbo.gov/publication/59590.