

DISCUSSION

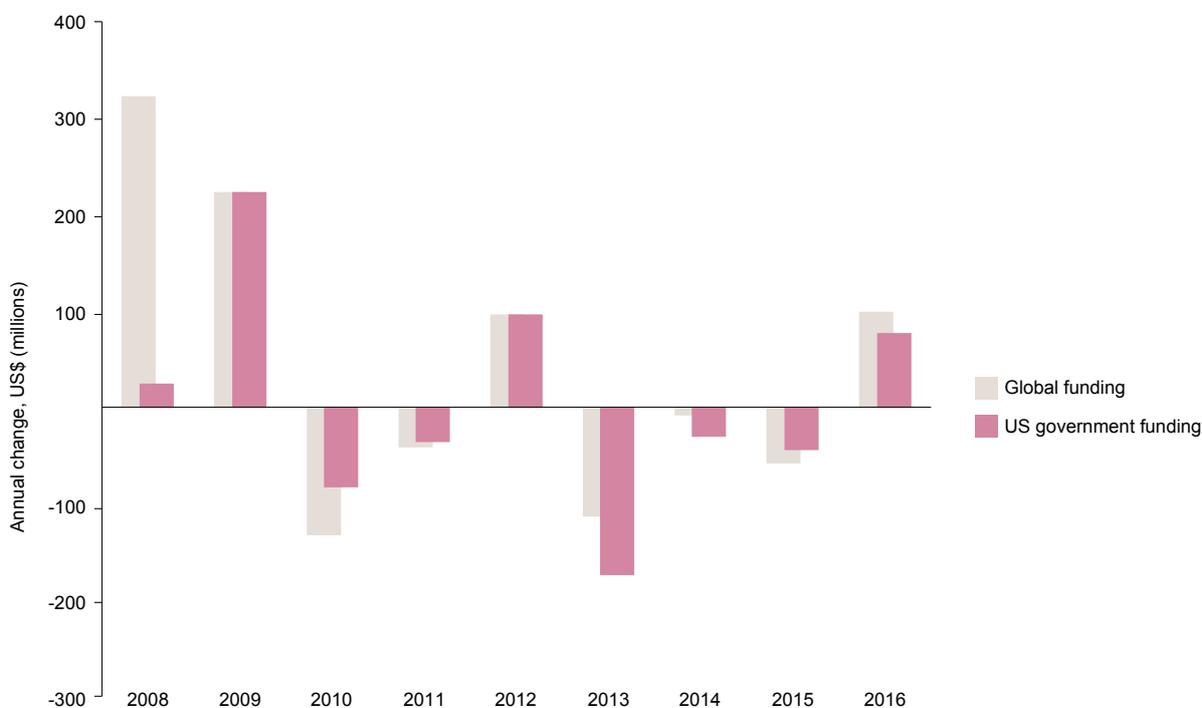
Global funding for neglected disease R&D increased for the first time since 2012, driven by an increase in funding from the US government

Global funding for neglected disease R&D increased (up \$99m, 3.4%) to \$3,203m in 2016. This was the first increase in global funding since 2012, and came on the back of an increase in neglected disease R&D investment by the US government (up \$78m, 5.5%), also for the first time since 2012. This in turn was due to increased investment in neglected disease R&D by the US NIH (up \$89m, 7.2%) – again, for the first time since 2012.

The US government was not alone in increasing funding for neglected disease R&D in 2016. The philanthropic sector (up \$28m, 4.4%) and the pharmaceutical industry (up \$22m, 5.3%) both increased their investment, with the latter driven by increased SME investment. There were also notable increases from the Dutch and UK governments, as well as from a host of governments outside of North America and Europe – Brazil, Japan and India in particular – which helped to offset reduced funding from the EC and a number of other European governments.

The US government is just one funder among many making critical contributions to neglected disease R&D. But as the largest funder of all, changes in total global investment are closely aligned to changes in US government investment: every increase or decrease in US government investment in neglected disease R&D over the last decade has been accompanied by a corresponding change in total global funding.

Figure 24. The US government’s influence on changes in annual funding for neglected disease R&D



An overreliance on US government funding is defining the shape of R&D for neglected diseases

In 2016, the US government was the source of 47% of global funding for neglected disease R&D, and 73% of all public sector funding. Its investment of \$1,490m was triple the combined investment of the rest of the world's governments, and fifteen times larger than that of the next biggest government funder (the UK, with \$101m).

The fact that the US government contributes such a large share of global funding means that not only are changes in US government funding the main driver of changes in total global funding for neglected disease R&D, but that the nature of neglected disease R&D is being defined by the focus of US government funding.

US government funding for neglected disease R&D is overwhelmingly focused on HIV/AIDS, TB and malaria, which received 82% of all US government funding for neglected disease R&D in 2016 (and 81% of its funding over the last decade). Despite the rest of the world (across all funding sectors) only directing 60% of their collective investment to these three diseases, they account for a full 70% of global funding.

US government funding for neglected disease R&D is also overwhelmingly focused on basic and early stage research. Two-thirds (67%) of all US government funding for neglected disease R&D in 2016 was for basic and early stage research, compared to just 28% for clinical or field development and post registration studies, with the remaining 5% not allocated to a specific R&D stage. But this headline figure doesn't quite tell the whole story, due to the US government's massive investment in clinical trials for HIV/AIDS vaccines, which totalled a quarter of a billion dollars (\$245m) in 2016.

If US government funding for HIV vaccine clinical trials is excluded, 80% of all US government funding for neglected disease R&D – and 70% of all funding from HIC governments – was for basic and early stage research, compared to just 14% for clinical or field development and post registration studies.

The sustained growth in industry investment in neglected disease R&D – lately driven by SMEs – continues to be a good news story

After a brief dip in 2011, industry investment in neglected disease R&D has increased in every one of the last five years, and reached new record highs in each of the last three years. In 2016, total industry investment was \$497m, accounting for 16% of all global funding for neglected disease R&D. Since 2008, reported industry investment in neglected disease R&D has increased by nearly 50%, while funding from both the public and philanthropic sectors has fallen over the same period.

The vast bulk of industry investment (79% in 2016) comes from MNCs, who have also been responsible for much of the growth in industry investment in neglected disease R&D over the last decade – driven by increased activity in malaria and HIV/AIDS especially. Since 2014 however, MNC investment has essentially plateaued, with annual increases of less than 1% in both 2015 and 2016.

Increased investment by SMEs since 2012, particularly from those in India, has helped to sustain the growth of overall industry investment. SME investment in neglected disease R&D tripled between 2012 and 2016 (from \$35m to \$106m); this was driven by Indian SMEs, whose investment increased from \$9.3m to \$70m over the same period, and now exceeds that of the Indian government. The \$22m increase in industry investment in 2016 came entirely from SMEs (up \$23m, 30%), who also provided their highest ever recorded investment, and the largest share of total industry investment (21%) since 2008. Importantly, much of this investment growth has also been in new areas: while 76% of MNC investment in 2016 was for malaria, TB and HIV/AIDS, none of these three diseases was in the top three diseases invested in by SMEs. Instead, 67% of SME investment in 2016 was for bacterial pneumonia & meningitis, *Salmonella* infections and diarrhoeal diseases.

In addition to SMEs, a number of other funders have been making a small but growing contribution in areas of need

As well as SMEs, a number of other traditionally smaller funders have been noticeably increasing their investment in neglected disease R&D: key global health initiatives (Unitaid, MSF and Gavi, the Vaccine Alliance), the Japanese government, and governments in LMICs.

Unitaid, MSF and Gavi have each expanded their focus to include support for neglected disease R&D, particularly for clinical or field development and post registration studies. Unitaid has expanded its focus from affordability, procurement and pricing to also include support for drug and diagnostic R&D for TB, malaria and HIV/AIDS. The first reported R&D funding from Unitaid was to FIND (\$6.9m in 2009), and the organisation has increased funding in four of the last five years. Unitaid invested \$40m in neglected disease R&D in 2016, providing more funding than all but six governments globally. This included \$28m for clinical development and post registration studies to the endTB partnership, which is focused on the development of new treatments for MDR-TB.

MSF supports R&D across multiple diseases and product areas. It helped found the product development partnership DNDi, and support to DNDi represents the vast majority (\$51m, 87%) of MSF's funding for neglected disease R&D over the last decade. But in recent years MSF has also become increasingly involved in direct collaborations with other R&D organisations – such as the recent Phase III trial of Serum Institute of India's BRV-PV rotavirus vaccine candidate in Niger – with non-DNDi funding accounting for over half of MSF's \$10m investment in neglected disease R&D in 2016.

Gavi has made a similar adjustment to Unitaid, expanding its focus from vaccine financing and supply to include support for clinical development and post registration studies of new vaccines for bacterial pneumonia & meningitis, diarrhoeal diseases and *Salmonella* infections. Gavi was the only one of the three global health initiatives to reduce its funding in 2016 (providing \$5.8m, down from a peak of \$19m in 2013), but it has the second highest contribution of the three over the last decade, with \$76m.

The Japanese government – along with Japanese pharmaceutical companies – is increasingly investing in neglected disease product development following the establishment of the GHIT Fund in 2013. Between 2007 and 2012, the Japanese government invested an average of \$5.5m per year in neglected disease R&D; since then, its annual investment has never been lower than \$10m, and reached a record high of \$17m in 2016. And, reflecting the focus of the GHIT Fund, this increased investment has been directed towards product development (both early and late stage), rather than basic research.

Finally, funding from LMIC governments increased strongly in 2016, to \$84m. More than 90% of this funding (\$78m, 93%) came from the three IDCs (India, Brazil, and South Africa) – all of whom increased their investment in 2016 – with India becoming the fourth largest government funder of neglected disease R&D, ahead of both France and Germany. And unlike HIC governments, which directed nearly half of all their funding for neglected disease R&D in 2016 to HIV/AIDS, LMIC governments invested more in each of TB, malaria, kinetoplastids, diarrhoeal diseases, dengue and leprosy in 2016 than they did in HIV/AIDS.

Conclusion

The US government's contribution to neglected disease R&D funding is unparalleled. But an overreliance on US government funding is reflected in the heavy concentration of global funding on HIV/AIDS, malaria and TB, and the overwhelming focus of HIC government funding on basic and early stage research. The growth of non-traditional funders is promising, but their collective contribution is still just a fraction of overall global funding. And while Gates Foundation investment in product development has consistently been relied on to balance the public sector focus on basic research – it has provided 55% of all funding to PDPs and 47% of all funding for platform technologies over the last decade – this is again a reflection of overreliance on a single funder. The world can ill afford to keep relying on the US government and the Gates Foundation to provide two-thirds of all global funding for neglected disease R&D over the next ten years, as they have done for the last decade.