GHTC
global health technologies coalition

POLICY CURES RESEARCH.

DOING WELL by DOING GOOD

Why investing in global health R&D benefits the United States and the world

Policy Cures Research

Policy Cures Research is an independent, non-profit global health policy and research organization whose mission is to promote the advancement of health for the world's poorest people and populations. The organization provides research, information, decision-making tools and strategic analysis for those involved in the development of new drugs, vaccines, diagnostics, and other tools for global health priorities including neglected diseases, emerging infectious diseases, and sexual & reproductive health issues.

Its flagship program, the G-FINDER project, tracks and reports annual investment into research and development (R&D) for new products and technologies to address a range of global health challenges and has been running since 2007. In addition, global health policy, normative, advocacy, and funding organizations engage Policy Cures Research to undertake targeted, in-depth research and analysis on a wide range of global health R&D facets, from historical sector funding trends, product pipelines and product prioritization exercises, to health and economic impact modeling, funding gap analyses and resource mobilization strategies.

Ultimately its aim is to provide governments, philanthropic funders civil society organizations and product developers with the information they need to make optimal, product-related R&D policy and funding decisions to improve the health outcomes of those who are most underserved.

Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is the premier advocacy organization focusing on R&D of new global health technologies. GHTC is a coalition of more than 45 non-profit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people.

The coalition promotes policy solutions that support R&D across a range of global health areas, from HIV/AIDS, malaria, and tuberculosis to epidemic preparedness, maternal and child health, neglected tropical diseases, antimicrobial resistance, and more.

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Key findings

This report provides in-depth analysis of US government investment in global health research and development (R&D), as well as analysis of the health impact and economic returns from these investments. First, it analyzes funding trends over time for US government investment in three broad categories of global health R&D: neglected diseases, which include HIV/AIDS, tuberculosis (TB), malaria, and other historically neglected pathogens; emerging infectious diseases, which include COVID-19, Ebola, and other epidemic-prone diseases; and sexual & reproductive health issues. Next, it examines the contributions of the US government to advancing the pipeline of products for neglected diseases and emerging infectious diseases (excluding COVID-19), with individual case studies highlighting examples of products created, the lives they have saved, and cost saving they have produced. Finally, it examines the broader returns from these investments, including how they drive improved research capacity and economic development in partner countries and deliver economic and health benefits in the United States as well.

This report aims to inform Congress, the Executive Branch, and other key stakeholders as they make policy and budget decisions that impact the future of US leadership in global health R&D.

US government investments in global health R&D have been indispensable to developing new drugs, vaccines, and other tools to address urgent global health challenges.

- Between 2007 and 2022, the US government invested just under $46b in R&D for neglected diseases, emerging infectious diseases, and sexual & reproductive health issues.
  - For context, in 2022 alone, the US government spent $751b on defense and $1.34 *trillion* on Medicare and Medicaid.
  - Recent estimates of the cost of developing an innovative drug range from $161m up to $4.5b.
- This relatively modest investment played a key role in advancing 67 new technologies approved since 1999 for neglected diseases and non-COVID-19 emerging diseases – including 12 new products for TB, 12 for Ebola, and 11 for malaria.
- The US government also supported 45 Food and Drug Administration (FDA) approved or authorized products for COVID-19 through the Biomedical Advanced Research and Development Authority alone; with an even wider range of products supported across other agencies.
- US investment backed another 261 promising products in late-stage development – including 206 candidates for neglected diseases and 55 candidates for non-COVID-19 emerging infectious diseases.

New tools advanced by the United States are already saving lives and reducing healthcare costs around the world.

- Pretomanid is a groundbreaking new treatment for drug-resistant TB developed with support from the National Institutes of Health and US Agency for International Development (USAID). Its use has reduced treatment time from up to 18 months to 6 months and dramatically improved outcomes, while also reducing costs. If all drug-resistant patients were changed to pretomanid-based regimens, it could generate global healthcare cost savings of up to $740m per year.
- Two new long-acting HIV/AIDS prevention options advanced with US support have potential to transform global HIV/AIDS prevention efforts by offering an alternative to daily pills for at-risk groups. Long-acting cabotegravir, delivered via a single bi-monthly injection, could avert 45% of new infections in the United States, and up to 28% of potential future HIV infections in low- and middle-income countries (LMICs). The dapivirine vaginal ring, a monthly product offering discreet protection, is another breakthrough option for use by women at high risk of infection.
- The US government's multi-agency Operation Warp Speed supported development of four FDA-approved or authorized COVID-19 vaccines which have since been deployed around the world. These vaccines helped to prevent 14.4m deaths in the first year of the pandemic alone, contributing to COVID-19 vaccines' estimated $895b saving in direct healthcare costs between December 2020 and March 2022.

US funding for global health R&D helps strengthen R&D capacities in partner countries and supports their economic development.

- US funding, which has flowed to more than 43 different LMICs since 2007, helps partner countries strengthen their domestic R&D and manufacturing capabilities.
- Improved health resulting from the use of new technologies removes a significant barrier to economic development. Costs of managing malaria alone can consume up to 8% of families' budgets in endemic regions, and cause a 1.3% reduction in gross domestic product (GDP).

US investments in global health R&D also directly benefit the US economy by fueling job creation and catalyzing additional industry investment and economic activity.

- Between 2007 and 2022, at least 86% of all funding the US government directed to global health R&D was re-invested in American companies and institutions.
- This investment has created an estimated 600,000 new American jobs and generated $104b in additional economic activity.
- Government R&D funding also spurs private sector R&D investment. Every $1 of public funding spent on basic research will, over the following eight years, generate an additional $8.38 in industry investment, meaning US investments in global health R&D from 2007 to 2022 will ultimately generate an additional $102b in industry investment.
- Government R&D funding yields additional longer term economic benefit from the scientific knowledge generated that leads to future discoveries. Every dollar of public basic research investment yields knowledge that will go on to generate 43 cents in annual benefits every year in the future by spurring new innovations, meaning US government investment in global health research between 2007 and 2022 will go on to inspire further innovations worth $255b in long-term benefits to the American economy.

US investments in global health R&D also protect the health and security of Americans, who are increasingly at risk from neglected and emerging diseases.

- US residents are increasingly vulnerable to neglected and emerging diseases, meaning that new global health technologies advanced through US investments also increasingly have the potential to directly benefit people in the United States as well as address global burden.
- While the COVID-19 pandemic, as well as recent Ebola, Zika, and mpox outbreaks, have demonstrated the threat that emerging infectious diseases pose to Americans, many neglected diseases are also gaining a foothold in the United States.
  - Climate change has expanded the regions in which the triatomine bug, which carries Chagas' disease and the *Aedes aegypti* mosquito, which carries dengue, Zika, and chikungunya, can thrive, leading to a rise in infections.
  - Last year saw the first incidents of locally acquired malaria since 2003, across four different states.
  - Cases of leprosy have also been identified across the United States with upwards of 150 cases reported annually over the past decade.

Despite the strong returns delivered through these investments, US funding for global health R&D is failing to keep pace with growing need and increasing health risks.

- US government funding for R&D for emerging infectious diseases has grown substantially in recent years, largely driven by emergency responses to individual crises like Ebola, Zika, and COVID-19; but funding for R&D for neglected diseases and sexual & reproductive health issues has not seen similar growth.
  - From 2020 to 2022, the United States contributed $8.0b to R&D for COVID-19, more than that invested in R&D for all neglected diseases and sexual & reproductive health issues combined ($6.4b).
  - In 2022, US government funding for neglected disease R&D fell by 11%.
- USAID, which plays an important role in advancing health technologies designed specifically for the needs of low-resource settings worldwide, has decreased its support for global health R&D significantly in recent years, from an average of $117m from 2007 to 2012, down to $83m in 2020. While funding increased to an all-time high of $129m in 2022, $50m of that growth was specifically for COVID-19.
- In 2022, the US government's investment in global health R&D accounted for just over two-tenths of one percent (0.21%) of the nation's GDP.

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Introduction

COVID-19 made the world acutely aware of the harm that can be caused by uncontrolled disease and of the massive benefits that can be delivered by a comparatively small investment in funding research for therapeutics, vaccines, and diagnostics. The US government led the world in supporting research and development (R&D) for COVID-19 and continues to lead the world in funding the R&D responses to a wide range of neglected and emerging diseases. Longstanding global health challenges like HIV/AIDS, malaria, and tuberculosis (TB) continue to cause massive loss of life around the world and hold back the development of the low- and middle-income countries (LMICs) that bear most of their burden. And, as with COVID-19, the United States is not immune to the impact of what are often thought of as purely "tropical" diseases. From the spread of malaria, dengue and Chagas' disease across multiple states, cases of leprosy appearing in Florida, to the ongoing threat from epidemic diseases like Ebola and Zika, US citizens remain at risk from these diseases both at home and abroad.

This report charts the history of US government support for R&D across three global health categories – poverty-related neglected diseases, emerging infectious diseases, and sexual & reproductive health issues – and briefly outlines some of the health and economic returns from these investments. It tells the story of US funding over the last 16 years, including its key role in the basic research that underlies many scientific advances, and its recent stagnation and decline. It also quantifies the new vaccines, therapeutics, diagnostics, and other tools for neglected and emerging diseases that US support helped to bring about, and looks ahead to the next generation of products it is currently supporting.

Alongside case studies showing the global health impact of US-supported innovations, this report also highlights research on the broader impact of these investments on R&D capabilities and wider economic development in LMICs and on the benefits to the US economy – including the American jobs it directly supports and the investments from the pharmaceutical industry it helps to catalyze.

This report aims to inform Congress, the Executive Branch, and other key stakeholders as they make policy and budget decisions that affect the future of US leadership in global health R&D.

What kinds of research and development are included in this report?

- This report measures US public R&D funding based on the criteria set out in the annual G-FINDER reports. For the purpose of the overall funding analysis presented in the first half of this report, and the subsequent economic impact estimates, this report includes *all* US government spending on basic research and product development from 2007 (when the G-FINDER survey began) to 2022 (the most recent year covered) across the three global health areas included in the survey: neglected diseases,[i] which includes HIV/AIDS, TB, malaria, neglected tropical diseases, and other historically neglected health areas; emerging infectious diseases, which includes COVID-19, Ebola, and other epidemic-prone diseases on the World Health Organization (WHO) R&D Blueprint priority pathogens list; and sexual & reproductive health issues, as well as funding jointly targeting more than one of these areas or core funding to organizations active across multiple areas. See the appendix for more details.
- However, for the purpose of attributing US government responsibility for individual products presented in the second half of this report, in the absence of reliable data covering product-specific investment in R&D for COVID-19 or sexual & reproductive health issues, these have been excluded from this analysis. The list of products the US government helped to develop therefore excludes these extremely important areas, meaning our product count significantly understates the full size of the US contribution at a product-specific level.

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i The burden of the disease or condition disproportionately affects people in LMICs; there is no existing product to treat/prevent the disease or condition, or a product exists but is poorly suited for use in LMICs; and there is no commercial market to stimulate R&D by industry.

Understanding the US government's investment in global health R&D

How much has the US government invested in global health R&D?

The US government provides critical investment for developing new drugs, vaccines, diagnostics, and other global health products.

In the 16 years from 2007 to 2022, the US government invested just under $46b in R&D for neglected diseases, emerging infectious diseases, and sexual & reproductive health issues, including a total of $5.4b in 2022. To put this in context, in 2022 alone, the US government spent $751b on defense and $1.34 *trillion* on Medicare and Medicaid,[1] while recent estimates of the cost of developing a single innovative drug range from $161m to up to $4.54b.[2ii]

The US government is the leading funder of global health R&D. In 2022, its investment accounted for over half (55%) of all global funding (including industry, philanthropic and other public funding).

Despite the United States' global leading role in global health R&D, its total funding is modest when viewed in the context of the US economy overall. In 2022, the US government devoted $21 per $100k of its gross domestic product (GDP) to global health R&D, or just over two-tenths of one percent (0.21%).

FIGURE 1: US government share of funding for global health R&D in 2022

ii This range comes from a meta-analysis examining 22 articles with 45 unique cost estimates of the average pre-capitalized costs for developing new molecular entities.

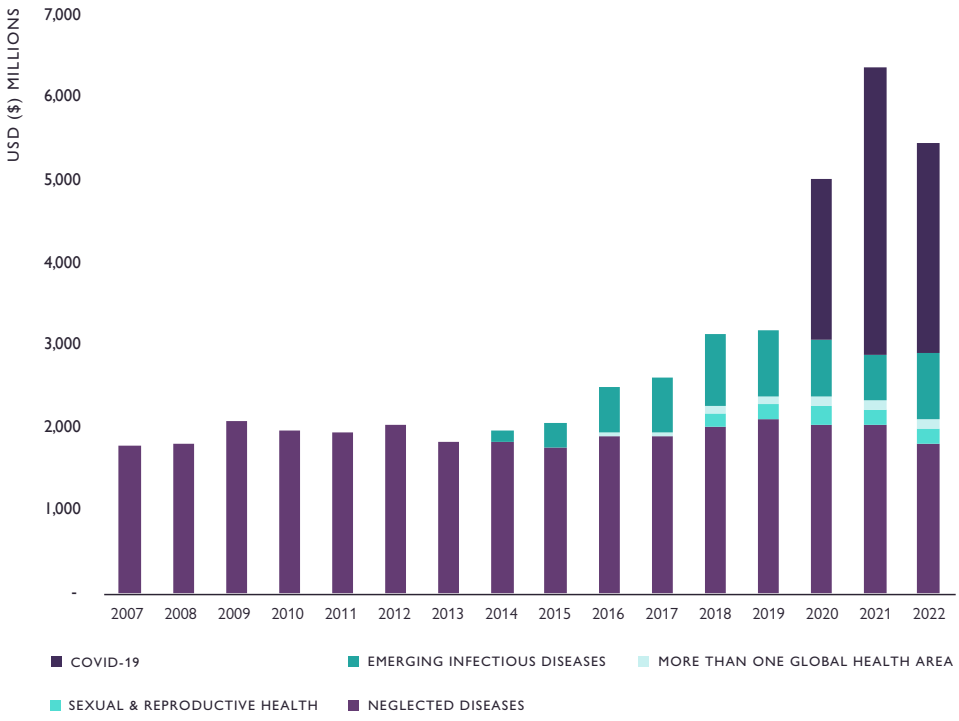
Which areas does the US government support?

In 2022, following a sharp overall drop in funding (–14%) partly driven by inflation and partly by the winding down of COVID-19 R&D, the largest share of US government funding still went to emerging infectious diseases ($3.3b, 61%), followed by neglected diseases ($1.8b, 33%). Sexual & reproductive health issues received just $0.2b (3.3%), with the remaining $0.1b (2.4%) covering more than one global health area.

As the figure below indicates, the focus of US support has shifted significantly over time, with growth in resources devoted to R&D for emerging infectious diseases in large part due to the responses to health emergencies including the COVID-19 pandemic, and Ebola and Zika outbreaks. In fact, investments in COVID-19 alone comprised 47% of this US government funding between 2020 and 2022. Prior to the COVID-19 pandemic in 2019, the US government allocated two-thirds of its funding to neglected diseases ($2.1b, 66%), more than double the share given to emerging infectious diseases ($0.8b, 26%).

While there has been significant growth in R&D funding for emerging infectious diseases, the same cannot be said of neglected diseases and sexual & reproductive health issues. Funding for R&D for neglected diseases has fluctuated over the years, seeing a significant 11% ($229m) decline in 2022, while funding for sexual & reproductive health issues has remained relatively stagnant since the G-FINDER survey began tracking it in 2018.

FIGURE 2: US government funding by global health area



Neglected diseases

Of the $1.8b the US government gave to neglected diseases in 2022, the largest share went to HIV/AIDS ($999m, 56%), followed by TB ($315m, 18%), and malaria ($208m, 12%). This picture has remained consistent since 2007, and over the past 16 years more than four-fifths (83%) of US government neglected disease funding has been given to these 'big three' diseases. This share is even higher than their share of overall global funding (68% in 2022), with the difference particularly pronounced for HIV/AIDS, which in 2022 received more than half of US funding but only 34% of the global total.

In 2022, the next largest shares of neglected disease funding went to diarrheal diseases ($65m, 3.6%), helminth (worm) infections ($42m, 2.4%), parasitic kinetoplastid diseases ($39m, 2.2%), and *Salmonella* infections ($33m, 1.8%). The remaining $91m (5.1%) was split across 11 other neglected disease areas and R&D targeting more than one neglected disease.

Emerging infectious diseases

Between 2020 and 2022, the United States contributed $8.0b to COVID-19 basic research and product development. It was the leading global funder of the COVID-19 R&D response, accounting for 48% of overall worldwide funding. Funding for other WHO R&D Blueprint priority pathogens, including as-yet-undiscovered pathogens ('Disease X') peaked at $872m in 2018 – due to the response to Ebola in the Democratic Republic of Congo (DRC) – before dropping to $543m in 2021, and bouncing back to $793m in 2022.

In 2022, filoviral diseases (which include Ebola, and the Marburg virus responsible for 2023 outbreaks in Equatorial Guinea) received the largest share of (non-COVID-19) emerging infectious disease funding ($217m, 27%), followed by R&D targeting a potential future Disease X ($158m, 20%) and Zika ($89m, 11%). Other non-COVID-19 coronaviruses (like Middle-East Respiratory Syndrome [MERS] and Severe Acute Respiratory Syndrome [SARS]), mpox (formerly monkeypox), and Lassa fever received similar shares of funding: respectively $72m, $68m and $60m. Nipah and its relatives, and the Bunyaviral diseases Rift Valley Fever and Crimean-Congo Hemorrhagic Fever received just under 5.0% each ($39m and $37m, respectively) and the remainder was evenly split between chikungunya and emergent non-polio enteroviruses ($27m each).

Sexual & reproductive health issues

US government funding for sexual & reproductive health issues R&D has remained relatively stagnant since 2018 – the year in which this data was first captured in the G-FINDER survey. From $154m in 2018, funding rose over two consecutive years to a peak of $214m in 2020 (up $60m, 39%), before dropping back to $181m in 2022.

Since 2018, US government funding of sexual & reproductive health issues R&D has consistently focused on sexually transmitted infections (STIs), which received $69m (38%) of funding in 2022. Total US government funding for human papillomavirus (HPV) and HPV-related cervical cancers peaked at $48m in 2020 and has since dropped to $37m. Funding for contraception followed the same pattern with its 2022 total of $35m slightly above 2018 levels. The smallest shares of funding in 2022 went to multipurpose prevention technologies (MPTs) designed for contraception and STI prevention ($26m, 14%), pre-eclampsia/eclampsia ($13m, 7.3%), and post-partum hemorrhage ($0.6m, 0.3%).

Funding across multiple global health areas

Funding applicable to more than one global health area hit a peak of $129m in 2022. Globally, much of this multi-disease funding comes in the form of untied core funding for R&D organizations, but, in the case of the US government, this was mostly funding for platform technologies. These are transferable technologies and techniques that are intended to be adapted for use against more than one disease, like the mRNA technology that underlies several COVID vaccines, which is being adapted for use in other areas. The US government's multi-disease funding has increased by a total of $98m (322%) from 2016 after several years of rapid growth. Half of this has gone to platform technologies ($303m, 50%), followed by $205m (33%) for multi-disease vector control products (products targeting creatures which can spread several diseases, mostly the mosquito which transmits the dengue, Zika and chikungunya viruses), and $99m (16%) for other uncategorized R&D (typically multi-disease projects). Unlike philanthropic funders and many European governments, the United States provides only a small portion of its R&D funding in the form of core funding of a multi-disease R&D organization ($5.4m, 0.9%), relying instead on its well-developed public and private R&D infrastructure and carrying out research in-house or contracting directly with the private sector or universities.

Consistent, not reactive, funding is needed to maximize the benefits from R&D

The surge of emergency supplemental funding which accompanied the COVID-19 pandemic and, to a lesser extent, the West African and DRC Ebola epidemics spurred huge advances in vaccine, diagnostic, and therapeutic technology. At its peak, in 2021, the US government provided nearly $3.5b in funding for COVID-19 R&D, roughly equal to its total funding across every other priority emerging infectious disease over the six years leading up to the pandemic. Ebola R&D funding more than doubled, to $254m, in the second year of the West African epidemic, slipped slightly as that epidemic was brought under control, and then nearly doubled again – to $433m – when the *next* outbreak began in the DRC. But the advances generated by these spikes in funding would not have been possible without the foundations laid by years of basic research and product development, which provided the platforms and R&D infrastructure on which our responses to COVID-19 and Ebola were built. When faced with the West African Ebola epidemic in 2014, the world lacked the kind of skills and knowledge necessary to develop products on the timelines required by the disease's exponential spread. We now have the tools to cure Ebola, but delivered much later than we could or should have and access remains a challenge.

It is much easier, and ultimately more cost effective, to maintain the COVID R&D infrastructure that was pulled together in eight months at the cost of billions of dollars than to let it wither before hurriedly rebuilding it in the wake of the next crisis. Already, the tools developed for COVID-19 and Ebola – tools like mRNA vaccines and the scaled-up production of monoclonal antibodies – are helping us make progress against other, less prominent diseases. Maintaining that progress is an investment in defeating our current global health challenges and in preparing to deal with the next wave.

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A whole-of-government approach to global health R&D: Funding by agency

Several US agencies support the US government's global health R&D efforts, with the US Agency for International Development (USAID), the Department of Defense (DoD), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Centers for Disease Control and Prevention (CDC), each providing substantial financial contributions. All the various agencies contribute in different, but complementary ways, reflecting their unique strengths, priorities, structure, and size.

Agencies leading the US government's global health R&D efforts

- **US AGENCY FOR INTERNATIONAL DEVELOPMENT:** Advances the development, introduction, and scale-up of affordable and appropriate health technologies to address diseases and conditions impacting LMICs, primarily through external funding. Focus is on late-stage research and trials in low-resource settings.
- **DEPARTMENT OF DEFENSE:** Supports R&D for infectious diseases that pose a risk to US service members abroad or to US national security. Research activities span all areas of development, from basic research to late-stage development.
- **DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS):** Oversees NIH, CDC, BARDA, and the Food and Drug Administration (FDA).
  - **NATIONAL INSTITUTES OF HEALTH:** The principal biomedical research agency in the United States. Conducts biomedical research in-house, as well as providing funding externally, with a primary focus on basic and early-stage research.
  - **BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY:** Supports development of medical countermeasures against threats to public health, including emerging infectious diseases, pandemic influenza, and antibiotic resistance. Research focus is on translational and late-stage development of products.
  - **CENTERS FOR DISEASE CONTROL AND PREVENTION:** Protects people in the United States and abroad through disease surveillance, rapid outbreak response, and research to develop health tools and evaluate health interventions.
  - **FOOD AND DRUG ADMINISTRATION:** Regulates the safety and efficacy of health products marketed in the United States, as well as works to strengthen global regulatory capacity and advance international standards.
- **DEPARTMENT OF STATE:** Coordinates the President's Emergency Plan for AIDS Relief (PEPFAR) and helps set priorities for US global health assistance.

NIH

The NIH plays the pre-eminent role in global health R&D, leading the way on the basic research that unlocks the path to clinical development and consistently provides more funding than any other organization globally – more, even, than any other national government. Drawing on an annual budget of more than $48b, the NIH has provided three-quarters of US government funding over the past 16 years. It was the single largest funder of COVID-19 R&D at $4.2b, more than the combined total contributed by industry. Outside of COVID, the NIH's funding steadily rose from $1.5b in 2007 to hit a peak of $2.5b in 2019, before dropping back slightly to $2.4b in 2022 as funding pivoted to COVID-19.

The NIH's funding has focused on HIV/AIDS, TB, and malaria, which collectively received three-fifths of its non-COVID funding in 2022. The NIH plays a key role in these diseases, particularly HIV/AIDS, with its contributions accounting for 65% of *global* HIV/AIDS funding over the past 16 years.

BARDA

BARDA was the second largest US government funder, after the NIH, providing 10% of US government funding since 2007. In the past five years, its funding has tripled, from $334m in 2018 to $1.1b in 2022, peaking at $1.4b in 2020 due to its funding for COVID-19 R&D.

In contrast to the NIH, which invests heavily in neglected disease R&D, BARDA's investments in global health R&D have almost exclusively been focused on emerging infectious diseases, including $3.2b to COVID-19 and $1.0b to Ebola, largely through emergency supplemental funds provided to the agency in response to these crises. This focus reflects both BARDA's mandate to protect US health security and the fact that its investments are guided by the health issues deemed by the Department of Homeland Security to be material threats to the United States.

DoD

The DoD was the third largest US government funder, providing 6.9% of US public funding since 2007 and tripling its funding from $105m in 2007 to $325m in 2022. The DoD's funding has focused on emerging infectious diseases and the creation of platform technologies designed to be adapted to various current and potential threats faced by US service members around the world. In 2022, it contributed 41% ($134m) of its funding to these platform technologies.

USAID

USAID's contributions to global health R&D have totaled $1.7b over the past 16 years. However, in contrast to other US government funders covered above, its contributions have trended downward – from an average of $117m between 2007 and 2012, down to $83m in 2020 (down $34m, –29%) – before bouncing back to an all-time high of $129m in 2022. These fluctuations were driven by a drop in its funding of HIV/AIDS, which more than halved from a peak of $97m in 2010 to $44m in 2022 (down $52m, –54%) as it shifted funding from HIV/AIDS to MPTs, and a jump in COVID-19

funding ($50m in new funding in 2022 to the Coalition for Epidemic Preparedness Innovations). Even after these changes, though, HIV/AIDS has still received just under three-quarters of USAID's overall funding.

CDC

The CDC has contributed a total of $370m since 2007. Like USAID's, the CDC's funding has fluctuated, falling from an average of $23m between 2007 and 2011 down to a record low of $4.9m in 2012, jumping to a peak of $42m in 2017 and dropping back down to $19m in 2022. The majority of CDC's investment has targeted neglected diseases ($297m, 80%), more than half of which went to TB ($202m, 55%), the driver of most of the variation in the CDC's funding over the last 16 years.

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The benefits of investing in global health R&D

Through its investments in global health R&D, the United States is delivering benefits both at home and abroad. These investments not only fuel the development of breakthrough technologies that save and improve lives worldwide, they also advance development goals, strengthening research capacity and economic development in LMICs, and deliver direct benefits to the United States by stimulating the domestic economy and safeguarding Americans from disease threats.

The US-supported tools that are already saving lives

Since 1999, 242 new health technologies have been approved[iii] globally for neglected and emerging diseases outside of COVID-19. These new tools – an array of drugs, vaccines, biologics, microbicides, diagnostics, and vector control products designed for use in LMICs – have helped contribute to the huge improvements in global health over the last two decades.

The US government supported[iv] the development of 67 of these 242 new global health products, over a quarter (52) of the 182 new products for neglected diseases, and exactly a quarter (15) of the 60 new products for (non-COVID-19) emerging infectious diseases. Since this count does not capture the large number of COVID products supported by the US government, or any of its contributions to the development of sexual & reproductive health issue products, it represents a significant undercount of the full range of products that have been launched thanks to investment from the US government.

Spotlight on US-supported COVID-19 products

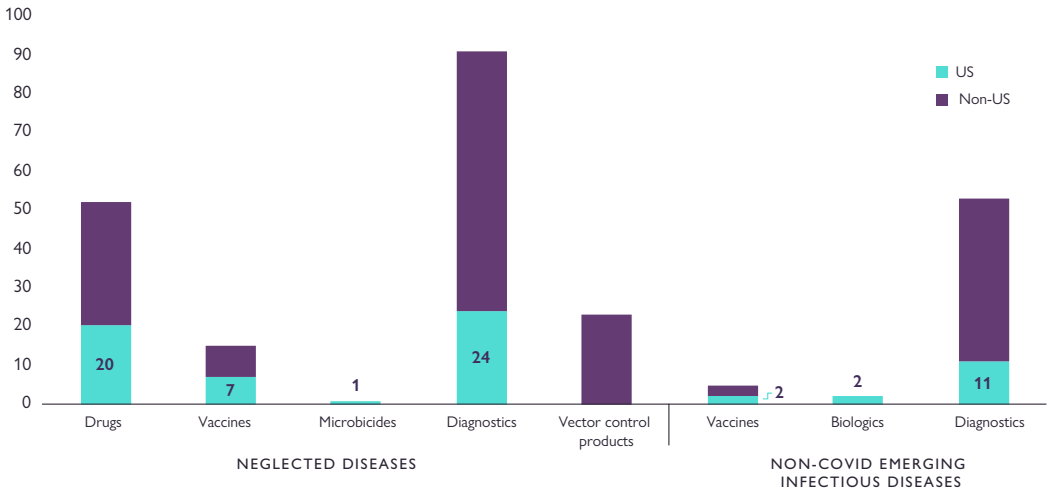
While this report is not able to provide a full picture of COVID-19 products supported by the US government, BARDA alone supported research into at least 98 distinct products to address COVID-19, including 45 products that have since received FDA authorization or approval,[3] and provided 40% ($3.2b) of all US government funding for COVID-19 R&D.

iii In this report, approved/registered refers to finished pharmaceutical products, drugs, vaccines, biologics, vector control products or diagnostics that had been granted a marketing authorization by a medicines regulatory authority or have obtained WHO prequalification.

iv In this report, 'support' includes both direct financial investment and non-financial contributions (active participation in R&D, or the provision of expertise, infrastructure, capacity building, or intellectual property and technology transfer).

A more granular examination shows that the level of US government involvement differed markedly across the different product categories. For those products that are more costly to develop, due to the need for large-scale clinical trials, and thus more historically reliant on public funding, US government support was more pronounced. Across neglected diseases and emerging infectious diseases, the United States supported nearly half (9 of 20) of approved vaccines, a third of the newly approved drugs (20 of 52), and the only microbicide[v] successfully approved in the last two decades. For those products that are less expensive to develop, and thus better able to be advanced independently by the private sector and LMIC governments, US support was less pronounced. Only a quarter of diagnostics (35 of 144) and none of the vector control products identified benefitted from US public funding.

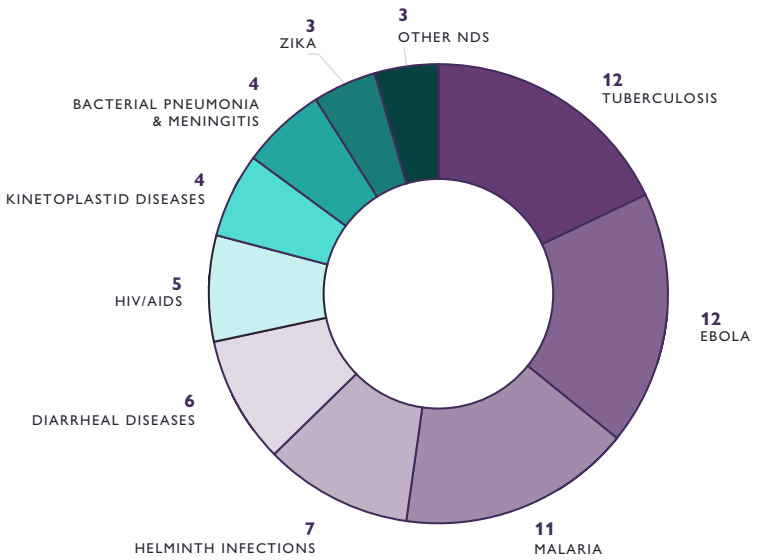
FIGURE 3: US government support for new global health technologies registered since 1999



More than half (54%) of new neglected disease products supported by US government were for the three diseases which habitually receive the bulk of global funding – TB (12), malaria (11), and HIV/AIDS (5). A further quarter targeted either helminth infections (7) or diarrheal diseases (6). The remainder are spread across bacterial pneumonia and meningitis (4), kinetoplastid diseases (4), and one product each for dengue, hepatitis C, and *Salmonella* infections. Of the new products targeting (non-COVID-19) emerging infectious diseases, the US government supported the development of 12 of the 24 products targeting Ebola, and all three products approved for Zika.

v Microbicides are biomedical products developed to protect HIV-negative people from acquiring HIV during sex.

FIGURE 4: Focus of US government support for new global health technologies registered since 1999



Which parts of the US government supported successful new products?

The largest US government funder of global health R&D, the NIH, was involved in almost three-quarters (46, 69%) of new US-supported global health technologies delivered since 1999; it was followed by USAID, which supported 20, DoD, which supported 19, CDC, which supported 17, BARDA, which supported 7, and the FDA, supported 2.[vi]

NIH

The NIH contributed to 46 of the 67 new global health technologies developed with US government support. Given that the NIH contributes the majority of US government funding for global health R&D, this may not seem surprising. The NIH's primary focus is on basic research (which is not focused on advancing a particular product, but instead lays the scientific foundation for later product development) and early-stage research (which has only a small chance of translating into an approved product). Its support for 46 successful products is therefore striking, given that it fails to capture the situations where the basic concepts discovered by the NIH were later put to use by other organizations. Of the 46 new products identified that were developed with NIH support, 40 (87%) were new products for neglected diseases – concentrated on drugs (16) and diagnostics (16), followed by vaccines (7), and the world's only approved microbicide. The remaining products were for emerging infectious diseases, evenly divided between vaccines (2), biologics (2), and diagnostics (2).

vi Some products received support from more than one US funder, meaning that the subtotals for individual organizations exceed the overall US total.

USAID

USAID contributed to just under a third (20, 30%) of the 67 new global health technologies developed with US government support. USAID focuses on late-stage[vii] (lower risk) product development and uses a collaborative funding approach, leveraging additional investment from other stakeholders. All the USAID-supported products were for neglected diseases, two-thirds of which were drugs (14), three vaccines, two diagnostics, and the only approved microbicide.

DoD

The DoD's primary motivation for investing in global health R&D is to protect US national security and the well-being of US service members. Accordingly, its focus is on R&D for products that work in low-resource or conflict settings and protect against infectious diseases that pose a risk to troops stationed abroad, as well as manmade and naturally occurring biological threats – all of which can also have applications in global health. Like the NIH, the DoD conducts its own research, as well as providing funding externally; unlike the NIH, though, its focus extends all the way from basic research through to late-stage product development. Since 1999, the DoD has played a role in delivering 19 new global health products, almost a third (29%) of all US government-supported products. Of the 19 new products developed with its support, more than half (63%) targeted neglected diseases – half of them diagnostics (6), five drugs, and one vaccine. The remaining seven products were for emerging infectious diseases, mostly diagnostics (4) but also two new vaccines and one biologic.

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vii This report defines late-stage development as drug, vaccine, biologics, and microbicide candidates in clinical trials (Phases I through III), diagnostics under clinical evaluation and vector control products undergoing testing in the field.

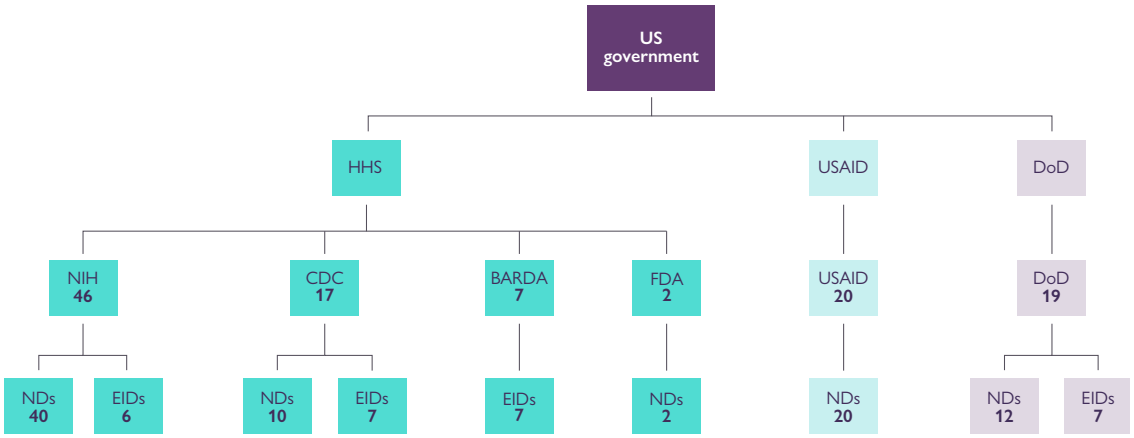
CDC

The CDC's principal mandate is to protect US public health against both domestic and external disease threats. Accordingly, it plays an important role in R&D to prevent, detect, and respond to threats from infectious disease. Since 1999, CDC has helped deliver 17 (25%) of the 67 new global health technologies, 10 of which target neglected diseases – with seven diagnostics, two drugs, and one vaccine – and seven products for emerging infectious diseases – six diagnostics and one vaccine.

BARDA

BARDA works closely with industry partners as part of its mission is to develop medical countermeasures for public health emergencies including emerging infectious diseases. While its mandate is focused on protecting Americans, the products it develops are deployed globally as well. Though it is the newest of the listed agencies, having been established in 2006, it has contributed to the development of seven of the 67 products, all of them targeting either Ebola or Zika – three diagnostics, two biologics, and two vaccines.

FIGURE 5: US government support for new global health technologies registered since 1999 by agency



NDs: Neglected diseases.

EIDs: Emerging infectious diseases. This does not include products for COVID-19.

Real world impact: Case studies of US-supported tools

Pretomanid: A cost-saving treatment for drug-resistant TB

TB is the world's second deadliest infectious disease after COVID-19, killing 1.5m people each year.[4] Drug-resistant TB (DR-TB) is also a major contributor to the emerging crisis of antimicrobial resistance, responsible for over 400,000 cases each year.[5] Traditionally, treatment for DR-TB has been lengthy, complex, costly, and toxic. Individuals suffering from DR-TB often had to take 20 or more pills a day – or as many as 14,000 in total over the course of treatment over 18 months or more.[6]

In 2019, the FDA approved pretomanid, a first-in-class medication for DR-TB, which was developed by TB Alliance with support from USAID and the NIH's National Institute of Allergy and Infectious Diseases (NIAID). It has since been WHO-prequalified and conditionally recommended for the treatment of DR-TB as part of a range of six-month all-oral regimens. These pretomanid-based regimens are shorter, cheaper, more effective, and have fewer side effects than the previously recommended treatments.[7]

The leading pretomanid-based regimen BPaL (an oral combination of pretomanid with bedaquiline, and linezolid), not only cured 90% of patients in clinical trials, it has also demonstrated a 57%-78% reduction in the cost of treatment in LMICs compared to conventional regimens.[8,9] If it were widely adopted, these savings would result in a 15-32% reduction in public spending on TB treatment, thanks to BPaL's shorter duration, fewer follow-ups and a reduced need for lab-based therapeutic monitoring.[10] Moving *all* patients with DR-TB to BPaL and similar pretomanid-based regimens, would generate global healthcare savings of up to $740m per year.[10]

Advancing long-acting HIV prevention options

Pre-exposure prophylaxis (PrEP) by HIV-negative individuals prior to sexual contact is a key strategy for controlling the spread of HIV/AIDS in the United States and globally. Although PrEP uptake amongst vulnerable groups in the United States has grown in recent years – from 13% in 2017 to 30% in 2021 amongst the 1.2m people for whom PrEP is recommended – ensuring adherence to regimens requiring a daily pill remains challenging.[11] Thanks in part to US government support, there are now alternative long-acting HIV prevention options that give those at risk of HIV expanded choice to pick a prevention option that best suits their needs.

Long-acting cabotegravir (CAB-LA), developed by ViiV Healthcare and approved by the FDA in 2021, represents an innovative option to improve adherence as the first long-acting injectable PrEP drug.[12,13] Pivotal clinical trials of CAB-LA were supported by the NIH NIAID and conducted

by the NIH-funded HIV Prevention Trials Network, which provided the platform for testing across priority populations in both the United States and high-burden LMICs.[14] The Prevention Trials Network is also supported by PEPFAR and the CDC.

Requiring just a single injection every two months, CAB-LA's convenience makes it appealing for many among the target population and gives it the potential to significantly reduce the global transmission of HIV.[15] Two pivotal trials demonstrated CAB-LA regimens were 88% more effective at reducing HIV acquisitions compared to daily oral PrEP, in high-risk populations.[16,17] Its introduction in the United States has the potential to increase the total life expectancy of existing patients by an estimated 28,000 (quality adjusted) life years[viii] compared with oral PrEP and avert up to 45% of new infections in the United States.[18,19] In LMICs like South Africa, up to 28% of potential future HIV acquisitions could be averted by the use of CAB-LA over existing pill regimens.[20]

The dapivirine vaginal ring, the world's only approved microbicide, represents another breakthrough in long-acting PrEP technology.[21] This silicone ring slowly releases the antiretroviral drug dapivirine over the course of a month, providing users with a discreet means of protecting against HIV. Developed by the International Partnership for Microbicides with support from USAID, PEPFAR, and NIH NIAID, the ring is recommended by the WHO as an option for HIV prevention in women at substantial risk of infection.[22] Early results from its B-PROTECTED Phase IIIb trial suggest it remains safe to use while breastfeeding and can reduce the risk of HIV infection by 30%, with each averted case representing cost savings of up to $120,000 for the health system.[22–24] USAID and PEPFAR continue to support implementation research and other efforts to support partner countries in increasing access to both the dapivirine ring and CAB-LA.

Monoclonal antibodies: Innovative therapeutics for Ebola and malaria

Monoclonal antibodies (mAbs) are a more flexible type of therapeutic than either drugs or vaccines, as they can both prevent *and* treat infections while also offering a more targeted approach that is generally safe and causes few side effects. When used in combination with vaccines, they have the potential to provide full coverage against infectious diseases, addressing a critical gap in our toolkits for combating them.

The 2014-2016 West African and 2018 DRC and Ugandan Ebola outbreaks spurred the US government to develop and deploy effective countermeasures including mAbs to protect the United States and the global community against Ebola. BARDA supported the development of Regeneron's Inmazeb and Ridgeback Biotherapeutics' Ebanga[25] – the latter of which was initially discovered at the NIAID Vaccine Research Center[26] – which were approved by the FDA in 2020 and recommended by the WHO in 2022. BARDA continues to play an active role in advancing anti-Ebola therapeutics, by funding their development, manufacturing scale-up, and procurement

viii A quality adjusted life year, or QALY, is a measure of extra life years delivered by healthcare, adjusted for the quality of life in which they are lived. This disability adjusted life year, or DALY, is a similar measure used in global health contexts.

post-licensure.[27] Utilized during African outbreaks under expanded-access protocols, these treatments significantly decreased mortality, from 54% without treatment to just 6% after receiving Inmazeb and 11% after treatment with Ebanga,[28] while also successfully averting disease in all close contacts. However, price and access remain an issue, particularly in LMICs.

Success against Ebola has demonstrated the potential for mAbs to be utilized in treating other infectious diseases like malaria. Populations in malaria-endemic regions in LMICs, including vulnerable populations like pregnant and lactating individuals, children, and travelers to these regions (who are the primary source of infections in the United States), may soon benefit from a single mAb injection that provides extended protection, eliminating the need for daily or weekly preventive drugs. Organizations steering the R&D efforts for these malaria mAbs are deploying innovative approaches focused on ensuring affordability for LMICs, with the aim of making these treatments suitable for malaria-endemic regions and high-income country travelers alike.

Three promising malaria mAbs are in clinical development, all supported by the NIH: CIS43LS and L9LS, both in Phase II development, and TB31F in Phase I trials. CIS43LS and L9LS were developed at NIAID's Vaccine Research Center and the NIH led clinical trials in the United States and several African nations, with controlled human malaria infection studies carried out at the US Army's Walter Reed Army Institute of Research.[29,30] It is projected that annual community-wide administration of the TB31F mAb in regions that experience seasonal malaria could reduce cases of malaria in low and high transmission areas by 54% and 75%,[31] respectively, with the greatest reduction experienced among children, who are also the most likely to die from malaria.

The United States reports about 2,000 cases of malaria each year,[32] most of which are the result of travel to malaria-endemic regions. However, while locally acquired malaria had not been seen in the United States since 2003, nine cases were recently identified in 2023 across Texas, Florida, Arkansas, and Maryland.[33] The emergence of community transmission raises concerns that cases may spread further, a risk that is elevated by climate change, since longer, hotter summers will expand the geographic range and seasonality of the mosquitoes that carry malaria. Single dose therapeutics like malaria-targeted mAbs mean faster outbreak responses and more effective disease control.

Lessons from outbreaks, epidemics and a pandemic

The US government has been pivotal in responding to outbreaks of emerging infectious diseases, not only by directly supporting the countries and regions impacted but also by playing the lead role in the development of vaccines, therapeutics, and diagnostics to combat these diseases. The resulting technologies not only safeguard against future outbreaks but also advance the science needed to engineer rapid responses to the future emergence of currently unknown pathogens. The rapid spread of COVID-19, Ebola, and – most recently – Marburg demonstrate how any increase in the speed of product development can save many lives.

The US response to Ebola has been deemed the largest effort by a single donor government during the 2014-2016 West African outbreak, with contributions from the NIH, DoD, BARDA, CDC, and USAID.[34] The US government – either via financing R&D or directly leading pivotal clinical trials[35] – supported the development of *all* approved Ebola vaccines: ERVEBO and the prime-boost two-dose regimen of Zabdeno and Mvabea, and the mAb therapeutics REGN-EB3 and mAB114. The resulting suite of vaccines and mAbs has the potential to provide complete protection against the virus, offering both treatment and prevention. In a late 2021 outbreak in the DRC, more than 1,800 people were vaccinated with existing stockpiles of the ERVEBO vaccine in a campaign that began just five days after the first case was detected.[36] The availability of a vaccine brought the outbreak under control quickly, with a reduction from 29,000 cases prior to vaccine availability down to just 11 cases in the October 2021 DRC outbreak, and a reduction in mortality from 63% to 25%.[37,38]

The response during the COVID-19 pandemic set a precedent for coordinated inter-agency mobilization, with Operation Warp Speed providing funding and support to bring vaccines and diagnostics to market at a record pace. The program brought together the DoD and HHS (including NIH, CDC, BARDA, and FDA), with industry partners with the aim to deliver safe and effective vaccines within a year. In just 11 months from identification of the pathogen, two vaccines received emergency use authorization from the FDA, including Moderna's mRNA vaccine,[39] which was supported through Operation Warp Speed.[40] It ultimately led to the successful development of four vaccines that were either FDA-approved or authorized for emergency use – all of which have since been deployed around the globe.

With these vaccines, and others like them, 14.4m deaths were prevented in 185 countries in the first year alone, saving an estimated $895b in direct healthcare costs between December 2020 and March 2022.[41] Project NextGen, led by BARDA and NIH NIAID, represents the next generation of COVID R&D funding, and is scheduled to disburse $5.0b for the development of a new generation of tools and technologies, with $1.9b already awarded as of mid-2023.[42] In recognition of the crucial role played by diagnostics in outbreak control, the US government also launched the Rapid Acceleration of Diagnostics (RADx) initiative in April 2020, investing $1.5b via the NIH, with the aim of accelerating innovation in diagnostic technologies and ensuring accessibility for the most vulnerable populations.

With the lessons learned from Ebola and COVID-19, agencies like BARDA are preparing for the next viral threat. This preparation extends to the recent outbreaks of Marburg and the Sudan species of Ebola, for which existing treatments – developed for the Ebola Zaire species – do not provide proven protection. BARDA is currently supporting development of three Marburg vaccine candidates, including candidates from the International AIDS Vaccine Initiative, Public Health Vaccines, and the Sabin Vaccine Institute, drawing on the earlier work developing vaccines for Ebola, a related virus. Two of these vaccines were included in a Phase III ring vaccination trial that took place under WHO guidance during the Marburg outbreaks in Equatorial Guinea and Tanzania in early 2023.[43] Given Marburg's mortality rate of up to 88%,[44] a proven vaccine capable of preventing disease and transmission would have the potential to significantly reduce loss of life.

The US government has also supported endemic countries in their response to outbreaks, providing over $2m to Equatorial Guinea during the 2023 Marburg outbreak, including funding from USAID establishing a temporary diagnostic laboratory, and deploying of technical experts from the CDC. However, as COVID-19 showed, non-pharmaceutical interventions can only go so far, and the real key is reducing the time between the beginning of an outbreak and the roll-out of effective diagnostics, treatments, and vaccines. By learning from the successes – and failures – of the US response to Ebola and COVID-19, especially the advantages that come from continuity of funding and a strong existing research base, we can put ourselves in a position to respond to the next crisis more quickly still.

The US government's role in the next generation of life saving technologies

In addition to its contributions to the products which have already been approved, the US government's financial support will ultimately make possible the launch of a wide array of products currently undergoing development.

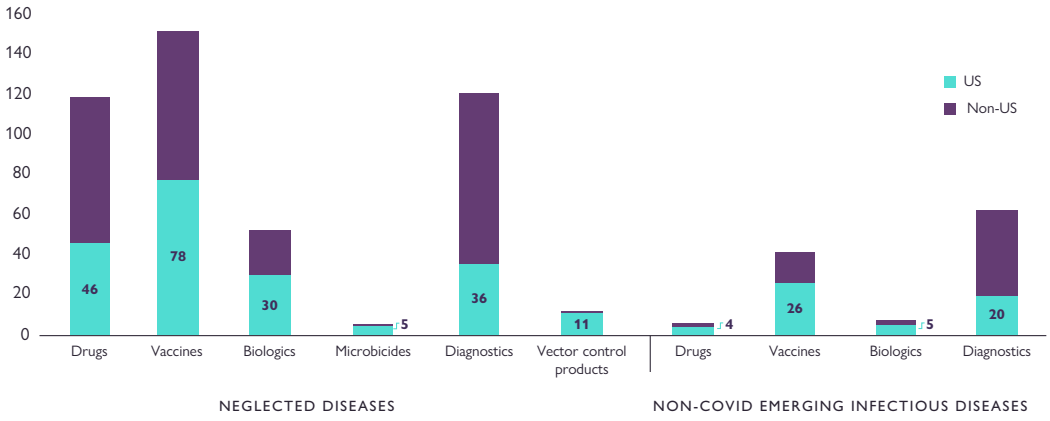
The 'health' of an R&D pipeline can be judged in two ways. First, by the number of potential new technologies in development – the larger the pipeline, the greater the chance at least some products will survive inevitable attrition and deliver desperately needed tools for global health. Second, by the distribution of products across the different stages of R&D – since it can take a decade or more for investments in early-stage R&D to translate into products that are saving lives in the field, and a significant percentage of candidates will fail or be abandoned, at every stage. The health of the pipeline therefore serves as an important forward-looking indicator of the potential future impact of today's investments, and how far they are from being realized.

The US government has played an integral role in building a pipeline of global health technologies which, as of 2022, was the largest ever recorded. More investment is still needed, though, to match the diversity and scale of global health needs.

At the end of 2022, there were 1,113 products under development in the global health R&D pipeline for neglected diseases and (non-COVID) emerging infectious diseases, with half (579) of these in late-stage development. The US government directly contributed to 261 (45%) of these 579 late-stage candidates, including 206 products for neglected diseases and 55 products for emerging infectious diseases.

US government support for neglected disease products included contributing to R&D of all chemical vector control products (7, 100%), a large proportion of all biological vector control products (4, 80%) and microbicides (5, 83%), over half of all vaccines (78, 51%) and biologics (30, 58%), over a third of all drugs (46, 39%), and almost a third of diagnostics (36, 30%) identified in the pipeline. The US government's support for emerging infectious diseases included over two-thirds of biologics (5, 71%) and drugs (4, 67%), almost two-thirds of vaccines (26, 63%), and almost a third of diagnostics (20, 32%).

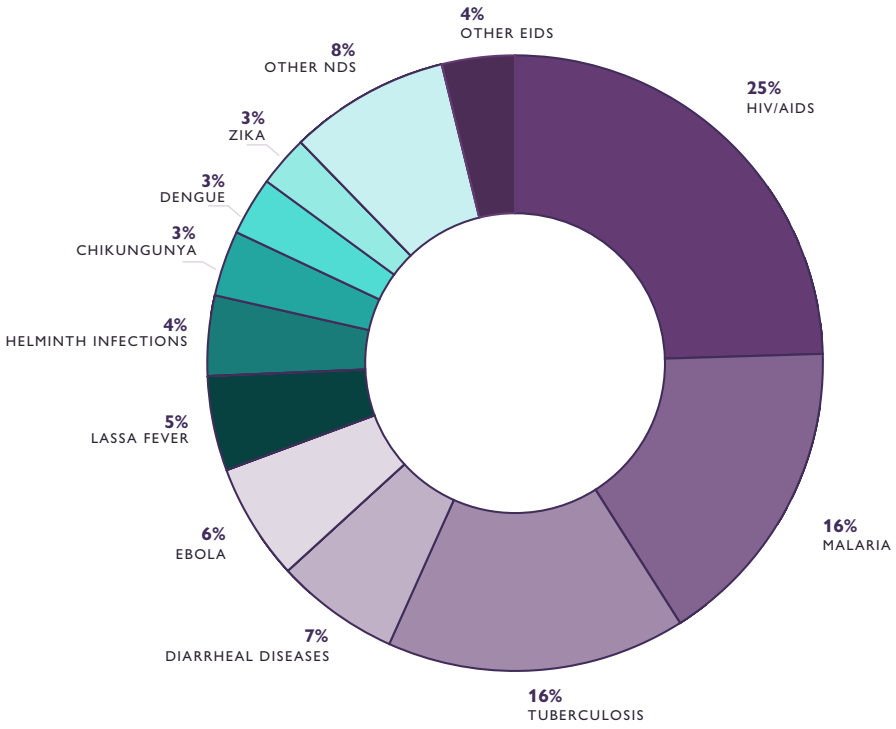
FIGURE 6: US government support for late-stage pipeline candidates by product type



The US government's historic focus on R&D for HIV/AIDS, TB, and malaria is also evident in the pipeline of forthcoming technologies it has supported. More than half of all the late-stage neglected disease pipeline candidates backed by the US government are for either HIV/AIDS (64, 31% of neglected disease candidates with US government support), malaria (43, 21%), or TB (41, 20%). The US government has also made important contributions toward the pipelines for diarrheal diseases (17, 8.3%) and helminth infections (11, 5.3%). The support from the US government was critical for advancing product development for some of the most neglected diseases, both the existing candidates for cryptococcal meningitis and the only two histoplasmosis candidates.

Along with its contributions to neglected diseases, emerging infectious diseases have also received vital US government support, most heavily concentrated on Ebola (16, 29% of US-backed non-COVID emerging infectious disease candidates), Lassa fever (13, 24%), chikungunya (9, 16%), and Zika (7, 13%), and all three of the Nipah candidates.

FIGURE 7: US government support for late-stage pipeline candidates by disease



How have the different US government agencies supported the R&D pipeline?

Each of the US government funding agencies play a distinct role as part of a broader whole-of-government approach to supporting global health R&D. The number and type of global health pipeline candidates each agency has supported reflects its unique focus and specialization, making it difficult to compare agency contributions to global health R&D using numbers alone, particularly since our approach to assigning credit excludes contributions to the basic and early-stage research that underpins product development or the health systems activities that bridge the gap between approval and LMIC access.

Those caveats aside, our data shows that NIH contributed to more than four-fifths (217, 83%) of all US government-supported late-stage pipeline candidates, the DoD a quarter (64, 25%), USAID 15% (40), the CDC 7.3% (19) and BARDA 5.4% (14).[ix]

ix More than one organization may have contributed to a single candidate.

NIH

The NIH contributed to more than four-fifths (217, 83%) of all US government-supported late-stage pipeline candidates. Looking exclusively at the 173 of those products that were for neglected diseases, three-quarters were for the traditional big three diseases – HIV/AIDS (60, 35%), TB (38, 22%), and malaria (32, 18%) – while other neglected diseases accounted for the remaining 25% (43). The NIH contributed to 44 emerging infectious disease candidates including products for Ebola (13, 30% of the EID total) and Lassa fever (13, 30%), while the remaining 15 candidates included products for Zika (5, 11%), chikungunya (4, 9.1%), and three candidates each for Marburg, MERS, and Nipah. Vaccines accounted for over a third (66, 38%) of the 173 NIH-supported neglected disease candidates. Drugs made up a further fifth (38, 22%), followed by diagnostics (30, 17%) and biologics (29, 17%). Its support for emerging infectious diseases focused even more heavily on vaccines, which accounted for half (22, 50%) of the emerging infectious disease products it supported. Diagnostics made up almost a third (14, 32%), followed by biologics (5, 11%), and drugs (3, 6.8%).

USAID

USAID contributed to 40 (15%) of the late-stage candidates supported by the US government, all but three of which were aimed at neglected diseases. USAID's primary focus was on products for the three most heavily funded diseases – HIV/AIDS (11, 30%), malaria (10, 27%), and TB (10, 27%) – which together accounted for more than three-quarters of all the late-stage neglected disease pipeline candidates it supported. Helminth infections (4, 11%) and dengue (2, 5.4%) accounted for the remainder of its contributions to neglected disease candidates. USAID also supported three vaccine candidates for emerging infectious disease R&D, including two candidates for Ebola and one for Lassa fever. Drugs (15, 41%) and vaccines (12, 32%) made up almost three-quarters of the USAID-supported neglected disease pipeline, with the remainder going to vector control products (5, 14%), biologics (2, 5.4%), and microbicides (2, 5.4%), as well as biological vector control products and diagnostics (both 1, 2.7%).

DoD

The DoD contributed to a quarter (64, 25%) of all US-supported late-stage candidates. Two-thirds (42, 66%) of these candidates were for neglected diseases, primarily HIV/AIDS (13, 31% of neglected disease candidates) and malaria (13, 31%), followed by diarrheal diseases (7, 17%) and TB (4, 9.5%). The remaining five candidates (12%) were for dengue, helminth infections, kinetoplastid diseases, and leptospirosis. A third of the 22 DoD-supported emerging infectious disease candidates were for Ebola (7, 32%), followed by four candidates each for Lassa fever and chikungunya. The remaining candidates were spread between MERS (2), Nipah (2), Rift Valley Fever (1), and Zika (1). Most of the DoD's focus across both emerging infectious diseases and neglected diseases was on vaccines (36, 56%), which accounted for almost two-thirds of all neglected disease candidates and almost half of all emerging infectious disease candidates.

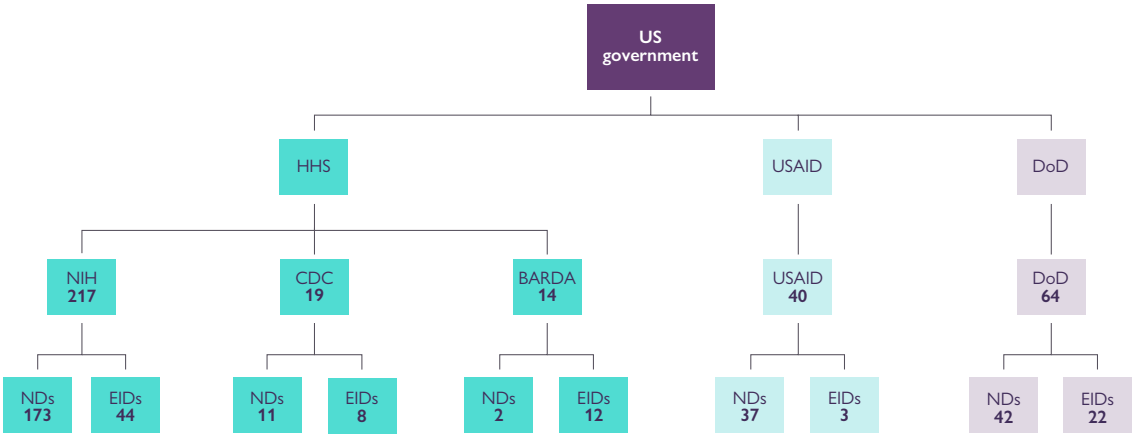
CDC

The CDC contributed to 19 (7.3%) of the late-stage candidates supported by the US government. Around a quarter of the 11 late-stage neglected disease candidates supported by the CDC were for helminth infections (3, 27%), followed by HIV/AIDS (2, 18%), and TB (2, 18%), with one candidate each across dengue, hepatitis C, histoplasmosis, and malaria. Half of the CDC-led support for emerging infectious disease candidates were for chikungunya (4, 50%), one quarter for Ebola (2, 25%), and one candidate each for Lassa fever and Nipah. Most of CDC's focus across both global health areas was on diagnostics (12, 63% of the candidates it supported).

BARDA

BARDA contributed to 14 (5.4%) of the US-supported late-stage candidates. In the neglected disease space, BARDA supported one biologic candidate for hepatitis B and one *Salmonella* vaccine. Its focus was primarily on emerging infectious diseases, most prominently filoviral diseases like Ebola and Marburg, which accounted for three-quarters of its emerging infectious disease candidates (9, 75%). Its remaining three candidates were for Zika (2) and MERS (1). Most of BARDA-supported emerging infectious disease candidates were vaccines (9, 75%), with biologics making up the other quarter (3, 25%).

FIGURE 8: US government support for late-stage global health pipeline candidates by agency



NDs: Neglected diseases.

EIDs: Emerging infectious diseases. This does not include products for COVID-19.

US funding strengthens R&D capacity and economic growth in partner countries

In addition to fueling the development of breakthrough medical innovations that save and improve lives worldwide, US government funding for global health R&D provides broader economic and societal benefits to the LMICs where neglected diseases are endemic and epidemic disease outbreaks often begin.

Since 2007, US government funding has flowed to 43 different LMICs, often accounting for a substantial share of their domestic R&D spending. This funding helps to strengthen the capability to conduct biomedical R&D in the nations that are best positioned to benefit from it and can help to seed future capacity for the manufacture and distribution of these products after launch. In addition, the reduced burden of disease that follows the use of new products removes a significant barrier to the development of LMIC economies. On the microeconomic level, studies show that dealing with malaria alone can consume up to 8% of families' budgets in endemic regions and lead to lengthy periods of absence from work.[45] A study examining one of Mozambique's 154 districts found the economic burden from malaria totaled $332k per year in that district alone.[46] At the national level, the World Bank estimates that malaria is responsible for a reduction of 1.3% of GDP annually in some endemic African countries.[45]

More broadly still, a study by the Lancet Commission on Investing in Health found that health improvements accounted for about 11% of economic growth in LMICs between 2000 and 2011.[47] Preliminary results from a forthcoming Policy Cures Research study of the overall impact of new health technologies shows that, once the value of health gains to society is taken into account, a dollar spent on neglected disease R&D yields a return on investment of well over $100.

US funding delivers direct benefits to the US economy, both now and in the future

The US government has provided more than $31b in neglected disease R&D funding since 2007, along with another $5.4b in funding for (non-COVID) emerging infectious disease R&D, $8.0b for COVID R&D, and $0.9b for sexual & reproductive health issues R&D. Of this, at least 86% – a total of more than $39b – was reinvested in American companies and institutions.

Beyond its obvious impact on combating disease, this funding delivers benefits to the US economy through a variety of channels. Most obviously, R&D funding leads to the creation of high-quality jobs across the United States: an estimated total of more than 600,000 American jobs, based on previous research conducted on the NIH's funding impact. These workers' wages, and the other domestic

spending that takes place as part of the domestic R&D supported by the US government, go on to contribute to local and national economies, ultimately generating $104b in additional economic activity as R&D funding flows through the US economy.[x]

As well as generating jobs and economic activity, publicly funded R&D flows, in part, to private sector organizations, helping to catalyze their own, self-funded R&D efforts. A little over $8.2b of the US government's global health R&D funding was, in turn, provided to US-based pharmaceutical companies, and these companies have already reported their own investments valued at least $6.6b in R&D for global health – a particularly important achievement in areas of research often *defined* by their absence of commercial incentives for product development.

This R&D funding from the US private sector reported to the G-FINDER survey is in line with broader research suggesting that, on average, every 10% increase in government-financed R&D leads – even in the short term – to a 5% to 6% additional increase in privately funded R&D in that area.[xi]

However, this private sector activity already observed via the G-FINDER survey is not the whole story. Basic research funding, in particular, can open up new investment opportunities for private companies decades after it was provided. Studies show that basic research funding – often from the public sector – can generate additional private investment as much as 24 years later, with these benefits seeming to peak around eight years after the initial government investment:

'*a $1.00 increase in public basic research generated an $8.38 increase in private pharmaceutical R&D investment after 8 years*' [xii]

This would imply that the $12.2b in US public basic research funding for global health R&D, 60% of which occurred within the last eight years, will ultimately lead to more than $102b in additional private sector investment thanks to the longer term impact of the US public funding between 2007 and 2022 – an amount roughly equal, and in addition to, the $104b in additional economic activity cited above.

Finally, we can consider the benefits of the additional knowledge generated by public R&D over even longer time horizons. Even when basic research does not directly catalyze new products, it can still guide future researchers in unexpected directions. Research on the long-term economics of R&D shows that a dollar of public basic research investment yields new scientific knowledge which will go on to generate about $0.43 in benefits through new molecular entity innovation every year afterwards – forever.[xiii] Applied to US public funding for global health R&D between 2007 and 2022, this suggests that the true ultimate value of the basic research funding alone is likely to exceed $255b via the additional stock of scientific knowledge it gives researchers to draw on.

x Extrapolated from the NIH budget impact calculation presented in the 2023 update of the Uniting for Medical Research Annual Economic Report https://www.unitedformedicalresearch.org/annual-economic-report/.

xi See Andrew A. Toole. "*The impact of public basic research on industrial innovation: Evidence from the pharmaceutical industry*." Research Policy 41.1 (2012): 1-12.

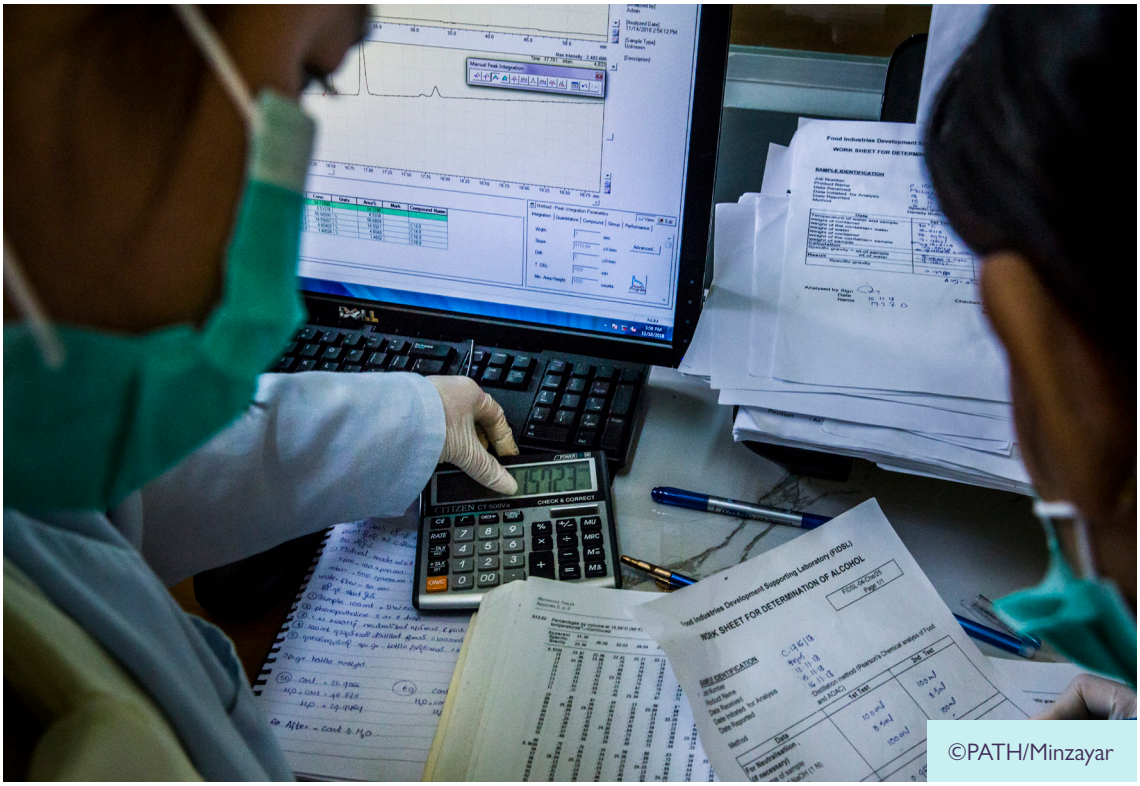
xii See, *inter alia*, Andrew A. Toole. (2007) "*Does Public Scientific Research Complement Private Investment in Research and Development in the Pharmaceutical Industry?*" Journal of Law and Economics, vol. 50

xiii Ibid.

US investments protect Americans from neglected and emerging disease threats

While the COVID-19 pandemic, as well as recent Ebola, Zika, and mpox outbreaks, have demonstrated the threat that emerging infectious diseases pose to Americans, climate change and globalization are increasing the share of the US population likely to be exposed to the neglected diseases covered in this report. In 2019, the most recent year for which formal data is available, the United States reported multiple severe cases of malaria, Chagas' disease, dengue, Zika and at least one case of the tropical parasite *Leishmania*. In 2021, there were 8,331 reported cases of TB.[48]

In recent years, shifts in the climate have aided in the transmission of leprosy – apparently transmitted by armadillo wrestling – the spread of the Chagas' carrying triatomine bug, and the rise of the *Aedes aegypti* mosquito – primary carrier of the dengue, Zika, and chikungunya viruses – in the southern United States, leading to a significant rise in infections and even community transmission well beyond the southern border. Since 2000, at least 76 confirmed or suspected cases of locally acquired Chagas' have been identified in the United States,[49] including a case as far north as Missouri.[50] Additionally, in 2023, the CDC announced instances of locally acquired malaria in four states – Florida, Texas, Arkansas, and Maryland – the first such incidents since 2003.[33] Cases of leprosy have been identified across the United States with upwards of 150 cases reported annually over the past decade.[51] Preparing for the potential spread of both neglected and emerging diseases is not just a moral necessity, it represents a sensible precaution for protecting the US population.



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Conclusion

The US government plays a vital role in global health R&D, delivering obvious benefits both at home and overseas. Not only does US government investment play a direct and catalytic role in the development of urgently needed vaccines, drugs, diagnostics, and other technologies that save lives worldwide, but it also serves as an engine that strengthens research capacity and economic development in LMICs. Alongside these global benefits come increased economic growth and jobs in the United States. This makes funding for global health R&D a huge opportunity for win-win investments which deliver international humanitarian and strategic gains while also supporting the domestic economy.

At present, however, the United States' funding commitment to global health R&D does not reflect the potential value of these returns; nor has it kept pace with growing needs and increased risks from disease. The last few years have been marked by a global pandemic and several epidemics – showing the devastating threat posed by emerging infectious diseases – as well as the spread of long neglected diseases into new areas of the world – and the United States – due to climate change. Yet despite the strong humanitarian, security and economic imperatives, US funding for neglected disease R&D has been largely stagnant, failing to build on earlier growth, or even keep pace with rising inflation. Our recent experiences with COVID-19, Zika and Ebola demonstrated the way funding for emerging infectious disease R&D cycles from neglect to panic, with funding surging in response to each new crisis before receding, allowing costly infrastructure to sink into disrepair, just in time for the next outbreak.

As policymakers search for strategic and cost-effective uses of taxpayer resources, global health R&D – which saves and improves lives and drives economic progress at home and around the world – is one of the best investments the United States can make. By not only sustaining but also strengthening the United States' commitment to global health R&D, Congress and Executive Branch officials have the opportunity to bring us closer to a healthier, safer, more prosperous world for all.

US-supported registered products

Global health area	Primary disease	Product type	Name	US agency
Neglected disease	Chagas' disease	Diagnostic	Rapid diagnostic tests for Chagas'	NIH
Neglected disease	Cryptosporidiosis	Diagnostic	Cryptosporidium II test	NIH
Neglected disease	Dengue	Diagnostic	CDC DENV-1-4 Real-Time RT-PCR Multiplex Assay	CDC
Neglected disease	Giardiasis	Diagnostic	GIARDIA II™ test	NIH
Neglected disease	Hepatitis C	Diagnostic	Hepatitis C qualitative and quantitative nucleic acid	DoD
Neglected disease	HIV/AIDS	Diagnostic	HIV qualitative nucleic acid test POC	NIH, DoD
Neglected disease	HIV/AIDS	Diagnostic	HIV 1/2 antibody (anti-HIV Ab) RDT	NIH
Neglected disease	HIV/AIDS	Diagnostic	HIV quantitative nucleic acid test	DoD
Neglected disease	HIV/AIDS	Drug	CAB-LA	NIH
Neglected disease	HIV/AIDS	Microbicide	Dapivirine Vaginal Ring	NIH, USAID
Neglected disease	Leishmaniasis	Diagnostic	CL Detect Rapid Test	DoD
Neglected disease	Leishmaniasis	Drug	Amphotericin B (liposome)	NIH
Neglected disease	Leishmaniasis	Drug	Miltefosine	NIH, USAID
Neglected disease	Lymphatic filariasis	Diagnostic	Bioline™ Lymphatic Filariasis IgG4	NIH
Neglected disease	Lymphatic filariasis	Diagnostic	Alere Filariasis test strip	USAID, CDC
Neglected disease	Malaria	Drug	Tafenoquine pediatric	NIH, USAID, DoD
Neglected disease	Malaria	Drug	Arakoda™	DoD
Neglected disease	Malaria	Drug	Pyramax®	NIH, USAID, DoD
Neglected disease	Malaria	Drug	Pyramax® granules	NIH, USAID
Neglected disease	Malaria	Drug	Coartem® Dispersible	NIH, USAID
Neglected disease	Malaria	Drug	ASMQ	NIH
Neglected disease	Malaria	Drug	Eurartesim®	NIH, USAID
Neglected disease	Malaria	Drug	Artesun®	NIH, USAID, DoD
Neglected disease	Malaria	Drug	Artemotil	USAID
Neglected disease	Malaria	Drug	Krintafel™	NIH, DoD
Neglected disease	Malaria	Vaccine	Mosquirix	NIH, USAID, DoD
Neglected disease	Meningitis	Diagnostic	Multiplex PCR assay	NIH
Neglected disease	Meningitis	Vaccine	MenAfriVac	NIH, USAID, CDC, FDA
Neglected disease	Multiple diarrheal diseases	Diagnostic	GIARDIA/ CRYPTOSPORIDIUM QUIK CHEK™ test	NIH
Neglected disease	Multiple diarrheal diseases	Diagnostic	Cryptosporidium/ Giardia Combination	CDC
Neglected disease	Onchocerciasis	Diagnostic	Ov16 ELISA	NIH, USAID, CDC
Neglected disease	Onchocerciasis	Diagnostic	SD BIOLINE Onchocerciasis/ LF biplex test	NIH
Neglected disease	Onchocerciasis	Diagnostic	SD Onchocerciasis IgG4 monoplex lateral flow assay	NIH

Global health area	Primary disease	Product type	Name	US agency
Neglected disease	Pneumonia	Vaccine	Synflorix	NIH
Neglected disease	Pneumonia	Vaccine	Prevenar 13	NIH
Neglected disease	Rotavirus	Vaccine	ROTASIIL	NIH
Neglected disease	Rotavirus	Vaccine	Rotavac	NIH
Neglected disease	Schistosomiasis	Diagnostic	Point-of-contact circulating cathodic antigen assay	CDC
Neglected disease	Strongyloidiasis	Diagnostic	Strongyloides ELISA	CDC
Neglected disease	Tuberculosis	Diagnostic	Xpert MTB/RIF and Xpert MTB/RIF Ultra assays	NIH, CDC, DoD
Neglected disease	Tuberculosis	Diagnostic	Moderate complexity automated NAATs	NIH
Neglected disease	Tuberculosis	Diagnostic	TB-LAMP	NIH
Neglected disease	Tuberculosis	Diagnostic	Low complexity automated NAATs	NIH, DoD
Neglected disease	Tuberculosis	Diagnostic	First-line line probe assays (LPAs)	NIH
Neglected disease	Tuberculosis	Drug	Bedaquiline	NIH, USAID
Neglected disease	Tuberculosis	Drug	Pretomanid	NIH, USAID
Neglected disease	Tuberculosis	Drug	Delamanid	NIH, USAID
Neglected disease	Tuberculosis	Drug	Linezolid	NIH, USAID
Neglected disease	Tuberculosis	Drug	Rifapentine	NIH, USAID, CDC
Neglected disease	Tuberculosis	Drug	Rifampicin/Isoniazid/ Pyrazinamide dispersible pediatric	USAID
Neglected disease	Tuberculosis	Drug	Moxifloxacin	CDC, FDA
Neglected disease	Typhoid and paratyphoid fever	Vaccine	Typbar-TCV	NIH, USAID
Emerging infectious disease	Ebola	Biologics	Ebanga	NIH, DoD, BARDA
Emerging infectious disease	Ebola	Biologics	Inmazeb	NIH, BARDA
Emerging infectious disease	Ebola	Diagnostic	OraQuick® Ebola Rapid Antigen Test	CDC, BARDA
Emerging infectious disease	Ebola	Diagnostic	FilmArray BioThreat-E test / AmpliSens EBOV Zaire 1-FRT PCR kit	NIH, DoD
Emerging infectious disease	Ebola	Diagnostic	FilmArray NGDS BT-E Assay	DoD
Emerging infectious disease	Ebola	Diagnostic	Xpert Ebola Assay	NIH, DoD
Emerging infectious disease	Ebola	Diagnostic	EZ1 Real-time RT-PCR Assay (DoD)	DoD
Emerging infectious disease	Ebola	Diagnostic	CDC Ebola Virus NP Real-time RT-PCR Assay (CDC)	CDC
Emerging infectious disease	Ebola	Diagnostic	CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC)	CDC
Emerging infectious disease	Ebola	Diagnostic	DPP Ebola Antigen System	CDC
Emerging infectious disease	Ebola	Vaccine	ERVEBO	NIH, CDC, DoD, BARDA
Emerging infectious disease	Ebola	Vaccine	Zabdeno + Mvabea (2-dose heterologous prime-boost vaccine regimen)	NIH, DoD, BARDA
Emerging infectious disease	Zika	Diagnostic	Zika virus IgM antibody detection immunoassay	CDC, BARDA
Emerging infectious disease	Zika	Diagnostic	Zika virus IgM antibody detection RDT	BARDA
Emerging infectious disease	Zika	Diagnostic	Zika qualitative RNA Nucleic Acid Test	CDC

Methodology

We have defined 'global health R&D' as including research and development for neglected diseases, emerging infectious diseases, and sexual & reproductive health issues based on the list of pathogens and conditions identified by the G-FINDER expert advisory committees and the WHO Blueprint priority pathogens list. See below for the full list of diseases and health issues covered in this report.

Neglected diseases	Emerging infectious diseases	Sexual & reproductive health issues
Buruli ulcer	Chikungunya	Chlamydia
Chagas' disease	Coronavirus disease 2019 (COVID-19)	Contraception – multiple or unspecified duration
Cholera	Crimean-Congo Hemorrhagic Fever (CCHF)	Contraception – on-demand
Cryptococcal meningitis	Ebola	Contraception – permanent
Dengue	Emergent non-polio enteroviruses (including EV71, D68)	Contraception – short-acting
Enteroaggregative *E. coli*	Lassa fever	Gonorrhea
Enterotoxigenic *E. coli*	Marburg	Herpes simplex virus 2 (HSV-2)
Hepatitis B[xiv]	Middle East Respiratory Syndrome (MERS)	Human papillomavirus (HPV) and HPV-related cervical cancer
Hepatitis C	Mpox	Human T-lymphotropic virus 1 (HTLV-1)
Histoplasmosis	Nipah	Multipurpose prevention technologies (MPTs)
HIV/AIDS[xiv]	Rift Valley Fever (RVF)	Post-partum hemorrhage (PPH)
Hookworm	Severe Acute Respiratory Syndrome (SARS)	Pre-eclampsia and eclampsia
Leishmaniasis	Severe Fever with Thrombocytopenia Syndrome (SFTS)	Syphilis
Leprosy	Zika	
Leptospirosis		
Lymphatic filariasis		
Malaria		
Mycetoma		
N. meningitidis		
Non-typhoidal *S. enterica*		
Onchocerciasis		
Rheumatic fever		
Rotavirus		

xiv Hepatitis B and HIV/AIDS are included under both the neglected diseases and sexual & reproductive health issues scope for the G-FINDER survey. The funding totals for hepatitis B and HIV/AIDS in this report have only been included under neglected diseases totals to avoid double counting.

Neglected diseases	Emerging infectious diseases	Sexual & reproductive health issues
Roundworm		
S. pneumoniae		
Scabies		
Schistosomiasis		
Shigella		
Sleeping sickness (HAT)		
Snakebite envenoming		
Strongyloidiasis		
Tapeworm		
Trachoma		
Tuberculosis (TB)		
Typhoid and paratyphoid fever (*S.* Typhi, *S.* Paratyphi A)		
Whipworm		
Yaws		

Funding data

All funding data for this report comes from the G-FINDER survey, conducted annually by Policy Cures Research. The G-FINDER survey has tracked global investment in R&D for a gradually expanding range of neglected diseases since 2007, emerging infectious diseases since 2014, and sexual & reproductive health issues since 2018. It covers basic research, drugs, vaccines, biologics, diagnostics, microbicides, and vector control products, as well as platform technologies (adjuvants & immunomodulators; drug-, vaccine- and biologics-based platforms; multi-disease diagnostics and diagnostic platforms).

Additional in-depth information on the scope and methodology of the G-FINDER survey, including how the set of diseases included has evolved over time, is available at: http://www.policycuresresearch.org/g-finder

Registered products and pipeline candidates

Data on registered products and pipeline candidates was collected by Policy Cures Research, building on previously developed comprehensive landscapes of these two categories.

The pipeline information presented here builds on the most recently available comprehensive landscape of the R&D product pipeline for neglected diseases and emerging infectious diseases, prepared by Policy Cures Research in 2022 and brought up to date as of August 2023. This included reviewing and cross-referencing all major sources of available data on registered products and the R&D pipeline for global health. Sources included: the G-FINDER R&D funding database; WHO advisory committee reports and background documents; publicly available and paid subscription product databases; clinical trial registry portals; disease-specific pipeline updates prepared by BIO Ventures for Global Health and the Treatment Action Group; academic literature and conference proceedings; grey literature; and university, government, and nonprofit organization websites.

The diagnostics field has many 'me too' products which utilize the same technology, and therefore large numbers of diagnostic tests for one disease does not necessarily translate to diversity in diagnostic type. Similarly, many chemical vector control products utilize the same chemical compounds and delivery technologies, which does not translate to diversity of products. Consequently, similar technologies, where applicable, have been represented as one record, so that the diagnostic and chemical vector control product pipelines and registered products are not artificially inflated.

Additional in-depth information on the scope and methodology of the registered products and pipeline is available at: https://www.policycuresresearch.org/pipeline-database/

References

1. Congressional Budget Office (CBO). The Federal Budget In Fiscal Year 2022 [Internet]. [cited 2024 Jan 26]. Available from: https://www.cbo.gov/system/files/2023-03/58888-Budget-Infographic.pdf
2. Schlander M, Hernandez-Villafuerte K, Cheng CY, Mestre-Ferrandiz J, Baumann M. How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment. Pharmacoeconomics. 2021 Nov;39(11):1243–69.
3. MedicalCountermeasures.gov. COVID-19 Portfolio [Internet]. 2024 [cited 2024 Feb 5]. Available from: https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx
4. World Health Organization (WHO). Tuberculosis [Internet]. 2023 [cited 2023 Nov 28]. Available from: https://www.who.int/health-topics/tuberculosis
5. World Health Organization (WHO). Global Tuberculosis Report 2023 [Internet]. 2023 [cited 2023 Nov 28]. Available from: https://www.who.int/publications/i/item/9789240083851
6. TB Alliance. Inadequate Treatment [Internet]. 2023 [cited 2023 Nov 28]. Available from: https://www.tballiance.org/why-new-tb-drugs/inadequate-treatment
7. Sweeney S, Berry C, Kazounis E, Motta I, Vassall A, Dodd M, et al. Cost-effectiveness of short, oral treatment regimens for rifampicin resistant tuberculosis. PLOS Glob Public Health. 2022 Dec 7;2(12):e0001337.
8. Conradie F, Bagdasaryan TR, Borisov S, Howell P, Mikiashvili L, Ngubane N, et al. Bedaquiline–pretomanid–linezolid regimens for drug-resistant tuberculosis. N Engl J Med. 2022 Sep 1;387(9):810–23.
9. Gomez GB, Siapka M, Conradie F, Ndjeka N, Garfin AMC, Lomtadze N, et al. Cost-effectiveness of bedaquiline, pretomanid and linezolid for treatment of extensively drug-resistant tuberculosis in South Africa, Georgia and the Philippines. BMJ Open. 2021 Dec 3;11(12):e051521.
10. Mulder C, Rupert S, Setiawan E, Mambetova E, Edo P, Sugiharto J, et al. Budgetary impact of using BPaL for treating extensively drug-resistant tuberculosis. BMJ Glob Health. 2022 Jan;7(1):e007182.
11. National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). PrEP for HIV Prevention in the U.S. [Internet]. 2023 Sep [cited 2023 Nov 17]. Available from: https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html#anchor_1637678358
12. ViiV Healthcare. ViiV Healthcare announces US FDA approval of Cabenuva (cabotegravir, rilpivirine) for use every two months, expanding the label of the first and only complete long-acting HIV treatment. [Internet]. 2022 Jan [cited 2023 Nov 17]. Available from: https://viivhealthcare.com/en-us/media-center/news/press-releases/2022/january/viiv-healthcare-announces-us-fda-approval-of-cabenuva/
13. U.S. Food and Drug Administration (FDA). FDA approves first extended-release, injectable drug regimen for adults living with HIV. [Internet]. 2021 Jan [cited 2023 Nov 17]. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-extended-release-injectable-drug-regimen-adults-living-hiv
14. HIV Prevention Trials Network (HPTN). The HIV Prevention Trials Network (HPTN) [Internet]. 2023 [cited 2023 Nov 17]. Available from: https://www.hptn.org/

15. Garris CP, Czarnogorski M, Dalessandro M, D'Amico R, Nwafor T, Williams W, et al. Perspectives of people living with HIV-1 on implementation of long-acting cabotegravir plus rilpivirine in US healthcare settings: results from the CUSTOMIZE hybrid III implementation-effectiveness study. J Int AIDS Soc. 2022 Sep;25(9):e26006.

16. HIV Prevention Trials Network (HPTN). HPTN 083 Study Summary: "A Phase 2b/3 double blind safety and efficacy study of injectable cabotegravir compared to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), for pre-exposure prophylaxis in HIV-uninfected cisgender men and transgender women who have sex with men." [Internet]. 2020 Jul [cited 2023 Nov 17]. Available from: https://www.hptn.org/research/studies/hptn083

17. HIV Prevention Trials Network (HPTN). HPTN 084 Study Summary: "A Phase 3 double blind safety and efficacy study of long-acting injectable cabotegravir compared to daily oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected women." [Internet]. 2020 Sep [cited 2023 Nov 17]. Available from: https://www.hptn.org/research/studies/hptn084

18. Neilan AM, Landovitz RJ, Le MH, Grinsztejn B, Freedberg KA, McCauley M, et al. Cost-effectiveness of long-acting injectable HIV preexposure prophylaxis in the United States: a cost-effectiveness analysis. Ann Intern Med. 2022 Apr;175(4):479–89.

19. Mitchell KM, Boily MC, Hanscom B, Moore M, Todd J, Paz-Bailey G, et al. Estimating the impact of HIV PrEP regimens containing long-acting injectable cabotegravir or daily oral tenofovir disoproxil fumarate/emtricitabine among men who have sex with men in the United States: a mathematical modelling study for HPTN 083. Lancet Reg Health Am. 2023 Feb;18:100416.

20. Jamieson L, Johnson LF, Nichols BE, Delany-Moretlwe S, Hosseinipour MC, Russell C, et al. Relative cost-effectiveness of long-acting injectable cabotegravir versus oral pre-exposure prophylaxis in South Africa based on the HPTN 083 and HPTN 084 trials: a modelled economic evaluation and threshold analysis. Lancet HIV. 2022 Dec;9(12):e857–67.

21. International Partnership For Microbicides (IPM). Dapivirine Ring [Internet]. [cited 2023 Nov 17]. Available from: https://www.ipmglobal.org/our-work/our-products/dapivirine-ring

22. World Health Organization (WHO). WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection [Internet]. 2021 [cited 2021 Nov 26]. Available from: https://www.who.int/news/item/26-01-2021-who-recommends-the-dapivirine-vaginal-ring-as-a-new-choice-for-hiv-prevention-for-women-at-substantial-risk-of-hiv-infection

23. The Microbicide Trials Network (MTN). Study suggests dapivirine vaginal ring is safe to use as HIV prevention during breastfeeding. [Internet]. 2023 Feb [cited 2023 Nov 17]. Available from: https://www.mtnstopshiv.org/news/study-suggests-dapivirine-vaginal-ring-safe-use-hiv-prevention-during-breastfeeding

24. Reidy M, Gardiner E, Pretorius C, Glaubius R, Torjesen K, Kripke K. Evaluating the potential impact and cost-effectiveness of dapivirine vaginal ring pre-exposure prophylaxis for HIV prevention. PLoS One. 2019;14(6):e0218710.

25. U.S. Department of Health and Human Services. Global collaboration with BARDA scientists successfully develop Ebola countermeasures [Internet]. 2021 [cited 2023 Nov 23]. Available from: https://www.medicalcountermeasures.gov/stories/ebola-story/

26. Intramural Research Program. An Ebola therapy two decades in the making [Internet]. 2021 [cited 2023 Nov 28]. Available from: https://irp.nih.gov/blog/post/2021/02/an-ebola-therapy-two-decades-in-the-making

27. Pharmaceutical Technology. Emergent secures $704m contract for Ebola treatment Ebanga [Internet]. 2023 [cited 2023 Nov 23]. Available from: https://www.pharmaceutical-technology.com/news/emergent-secures-704m-contract-for-ebola-treatment-ebanga/
28. Dyer O. Two Ebola treatments halve deaths in trial in DRC outbreak. BMJ. 2019 Aug 13;l5140.
29. National Institutes of Health (NIH). Monoclonal antibody prevents malaria infection in African adults [Internet]. 2022 [cited 2023 Nov 23]. Available from: https://www.nih.gov/news-events/news-releases/monoclonal-antibody-prevents-malaria-infection-african-adults
30. National Institutes of Health (NIH). Monoclonal antibody prevents malaria in U.S. adults, NIH trial shows [Internet]. 2022 [cited 2023 Nov 23]. Available from: https://www.nih.gov/news-events/news-releases/monoclonal-antibody-prevents-malaria-us-adults-nih-trial-shows
31. Challenger JD, van Beek SW, ter Heine R, van der Boor SC, Charles GD, Smit MJ, et al. Modeling the impact of a highly potent plasmodium falciparum transmission-blocking monoclonal antibody in areas of seasonal malaria transmission. J Infect Dis. 2023 Apr 12;228(2):212–23.
32. Centers for Disease Control and Prevention (CDC). Malaria Disease Basics [Internet]. 2023 [cited 2023 Nov 23]. Available from: https://www.cdc.gov/malaria/about/index.html
33. Centers for Disease Control and Prevention (CDC). Locally acquired cases of malaria in Florida, Texas, Maryland, and Arkansas [Internet]. 2023 [cited 2023 Nov 23]. Available from: https://www.cdc.gov/malaria/new_info/2023/malaria_US.html
34. The Henry J. Kaiser Family Foundation (KFF). The U.S. response to Ebola: status of the FY2015 emergency Ebola appropriation [Internet]. 2015 [cited 2023 Nov 23]. Available from: https://www.kff.org/global-health-policy/issue-brief/the-u-s-response-to-ebola-status-of-the-fy2015-emergency-ebola-appropriation/
35. Torreele E, Wolfe D, Kazatchkine M, Sall A, Ruxrungtham K, Fitchett JRA, et al. From private incentives to public health need: rethinking research and development for pandemic preparedness. The Lancet Global Health. 2023 Aug 28;11(10):e1658–66.
36. World Health Organization (WHO). Democratic Republic of the Congo declares Ebola outbreak over [Internet]. 2021 [cited 2023 Nov 23]. Available from: https://www.afro.who.int/news/democratic-republic-congo-declares-ebola-outbreak-over
37. Centers for Disease Control and Prevention (CDC). History of Ebola disease outbreaks [Internet]. 2023 [cited 2023 Nov 23]. Available from: https://www.cdc.gov/vhf/ebola/history/chronology.html
38. Rupani N, Ngole ME, Lee JA, Aluisio AR, Gainey M, Perera SM, et al. Effect of recombinant vesicular stomatitis virus–Zaire Ebola virus vaccination on Ebola virus disease illness and death, Democratic Republic of the Congo. Emerg Infect Dis. 2022 Jun 28;28(6):1180–8.
39. National Institutes of Health (NIH). Statement from NIH and BARDA on the FDA Emergency Use Authorization of the Moderna COVID-19 Vaccine. [Internet]. 2020 [cited 2023 Nov 24]. Available from: https://www.nih.gov/news-events/news-releases/statement-nih-barda-fda-emergency-use-authorization-moderna-covid-19-vaccine
40. Siddalingaiah SV. Operation Warp Speed contracts for COVID-19 vaccines and ancillary vaccination materials. 2021 Mar 1;
41. Watson OJ, Barnsley G, Toor J, Hogan AB, Winskill P, Ghani AC. Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. The Lancet Infectious Diseases. 2020 Jun 23;22(9):1293–302.

42. U.S. Department of Health and Human Services. Project NextGen selects initial vaccine candidates and awards over $500 million to advance development of vaccines and therapeutics [Internet]. 2023 [cited 2023 Nov 23]. Available from: https://www.hhs.gov/about/news/2023/10/13/project-nextgen-selects-initial-vaccine-candidates-awards-over-500-million-advance-development-vaccines-therapeutics.html

43. World Health Organization (WHO). WHO Technical Advisory Group – candidate vaccine prioritization. Summary of the evaluations and recommendations on the four Marburg vaccines [Internet]. 2023 [cited 2023 Nov 24]. Available from: https://www.who.int/publications/m/item/who-technical-advisory-group---candidate-vaccine-prioritization.--summary-of-the-evaluations-and-recommendations-on-the-four-marburg-vaccines

44. World Health Organization (WHO). Marburg virus disease [Internet]. [cited 2023 Nov 23]. Available from: https://www.who.int/news-room/fact-sheets/detail/marburg-virus-disease

45. Andrade MV, Noronha K, Diniz BPC, Guedes G, Carvalho LR, Silva VA, et al. The economic burden of malaria: a systematic review. Malar J. 2022 Oct 5;21(1):283.

46. Alonso S, Chaccour CJ, Elobolobo E, Nacima A, Candrinho B, Saifodine A, et al. The economic burden of malaria on households and the health system in a high transmission district of Mozambique. Malar J. 2019 Nov 11;18:360.

47. Jamison DT, Summers LH, Alleyne G, Arrow KJ, Berkley S, Binagwaho A, et al. Global health 2035: a world converging within a generation. Lancet. 2013 Dec 7;382(9908):1898–955.

48. CDCTB. Reported TB in the U.S., 2021 – National Data [Internet]. Centers for Disease Control and Prevention. 2023 [cited 2024 Jan 30]. Available from: https://www.cdc.gov/tb/statistics/reports/2022/national_data.htm

49. Lynn MK, Bossak BH, Sandifer PA, Watson A, Nolan MS. Contemporary autochthonous human Chagas disease in the USA. Acta Trop. 2020 May;205:105361.

50. Paridon B van. Possible Case of Locally Acquired Chagas Disease in Missouri [Internet]. Infectious Disease Advisor. 2020 [cited 2024 Jan 30]. Available from: https://www.infectiousdiseaseadvisor.com/home/topics/vector-borne-illnesses/first-case-of-a-patient-who-likely-contracted-chagas-disease-in-the-united-states/

51. Health Resources and Services Administration. National Hansen's Disease (Leprosy) Program Caring and Curing Since 1894 [Internet]. 2023 [cited 2024 Feb 2]. Available from: https://www.hrsa.gov/hansens-disease