

Transparency Matters: Disclosing the Costs of Publicly Funded Research & Development for COVID-19 Medical Tools and Beyond

MAIN ISSUE: High prices limit people's access to lifesaving vaccines, therapeutics, and diagnostics the world over. The pharmaceutical industry often claims 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. The struggle against COVID-19 in the United States (US) and around the globe only makes clearer the urgent need for medical tools that are accessible and affordable to everyone. Public dollars are pouring into COVID-19 R&D at an unprecedented rate in the US, but there is little transparency regarding what those public funds are used for, including the actual costs of COVID-19 clinical trials.^{1,2,3} Without this information about COVID-19 and all other federally funded R&D, lawmakers and the public cannot assess the fair pricing of products resulting from taxpayer-supported R&D investment, negotiate lower prices based on true costs, nor design policies to orient future innovation toward public health needs.

WHAT WE ARE CALLING FOR: US government agencies that fund R&D, particularly those under the Department of Health and Human Services (HHS) including the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA), should be required to disclose the costs of all clinical trials they fund. 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 the purchases of drugs and other medical products per capita.^{4,5,6} US leadership on transparency would have a significant impact on the biomedical innovation system both globally and domestically, helping to better align prices, product development, and public health, delivering more affordable and accessible products that respond to the health needs of everyone.

Introduction

As an international medical humanitarian organization, Médecins Sans Frontières (MSF), or Doctors Without Borders, witnesses daily the significant gaps in the availability of the necessary vaccines, therapeutics, and diagnostics required to address the health needs of people suffering in humanitarian and medical crises. MSF teams have seen for decades the deadly consequences of populations being unable to access the lifesaving medical products they need. Drawing on these experiences in many different settings, MSF has analyzed how the prevailing monopoly-based system for research and development (R&D) of medical tools forces people around the world to pay high prices, excludes many patients from access altogether, and provides little if any incentive for pharmaceutical and biotechnology corporations to develop tools to meet many pressing public health needs.⁷

The COVID-19 pandemic has both compounded and exposed these existing access issues, not only in the places where MSF works, but all around the globe, including in high-income countries like the United

States (US). This global crisis has given rise to new and urgent needs for medical tools, many of which are still in development. As the pharmaceutical and biotechnology industries rush to develop COVID-19 products, people in the US and around the world are left to wonder how much corporations will charge for the resulting vaccines, therapeutics, and diagnostics, and to whom they will be made available. With the US committing billions of taxpayer dollars for COVID-19 R&D, now is the moment to make meaningful policy changes that can help deliver more affordable medical products to meet the health needs of people everywhere. The current profit-driven and monopoly-based biomedical R&D model prioritizes lucrative markets rather than public health needs and does not make industry accountable for the public dollars it relies upon. In order to address current and prospective access crises and the systemic problems that helped create them, there is a critical first step to take: the US government should stand up for the public's right to know how their money is spent by demanding transparency in R&D.

Development of new tools undoubtedly requires substantial investment, but little is known about the real costs of R&D because the pharmaceutical industry does not disclose detailed, disaggregated information about these expenses. As companies benefit from public funding and resources from US government agencies, the costs of developing COVID-19 and other medical tools should be made crystal clear. Lifting the veil on the cost of R&D would greatly benefit the public and policymakers, not only in the time of COVID-19 but over the long term, equipping them for future debates around the fairness of drug pricing and the appropriate levels of reward for R&D. Right now, corporations hold all the cards, and the public is being dealt a losing hand. The pandemic has seen citizens struggling financially while the nation's billionaires, including pharmaceutical and biotechnology CEOs, experience unprecedented growth in their wealth.⁸ Requiring transparency is an indispensable first step toward achieving the basic accountability in R&D that the public deserves.

Skewed Priorities for R&D, People Priced Out

High prices limit people's access to safe and effective vaccines, therapeutics, and diagnostics all around the world. The current system of biomedical discovery, development, and dissemination not only fails to control exorbitant prices, but neglects therapeutic areas that developers deem insufficiently lucrative – such as antibiotic resistance, or conditions that affect limited or low-income populations.^{7,9} People who live in low- and middle-income countries – the settings in which MSF has traditionally carried out its humanitarian medical programs – are disproportionately impacted by this profit-driven model of drug innovation in which pharmaceutical corporations set prices as high as the market will bear. Increasingly, residents of wealthier nations are also experiencing the hardships and health repercussions of unaffordable drugs.¹⁰ MSF has advocated for decades, alongside many allies, for a more people-centered system that delivers safe and effective medical tools that are affordable and adapted for use in diverse settings. The movement for reform has broadened and intensified in recent years as people in high-income countries like the US find themselves impacted by skewed priorities in biomedical innovation – struggling to afford prescriptions and even rationing lifesaving drugs like insulin.

The global COVID-19 pandemic highlights the urgent need for safe and effective medical tools that are available and affordable to all. While racing to scale up preparedness measures and adapt existing medical activities to the realities of COVID-19, MSF teams opened programs in some wealthier nations for the first time in the organization's history, including the US. The US government has likewise broken new ground in the scale of its commitment of public dollars to R&D for COVID-19 tools, including more

than \$10 billion to flow through agencies under the Department of Health and Human Services (HHS) – National Institutes of Health (NIH), Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) – as well as additional funds through the Department of Defense and the National Science Foundation.^{1,2,3}

This enormous investment of taxpayer dollars should obligate the US to move the world toward an approach to biomedical innovation that aligns prices, product development, and public health. By and large, however, no conditions are attached to these sums to ensure accountability to the public on how the funds are spent, or that they will have affordable access to the resulting products. As US policymakers consider how to address the need for COVID-19 medical tools domestically, it is time for meaningful policy changes that deliver products that respond to the health needs of people everywhere.

Need for Greater Transparency in R&D

In the context of R&D, transparency refers to the provision of easy public access to broad stores of knowledge about medical tools under study or in development, and to the underlying data that generates that knowledge. The public and policymakers need straightforward and complete access to this information to make sure publicly funded R&D projects are truly geared toward meeting public health needs and not just benefiting pharmaceutical company shareholders and executives.

Transparency in five key areas is needed to ensure that the R&D system is fiscally accountable and prioritizes public health:

1. **R&D and manufacturing costs (including clinical trial costs) and all sources of funding:** the public should know how taxpayer money is being spent and how public contribution levels compare with funding levels from other sources (private and philanthropic), so that treatment providers, the government, and other purchasers can assess final product prices and negotiate to make them fair.
2. **Terms and conditions included in R&D funding agreements:** the public should know what strings, if any, the federal government attaches when it agrees to fund R&D projects, to ensure that the resulting products are affordable and accessible.
3. **Prices of vaccines, therapeutics, and diagnostics:** the public should know what, exactly, companies are charging for products in different contexts where they are sold.
4. **Preclinical and clinical trial data:** the public and impartial experts should be able to determine how safe and effective products are, and whether they offer real therapeutic benefit over existing products.
5. **Status of patents and other intellectual property and licensing agreements:** the public should know who has the “rights” to produce and supply medical products and be able to challenge any barriers limiting access to needed products.

The primary focus of this briefing document is transparency of R&D costs, and clinical trial costs in particular. This is because of the significant impact such disclosure could have on medical tool pricing and development, and because reform is eminently achievable in the US, as an existing federal platform already in use for disclosing clinical trial results can be adapted to report costs. Transparency in all five key areas, however, combined with the actions of an engaged public and responsible policymakers, promises to serve public health. Increased disclosure would accelerate and streamline innovation and

competition; ensure ethical practices and prioritization of patient safety; bring down costs and prices; and help focus R&D activity where health needs are highest and therapeutic benefits greatest.

The US has taken some significant action to achieve greater transparency in one area of R&D: more than 10 years ago, Congress took the important step of 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.^{11,12} The availability of such data helps prevent dangerous selective “cherry-picking” of data (drug companies have incentives to suppress negative results, and have done so in years past), helps avoid costly and inefficient duplication of research for urgently needed new medical tools, and helps safety regulators and treatment providers make more informed assessments about the safety and efficacy of new products.^{13, 14, 15} Enforcement of this requirement to share clinical trial results needs significant strengthening, however, and in other key ways, the US lags on transparency – and has even become less transparent in the last two decades.^{16, 17, 18, 19, 20, 21} While the US compels the sponsors of clinical trials of drugs and medical devices to register these trials and report trial *results*, the US government currently permits drug developers to keep the *costs* of clinical trials secret—even when it funds those trials.

Numerous efforts in the US and globally have tried to achieve greater transparency in the biomedical R&D process. In recent years, proposals at the federal level have sought to mandate R&D cost disclosure, ranging from legislation that would compel manufacturers of all FDA-approved drugs to disclose R&D expenditures, to more modest legislation with bipartisan support requiring the pharmaceutical industry to disclose R&D costs in justifying price increases above a certain threshold.^{22,23,24,25} Some US states have also enacted legislation to require industry to justify certain price increases, including disclosure of R&D costs.^{26,27} The pharmaceutical industry has used its extraordinarily powerful lobbying presence in the US to fight such initiatives.²⁸ This is because information asymmetry between the industry, on the one hand, and the public, government, and other purchasers on the other, serves the industry's ends. Without full and accurate information on R&D costs, governments and purchasers have limited negotiating power, and pharmaceutical companies can charge just about any price they want for their drugs.

Increasingly, governments around the world are considering actions to rectify this power imbalance. The 72nd World Health Assembly (WHA) passed a non-binding resolution in 2019 urging member states to create laws and policies that expand and protect transparency in various components of the biomedical innovation system, especially pricing data.^{29,30} Calls from legislators, policymakers, and civil society groups for greater transparency made in the lead-up to and after the resolution's passage have been renewed in the COVID-19 pandemic and become more urgent than ever.^{31,32,33,34,35} In July 2020, as it recovered from a devastating first wave of the novel coronavirus, Italy passed a landmark law requiring pharmaceutical corporations to disclose previously secret data about public subsidies received for drug development, R&D costs, sales revenue, marketing costs, the status of relevant patents, and prices charged in other countries.³⁶ The new decree promises to undercut pharmaceutical corporations' ability to charge exorbitant prices, which are more often than not disconnected from actual R&D costs and funded with Italian taxpayers' money.³⁷ France also recently adopted a modest amendment asking pharmaceutical companies to disclose public funding received for R&D.³⁸ Such initiatives - Italy's more robust law, especially – demonstrate the kind of concrete steps that governments motivated to achieve greater transparency can take on behalf of the public they serve.

Why Require Clinical Trial Cost Transparency of Federal Agencies and Their Grantees?

One crucial step US lawmakers can take right now to address ever-increasing drug prices is to require federal agencies under HHS – including NIH, the largest public funder of biomedical research in the world, and BARDA, the chief disburser of funds for COVID-19 R&D – to disclose the cost of clinical trials that these agencies fund.³⁹ Mandating disclosure of clinical trial costs by federal agencies and their grantees would be a critical step towards lowering the prices of medical tools in two ways:

1. A detailed accounting of clinical trial costs will allow policymakers and the public to negotiate fair final product prices and evaluate the pharmaceutical industry's claims of the need for high prices in order to recoup high R&D costs.⁴⁰
2. Accurate cost data will allow policymakers to design policy mechanisms that can incentivize innovation without the monopoly pricing associated with the patent system, such as grants and prizes.⁴¹

Clinical trials represent the largest percentage of R&D expenditure, so having reliable data on clinical trial costs would provide essential insight into overall R&D costs.⁴² NIH's data would be especially illuminating, as the agency's spending has contributed to every new drug approved for marketing between 2010 and 2016.⁴³ As a result of the current secrecy surrounding clinical trial costs, existing studies of pharmaceutical R&D costs rely primarily on opaque, self-reported data from pharmaceutical companies and/or on proprietary databases. Studies that rely on these curated figures and/or certain limited forms of information from public databases (e.g. Securities and Exchange Commission filings, which include only publicly traded companies and do not disclose product-specific data) paint a picture of expenditures that is incomplete and distorted.⁴⁴ The most widely cited estimates of the average cost of developing a drug – \$802 million to \$2.6 billion – are based on industry-funded studies whose methodology has been widely challenged by observers, and even by pharmaceutical industry leaders, for including spurious, inflationary factors.⁷

There is ample reason to doubt the industry's narrative that R&D costs are what actually drive high prices. For example, when the company Pharmasset developed the breakthrough hepatitis C drug sofosbuvir, it anticipated that it could "profitably sell the drug in the United States for \$36,000" for a standard treatment. But the large multinational pharmaceutical corporation Gilead Sciences purchased Pharmasset before sofosbuvir reached the market, and set its price at \$84,000, instead.⁴⁵ Recent studies show that prices in the US "generates substantially more than the companies spend globally on their research and development",⁴⁶ and that revenues on 10 cancer drugs approved between 2006 and 2015 are "substantially higher than the preapproval research and development spending."⁴⁷

Moreover, even as pharmaceutical companies justify high prices of medicines with R&D costs, they maintain that "prices should reflect the therapeutic value of medicines and positive outcomes for patients and society, rather than simply the cost 'input' of an individual medicine" – suggesting that medicines are not, in fact, priced on the cost of development.⁴⁸ In June 2020, for example, Gilead Sciences announced that its drug remdesivir, an investigational drug authorized for use in treating certain severe COVID-19 cases, would be priced at \$2,340 for a five-day treatment course for most countries in their "commercial" market, and higher in the US, at \$3,120 per treatment. This price has drawn criticism, especially since a recent pricing study estimated the manufacturing cost of remdesivir to be about \$9 for a 10-day treatment course.^{49,50}

Rather than basing the price on manufacturing costs and making the drug affordable to all during the pandemic, Gilead pegged its pricing instead to remdesivir's potential to reduce hospital stays by an estimated four days.^{51,52} This pricing approach is galling, not only because it uses high fees from hospitals to justify high prices for drugs, but also because it ignores the large investment of US tax dollars that went into remdesivir's R&D.⁵³ Further, a clinical trial launched by the World Health Organization announced interim results in October 2020 showing that remdesivir had little or no effect on overall mortality, initiation of ventilation, and duration of hospital stay in hospitalized patients.⁵⁴ Remdesivir's apparent lack of efficacy underscores the need for greater transparency – not only into costs, but clinical trial results, as there is evidence suggesting Gilead withheld negative clinical trial data in its possession to boost sales of the drug.¹³

As the US now commits billions more public dollars to R&D of COVID-19 vaccines, therapeutics, and diagnostics, taxpayers have every right to know how resources are being spent in order to demand fair prices to ensure that they are not forced to pay twice for the development of needed medical tools – once through their tax dollars and again through exorbitant prices at the pharmacy.

What Can Be Done Now? Taking Action for Enduring Impact

Lawmakers can and should act immediately to ensure transparency for publicly funded clinical trials. Having taken the initiative more than 10 years ago to expand ClinicalTrials.gov and compel disclosure of clinical trial results there, Congress and HHS should begin enforcing this mandate effectively and use the same platform to publicly report the costs of all clinical trials funded by federal agencies under HHS.

Expanding sharing of clinical trial cost data will not only help increase access to medicines, it will facilitate public oversight, build trust, and help protect federal agencies' credibility. Disclosure of clinical trial costs faces no legal barriers, and the existing ClinicalTrials.gov database provides a built-in structure for presenting specific clinical trial cost data, since the website is already designed to collect and display detailed information about each registered trial. Researchers at the New York University School of Law have pointed out that only small changes would be necessary to include the NIH's cost data on the website, and that Congress can achieve this reform by amending the statute that governs ClinicalTrials.gov.⁴⁴ Lawmakers could require that HHS post on ClinicalTrials.gov the cost data they already possess for any HHS-funded clinical trial, and that all current and future sponsors of HHS-funded clinical trials submit complete cost data to HHS for posting upon study completion.⁴⁴ HHS could also implement clinical trial cost sharing through rulemaking. Mandating clinical trial cost disclosure would only be the first step toward achieving the transparency needed to better align biomedical innovation with human need, but it is an essential one and must happen now.

Every day, MSF staff confront significant gaps in the availability of the necessary vaccines, therapeutics, and diagnostics to address the health needs of those they aim to care for – gaps that contribute to preventable deaths and exacerbate ongoing humanitarian and medical crises. These access issues stem from a biomedical innovation system that fails to:

- deliver affordable products
- deliver medical tools for diseases that are not financially lucrative
- prioritize R&D according to public health needs
- use scientific and financial resources efficiently and effectively.⁷

US action to increase transparency will not only hasten an end to the COVID-19 pandemic by helping ensure that the fruits of its historic investment in COVID-19 R&D will be affordable and accessible to everyone, it can also make significant and enduring inroads in addressing these longstanding failures of the current medical innovation system – failures increasingly felt both domestically and abroad. As the largest single contributor to R&D funding globally, US leadership on transparency will not only have an enormous impact on R&D in the US, but also set a new standard against which all funders across the global community will be measured.^{55,39} Transparency will empower both the US public and the world community to have a meaningful say in the R&D projects they help fund and gain access to the medical tools their lives depend on.

How Secrecy Around the Costs of Clinical Trials Hurts Those MSF Serves

In its medical programs, MSF grapples with two major problems perpetuated by secrecy around clinical trial costs and details: misalignment between R&D priorities and global disease burden; and prohibitively high prices of essential vaccines, therapeutics, and diagnostics. R&D neglects populations and therapeutic areas not deemed immediately profitable by the pharmaceutical industry.

As MSF responded to the 2014 Ebola epidemic in West Africa – the largest ever outbreak of one of the world’s most deadly diseases – front-line healthcare workers were severely hampered by the lack of effective medical tools. Although Ebola had emerged decades before, R&D had been limited because the disease had been perceived as causing only small-scale outbreaks in poor rural communities in sub-Saharan Africa. MSF has likewise struggled to treat thousands of patients for the parasitic diseases Chagas and visceral leishmaniasis, historically neglected in R&D efforts due to the smaller, poorer populations most affected. Pediatric HIV and TB have become rare in wealthy countries, so the needs of millions of children living with HIV and TB around the world have also been consistently overlooked. The lack of private sector interest in developing and testing new treatment regimens for diseases like TB has spurred MSF to become directly involved in R&D efforts – including funding and conducting clinical trials.⁷ Greater R&D cost transparency from corporations would facilitate public-interest efforts like MSF’s and also equip governments to catalyze or stand in for private sector activity.

When crucial breakthroughs finally do arrive, high prices set by pharmaceutical corporations, justified by their claims about clinical trial and other R&D costs, too often place new medical products out of reach of the people whom MSF teams serve. MSF has been hindered by high drug prices in its efforts to treat hundreds of thousands of people living with HIV who require lifelong antiretroviral treatment.⁵⁶ Due to expensive vaccines, MSF has also faced hurdles in scaling up immunization against pneumonia, the leading cause of death for young children worldwide.⁷

MSF’s experience treating drug-resistant TB – with which nearly half a million people fall ill globally each year – is also starkly illustrative. After almost 50 years without progress in the treatment of TB, the Johnson & Johnson (J&J) drug bedaquiline received FDA approval in 2012, holding the promise of an oral treatment regimen that is not only more effective than existing injectable drugs for drug-resistant TB, but also has less debilitating side effects and is better-suited for use in under-resourced settings. However, despite the substantial public and philanthropic funding and support that went into bedaquiline’s R&D⁵⁷ – including direct participation by MSF in testing the drug – bedaquiline’s high price delayed scale-up so severely that MSF ultimately mounted a public campaign to reduce the price.⁵⁸

Using cost estimates made by university researchers, MSF contested the company's claims that bedaquiline's price in countries with high burdens of TB was "not-for-profit" – a claim J&J is now making about the prospective price of its experimental COVID-19 vaccine. Under MSF and public pressure, J&J did ultimately cut bedaquiline's price significantly. The company never, however, publicly disclosed the actual costs on which it had purportedly based its pricing.

Similarly, newly available direct-acting antiviral (DAA) medicines for hepatitis C, such as Gilead's sofosbuvir, have the potential to transform outcomes for this deadly disease by shortening treatment length, eliminating serious side effects, and radically improving cure rates. MSF conducts screening, diagnosis, and treatment for hepatitis C in multiple countries where generic DAAs can be used, but in countries where patents prevent use of generics, expanding access to these breakthrough drugs has been hampered in large part by Gilead's price tag. While Gilead launched sofosbuvir at \$84,000 per treatment in the US, researchers have calculated that the cost of producing sofosbuvir is a small fraction of the drug's price (<\$50 per treatment).⁵⁹ Gilead has fought efforts to compel transparency into its R&D costs, including requests from the US Senate.⁴⁵

This briefing document complements the report "Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations" by the Technology Law & Policy Clinic and Engelberg Center on Innovation Law & Policy of NYU School of Law.⁴⁴

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