Response from the American Society for Clinical Pharmacology and Therapeutics on the Proposed OMB Revisions to Federal Financial Assistance Regulations

The American Society for Clinical Pharmacology and Therapeutics (ASCPT) and the clinical pharmacology and translational science community are deeply concerned that the proposed revisions to the Office of Management and Budget (OMB) regulations governing Federal Financial Assistance (OMB-2026-0034) will have profound negative consequences for biomedical research and public health. If implemented as proposed, these changes would weaken the scientific infrastructure that underpins biomedical innovation, slow the development of life-saving therapies, and ultimately harm patients. ASCPT is a global catalyst for clinical translational pharmacology and has a diverse membership of scientists and clinicians from academia, industry, and governmental agencies, including the NIH and FDA.

The United States is the global leader in pharmaceutical innovation because of a unique partnership among federal agencies, academic medical centers, health systems, biotechnology companies, and the pharmaceutical industry. This ecosystem fosters the best and the brightest scientific minds and has produced transformative advances in cancer, neuroscience, infectious diseases, and other areas critical to public health. The proposed OMB changes threaten the very foundation of this success and jeopardize the United States' position as a global leader in pharmaceutical innovation.

Consequences for Patients and Public Health

Clinical and translational pharmacology research provides the evidence needed to identify novel therapeutic targets, develop new drug entities, optimize dosing, minimize adverse drug reactions, and understand variability in treatment response. Reductions in research capacity or de-prioritizing areas of research where innovation is bringing demonstrable progress towards solving age-old problems translate directly into fewer clinical trials, slower therapeutic advances, and diminished opportunities for patients to access innovative treatments. At a time when the United States faces growing challenges from chronic disease, mental illness, neurodegenerative disorders, antimicrobial resistance, and emerging public health threats, policies that reduce research capacity or shift priorities away from unmet healthcare needs are counterproductive to national health priorities (§200.202).

Impact on the Clinical Pharmacology Workforce

The proposed changes in how grants are funded, including changes to peer review (§200.205) and allowing grants to be cancelled at any time for any reason (§200.340), would be particularly damaging to the next generation of scientists, especially those focused on clinical and translational pharmacology. Graduate students, postdoctoral fellows, physician-scientists, pharmacists, and other related trainees in clinical pharmacology rely on federally supported research environments for education and career development (e.g., T32 grants). Research institutions facing financial uncertainty due to disruptions in federal grant funding are reducing the number of trainees and, in some cases, are eliminating training opportunities altogether. With fewer trainees, there are fewer faculty being produced, leading to reductions in faculty recruitment, which further limits the number of labs able to train and mentor future clinical pharmacologists. Such outcomes would exacerbate existing workforce shortages and weaken the nation's long-term scientific competitiveness and leadership in producing scientists who contribute to our need for new therapeutic options for patients. The impact felt by individual scientists today will translate into substantial societal impact of delayed therapeutic advancements tomorrow.

528 North Washington Street, Alexandria, VA 22314
Phone: (703) 836-6981 • Fax: (703) 836-5223
www.ascpt.org • info@ascpt.org

Modern pharmacology research depends on a complex ecosystem of shared resources, including biostatistics support, data management systems, regulatory expertise, clinical research units, advanced laboratory technologies, and highly trained clinicians and scientists. Reductions in support for these essential functions would disproportionately harm academic medical centers, public universities, children's hospitals, and nonprofit research institutions. Reductions in trained scientists result in a diminished pipeline for pharmaceutical companies that rely on universities to train PhD scientists.

Diminished Scientific Exchange

Scientists make some of their most important discoveries not only through experiments, but also through the exchange of ideas. This happens through membership in scientific societies such as ASCPT, which is the professional society for clinical and translational scientists. ASCPT facilitates training of the next generation through coordination and support of the training directors (i.e., T32 fellowship directors) and mentorship by more senior members.

Scientific conferences provide a unique environment where researchers from different disciplines, institutions, and career stages can share unpublished findings, discuss emerging technologies, challenge assumptions, learn about revolutionary cutting-edge methodological advances, and identify new opportunities for collaboration. These face-to-face interactions spark innovative approaches that would not emerge through virtual communication alone. Conferences also accelerate the translation of research by connecting basic scientists, clinicians, industry partners, regulators, and patient advocates, enabling discoveries to move more rapidly from the laboratory to real-world applications. By fostering collaboration, constructive scientific debate, and the cross-pollination of ideas, conferences strengthen the quality, rigor, and pace of scientific progress, ultimately leading to better therapies, improved public health, and a more innovative research ecosystem. Around 30% of the ASCPT annual meeting attendees (total 800-1000) are academic members who use grant funding to attend our meeting, and without grant support would not be able to attend and contribute to the essential scientific exchange, mentorship, and opportunities for future collaboration. Grant funding is the only source of financial support for academic members to attend scientific conferences, and therefore we urge OMB to continue to allow grant funding to be used for travel to scientific conferences such as the ASCPT annual meeting (§200.432).

Publication in rigorously peer-reviewed scientific journals is not an optional byproduct of federally funded research, but an essential component of the research process and a critical mechanism of public accountability, ensuring that discoveries supported by taxpayer dollars become part of the permanent scientific record where they can be evaluated, replicated, challenged, and built upon. Publication costs, including article processing charges when necessary to provide broad public access, represent a small fraction of the overall investment in biomedical research, but substantially increase the value of that investment by accelerating scientific progress, informing clinical practice, supporting regulatory decision-making, and reducing unnecessary duplication of research. Restricting the use of NIH funds for peer-reviewed publication would not reduce the cost of conducting research; rather, it would impede the dissemination of discoveries, slow the translation of scientific advances into new therapies and improvements in public health, and lead to unnecessary duplication, ultimately increasing the cost of research. Additionally, the proposal creates a policy contradiction. Federal agencies require researchers to make the results of federally funded research openly and immediately accessible (2022 OSTP open access mandate), yet open-access publication generally requires payment of article processing charges. Prohibiting the use of grant funds for these costs would make compliance with federal open-access requirements significantly more difficult, creating barriers to the dissemination of scientific knowledge and stagnating scientific progress. Therefore, we urge OMB to continue to allow grant funding to be used for scientific publication costs (§200.461).

Thus, it is essential that costs associated with scientific exchange and dissemination remain an allowable budgetary expense.

A Direct Threat to Drug Development

Every new medicine depends on decades of federally supported scientific research. Clinical pharmacologists play a central role in translating discoveries into treatments, including the generation of

evidence required for regulatory approval. Weakening the infrastructure that supports federally funded research will not simply reduce administrative costs—it will slow the development pipeline itself. Fewer resources for research institutions means fewer early-phase studies, fewer translational programs, fewer clinical trials, and fewer opportunities to advance promising discoveries toward FDA approval. The inevitable result will be delayed development timelines, increased development costs, and fewer therapies reaching patients. We urge OMB to preserve sustainable support for the research infrastructure required to conduct federally funded pharmacology research.

Jeopardizing FDA-Regulated Research

The public often assumes that clinical trials are funded by industry. In reality, the infrastructure required to conduct FDA-regulated research safely and efficiently is heavily supported through federally funded institutions. Clinical trial units, biostatistics cores, regulatory affairs specialists, data management systems, pharmacometricians, pharmacogenomics laboratories, safety monitoring programs, clinicians, and research pharmacists are all essential components of the drug development ecosystem. These resources ensure compliance with FDA requirements, protect patient safety, maintain data integrity, and enable efficient collaboration between academia, government, and industry. If institutions are forced to reduce these capabilities, the result will be fewer clinical trials, slower enrollment, delayed study completion, and increased barriers to bringing innovative therapies to market. This is not a theoretical concern. It is a predictable consequence of weakening the infrastructure on which FDA-regulated research depends. Furthermore, academic scientists funded through government grants research diseases that are not considered profitable, including rare diseases, neonatal and pediatric disorders, antibiotics, and some CNS medications. Academics conduct clinical trials, often through government-funded trial networks, which require consistent investment to produce high-quality data to inform clinical practice.

Decisions Should be Guided by Merit

Breakthroughs that transformed medicine emerged because scientists were empowered to pursue evidence-driven questions rather than predetermined outcomes. Any system that diminishes the role of peer review risks discouraging innovation, driving talented investigators away from federally funded research, and eroding international confidence in the objectivity and excellence of U.S. science. The long-term consequence will be fewer discoveries, fewer cures, and a devastating public health impact felt for generations. Peer review has been the gold standard because it subjects research proposals to rigorous evaluation by independent scientists with the knowledge necessary to assess scientific merit and potential impact. When political or ideological considerations override peer review, the result is not greater accountability, but a less effective research enterprise and greater unmet need. We urge OMB to continue to let peer review be the benchmark in which to decide on federal grant funding for clinical and translational pharmacology research, and other important and essential scientific research (§200.205).

Scientific progress depends on the ability of researchers to pursue the most promising ideas based on scientific merit rather than political priorities or ideological considerations (§200.202). The peer review system is not perfect, but it remains the internationally recognized gold standard for evaluating research proposals because it relies on independent expert assessment of scientific rigor, innovation, feasibility, and potential impact. Excessive government influence over funding decisions (§200.202) risks replacing evidence-based evaluation with political considerations, discouraging bold, high-risk, high-reward science. History demonstrates that many of the most transformative therapeutic discoveries were not predictable at their inception and emerged from investigator-initiated research selected through rigorous peer review. The proposed changes that allow for delay or cancellation of a grant, including clinical trials, at any time for any reason (§200.340) would be catastrophic to trials, to scientific progress, and to individuals and patient populations whose lives depend on these trials. Further, it is unethical, as participants signing consent forms for trial participation have a contract with the trial leadership to produce the data needed to answer the pre-specified scientific questions. Cancellation of trials before their predetermined endpoints without evidence of safety concerns is a gross abdication of the responsibilities we take when a subject initiates a study and further erodes public trust in research.

Thus, funding decisions for clinical and translational pharmacology research should be guided by scientific excellence, not political influence, and we urge OMB to reconsider allowing political appointees to have influence over the grant funding process (§200.340), continue research funding that is based on scientific merit as determined by scientific experts (§200.202) rather than by an undefined “standard” (§200.205), and maintain transparency by continuing to require grant competitions be announced to the public (§200.204)..

Federal Research Funding Is the Foundation of Therapeutic Innovation

The success of the U.S. pharmaceutical sector is the direct result of decades of sustained federal investment in biomedical research, particularly through the National Institutes of Health (NIH). Multiple analyses have demonstrated that NIH-funded research contributed to the scientific foundation underlying virtually every major class of modern therapeutics. NIH-supported research was associated with ALL 210 new molecular entities approved by the FDA between 2010 and 2016, either through direct investigation of the drug itself or through research on the biological targets and pathways that made the therapy possible.

More broadly, NIH-supported science has contributed to the knowledge base underlying most of the FDA-approved medicines developed over the past several decades. Basic discoveries regarding receptors, signaling pathways, disease mechanisms, biomarkers, genetics, and drug targets frequently originate in federally funded laboratories years or even decades before a therapy reaches patients. The implication is clear: federal research funding is not peripheral to therapeutic development—it is the starting point. Every successful biotechnology company, every transformative medicine, and every breakthrough therapeutic area rests upon a scientific foundation built through public investment. We urge OMB to conduct a rigorous assessment of the effects on scientific productivity, workforce development, and patient outcomes before instituting any reforms.

An Extraordinary Return on Investment

Federal support for biomedical research is among the highest-return investments made by the United States government. Studies have estimated that every dollar invested in NIH-supported research generates multiple dollars in economic activity through job creation, commercialization, startup formation, intellectual property development, healthcare innovation, and private-sector investment. NIH-funded discoveries have helped launch entire industries, including genomics and cell therapies, immuno-oncology, and advanced biologics. The return extends far beyond economic measures. NIH-funded science has contributed to dramatic reductions in mortality from cardiovascular disease, major advances in cancer survival, transformative treatments for rare diseases, and the rapid development of vaccines and therapeutics during public health emergencies. Few public investments can claim comparable returns across both economic and societal dimensions.

The proposed OMB regulations risk disrupting the research ecosystem that produces these extraordinary returns. Drug discovery is a long-term enterprise. Therapies approved today often arise from basic research initiated 10 to 30 years earlier. Reductions in research capacity today may not be visible immediately, but they can create profound downstream consequences for future therapeutic innovation. The most significant impact may therefore be invisible in the short term: discoveries that are never made, therapies that are never developed, companies that are never formed, and patients who never receive treatments that otherwise would have existed. At a time when nations around the world are increasing investments in biomedical innovation, policies that weaken the research enterprise risk sacrificing one of America's most successful engines of economic growth, scientific leadership, and public health advancement.

Conclusion

The United States leads the world in biomedical innovation because it has built a research ecosystem that supports discovery, translation, and implementation. Policies that undermine the financial and operational foundations of that ecosystem will not simply reduce administrative costs—they will slow scientific progress, weaken the workforce, delay therapeutic advances, displace the US as a global leader, and

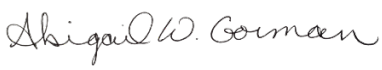
ultimately harm patients. Every delay in drug development represents delayed access to treatments for cancer, Alzheimer's disease, psychiatric disorders, rare diseases, cardiovascular disease, and countless other conditions. Every reduction in clinical trial capacity means fewer opportunities for patients to participate in research and gain access to innovative therapies. The proposed regulations risk slowing scientific progress at precisely the moment when advances in genomics, artificial intelligence, data science, and precision therapeutics are creating unprecedented opportunities to improve human health.

We urge OMB to withdraw or substantially revise these proposed changes and engage directly with clinical and translational pharmacology, biomedical research, regulatory science, biotechnology, and patient advocacy communities. Any reform effort should strengthen accountability and efficiency while preserving the research infrastructure that drives discovery, innovation, and therapeutic advancement.

Sincerely,

Kristin L. Bigos, PhD

President, American Society for Clinical Pharmacology and Therapeutics



Abigail W. Gorman

CEO, American Society for Clinical Pharmacology and Therapeutics