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Medical philanthropy pays dividends

The impact of philanthropic funding of basic and clinical research goes beyond mere finances by reshaping the whole research enterprise

Melissa L Stevens

Philanthropy is a bright light in a dim reality of medical research and drug development. Only 1 in 10,000 academic discoveries make their way into a new therapy or diagnostics that helps patients. Those few discoveries that are taken up by biotech or pharma companies take 15 years and over US$1 billion to bring a new product to the market—if they ever make it that far. Moreover, there are between 7,000 and 9,600 known rare diseases, for which there are 773 FDA-approved orphan drugs as of 2019 (https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm). These data are primarily US-centric, but they represent the challenges faced around the world.

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Philanthropy is a relatively small player in the medical research ecosystem. It accounts for < 3% of all of US funding for R&D (https://www.researchamerica.org/sites/default/files/Policy_Advocacy/2013-2017InvestmentReportFall2018.pdf), which pales in comparison with the billions of dollars spent by government entities, such as the NIH, and the biopharma industry. Yet, underdog as it may be, it can still punch well above its weight. Time and again, philanthropy has shown to wield a profound and outsized impact because it is not subject to the same constraints as other sources of capital.

Michael Milken, a medical philanthropist and Chairman of the Milken Institute, said "Philanthropy is far more than just writing checks. It takes an entrepreneurial approach that seeks out best practices and empowers people to change the world" (https://givingpledge.org/Pledger.aspx?id=245). When philanthropists and foundations fully embrace the unique attributes of their capital and use it strategically to fill key funding gaps, incentivize new behaviors, and innovate the medical research system, we see positive impacts for science and for patients.

Philanthropy primed for long-term growth

The United States is in a second gilded age of philanthropy: Giving has set new records with US$410 billion given to charitable causes in 2017 [1] (*Giving USA 2018*). In terms of GDP, the US philanthropy market would be the 28th largest economy in the world, falling between Austria and Norway. And during the next 30–40 years, about 30–40 trillion dollars are expected to be passed from baby boomers to their heirs [2]. This will be the largest ever intergenerational exchange of wealth with significant impacts on philanthropy. While the United States is the most philanthropic nation in the world, the charitable sector is robust in Europe and about to take off in Asia. As of 2016, foundations in the EU accounted for an additional €60 billion, up by 13% from 2014 (http://dafne-online.eu/wp-content/uploads/2016/10/PBF-Report-2016-9-30-16.pdf). Philanthropy in Asia is poised for exponential growth: Giving from the top 100 philanthropists in China amounted to $4.6 billion in 2016, three times what was given by that cohort in 2010 (http://dafne-online.eu/wp-content/uploads/2016/10/PBF-Report-2016-9-30-16.pdf).

Against this background, there is good reason to assume that medical philanthropy will flourish. Among the 190 billionaires who have promised to donate at least half of their wealth, health is noted as the highest priority (https://givingpledge.org/PledgerList.aspx). Some of these philanthropists have already transformed research through their giving [3]. Examples include Bill and Melinda Gates for global health and Michael Milken for prostate cancer. Others, such as Mark Zuckerberg and Priscilla Chan, are just getting started, looking to build tools and infrastructure to accelerate the pace of research across all therapeutic areas.

Other important players are the patient advocacy groups and disease research foundations deemed by industry analysts as the "New Power Players in Drug R&D" (https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/xconomy_power_players.pdf). Household names such as the Juvenile Diabetes Research Foundation, National Multiple Sclerosis Society, and Michael J. Fox Foundation for Parkinson's Research, along with other public charities, are using their financial resources, trust from the patient communities, and nonprofit status to advance medical research. These medical research organizations increased their fundraising by almost 5% between 2016 and 2017 [4].

The comparative advantage of philanthropy

On a superficial glance, it looks like life science research is flush with cash. In the United States alone, the NIH enjoyed a budget increase in 2018 of US$3 billion (or 9%) over its 2017 budget which brings its overall funding to US$37 billion, the highest ever. The pharmaceutical industry invested about US$122 billion in R&D in the United

Center for Strategic Philanthropy, Milken Institute, Washington, DC, USA. E-mail: mstevens@milkeninstitute.org
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States in 2017 [5]. A look at historical data shows that R&D investment has grown faster than revenues, suggesting that pharma is not backing away from R&D at a macro-level. In 2017, the life science venture capital industry has seen record financings, and funding is up over 250% since 2013 (https://lifescivc.com/2018/06/biotech-ceo-pay-inflation-held-at-bay/). In fact, 2018 saw record of US$17B across ~700 deals in pharma and biotech.

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However, despite an overall rising tide, not all boats are being lifted. Although NIH funding is higher than ever, it is still operating at a loss after inflation and was significantly stifled over the last decade. Between 2003 and 2015, the NIH's purchasing power dropped by 22%, such that only one in five meritorious grant applications could be funded because of budgetary constraints (https://fas.org/sgp/crs/misc/R43341.pdf). Those who fared worst were young and mid-career investigators: the average age for securing an investigator's first NIH grant rose from the mid-30s to 43 (https://grants.nih.gov/grants/new_investigators/Age_Degree-First-Time-117-16_RFM_lls_25march2016_DR-Approved.xlsx). This threatens the pipeline of scientific talent, delays scientific independence, and stunts research. Additionally, proposals that already had some scientific data often scored more favorably in review [6]. The academic research community understandably responded with relatively less risky projects. Unfortunately, US budget woes of the past have left the country with a leaky talent pipeline and years of risk aversion.

We need industry R&D investment to commercialize new therapies, but while the overall corporate funding may seem to be steady or increasing, the majority of that funding supports later-stage clinical development. The well-documented "valley of death"—the gap between discovery and the point at which a company is willing to step in—still exists, and more funding is needed to support preclinical and early clinical work to determine scientific and clinical proof of concept. Additionally, industry investments congregate in therapeutic areas with lower risk, resulting in fewer dollars allocated to clinical areas with significant unmet need such as neurodegeneration, mental health, and cardiovascular disease. Capital is needed to derisk these areas by advancing our understanding of the underlying biology, mechanism of disease, and early diagnostic criteria to make these fields more attractive for industry investment.

Philanthropy is uniquely positioned to address these cracks in the system, and there are a number of reasons why. Most importantly, philanthropic capital has a high tolerance for risk. It is not constrained by the need to deliver financial returns to shareholders or investors. It has the opportunity to test big and bold ideas. It can chase unconventional avenues of scientific inquiry, help attain proof of concept, and build research tools and human capital. Philanthropy is also patient. It is not beholden to earnings or election cycles, so it is well positioned to fund longer-term efforts that may need years or even decades. Philanthropy already has had and continues to have a tremendous impact on medical research by closing critical funding gaps, improving research culture, and driving fundamental system change.

Philanthropy fills key funding gaps to derisk science

One of the most prominent gaps that philanthropy has filled over the past two decades is the translational "valley of death". Many foundations have adopted a "venture philanthropy" strategy, funding not only translational academic research programs but also commercial entities. Venture philanthropy treats funding as an investment rather than a gift, with expectations of social return, efficiency, and oversight. There is growing evidence that these programs are efficient in moving early-stage assets into the clinic and setting them up for longer-term development and regulatory approval.

The most well-known success story is the Cystic Fibrosis Foundation (CFF), which has deployed a successful venture philanthropy model for the last 20 years. To date, it has invested nearly US$500 million in medical products, the most well-known being Kalydeco, the first disease-modifying therapy for cystic fibrosis by Vertex Pharmaceuticals. CFF negotiated a term that allowed them to receive a royalty stream from the sales of the product. Kalydeco was approved in 2012, and CFF sold its royalty stream for US$3.3 billion to Royalty Pharma in 2014. Cystic Fibrosis Foundation also developed a network of more than 120 care centers that allowed for swift enrollment of patients with a particular kind of genetic mutation for clinical trials. This is an example of how philanthropic capital can unlock a path to system change.

Many other disease research organizations have crafted programs that direct funding toward research in academic laboratories or early-stage biotech companies to bridge the valley of death. Take, for example, the Leukemia and Lymphoma Society, which funds over US$45 million in blood cancer research annually. Their Therapy Acceleration Program (TAP) with 19 projects in the portfolio is a venture philanthropy started in 2007 that partners with biotech companies to accelerate the development of novel therapies (https://www.lls.org/therapy-acceleration-program). During the past decade, TAP has helped to move dozens of preclinical efforts into clinical trials, and in 2017, two of their partnerships yielded FDA approvals: Celator's (acquired by Jazz Pharmaceuticals) for treating high-risk acute myeloid leukemia and Kite Pharma's (acquired by Gilead) CAR T-cell therapy for lymphoma patients.

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Several other foundations have followed suit and established venture philanthropy funds. The National MS Society launched its Fast Forward program in 2009 and has deployed more than US$20 million to 46 preclinical projects in academic and biotech with a goal of advancing them for additional follow-on funding (https://www.nationalmssociety.org/Research/). Last year, the Juvenile Diabetes Research Foundation launched T1D Fund, with US$65 million to invest into early-stage companies to derisk them for later-stage investment (https://t1dfund.org/about-us/).

However, there is still a substantial need to understand the basic biology of many diseases. While government funding in the United States largely supports basic science, foundation funding has a comparative advantage by providing a longer timetable, deploying awards on a rolling basis, funding work to test novel hypothesizes, and establishing large, multi-institution research teams, among others. According to a survey conducted by the Science Philanthropy Alliance, a US-based nonprofit, 46 universities received just over US$2 billion in philanthropic funding in 2017 to support basic science research [7]. Perhaps more impressive than the absolute amount donated is the rate of growth. Between 2015 and 2017, charitable giving to basic science grew about 40% among the sample set [7].

Investing in people

The Howard Hughes Medical Institute is one of the largest and longest-standing philanthropies focused on advancing basic research by giving talented scientists the resources to freely explore their interests. With annual program expenses near US$1 billion, HHMI supports more than 300 investigators at over 60 institutions. Since they began their work 60 years ago, their efforts have yielded 29 Nobel Laureates, signifying the importance of the scientific work and the contributions to mankind (https://www.hhmi.org/press-room/fast-facts).

The Simons Foundation Autism Research Initiative, founded by Jim and Marilyn Simons, focuses on basic research for autism. One of their award mechanisms, the Explorer Award, is an US$80,000, 1-year grant to support researchers to strengthen their hypothesis, in addition to attracting new talent (https://www.sfari.org/grant/explorer-awards-rfa/). This kind of award facilitates new scientific approaches and positions scientific talent to be competitive for the larger pools of government funding. It has also been effective at recruiting computer scientists, engineers, and researchers from different disciplines into the life sciences. Along the same lines, the Prostate Cancer Foundation (PCF) focuses on funding young investigators, typically younger than 35, in postdoctoral fellowships or junior faculty positions. In addition to receiving funding for 3 years, they are paired with leading experts in the field as mentors. Since 2007, PCF has invested more than US$53 million to help 255 young investigators pursue new lines of scientific inquiry and preparing them as future leaders in this field.

These kinds of investments in early-career scientists can have huge payoffs. In 2016, the Milken Institute Center for Strategic Philanthropy analyzed over 100 young investigator and postdoctoral fellowship awards that the Milken Family Foundation had made between 1989 and 2007 (http://www.milkeninstitute.org/blog/view/1069). As of 2016, 100 and 80% of them, respectively, were still active in research, while only 7% of the distinguished NIH investigators still had an active government grant. This cohort was also significantly more successful in securing NIH R01 grants than the general pool of new investigators.

Retooling the toolbox

Foundations look not just at the science, but the entire research system to lower the risks for other players to enter. This can include creating, aggregating, and improving accessibility of tools and data. The Michael J. Fox Foundation for Parkinson's Research has done this well. They have curated a catalog of research tools, from animal models to viral vectors, to make it easier for scientists to find and obtain existing resources (https://www.michaeljfox.org/research/research-tools-catalog.html?navid=research-tools-catalog). They have characterized preclinical models to better inform selection of appropriate tools, and they manage the Parkinson's Disease Research Tools Consortium, a precompetitive group of eight companies that is working to create new tools from animal models to antibodies to assays, and to improve existing ones (https://www.michaeljfox.org/page.html?tools-consortium). Foundations have similarly built virtual toolboxes for Alzheimer's disease, autism, chordoma, and others.

Some foundations also focus on biomarkers that are perhaps one of the most critical research and clinical tools, but particularly challenging to develop without collaboration and patient engagement. As commercial entities find it difficult to justify investing into biomarkers because of the lack of immediate commercial return, it makes them prime opportunities for philanthropic funding. The Michael J. Fox Foundation launched the Parkinson's Progression Marker Initiative in 2010 and has deployed over US$60 million through an observational clinical study to investigate existing markers and identify new clinical, imaging, and biological markers of disease progression (http://www.ppmi-info.org/).

More recently, philanthropists Bill Gates and Leonard Lauder made headlines by backing a new Diagnostic Accelerator as part of the Alzheimer's Drug Discovery Foundation (https://www.reuters.com/article/us-alzheimers-diagnostics-fund/bill-gates-backs-30-million-push-for-early-alzheimers-diagnostics-idUSKBN1K728L). This effort pools funding from other philanthropic families to develop novel biomarkers for early detection of Alzheimer's disease and related dementias. A biomarker that could help to diagnose Alzheimer's in its early stages would dramatically derisk clinical research and incentivize even more clinical activity.

Targeting ignored diseases

Finally, philanthropic capital can be a game-changer for nascent fields that are not competitive for most established funding sources. At the Milken Institute Center for Strategic Philanthropy (CSP), we have worked with families touched by rare, hard-to-diagnose diseases—some of which are not even recognized as a disease by the medical community—to marshal resources that can jump-start an entire field of science. The initial investment to define and characterize these diseases is one of the first major steps to derisk R&D for other funders and can result in significantly outsized impacts.

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Take for instance lipedema, a painful, chronic condition that manifests as symmetrical buildup of fat and swelling in the limbs, predominantly in women. The lack of consensus in the field around the mechanism of disease, the lack of diagnostic criteria, and lack of awareness, compounded with the stigma of weight gain, have resulted in a majority of patients being misdiagnosed and offered merely symptomatic treatment with minimal scientific backing. No grants had ever been awarded

from the NIH to research lipedema. In recent years, the Lipedema Foundation has deployed nearly US$6 million, which has galvanized both a scientific and patient community, attracted new talent to the field, and kick-started research efforts. The foundation strategically engaged the NIH early on to raise awareness about the condition and to determine how its grantmaking could produce enough evidence to unlock further government investment.

Cultural revolution: philanthropy shifts the norms

What philanthropy funds certainly has had a significant impact on the medical research ecosystem, but how philanthropy funds can also play a big part. Foundations and philanthropists understand that their capital can incentivize new behaviors such as collaboration and data sharing, which promote more efficiency in research.

Discovering and developing new therapies takes a village. Philanthropy has responded by offering funding structures that enable teams of researchers to reach across institutional boundaries and collaborate. For example, Stand Up To Cancer, started by leaders in the US entertainment industry, has funded 21 research "dream teams" that on average engage 12 members, including investigators, project managers, and patient advocates, with 7–8 figures of financial support.

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Other foundations have facilitated multi-investigator and multi-sector teams through smart structuring of their grants. For example, the Melanoma Research Alliance (MRA), founded by Debra and Leon Black, has made collaboration the cornerstone of its awards. Their Team Awards bring together multiple investigators across a variety of disciplines to address critical translational research questions that will expedite research into the clinic. MRA also supports Academic Industry awards that facilitate collaboration between university and pharma research teams. These award mechanisms are important for razing the silos between laboratories, institutions, disciplines, and sectors.

Since data are the main currency in medical research, it is understandable that investigators have been cautious with sharing their results before publication. A recent survey of Wellcome Trust awardees confirmed that concerns over publication opportunities was a key factor for a lack of data sharing [8]. Philanthropic capital has been instrumental in changing this practice. More and more foundations, including the Wellcome Trust and Bill & Melinda Gates Foundation, are using their positions to facilitate faster and earlier knowledge sharing. They are doing this by requiring the submission of research data, including clinical trials data, into a central repository that is accessible by other grantees and paying for the effort needed to organize and upload data [8]. Often, milestone payments are being tied to the submission of data to enforce the practice. The repositories have managed access, embargo periods, and data use requirements so that investigators can remain confident that the confidentiality of their research is respected until publication while their data are being used appropriately.

One of the most significant impacts philanthropy has had on the medical research system is giving patients a seat at the table. Philanthropy-driven efforts at disease research foundations and patient advocacy groups have been instrumental in ushering in new patient engagement practices: building patient registries that aggregate longitudinal clinical data to elucidate the natural history of disease; administering patient-preference studies; providing input on the design of clinical trial protocols and consent processes; informing regulators about patient perspectives on benefit-risk trade-offs; and supporting interpretation of study results [9]. More patient input in the R&D process can yield positive benefits for all stakeholders, ultimately leading to better and safer treatments that really matter to patients.

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At the Milken Institute CSP, we worked with the Depression and Bipolar Support Alliance to collect input from 6,000 patients to understand their lived experience. The data collected will help the R&D community understand the issues that are of priority concern for these people. The intent is that these published data will inform funding, research priorities, and regulatory frameworks for considering new therapeutic interventions. The findings were shared with the FDA as part of its Patient-Focused Drug Development program and will be a helpful context for reviewers as they consider submissions for Investigational New Drug and New Drug Applications.

Winds of change

In addition to incentivizing individual behavior change, philanthropy is reimagining the medical research system by driving change in policy, appropriations, and regulatory paradigm. For example, Act for the NIH, backed primarily by philanthropist Jed Manocherian, has advocated for increases to the NIH budget since 2014 (https://www.actfornih.org/). Although there are several contributing factors, Act for the NIH can claim credit for the success of a US $7 billion budget increase over the past 3 years that helped to reduce the inflationary loss from 25% down to 13%. More work needs to be done, but philanthropy has been essential at reversing the trend of US federal government cuts to medical research.

Other nonprofit organizations are helping to transform policy and regulation. The Milken Institute's *FasterCures* center was a central player in helping to advance the 21st Century Cures Act that was passed into law in December 2016 (https://www.fastercures.org/programs/r-and-d-policy/21cc/). The legislation included NIH budget increases, particularly for brain and cancer research, as well as system improvements such as changes in regulatory requirements to expedite drug approval processes.

Further, philanthropy-supported Friends of Cancer Research, a nonprofit advocacy group, has been instrumental in improving research policy and regulatory processes for developing cancer therapies. One standout example is the 2013 establishment of the Lung-MAP clinical trial model that assigns patients to a specific drug arm based on their individual tumor profile (https://www.focr.org/lung-map). This model has the potential to save time and money in the research process while delivering better outcomes for

patients. *FasterCures* has provided a platform for collaboration that has brought together all facets of the medical research system across government, academia, industry, nonprofits, and patients. Through its Partnering for Cures conference and virtual convenings, the organization has established dialogues between nontraditional allies. The Laura and John Arnold Foundation has focused on improving research integrity to improve the reliability and validity of scientific research. They are funding programs that enable more transparency, such as the Open Science Framework that is building a publicly available resource of research hypotheses and corresponding results, data sets, and code, and by supporting major efforts to replicate landmark studies to improve reproducibility of research (https://osf.io/).

Not the cure for all that ails us

While philanthropy has made an impact on specific therapeutic areas and is improving the overall efficiency and effectiveness of the medical research system at large, it is only one tool, and it comes with its limitations and legitimate critiques. The first limitation is philanthropy's scale. While we expect giving to grow, it will always be just a fraction of the investments by governments and companies. Although more venture philanthropy models are funding across the valley of death, most efforts are only able to support discovery, preclinical, or some early clinical trials. In 2016, the average cost of phase II trials was between US$7M and US$20M and the average cost of phase III trials ranged from US$12M to US$53M across therapeutic areas (https://www.centerpointclinicalservices.com/blog-posts/driving-drive-drug-innovation-and-market-access-part-1-clinical-trial-cost-breakdown/). Most foundations do not have the financial resources to meaningfully fund these later-stage trials.

For philanthropy to amplify its impact, it needs to support the best science and collaborate with other funders, particularly the ones with the financial wherewithal, expertise, and distribution machinery to push an asset over the goal line and ensure it gets into the hands of patients. Many foundations need in-house expertise to collaborate with third parties so they can ensure a handoff to a commercial partner. Foundations also need to ensure they are promoting data sharing so that other scientists and funders can move forward research programs that they are not financially able to support. Without that, there is risk that great science is put on a shelf while searching for new financial partners.

There are other issues impacting the efficiency and effectiveness of philanthropic organizations. First, public charities are rated according to a number of different factors including their overhead costs. Pressures to keep administrative costs low make it difficult for nonprofits to compete for talent with the skill necessary for drug development, thereby creating a perverse disincentive to invest in organizational capacity, infrastructure, and human capital that is needed to deliver quality.

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Additionally, there are often multiple foundations dedicated to the same disease with very similar missions. For example, according to GuideStar, an online charity rating agency, there are more than 1,500 organizations working in the area of breast cancer, though not all fund research (https://www.guidestar.org/). Often this happens because philanthropists want to leave their own legacies rather than join an existing effort. Moreover, approximately 75% of all public charities reporting to the IRS in the USA have expenses of less than US$1 million (https://nccs.urban.org/publication/nonprofit-sector-brief-2018#size). A fragmented ecosystem with many small players can result in duplication of research or administrative costs, and other inefficiencies. Foundations, particularly those with smaller budgets, also have limited ability to bring onboard in-house scientific talent or access external expertise to properly vet research proposals and set a scientific agenda. There is also not enough meaningful coordination and collaboration across organizations with related missions. Thus, while some all-star organizations might be making exceptional progress, this kind of ecosystem results in an increasingly complex funding environment for researchers, as multiple public charities are vying for public donations.

Another common critique of philanthropy is that it is used to advance personal agendas and does not have proper accountability measures built in, especially since philanthropies are tax exempt. This argument has been punctuated for medical research, and critics assert that it is unjust and undemocratic for philanthropists to direct funding to R&D for rare diseases that affect their families, rather than have this funding being allocated as part of a larger, national agenda. While it is hard to blame families for using any means available to improve the health of loved ones, we have seen some instances where funding priorities pivoted in step with a patient's clinical case, thereby prematurely ending financial support for otherwise promising research programs. While this is a risk for private philanthropy, disease research foundations that are public charities are often guided by longer-term strategic plans and research agendas. An alternate view is that high-risk, high-reward research for one disease, even if it is extremely rare, could have significant impact for many other diseases by advancing a certain technology.

Finally, there is concern that private philanthropic funding reinforces the widening disparity between the haves and have-nots. Because wealth creation has occurred primarily for whites, philanthropy is disproportionately allocated to diseases that predominantly affect white people, thereby perpetuating differences in health outcomes across races and ethnicities. There are also many examples of well-funded universities that use philanthropic gifts to start new centers or institutions—the rich become richer in the world of academia. Philanthropists fund alma maters, rather than research programs that seek and rigorously evaluate ideas and programs to find the best science.

What is to come?

As the amount of giving increases, we expect philanthropists and foundations to become more vibrant players and expand their mark on the global medical research system. We expect more collaborations between funders, allowing for more coordinated deployment of capital within and across therapeutic areas. We expect philanthropists to become more sophisticated in using the many arrows in their quivers—from grants to private

investments and from advocacy to influence—to drive forward progress.

But what is most exciting is the expected return for patients. Because of philanthropy, some patients may finally receive a diagnosis for their illness or can connect with other patients who are experiencing similar health challenges. Their doctors may finally be able to explain the underlying mechanism of disease and know how to prevent further progression. Patients may be more empowered to fully engage in the R&D process in the search for a medical solution. They may be able to participate in more clinical trials because philanthropy funding has helped to move experimental assets into the clinic and to overcome translational research funding gaps. Patients may now have innovative, disease-modifying, life-saving treatments where they did not previously exist. And for all of us—past, present, or future patients—philanthropy gives us hope for a healthy future. The cost of that? Priceless.

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