**DATE**: January 31, 2022

**TO:**

Eric Lander, Director, Office of Science and Technology Policy (OSTP) and Science Advisor to the President

Carrie Wolinetz, Principal Assistant Director for Health and Life Sciences, OSTP

Xavier Becerra, Secretary of Health and Human Services (HHS)

Lawrence A. Tabak, Acting Director, National Institutes of Health (NIH)

Deb Tucci, Director, National Institute on Deafness and Other Communication Disorders, NIH

Lyric Jorgenson, Acting Associate Director for Science Policy and the Acting Director of the Office of Science Policy, NIH

John Gallin, Chief Scientific Officer and the Scientific Director of the NIH Clinical Center, Associate Director for Clinical Research in the Office of Clinical Research, Office of the Director, NIH

Michael Lauer, Deputy Director for Extramural Research, NIH

Gary Disbrow, Director, Biomedical Advanced Research and Development Authority (BARDA)

**RE: The US Government Should Disclose the Costs of Clinical Trials it Funds to Make Medical Tools Affordable, Accessible, and Suited to Public Health Needs**

Dear OSTP, HHS, NIH, and BARDA colleagues:

We read with interest the recent piece in *JAMA* "Incentivizing a New Culture of Data Stewardship" and welcome the intention that authors Drs. Jorgenson, Wolinetz, and Collins express to use the National Institutes of Health (NIH) Policy for Data Management and Sharing to integrate effective data management and sharing practices into the process of scientific discovery, "not as an afterthought… but rather as an integral part of how to conduct science."[1] We share the authors' perspective that data sharing is essential – not only for biomedical research to fulfill "its mission to improve human health but also in leading the enterprise toward a culture that maximizes the public's investment in research."

As non-profit organizations and individuals concerned with public health and the affordability of drugs and other medical tools, the undersigned are similarly committed to these two key objectives of improving human health and maximizing the benefits that flow from public

[1]Jorgenson LA, Wolinetz CD, Collins FS. Incentivizing a new culture of data stewardship: the NIH policy for data management and sharing. *JAMA.* Published online November 04, 2021. https://doi.org/10.1001/jama.2021.20489

investment in research. In our view, however, neither objective can be achieved if such transparency does not extend to data on the costs of research. The prevailing model of biomedical discovery, development, and delivery fails to control exorbitant prices and make medical tools accessible to all who need them, despite the significant public investment made to bring these health technologies into being. This happens, in large part, because pharmaceutical and biotechnology companies are able to claim that the high costs of research and development (R&D), clinical trials in particular, justify high prices for drugs and other medical tools - yet they do not disclose these costs in any detail. What limited information is available indicates that R&D expenditures are far outpaced by revenues.[2]

As the largest funder of biomedical research in the world, the US government can and must begin lifting the veil on clinical trial costs. The Department of Health and Human Services (HHS) and its agencies and offices, especially the NIH and the Biomedical Advanced Research and Development Authority (BARDA), should disclose the costs of all clinical trials they fund or conduct in full, disaggregated detail.

Making clinical trial cost information public would allow governments and other purchasers of medical tools to: interrogate claims about the need to recoup R&D costs through high prices; estimate more accurately the true cost of late-stage clinical research; and ultimately – when such transparency is expanded and coupled with the capability to negotiate prices – negotiate more effectively, less hobbled by information asymmetry. It would also allow the public and independent experts to determine whether NIH may conduct certain kinds of research more efficiently than industry and should play an even bigger role in the research ecosystem.

We recognize that uniform disclosure of disaggregated trial costs would not be an effortless undertaking. As we describe in greater detail in the attached addendum, however, there are no legal barriers to disclosure, the administrative obstacles are surmountable, and the benefits of disclosure and the government's responsibility to the public warrant the resources that would be required for implementation.

Cognizant of the need for public access to cost data, lawmakers and civil society groups in the US and globally have made a number of efforts to achieve greater R&D cost transparency in recent years.[3] In 2019, the US government agreed to a resolution at the World Health

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[2] US Congress House Committee on Oversight and Reform. Drug Pricing Investigation: Majority Staff Report. 117th Cong. 2021. https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf

[3] US Congress. Transparent Drug Pricing Act of 2017, H.R. 4116, 115th Cong. https://www.congress.gov/bill/115th-congress/house-bill/4116/text; US Congress. Prescription Drug Affordability Act, H.R. 3513, 114th Cong. § 601(a). 2015. https://www.congress.gov/bill/114th-congress/house-bill/3513/text?q=%7B%22search%22%3A%5B%22Medicare+%22%5D%7D&resultIndex=7; US Congress. Prescription Drug Affordability Act, S. 2023, 114th Cong. § 601(a). 2015. https://www.congress.gov/bill/114th-congress/senate-bill/2023/text; US Congress. Fair Accountability and Innovative Research Drug Pricing Act, H.R. 2439, 115th Cong. § 39900(c). 2017. https://www.congress.gov/bill/115th-congress/house-bill/2439; US Congress. Fair Accountability and Innovative Research Drug Pricing Act, S. 1131, 115th Cong. § 39900(c). 2017.

Assembly, committing to take the necessary steps to make available the costs of clinical trials when publicly available or voluntarily provided, and the actions we are proposing would give effect to that commitment.[4]

We believe that right now is the moment for action. Amidst the global pandemic, the US government is investing tens of billions of dollars to develop tools to fight COVID-19 and future infectious threats, atop the multiples of this that it normally spends on biomedical R&D - $40 billion annually from NIH alone. This massive infusion of public resources only intensifies a longstanding need for greater transparency and, ultimately, a more effective and equitable approach to biomedical R&D that answers the most pressing public health needs and also ensures equitable access to the fruits of scientific progress.

Coinciding with this unprecedented pandemic is a historic transition in leadership at the NIH – which dispenses most of this grant money – as Dr. Francis Collins concludes more than ten years of service as Director. In nominating the next NIH Director, the Biden administration must heed the lessons of COVID-19 and reflect upon the mission of this public medical research agency, particularly its goal to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."[5] Shedding light on the significant contribution American taxpayers make to biomedical innovation and facilitating access to resulting tools by making publicly available the costs of clinical trials falls squarely within NIH's mission and should be a priority for whoever steps into this role.

Sincerely,

Doctors Without Borders/Médecins Sans Frontières (MSF) USA

Doctors for America

Drugs for Neglected Diseases initiative (DNDi), North America

Knowledge Ecology International

Christopher Morten, Associate Clinical Professor of Law, Columbia Law School

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https://www.congress.gov/bill/115th-congress/senate-bill/1131/text; US Congress. S-B 17, 2017-18 Reg. Sess. (Ca. 2017). https://www.cov.com/-/media/files/corporate/publications/2017/10/california_sb_17_new_requirements_for_drug_manufacturers.pdf; US Congress. H.B. 4005, 79th Leg. Assembly, Reg. Sess. (Or. 2018). https://gov.oregonlive.com/bill/2018/HB4005/; Vijay SL. Italy Publishes National Regulation Requiring Pharma Disclosure Of Public Support For R&D On New Drugs. *Health Policy Watch*. July 28, 2020. https://healthpolicy-watch.news/76047-2/; Mancini S. Transparency matters: Italy moves against the secrecy surrounding the cost of medicines. MSF. 2020 Sep 23. https://medium.com/@MSF_access/transparency-matters-italy-moves-against-the-secrecy-surrounding-the-cost-of-medicines-4468a6e0ced6; Londeix P. A historic, but also insufficient transparency amendment adopted by French Parliament. Mediapart, 2020 November 25. https://blogs.mediapart.fr/edition/transparence-dans-les-politiques-du-medicament/article/251120/historic-also-insufficient-transparency-amendement-ado

[4] WHO. Improving the transparency of markets for medicines, vaccines, and other health products. WHA Resolution A72/A/CONF./2 Rev.1. 2019 May 28. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

[5] NIH. Mission and goals. https://www.nih.gov/about-nih/what-we-do/mission-goals

**Co-signatories:**

Adrian Dominican Sisters, Portfolio Advisory Board

Center for Policy Analysis on Trade and Health (CPATH)

Center for Popular Democracy

Chronic Illness Advocacy & Awareness Group

Consumer Action

Foundation for Integrative AIDS Research (FIAR)

Health Care Voices

Health Global Access Project

Interfaith Center on Corporate Responsibility (ICCR)

Justice is Global

Lower Drug Prices Now

Maryknoll Sisters

Mercy Investment Services, Inc.

Network Lobby for Catholic Social Justice

Northwest Coalition for Responsible Investment

Oxfam America

Patients for Affordable Drugs Now

PrEP4All

Prescription Justice

Public Citizen

Right to Health Action

Salud y Farmacos

Sisters of Charity of Saint Elizabeth

Sisters of St. Francis of Philadelphia

Social Security Works

Socially Responsible Investment Coalition

T1International

Trade Justice Education Fund

Treatment Action Group

U.S. PIRG (Public Interest Research Group)

Seventh Generation Interfaith Coalition for Responsible Investment

Dr. Luca Li Bassi, MD, Dip Mgt, DPH; Global Health Adviser; Geneva, Switzerland; Former Director General of the Italian Medicine Agency (AIFA) 2018-2019 Chair of the Negotiating Group for WHA Resolution 72.8

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**(Please see addendum beginning on page 5.)**

**Addendum:**

***Background***

The COVID-19 pandemic has drawn the entire world's attention to both the importance and shortcomings of the system of biomedical research and development (R&D) that makes new medical tools – vaccines, therapeutics, and diagnostics – available for clinical use. On the one hand, rapid development of multiple highly effective COVID-19 vaccines has been a scientific triumph, but on the other, efforts to equitably distribute vaccines globally have been a colossal global health failure. While 63% of our population here in the US is fully vaccinated and 41% of those have received boosters, less than 12% of people in low-income countries have received even a single dose.[6]

Long before the pandemic, our groups saw an urgent need to bring the innovation system into closer alignment with public health needs. The prevailing model of biomedical discovery, development, and dissemination fails to control exorbitant prices and make medical tools accessible to all who need them, despite the significant public investment made to realize these health technologies People in low- and middle-income countries have long been disproportionately impacted by these dynamics, but people in high-income countries like the US also find themselves increasingly impacted by distorted valuations and skewed priorities in biomedical innovation.

Pharmaceutical corporations argue that high prices are necessary to subsidize innovation, but only a small proportion of new drugs are meaningfully innovative: between 1975 and 2012, only 10 to 15 percent of drugs entering the market were actual therapeutic advances - most simply tweaked existing tools with little clinically significant impact.[7] Moreover, what limited information is available indicates that R&D expenditures are far outpaced by revenues.[8] At the same time, 40% of Americans struggle to afford their prescriptions, many are rationing lifesaving drugs like insulin, and 90% of voters say they think it's extremely important for the federal government to do something about high drug prices.[9] And in the context of a pandemic, the threat of variants vividly illustrates how inseparable global access to medical tools is from domestic public health.

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[6] CDC. COVID data tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total;UNDP. Global dashboard for vaccine equity. https://data.undp.org/vaccine-equity/accessibility/

[7] Light DW, Lexchin JR. Pharmaceutical research and development: what do we get for all that money? *BMJ* 2012;345:e4348. https://doi.org/10.1136/bmj.e4348; Kesselheim AS, Tan YT, Acorn J. The roles of academia, rare diseases, and repurposing in the development of the most transformative drugs. *Health Affairs* 2015;34(2): 286-93. https://doi.org/10.1377/hlthaff.2014.1038

[8] US Congress House Committee on Oversight and Reform. Drug Pricing Investigation: Majority Staff Report. 117th Cong. 2021. https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf

[9] Nguyen A. Survey: Americans struggle to afford medications as COVID-19 hits savings and insurance coverage. *Good Rx Health*. March 22, 2021. https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/; POLITICO/Harvard T.H. Chan School of Public Health, The American public's priorities for the new president and

As the single largest public funder of biomedical research in the world, the US government has the power – and the obligation – to significantly alter the way R&D is done and place the needs of the US public and the broader global community at the center of this system. We believe that right now is the moment for bold action. Amidst the global pandemic, the US government is investing tens of billions of dollars to develop tools to fight COVID-19 and future infectious threats, atop the multiples of this that it normally spends on biomedical R&D - $40 billion annually from NIH alone.[10] This massive infusion of public resources only intensifies a longstanding need for greater transparency and, ultimately, a more effective and equitable approach to biomedical R&D that answers the most pressing public health needs and also ensures equitable access to the fruits of scientific progress.

Coinciding with this unprecedented pandemic is a historic transition in leadership at the NIH – which dispenses most of this grant money – as Dr. Francis Collins concludes more than ten years of service as Director. In nominating the next NIH Director, the Biden administration must heed the lessons of COVID-19 and reflect upon the mission of this public medical research agency, particularly its goal to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."[11]

There is much that the US can do to ensure that medical tools resulting from taxpayer investment in R&D are affordable and accessible to all who need them, including requiring recipients of federal funding to charge reasonable prices for products they develop and refrain from using intellectual property claims to stymie geographically diversified manufacturing. As the US continues to invest heavily in R&D through existing mechanisms, new ones such as the $3.2 billion Antiviral Program for Pandemics, and ambitious future programs such as the proposed Apollo-like pandemic preparedness program and Advanced Research Projects Agency for Health, such access provisions should be structured into governance and funding agreements from the start.[12]

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Congress, December 15 – 20, 2020. January 2021. https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/01/Politico-HSPH-Jan-2021-PollReport.pdf

[10] Azar AM. US Department of Health & Human Services. Secretary Azar White House Remarks on Operation Warp Speed. 2020 May 15. https://www.hhs.gov/about/leadership/secretary/speeches/2020-speeches/secretary-azar-white-house-remarks-on-operation-warp-speed.html; US Congress. H.R. 6074. Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. 2020 Jan 3. https://www.congress.gov/116/bills/hr6074/BILLS-116hr6074enr.pdf; US Congress. H.R. 748. Coronavirus Aid, Relief, and Economic Security Act (CARES) Act. 2020 Mar 27. https://www.congress.gov/bill/116th-congress/house-bill/748

[11] NIH. Mission and goals. https://www.nih.gov/about-nih/what-we-do/mission-goals

[12] NIH. Biden administration to invest $3 billion from American Rescue Plan as part of COVID-19 antiviral development strategy. June 17, 2021. https://www.niaid.nih.gov/news-events/biden-administration-invest-3-billion-american-rescue-plan-part-covid-19-antiviral; White House. Press briefing. September 3, 2021. https://www.whitehouse.gov/briefing-room/press-briefings/2021/09/03/on-the-record-press-call-by-office-of-science-and-technology-policy-director-dr-eric-lander-and-nsc-director-for-global-health-security-and-biodefense-dr-beth-cameron-on-american-pandemic-preparedne/; NIH. Lander, Collins set forth a vision for ARPA-H. June 22, 2021. https://www.nih.gov/news-events/news-releases/lander-collins-set-forth-vision-arpa-h

**Perhaps the simplest and most uncontentious step that the US can take, however, is to provide and insist upon transparency into the costs of the R&D it funds – in particular, the costs of clinical trials, frequently claimed to be the most expensive part of bringing a new product to market and the most compelling rationale for exclusive rights and high prices**.

To ensure that the biomedical innovation system is efficient, accountable, and prioritizes public health, transparency is needed throughout the entire process, from discovery through delivery. This transparency should encompass not only R&D costs – including clinical trial costs – but should also include:

- manufacturing costs
- terms and conditions of R&D funding agreements and all sources of funding
- prices of resulting medical tools
- complete preclinical and clinical trial data, and
- status of patents and other intellectual property and licensing agreements
- supply and procurement agreements.

Congress made an important stride in one of these areas over a decade ago by directing NIH to expand the ClinicalTrials.gov website and compel disclosure of clinical trial results there, creating the world's largest publicly accessible database of clinical trial data.[13] **As a crucial next step toward the more comprehensive transparency that is needed, we urge the HHS and all its agencies and offices – especially the NIH and the Biomedical Advanced Research and Development Authority (BARDA) – to disclose the costs of all clinical trials they fund in full, disaggregated detail**.[14] HHS should also require parties that license NIH-owned patents to provide transparency of the costs of trials used to bring inventions to practical application.

***Benefits of Clinical Trial Cost Transparency***

Pharmaceutical and biotechnology companies often claim that the high costs of R&D – clinical trials, in particular – justify high prices for drugs and other medical tools, yet they do not publicly disclose these costs in any detail. Public sector funding, meanwhile, not only underpins the basic science foundation upon which most R&D is built, but also plays a major and often underappreciated role in late-stage development of new medical tools - through direct funding of late-stage research or through spin-off companies created from public sector research

[13] US National Library of Medicine. ClinicalTrials.gov. https://www.clinicaltrials.gov/; Tasneem A, Aberle L, Ananth H, Chakraborty S, Chiswell K, McCourt BJ, Pietrobon R. The Database for Aggregate Analysis of ClinicalTrials.gov (AACT) and subsequent regrouping by clinical specialty. *PLOS One* 2012; 7(3): e33677. https://doi.org/10.1371/journal.pone.0033677

[14] MSF Access Campaign. Transparency matters: disclosing the costs of publicly funded research and development for COVID-19 medical tools and beyond. January 26, 2021. https://msfaccess.org/transparency-matters-disclosing-costs-publicly-funded-research-development-covid-19-medical-tools; Barel A, Boman L. Clinical trial cost transparency at the National Institutes of Health: Law and policy recommendations. New York University. 2020 Aug. https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH

institutions.[15] Making clinical trial cost information in HHS's possession public would allow governments and other purchasers of medical tools to: interrogate claims about the need to recoup R&D costs through high prices; estimate more accurately the true cost of late-stage clinical research; and ultimately – when such transparency is expanded and coupled with the capability to negotiate prices – negotiate more effectively, less hobbled by information asymmetry. It would also allow the public and independent experts to determine whether NIH may conduct certain kinds of research more efficiently than industry and should play an even bigger role in the research ecosystem.

The US is home to most of the largest pharmaceutical and biotechnology companies and spends more on publicly funded biomedical research than any other nation (and far more than any nation on purchases of drugs and other medical products per capita).[16] US leadership on clinical trial cost transparency would not only unlock key data, but would set a new standard against which all funders across the global biomedical innovation ecosystem will be measured, much as its leadership on trial results transparency did. There are no legal obstacles to the government's disclosing the cost of clinical trials it funds just as it does trial results, and the ClinicalTrials.gov database - or a separate, cross-linked data repository - would be a natural place for prospective disclosure of trial costs to be made public.[17]

Currently, clinical trial costs are a black box – particularly for academics, public payers, and public interest groups that cannot access expensive proprietary cost databases heavily utilized by industry – and policy debate is hampered as a result.[18] Transparency of such costs by HHS would capture trials led by a broad cross-section of sponsors including federal, university, and

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[15] Ledley F, Cleary E, Jackson M. US Tax Dollars Funded Every New Pharmaceutical in the Last Decade. Institute for New Economic Thinking. September 2, 2020. https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade; Nayak RK, Avorn J, Kesselheim AS. Public sector financial support for late stage discovery of new drugs in the United States: cohort study. *BMJ* 2019; 367 doi: https://doi.org/10.1136/bmj.l5766; Nayak RK, Lee CC, Acorn J. Public-sector contributions to novel biologic drugs. *JAMA Intern Med*. 2021;181(11):1522-1525. https://doi.org/10.1001/jamainternmed.2021.3720; Kassir Z, Sarpatwari A, Kocak B, et al. Sponsorship and Funding for Gene Therapy Trials in the United States. *JAMA.* 2020;323(9):890-891. https://doi.org/10.1001/jama.2019.22214

[16] Burke H. Who are the top 10 pharmaceutical companies in the world? (2021). Proclinical. June 7, 2021. https://www.proclinical.com/blogs/2020-8/the-top-10-pharmaceutical-companies-in-the-world-2020; Lazonick W, Tulum O. US Biopharmaceutical finance and the sustainability of the biotech business model. *Research Policy* 2011 40(11): 1170-1187. http://dx.doi.org/10.2139/ssrn.2257932; OECD. Pharmaceutical spending (indicator). 2021. https://doi.org/10.1787/998febf6-en https://data.oecd.org/healthres/pharmaceutical-spending.htm

[17] Barel A, Boman L. Clinical trial cost transparency at the National Institutes of Health: Law and policy recommendations. New York University. 2020 Aug. https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH

[18] Moore TJ, Heyward J, Anderson G, Alexander GC. Variation in the estimated costs of pivotal clinical benefit trials supporting the US approval of new therapeutic agents, 2015-2017: a cross-sectional study. *BMJ Open*. 2020 Jun 11;10(6):e038863. https://doi.org/10.1136/bmjopen-2020-038863; Sertkaya A, Wong HH, Jessup A, Beleche T. Key cost drivers of pharmaceutical clinical trials in the United States. *Clin Trials*. 2016 Apr;13(2):117-26. https://doi.org/10.1177/1740774515625964; Baker-Smith CM, Benjamin DK Jr, Grabowski HG, Reid ED, Mangum B, Goldsmith JV, Murphy MD, Edwards R, Eisenstein EL, Sun J, Califf RM, Li JS. The economic returns of pediatric clinical trials of antihypertensive drugs. *Am Heart J*. 2008 Oct;156(4):682-8. https://doi.org/10.1016/j.ahj.2008.05.001

private sector agencies and organizations. Moreover, a standardized, detailed set of data points for disclosure would allow for an apples-to-apples comparison of costs for trials of similar products or conditions. In some cases, this cost transparency might well bolster arguments for increasing the share of funding that goes to federal researchers to carry out late-stage research, particularly in areas that are overlooked by private research sponsors but nonetheless of great public health significance.

***Overcoming Administrative and Financial Barriers to Clinical Trial Cost Transparency***

We understand that record-keeping related to trial costs is not standardized throughout HHS or NIH's many centers and institutes, and that uniform disclosure of disaggregated trial costs is not a simple undertaking. The benefits of disclosure described above and the government's responsibility to the public, however, warrant the administrative and technological resources that would be required for implementation. Moreover, standardization across HHS will generate efficiencies in reporting from trial sponsors and facilitate the research process: university researchers have in fact expressed a desire for more uniform templates and guidance in the budget submission process for federal grants.[19]

Clinical trial cost disclosure is not an unattainable goal. Already, some federal agencies – such as the Veterans Administration – furnish readily upon request quite comprehensive accountings of the per-patient costs of individual trials, as do some state-level institutions. Furthermore, as we understand it, while record-keeping regarding trial costs is not standardized across divisions within HHS, it is nonetheless already happening and there are some discrete and meaningful stores of data in the possession of HHS which are already uniform and therefore readily disclosable in short order. We have heard in discussion with NIH officials, for example, that large-scale clinical trials consortia that receive funding through NIH's extramural program have uniform cost reporting and data retention practices. If such consortia – such as those programs specifically supporting clinical trials for COVID-19 vaccines, treatments, and diagnostics – would release their cost data, it would be of great value.

Some of our groups have requested such data from BARDA and received only redacted tables, indicating the data is retained but inaccessible to the public. Given the enormous sums of money that the US and other governments have invested in R&D for and purchasing COVID-19 medical tools, as well as their public health importance and persistent scarcity, lawmakers in the US and Europe have specifically condemned the lack of transparency around the research and development of COVID-19 tools and begun to propose legislative and parliamentary remedies.[20]

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[19] Nevens H, Harrison J, Vrijens F, et al. Budgeting of non-commercial clinical trials: development of a budget tool by a public funding agency. *Trials* 2019; 20(714). https://doi.org/10.1186/s13063-019-3900-8; McLennan S, Griessbach A, Briel M, Making Randomized Trials Affordable (MARTA) Group. Practices and attitudes of Swiss stakeholders regarding investigator-initiated clinical trial funding acquisition and cost management. *JAMA Netw Open*. 2021;4(6):e2111847. https://doi.org/10.1001/jamanetworkopen.2021.11847

[20] US Congress.Taxpayer Research and Coronavirus Knowledge Act of 2021, H.R. 1391, 117th Cong. 2021. https://www.congress.gov/bill/117th-congress/house-bill/1391?s=1&r=162; European Parliament. European Parliament resolution on EU transparency in the development, purchase and distribution of

It is already in the Biden administration's power, however, to release this data – and all cost data for the trials the federal government funds – without a legislative mandate.

Another example of valuable data that the US could readily disclose is the cost of clinical trials federal researchers run themselves. While we recognize that federal investigators conduct only a relatively small number of late-stage clinical trials, the data HHS retains on these trials is of great value to analysts concerned with access to medical tools (including, for example, the costs of contracted-out manufacturing of drug substance, which we understand are figures NIH retains). University researchers drawing on limited sources now go to great lengths to estimate such figures and disclosure by the US government would strengthen the efforts of such independent analysts and cast a much-needed raking light on industry's own inflated estimates of expenditure.[21]

HHS can and should disclose the costs of significant trials that federal researchers have run, in particular the massive Phase III clinical trial that helped bring the Moderna COVID-19 vaccine into clinical use, as well as federally-supported trials for versions of the vaccine adapted to address COVID-19 variants.[22] This vaccine's development was almost 100% funded by taxpayer dollars and the US government is even a part-owner of the technology its production relies upon, yet the government has not disclosed how those dollars were spent – including on that crucial Phase III trial. Given profound inequities we are seeing in the global distribution of this lifesaving product, as well as the company's effort to deny federal researchers credit for their pivotal roles in inventing the vaccine, this opacity is rankling.[23] These clinical trial costs are also of great relevance in the domestic context: the US government has not only spent additional billions to purchase these vaccines that taxpayer dollars developed, but COVID-19 vaccines may be needed for years to come and if flu shot pricing is any indication, "post-pandemic" pricing may place still more significant economic burdens on patients and our health system.[24]

COVID-19 vaccines illustrate the need for clinical cost transparency, but this transparency is equally necessary across all HHS-funded trials, for all disease areas and all medical tools – vaccines, treatments, and diagnostics. The cost data that HHS has and receives is relevant across the board to policy debates around medical tool affordability and R&D incentive

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COVID-19 vaccines (2021/2678(RSP)). Motion for a Resolution. [Online] 2021 Oct 13. https://www.europarl.europa.eu/doceo/document/B-9-2021-0519_EN.html

[21] Barber M, Gotham D. Estimated cost-based generic prices for molnupiravir for the treatment of COVID-19 infection. October 2021. https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_molnupiravir_for_the_treatment_of_covid-19_infection.pdf

[22] NIH. Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine. November 16, 2020. https://www.nih.gov/news-events/news-releases/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine

[23] Tin A. Moderna offers NIH co-ownership of COVID vaccine patent amid dispute with government. CBS News. November 15, 2021. https://www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health/#app

[24] Ramachandran R, Dhodapkar M, Ross J S, Schwartz J L. Future of covid-19 vaccine pricing: lessons from influenza *BMJ* 2021; 373 :n1467 https://doi.org/10.1136/bmj.n1467

structures. NIH-funded research, for example, played a part in all 356 new drugs that were approved by the Food and Drug Administration from 2010 to 2019.[25]

Cognizant of the need for public access to cost data, lawmakers and civil society groups in the US and globally have made a number of efforts to achieve greater R&D cost transparency in recent years.[26] The Biden administration can take immediate action, however, and we urge it to do so. In our discussions with officials in the Office of Science and Technology Policy and NIH and in the *JAMA* piece cited above, we have heard that these agencies are philosophically aligned with us on the need for transparency. What we are asking for now is a commitment – from the White House and agency leadership – to turn that alignment into action.

[25] Ledley F, Cleary E, Jackson M. US Tax Dollars Funded Every New Pharmaceutical in the Last Decade. Institute for New Economic Thinking. September 2, 2020. https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade

[26] US Congress. Transparent Drug Pricing Act of 2017, H.R. 4116, 115th Cong. https://www.congress.gov/bill/115th-congress/house-bill/4116/text; US Congress. Prescription Drug Affordability Act, H.R. 3513, 114th Cong. § 601(a). 2015. https://www.congress.gov/bill/114th-congress/house-bill/3513/text?q=%7B%22search%22%3A%5B%22Medicare+%22%5D%7D&resultIndex=7; US Congress. Prescription Drug Affordability Act, S. 2023, 114th Cong. § 601(a). 2015. https://www.congress.gov/bill/114th-congress/senate-bill/2023/text; US Congress. Fair Accountability and Innovative Research Drug Pricing Act, H.R. 2439, 115th Cong. § 39900(c). 2017. https://www.congress.gov/bill/115th-congress/house-bill/2439; US Congress. Fair Accountability and Innovative Research Drug Pricing Act, S. 1131, 115th Cong. § 39900(c). 2017. https://www.congress.gov/bill/115th-congress/senate-bill/1131/text; US Congress. S-B 17, 2017-18 Reg. Sess. (Ca. 2017). https://www.cov.com/-/media/files/corporate/publications/2017/10/california_sb_17_new_requirements_for_drug_manufacturers.pdf; US Congress. H.B. 4005, 79th Leg. Assembly, Reg. Sess. (Or. 2018). https://gov.oregonlive.com/bill/2018/HB4005/; https://healthpolicy-watch.news/76047-2/; Mancini S. Transparency matters: Italy moves against the secrecy surrounding the cost of medicines. MSF. 2020 Sep 23. https://medium.com/@MSF_access/transparency-matters-italy-moves-against-the-secrecy-surrounding-the-cost-of-medicines-4468a6e0ced6; Londeix P. A historic, but also insufficient transparency amendment adopted by French Parliament. Mediapart, 2020 November 25. https://blogs.mediapart.fr/edition/transparence-dans-les-politiques-du-medicament/article/251120/historic-also-insufficient-transparency-amendement-ado; WHO. Improving the transparency of markets for medicines, vaccines, and other health products. WHA Resolution A72/A/CONF./2 Rev.1. 2019 May 28.https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf; In 2016, the US government also approved a Resolution with Pan-American Health Organization countries to "work together with the pharmaceutical sector to improve transparency and access to timely and comprehensive information, including in relation to comprehensive research and development costs and trends, as well as pricing policies and price structures, supply chain management, and procurement practices in order to improve decision-making, avoid waste, and improve affordability of medicines and other health technologies." PAHO. Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies. CD55/10, Rev.1. 2016. https://www.paho.org/hq/dmdocuments/2016/CD55-10-e.pdf