

REALIZING THE RIGHT TO SCIENCE



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By Erica Lessem and Suraj Madoori

As science-based activists, the right of everyone “to share in scientific advancement and its benefits”¹—or more simply, the right to science—offers tremendous potential for our work. Yet this right has been underexplored and underutilized. Under the leadership of Mike Frick, now co-director of our TB project, TAG began framing our advocacy within a right to science lens in 2015, adding to the small but growing body of work to understand and apply the right.² Building off the body of work that has resulted over the past five years, we decided to dedicate an edition of *TAGline* to the right, in light of upcoming official detailed communications on what the right to science means (see Frick [page 4](#)). We had no idea that by edition launch, we’d be in the throes of a pandemic, with the need to realize the right to science more important than ever.

The emergence of the SARS-CoV-2 virus, and the resultant pandemic of COVID-19 disease facilitated by many countries’ horrible mismanagement of it, are tragic demonstrations of why the right to science is so essential. Science underpins all the tools we need to combat a pandemic: evidence-driven epidemiology and public policy; sound information and public communications; and eventually, new diagnostics, therapeutics, and possibly vaccines. Only a science-based response will get us out of this with as minimal impact and lives lost as possible. Such a response requires strong political will and effectual governments to make adequate fiscal and policy investments to—in the language of the right to science—both develop and diffuse those advances to all who need them.

On the investment side, we see clearly from recent events that waiting until an emergency to make investments in research and development (R&D) means that high-quality, life-saving tools come far too late. While it can be hard, if not impossible, to predict what pathogen will explode as the next global health crisis, proactive and sustained investing in infectious disease research and product development helps support an infrastructure that can be readily deployed and adapted to respond to emerging threats. Instead, years of a free market-driven approach to R&D means that many companies have abandoned their infectious disease drug and

vaccine development units in favor of more lucrative, yet less essential therapeutic areas. Chronic underfunding of science directly threatens the rigor of biomedical research, with fewer resources to conduct and power randomized controlled trials to generate quality data.³ Underinvesting in research and accepting potentially biased or anecdotal evidence in place of randomized trials result in weak guidelines and challenge uptake of new interventions. Sustained and increased investments in public research institutions, such as the U.S. National Institutes of Health, are critical for building a basic science knowledge base to understand conditions and underpin product development, as well as providing funding opportunities to attract private sector endeavors. Investments also ensure that our best and brightest engage in advancing crucial research, while bringing promising, early-career researchers into the fields of emerging and neglected infectious diseases.

But developing the tools is only half of the battle. Making sure they equitably reach those affected is equally essential. With the COVID-19 pandemic, we are already seeing the breakdown of who benefits from science, including publicly-funded science, as we continue to see with the HIV, TB, and HCV epidemics. This inequity applies both within and across borders. For example, though the human right to science and its benefits is universal, the ability to obtain testing for COVID-19 hugely depends upon in which country one lives (compare early testing rates in South Korea versus the U.S., for example)³ as well as how resources and health care coverage are distributed within a country.⁴ A particularly egregious example of this breakdown is President Trump attempting to buy exclusive rights to a vaccine candidate from a German company, with an eye toward making it available only in the U.S.⁵ Or the case of U.S. Secretary of Health and Human Services Azar not committing to ensure that any vaccine developed would be affordable.⁶ In a time where rapid and unfettered access is vital, the policies lobbied by industry in the name of protecting innovation and intellectual property rights are barriers to meeting urgent health needs and limits the realization of the right to science for all. So while economic stimulus packages to incentivize private sector development may help produce

tools, they raise important questions about what safeguards are needed in terms of who will ultimately benefit from them, in order to ensure that human rights are respected, protected, and fulfilled. As you'll see in the following pages, the right to science offers us important insights to answer these questions.

Putting the Right to Science into Practice in U.S. Policy

In the U.S., as we enter the fiscal year 2021 appropriations season, there are clear opportunities to put the right to science into practice. Investments across the full spectrum of research and development—in the National Institutes of Health, the Center for Disease Control and Prevention, U.S. Agency for International Development, the Biomedical Advanced Research and Development Authority, and the Food and Drug Administration—are essential. And not just for COVID-19, but for longer-standing epidemics as well—we cannot rob Peter to pay Paul. We cannot leave unfinished the job of ending the HIV, HCV, and TB epidemics, which would be greatly facilitated by preventive vaccines, a cure for HIV, and shorter cures for HCV and TB. Such public investments should come with access guarantees and transparency, so taxpayers don't pay twice for developing and using an intervention. The government should not be afraid to exercise existing Bayh-Dole march-in rights to ensure affordability of tools when we need them most. Sustaining and increasing investments to strengthen disease response programs are also necessary: for example, as experts in addressing airborne infectious diseases, TB controllers are incredible front-line responders to COVID-19, and their expertise is being relied upon in this current crisis; however, years of chronic underfunding for TB mean limited capacity to respond to both challenges. These oft-neglected programs provide necessary infrastructure to smoothly implement new tools resulting from publicly funded research and to shift healthcare capacity to respond to emergencies; these programs need increased resources to flexibly respond to emerging and concurrent epidemics.

In this edition, we explore the right to science and its applications, moving from the theoretical to the practical. We begin with an interview with human rights expert Gisa

Dang ([page 9](#)) about the right to science, its interplay with other rights, and how it can inform and empower activists. Mike Frick ([page 4](#))—who started TAG's work on right to science back in 2015—then explains the United Nations general comment process to provide authoritative legal interpretation of the right, and what we hope and need to see from it. Annette Gaudino and Bryn Gay then begin to move us into applications of the right to science, as they explore what the right means in the context of diagnostics development in interviews with developer BLINK Diagnostics and the Access Campaign of leading implementing organization Médecins Sans Frontières. David Branigan homes in even more concretely on implications of the right to science on development of and access to molecular diagnostics to better detect TB.

Whether fighting the oldest infectious disease known to humans, or this new pandemic, the right to science offers us an invaluable frame for our activism and for reframing government policy. A transnational emergency—with unprecedented political attention and investments in health and research—is also a unique opportunity for incorporating, advancing, and codifying the right to science in fiscal, healthcare, trade, and regulatory policies to benefit vulnerable communities. We need science more than ever. What greater benefit of science is there than saving lives?

Endnotes

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THE RIGHT TO SCIENCE FINALLY COMES INTO SIGHT

What the General Comment on the Right to Science Means for Health Advocacy

By Mike Frick

Cameroonian artist Barthélémy Toguo's 10-meter-long watercolor *Purification* takes up an entire gallery wall in London's Tate Modern museum.¹ Text from the Universal Declaration of Human Rights (UDHR) expressing basic human rights runs along the top and bottom of the paper, handwritten in pencil. In between these lines of cursive text, a procession of human heads, torsos, necks, and arms painted in blurred red and gray tumbles, reaches, and stretches horizontally across the paper. The motions resemble the movements a person would make to shield one's face from the sun, turn away from a threat, or brace for a fall.

The size of Toguo's watercolor makes it impossible for a viewer to simultaneously take in the entirety of the painting and clearly read the thirty articles of the UDHR. Appreciating the whole of the UDHR as reproduced by Toguo requires standing at a distance that renders individual rights illegible. To locate specific human rights, one must move closer to the piece, examining one section at a time. This forced compromise in perspective is similar to how human rights are interrelated, interdependent, and indivisible—all rights are equal in importance, and none can be fully enjoyed without the others. Even so, acting on human rights often requires that one focus attention on the meaning of a single right, without considering the whole.

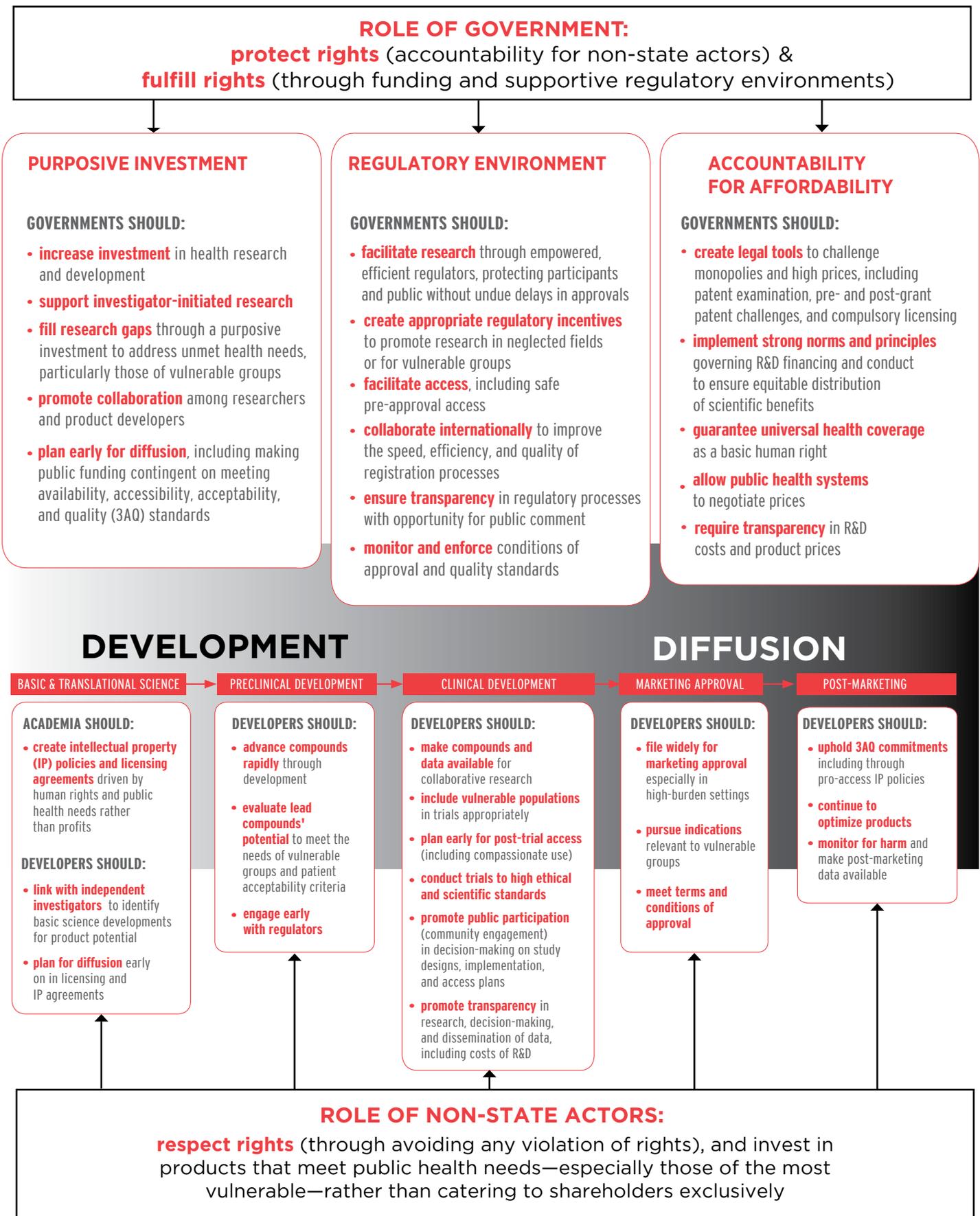
Article 27 of the UDHR—including the right of everyone “to share in scientific advancement and its benefits”—appears in the middle of Toguo's painting. Paradoxically, this positioning does not place the “right to science” in the center of the frame, but rather relegates it to a disappearing middle ground easily overlooked by the viewer. This placement—in plain sight, yet somehow just out of view—mirrors reality. The scope and nature of state obligations under the right to science, expressed in general terms by UDHR Article 27, are further elaborated on in Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). At fewer than 150 words, however, the ICESCR treaty text leaves much

unsaid. For their part, legal scholars, human rights activists, and governments have rarely acted on this right. As a result, human rights scholars have referred to the right to science as “the forgotten human right,” one so rarely invoked that it has occupied “the vanishing end of economic, social, and cultural rights.”^{2,3}

Finally, the right to science is becoming more visible. In April 2020, the Committee on Economic, Social and Cultural Rights (CESCR) released a general comment on Article 15 of the ICESCR. General Comment No. 25 offers the first authoritative legal interpretation of the right by the committee charged with guiding and monitoring how states implement economic, social, and cultural rights.⁴ The General Comment focuses on the parts of Article 15 that address the “right of everyone to enjoy the benefits of scientific progress and its applications” (Art. 15.1.b). This aspect of the right raises a long list of big questions: Who produces science? What do “scientific benefits” entail, and is there a difference between scientific knowledge and applications? Who can access these benefits? How should governments best promote science when non-state actors carry out so much research?

These questions are longstanding concerns for activists working to end HIV, tuberculosis (TB), and hepatitis C virus (HCV), and they are made freshly urgent as societies across the globe try to assemble the public health and scientific resources needed to confront the COVID-19 pandemic. In this sense, the General Comment arrives both long overdue and exactly on time.

General Comment No. 25 addresses the above questions and many more in 89 paragraphs written in straightforward prose. The potential impact of the General Comment in this moment extends far beyond the page: the document gives activists a framework for holding governments accountable for recognizing scientific progress and the enjoyment of its benefits as a fundamental human right.



General comments on other rights (e.g., General Comment No. 14 on the right to health) have helped galvanize advocacy by clarifying the individual entitlements and government obligations created by a right. A strong general comment might rally civil society to ensure that all people can enjoy the benefits and applications of scientific progress without discrimination. One can imagine right to science principles informing campaigns to increase government funding for research, achieve equitable access to essential medicines, or fight the privatization of knowledge by reclaiming science as a public good. A weak general comment would leave everyone from activists to governments confused and directionless.

With so much at stake, TAG carefully reviewed an earlier draft of the General Comment and submitted feedback to CESCR during an open comment period.⁵ This feedback adds to the significant body of work that TAG has produced to define and apply the right to science in the context of health.⁶ Overall, TAG felt that CESCR did a fantastic job. However, in some areas, particularly with respect to defining the actual steps governments must take to fulfill the right to science, TAG challenged CESCR to be more specific. It is gratifying to see that the final text reflects much of the feedback offered by TAG. The final General Comment stands out as one of the rare United Nations documents that becomes more concentrated in expression and focus between draft and publication rather than watered down with compromise between opposing constituencies (e.g., reconciling the divergent views of civil society and Big Pharma, or developed and developing country governments).

The following sections call attention to aspects of the General Comment particularly relevant to activists working on science and health. Throughout the following discussion, citations in parentheses refer to the paragraph of the General Comment where relevant text appears.

Participation

- CESCR has clearly identified participation as an animating value of the right to science. Crucially, participation must include more than the activities of scientists themselves: “The right...cannot be interpreted as establishing a rigid distinction between the scientist who produces science and the general population entitled only to enjoy benefits derived from research conducted by scientists” (¶19). Instead, every person has a right “to take part in scientific progress and in

decisions concerning its direction” (¶10). This language echoes the call for self-determination in medical care and research in the 1983 Denver Principles, as well as the “nothing about us, without us” mantra that underpins community engagement in research.⁷ Such a broad, inclusive view of participation supports the efforts of community advisory boards to shape health research agendas by elevating the perspectives of affected communities to the forefront of scientific decision-making.

- Participation is so central to the right to science that CESCR used the General Comment to greatly expand the scope of the right—starting by recasting its very name. The final text of General Comment No. 25 adds the phrase “to participate” to the longform name of the right: “Thus, it is the right to *participate* and to enjoy the benefits from scientific progress and its applications (Hereinafter: RPEBSPA)” (¶11, emphasis added). The long, unpronounceable acronym belies the significance of the shift in language here. In essence, CESCR decided to elevate participation from the background (one element of the right among many) to the foreground (something inherent to the idea of the right itself). CESCR justified this move through a careful textual analysis of UDHR Article 27, its evolution into Article 15 of the ICESCR, and the historical record of the debates that informed both processes. This is exactly the kind of conceptual advance one hopes to see a General Comment make, and advocates should celebrate CESCR for taking this bold step.

Access to scientific benefits

- Of central importance to TAG, CESCR has unequivocally stated that the “benefits” of science include both intangible knowledge and information as well as “the material results of the applications of scientific research, such as vaccination...” (¶18). This establishes a strong justification for claiming the tangible outputs of science (e.g., new health technologies) as benefits that should be accessible to all, and in doing so, strengthens the access to medicines movement. Although the General Comment does not use this language, former special rapporteur in the field of cultural rights Farida Shaheed has argued that a core principle of the right is that “innovations essential for a life with dignity should be accessible to everyone, in particular marginalized

populations.”⁸ Special attention to marginalized groups appears throughout the General Comment, suggesting that non-discrimination in access is at the heart of the right to science.

- One of the most practical parts of the General Comment stems from the decision by CESCR to define the right to science in terms of “five interrelated and essential elements”: availability, accessibility, acceptability, quality, and the protection of freedom of scientific research (¶16–20). The first four are known as the 3AQ, a framework that also appears in General Comment No. 14 on the right to health, where it has become one of the more powerful and enduring tools in the right to health movement. TAG was happy to see the 3AQ concept applied to the right to science and paired with protections for scientific freedom. Between draft and publication, CESCR significantly strengthened its analysis of what “availability” entails, specifying: “Research findings and research data funded by States should be accessible to the public.” This added point supports the position of TAG and other advocacy groups that public funding of science should result in public goods. Furthermore, CESCR established an explicit link between science and health, writing that states must make available and accessible “the best available applications of scientific progress necessary to enjoy the highest attainable standard of health.”

State obligations

- ICESCR Article Art 15.2 names three steps that states must take to fully realize the right to science: *develop*, *diffuse*, and *conserve*. The draft general comment was oddly silent on the specifics of these three actions. Because defining these terms is key to identifying state obligations under the right, TAG opened its feedback by proposing definitions. TAG framed development as a state responsibility to fund research and support a “purposive development” of science and technology to meet the needs of marginalized groups who are often overlooked by market-based incentives for research. TAG emphasized that diffusion is an “essential precondition” of participation in science since without access to scientific knowledge and applications, the public cannot engage with science in an informed, meaningful way. Finally, TAG argued that conservation means ensuring that the benefits of science are lasting, that is,

Major Milestones in the Development of the Right to Science

**May
1948**

Article XIII of the American Declaration of the Rights and Duties of Man contains the earliest expression of what will become the right to science.

**Dec
1966**

Article 27 of the Universal Declaration of Human Rights enshrines the right “to share in scientific advancement and its benefits.”

**Dec
1948**

Article 15 of the International Covenant on Economic, Social and Cultural Rights elaborates on the scope and nature of state obligations under the right to science.

**May
2012**

United Nations Educational, Scientific and Cultural Organization convenes series of expert meetings “to further elucidate the normative content of the right to enjoy the benefits of scientific progress,” culminating in the Venice Statement.

**July
2009**

Special Rapporteur in the field of cultural rights Farida Shaheed delivers the first report on the right to science to the United Nations Human Rights Council.

**April
2020**

Committee on Economic, Social and Cultural Rights (CESCR) releases draft general comment on Article 15; TAG comments.

**Jan
2020**

Publication of General Comment No. 25 on the right to science by CESCR.

available for present and future generations. The final General Comment contains a much stronger discussion of development, diffusion, and conservation along lines that largely reflect the definitions TAG suggested. Most importantly, the General Comment frames each as requiring action: “States must take positive steps for the advancement of science (development) and for the protection and dissemination of scientific knowledge and its applications (conservation and diffusion).” In other words, governments cannot sit back and merely observe that the right to science is not violated by others, they must actually do something themselves to fulfill entitlements under the right.

- The General Comment devotes an entire section to discussing special protections for Indigenous Peoples and their traditional knowledge (¶¶39–40). The text rightly points out that Indigenous Peoples’ free, prior, and informed consent to participate in research (or not) must be protected, and reaffirms “the rights of Indigenous Peoples [to] their land, their identity, and the protection of the moral and material interests resulting from their knowledge of which they are authors, individually or collectively.” This affirmation is powerful; however, the General Comment overlooks other important ethical and legal safeguards. TAG had urged CESCR to include references to relevant international law (e.g., the Bonn Guidelines and the Nagoya Protocol to the Convention on Biological Diversity), but these do not appear in the final draft. These treaties and protocols require states to ensure that any research involving traditional knowledge held by Indigenous Peoples proceeds with informed consent, under mutually agreed terms, and in the context of access and benefit-sharing agreements between traditional knowledge holders and those who use such knowledge, whether for academic study or commercialization.^{9,10}

Human rights and intellectual property

- The role of intellectual property (IP) in scientific research is one of the thorniest issues that any comprehensive discussion of Article 15 must confront. The same part of Article 15 that establishes the right of everyone to enjoy the benefits of scientific progress (15.1.b) also recognizes the rights of authors “to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production” (15.1.c). CESCR smartly addressed this apparent tension by referring to its earlier General Comment No. 17, which stated in no uncertain terms that moral and material interests in human rights law are not the same as IP protections as currently defined by international trade law.¹¹ A section of the General Comment on “private scientific research” (¶¶58–62) discusses three negative effects of IP: 1) it distorts scientific funding; 2) it blocks sharing of scientific results and methods; and 3) it prevents people from accessing scientific benefits that may be necessary to enjoy other rights (e.g., health rights). Although the language on IP softened a bit

after the public consultation, the heart of this analysis remains strong. Most importantly, CESCR recognized that IP protections such as patents are not the only way to encourage innovation. In ¶¶62, CESCR highlights alternative approaches that delink investments in research and development from the final product prices and volumes of sales (a concept called “delinkage”). In a later section on the right to health (¶¶67–71), CESCR calls on State parties to use flexibilities in patent law (e.g., compulsory licensing) to promote access to essential medicines and endorses the use of generic drugs over brand-name medicines. It appears that CESCR sought to position the right to science as a practical tool, one that can “become a significant mediator between a human right (the right to health) and a property right (IP)” (¶¶69).

Ultimately, the General Comment must become more than an object of study. It must provide a rallying point for activists and members of civil society seeking a more responsive research agenda, a more equitable distribution of scientific benefits, and a more secure commitment by states so that present and future generations will enjoy the benefits of scientific advancement free from discrimination. TAG stands ready to help communities that are working to end the epidemics of HIV, TB, and HCV apply the framework and principles set forth by General Comment No. 25 to advocacy so that they can claim scientific progress as a fundamental entitlement common to all peoples. Our hope at TAG is that the General Comment moves the right to science from the vanishing end of human rights to the center of state attention and civil society action.

Endnotes

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OPPORTUNITIES FOR ACTIVISM WITH THE RIGHT TO SCIENCE

By Erica Lessem

Interview with Human Rights Expert Gisa Dang

What do you see as the relationship between human rights and activism, and how can a human rights frame bolster activism?



Human rights and activism are closely intertwined. Having a human rights framework, and accompanying human rights mechanisms through the United Nations, enables activism that might not have otherwise been possible. For example, in countries that have rather oppressive systems, a human rights

framework enables people to access advocacy channels globally that they might not have domestically. This acts as a loop: people who might not be able to march up to their government can appeal to global standards and mechanisms, which then may bring action that benefits the activists' home country.

A human rights framework is about uniting—also a key aspect of activism. It is uniting first because human rights are universal. Second, because a human rights framework gives a common language to issues activists encounter around the world. This specific language allows framing an individual experience as part of a systematic issue. It enables an individual or community to move from understanding a specific plight as happenstance, to seeing it as a systemic issue and doing something about it.

Moving to the right to science in particular, what dimension do you think the right to science adds to health and social justice activism?

On a very basic level, the right to science says that governments have to make sure everyone can enjoy the benefits of scientific progress and its applications. States have to develop, diffuse, and conserve science. This identification of a state role in ensuring that certain things that support science, and therefore health, happen, is an additional tool for activism. For example, where treatment doesn't exist, and where research or financing to find it doesn't exist, the government needs to find ways to make the funds available and allocate health budget to make evidence-based interventions available once developed.

How would you define participation in relation to the right to science? What does nothing about us, without us look like under a right to science lens?

There are at least two layers here, and I say at *least* because we're still at the beginning of understanding and applying the right to science. At the basic level, participation means scientists need to be able to *do* science. They need to have the means, methods, and tools of science, the freedom to conduct research, the means of knowledge, access to data. At the same time, activists and affected communities need to have a voice in *doing* science—the process *and* the decision-making. If we look at how the AIDS movement evolved, understanding the science gave the movement a lot of power. Even though back then people were not talking about the right to science, the fact that activists were able to gain and use this knowledge in negotiating with policymakers reflects the right to science and what it stands for. In fact, the text of the General Comment No. 25 on the right to science, just published this April, elevates participation of anyone as a core tenant of the right. It makes clear that participation in all facets of scientific inquiry is not limited to only one group of people, and in fact obligates states to make participation by anyone possible.

You've already worked with TAG on a fair amount of health advocacy and treatment literacy using a right to science angle. How do you see this work changing or evolving, in light of the general comment the United Nations Committee on Economic, Social, and Cultural Rights (CESCR) recently issued?'

A general comment is an extensive analysis of a specific right within an international covenant. For example, because we have a general comment on the right to health, accessibility, affordability, acceptability, and quality (AAAQ) are accepted as the four important pillars of the right to health. Till now, we didn't have a similarly accepted interpretation of the right to science. Now that we have an authoritative analysis of the dimensions of the right to science, we know what obligations states as duty bearers have. We now have fairly clear standards against which each country's progress on right to science implementation will be measured by CESCR in their reporting. And we as activists have additional authority to make our arguments, e.g., public funding should lead to publicly available goods, which is mentioned in the GC. Now, we'll be able to move away from rather lonely desk work to activism and organizing. For example, we can create educational materials like toolkits, guides, and workshops, so that people can better understand the right and how it applies to them, so they can start actively engaging and utilizing the right in their activism. It's a coming-to-life process.

Do you have any concerns about how the right might be interpreted, in ways that could limit knowledge sharing or access?

I always have concerns about how human rights might be interpreted because we have to understand that just because a right exists doesn't mean that it is implemented in reality. With development and diffusion being part of the right to science, we have to look at who owns the knowledge and who owns the process of doing science. It is very exciting that the GC, for example, recognizes Indigenous People's ownership of their knowledge, land, and moral and material interests, including collective authorship. The GC also talks about IP, public funding resulting in public goods. However, the GC language is also one of "could" and "should". It is not a prescriptive "you must do this"- type of document. And while rights are interconnected and interdependent, they are not always interpreted as such; some countries interpret the right

to development, for example, as meaning they can infringe on other rights to realize that right. This is why it is important that the GC reminds states that if they need to limit the right, limitations have to be in accordance with law and must still respect the core obligations of the right. Use of science and technology can also be restricted to protect the safety of people involved, those using and subject to research or new technology. The GC suggests, for example, Human Rights Impact Assessments as one way to safeguard individual's dignity, as well as consent.

Legal challenges have been an important tactic in human rights-based activism. Could the right to science start to underpin legal challenges?

I strongly believe that activists are going to seize on it as an additional tool for their legal advocacy. The Optional Protocol to the International Covenant on Economic, Social, and Cultural Rights (ICESCR, which enshrines the right to enjoy the benefits of science and its applications) allows an individual to submit claims to the CESCR on any of these rights mentioned in the ICESCR if that individual has exhausted domestic measures to adjudicate this right. Now that we have clear core obligations, that will become an easier option.

I was curious if right to science had been used in legal advocacy, and I did find one case that cites right to science in both state and international law. In 1999, people living with HIV in Venezuela brought a case to the Constitutional Court² about the failure of the ministry of health to provide triple-drug therapy. The case mentioned the right to science because this right is part of the Venezuelan constitution. When I was working on [Universal Periodic Review submissions](#) for TAG, we found that the right to science is mentioned already in some regional human rights treaties as well as some constitutions and domestic legislation, e.g., Mexico has legislation that includes right to science.³ I think we'll see an increase in domestic cases, and once we have the normative content, we can then build the tools and the strategies to utilize the right to science.

Health activism often targets, in addition to state actors, non-state actors such as pharmaceutical companies, other product developers, and private philanthropies. How can the right to science be leveraged to influence and hold accountable these non-state actors?

Activism isn't a straight arrow approach. The challenge here is that governments are the ones responsible to uphold and implement human rights, but at the same time, there's a whole field of holding non-state actors that need to be accountable, including international businesses and conglomerates. Governments have a role to play here. They have the duty to ensure research happens and is made available, and it is secure for future use. States can give incentives as well as hold other actors accountable. While the GC doesn't go into much detail, it does mention the role of the state vis-à-vis multinationals, for example. Consumers can also have great influence on businesses, e.g., through movements to call for divesting assets from specific companies.

What about when governments themselves don't seem to care about human rights? The U.S., for example, has never even ratified important human rights conventions such as the ICESCR.

Human rights are universal. Even though a country may not have ratified the ICESCR, many of these rights, such as the right to science, already exist within the Universal Declaration of Human Rights. It's not as if not ratifying the ICESCR frees one of any responsibility of upholding these rights or that rights don't exist for people within a country's borders. It also doesn't mean that there isn't already national legislation

about any of these rights. On the other hand, the fact that laws are on the books doesn't mean that those rights are being implemented. This brings us to the one really important principle of participation which underpins all of it—you have to really understand your local context to find the best advocacy strategy. Depending on your audience, you can talk about and leverage human rights without saying *human rights*.

You have to think about who has the power to address what you need, who exerts power over them, and what information and strategies will get them to do what you need.

Endnotes

Gisa Dang is an experienced human rights activist who has been consulting with TAG for several years as we develop our right to science activism on tuberculosis, hepatitis C, and HIV. Previously, she worked with community groups in Asia to support their rights-based activism.

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(Continued from page 8)

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THE RIGHT TO QUALITY TB DIAGNOSTIC TESTING

By David Branigan

Rapid molecular tests, such as Cepheid’s Xpert and Molbio’s Truenat, offer the potential to dramatically improve rates of diagnosing tuberculosis (TB), including drug-resistant TB, when used as the initial TB test in place of the more common, century-old technique of smear microscopy. Yet, despite clear advantages compared to smear microscopy (see table), the scale-up of rapid molecular tests since their introduction in 2010 has been slow and suboptimal,

Many countries failed to fully scale-up and implement rapid molecular tests as the initial TB test for all, failing to meet their human rights obligations under the right to science.

resulting in continued reliance on smear microscopy, and contributing to an estimated three million people with TB who go undiagnosed each year.¹ Reasons for this slow uptake and implementation of rapid molecular tests include “high costs,” “poor sensitization of clinical staff,” “insufficient service and maintenance provision,” and “inadequate resources for sustainability and expansion.”² Scaling up access to rapid molecular testing for all people who are evaluated for TB is necessary to improve diagnosis of TB and drug-resistant

TB. Moreover, implementing these tests is a human rights obligation under the right to science.

In its draft general comment on the right to science (see Frick [Page 4](#)), the Committee on Economic, Social and Cultural Rights (CESCR) established that under this right, everyone should have “fair access to the applications of science.” An essential element of the right is “quality,” defined as “the most advanced, up-to-date and generally accepted science available at the time, which is considered by the scientific community to meet certain minimum standards.”⁹ The World Health Organization (WHO) is the primary body for determining the quality of TB diagnostic tests, and since 2013 it has recommended that countries implement rapid molecular tests as the initial TB test for all people who are evaluated for TB, rather than smear microscopy.¹⁰ Even after this recommendation, many countries failed to fully scale-up and implement rapid molecular tests as the initial TB test for all, failing to meet their human rights obligations under the right to science.

The reasons for this failure can ultimately be traced to insufficient country and donor budgets for procuring and implementing TB tests and also to the high prices of rapid molecular tests. Taken together, these factors limit “fair access” to quality TB diagnostic testing. Even if country and donor budgets expand, the current prices of Xpert and Truenat—both around \$10—make fully scaling up and implementing these tests too expensive,¹¹ especially in comparison to the cost

Rapid Molecular Tests vs. Smear Microscopy for Tuberculosis Detection

TB Diagnostic Tests	Sensitivity	Specificity	Time to Results	Price per Test	WHO Target Price ³
Smear microscopy ^{4,5}	50% (20-80%)	98%	< 5 min	\$0.26 to \$10.50	NA
Cepheid’s Xpert MTB/RIF Ultra ⁶	90%	96%	90 min	\$10	\$4-\$6
Molbio’s Truenat MTB Plus ^{7,8}	89%	98%	60 min	\$12	\$4-\$6

Sensitivity: the proportion of people with a disease who are correctly identified by a diagnostic test as having the disease

Specificity: the proportion of people without a disease who are correctly identified by a test as not having the disease

of smear microscopy and the WHO target price for smear replacement tests (see table). The good news is that the cost of manufacturing these tests is only a fraction of their price. A 2018 cost-of-goods analysis of Xpert tests found that at annual volumes of 10 million tests—which have already been reached for TB tests—the cost of manufacturing each test may be as low as \$3. The bad news is that in spite of reaching this economy of scale, Cepheid has not lowered the price of Xpert tests and has instead continued to charge a monopoly price that takes the lion’s share as profit.¹² Who then, under the right to science, is responsible for addressing the predicament that the right to quality TB diagnostic testing remains unfulfilled at global and national levels?

The responsibility to realize fair access to quality TB diagnostic testing rests largely on states, due to their treaty-based obligations to fulfil the right to science. According to the CESCR, governments are obligated to allocate the “maximum available resources” to fulfill the right to science, using “all appropriate means,” including “the adoption of legislative and budgetary measures,”¹³ and to seek “business cooperation and support to implement the Covenant rights.”¹⁴ Private companies, while not bound by the same treaty-based obligations as states, do bear some responsibility under the right to science to realize fair access to quality TB diagnostic testing. The United Nations Guiding Principles on Business and Human Rights establish that private companies have a responsibility to respect human rights, and that “[b]usiness enterprises should not undermine States’ abilities to meet their own human rights obligations.”¹⁵ In order to realize fair access to quality TB diagnostic testing under the right to science, states would have to increase government expenditure, mobilize additional resources, and negotiate lower prices for tests with diagnostics companies. Meanwhile, diagnostics companies would have to proactively work with states to achieve fair pricing structures that support states to fulfill their human rights obligations.

The diagnostics company Cepheid is failing to meet its responsibility to respect human rights by charging high prices for Xpert tests, thus undermining states’ abilities to implement these tests according to WHO recommendations. While many countries have struggled since 2010 to procure and implement rapid molecular tests due to their cost, Cepheid reaped huge profits from the sale of Xpert tests. In 2018, this amounted to approximately \$81.2 million profit from the sale of 11.6 million Xpert TB tests to high burden developing countries alone.^{16,17} Danaher, the company that acquired Cepheid in

2016, has since enjoyed soaring stock prices and record profits, with a net income of \$3 billion in 2019.^{18,19} Bolstered by its decade-long monopoly over the rapid molecular test market, Cepheid kept Xpert test prices high in spite of public investments in GeneXpert technology,²⁰ lower manufacturing costs, and its human rights responsibilities. Now that Molbio and other diagnostics companies are introducing new rapid molecular tests into the market, we must hold them to the same human rights standards as Cepheid.

Bolstered by its decade-long monopoly over the rapid molecular test market, Cepheid kept Xpert test prices high in spite of public investments in GeneXpert technology, lower manufacturing costs, and its human rights responsibilities.

Realizing the right to quality TB diagnostic testing will require concerted action by all stakeholders. Countries and donors must increase investments, expand budgets, and use their combined leverage to negotiate lower prices for rapid molecular tests. Governments must use all mechanisms at their disposal—including but not limited to placing conditions on research and development funding and on procurement contracts—to apply pressure on diagnostics companies to make their cost of goods transparent and commit to volume-based price reductions. Diagnostics companies must take on a more proactive role in meeting their human rights responsibilities. They can accomplish this by setting test prices that reflect actual production costs—as well as public investments—with clear volume thresholds for price reductions based on manufacturing efficiencies, and by aligning fiscal strategies to pursue reasonable profit through high volumes rather than high prices. Activists must continue to monitor and hold countries, donors, and diagnostics companies accountable for meeting their human rights obligations and responsibilities in order to establish fair pricing structures that enable the scale-up and implementation of rapid molecular tests as the initial TB test for all.

Rapid molecular tests have been commercially available and recommended by the WHO for nearly a decade. At the United Nations General Assembly in 2018, governments made commitments to end the TB epidemic by 2030, and to close the diagnostic gap by diagnosing and treating 40 million people with TB by 2022.²¹ It's time that government commitments to end TB translate into increased funding and action; that diagnostics companies price tests in a way that maximizes benefit to human lives; and that the right to science is fulfilled for all people at risk of TB, through universal access to rapid molecular testing as the initial TB test. We don't have another decade.

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CONSIDERATIONS ON THE RIGHT TO SCIENCE FOR DEVELOPING SIMPLER, POINT-OF-CARE DIAGNOSTICS

By Annette Gaudino and Bryn Gay

Interview with:

Amy Yorston, BLINK Diagnostics¹

Stijn Deborggraeve, Jessica Burry, Yuanqiong Hu, and Greg Elder, Médecins Sans Frontières (MSF) Access Campaign²

To understand different perspectives on the right to science and how it can be applied to diagnostics, we interviewed a unique, open access diagnostics company, BLINK, and the international humanitarian medical non-governmental organization, MSF. Open Science and an open access business model can democratize people's access to the benefits of scientific technologies.

Do you think the right to science framework is useful for making the case for investing in new medical technologies?

BLINK: The right to science addresses issues of cooperation and the sharing of ideas and technology. It speaks to the accretive power of knowledge, education, and research. Not only is it useful, but it's fundamental for developing a clear and logical case for investment.

MSF: The way science is currently financed, owned, and disseminated often neglects vulnerable populations in developing countries, which could contribute to violations of human rights.

How do you see diagnostics as falling within the scope of the right to science?

BLINK: Diagnostics have not always received the attention they should, whether that is for R&D investment, regulatory frameworks, or development of algorithms [or pathways for making medical decisions within clinical settings]. The right to science exists to ensure the benefit of scientific developments is experienced by all individuals; diagnostic tests most definitely fall within the category of scientific development.

MSF: Diagnosis is the starting point of medical care, and good quality and affordable diagnostics are particularly important for developing countries with fragile health care systems.

Profit-making diagnostic companies often receive extensive public funding for R&D of new diagnostic tests, but once in the market, tests are not affordable for most people. In addition, new diagnostic tests for infectious diseases are extensively evaluated using important contributions by developing countries, whereby the patients participating in such trials may never see the test once it's in the market because it's simply too expensive.

The cost of R&D at companies should be delinked from end-product prices and sales volumes. - MSF

How do you see the current field of diagnostics—particularly for infectious diseases, such as hepatitis C—as meeting or failing people's needs and rights to science?

BLINK: For many diagnostic companies, infectious diseases just don't make a good business case because they exist within flawed and fragmented ecosystems, and so the necessary products don't get developed.

MSF: In addition to failing universal rights to scientific innovation in diagnostics, the most vulnerable populations are often neglected, such as children, pregnant women, people living with HIV, and people who use drugs.

How do you see intellectual property (IP) and privatization of scientific research as advancing or impeding scientific progress and people's enjoyment of the right to science?

BLINK: The knowledge created by publicly funded research must be widely known and must be accessible to everyone, without limitations. We believe that IP does not impede the right to science, as whenever a healthy market is present,

The knowledge created by publicly funded research must be widely known and must be accessible to everyone, without limitations. – BLINK Diagnostics

companies with different approaches will compete to deliver the best solution. However, in other markets—like in low- and middle-income countries, neglected diseases, etcetera—this may not be the case, and public funders have to step in.

In the course of our technology development work, we have generated IP that we want and need to protect, but we're trying to balance this by placing it within an open access business model. The proof will be in trying to implement this in a real-world setting—but if we don't try then it definitely won't work, will it?

Expanding access to original research by having more available for free—out from behind paywalls—would serve the right to science well. Original research needs to be available to anyone, anywhere for free.

MSF: There are recognized incoherencies among human rights and IP systems in the context of access to medicines.³ Although IP has been used as one of the means of stimulating innovations, it has not delivered innovation according to health needs, especially for vulnerable populations.

For more than 20 years, the MSF Access Campaign has been challenging the unjust situation of how IP—particularly patents and exclusivity rights on test data—has been manipulated by companies and hindered access to medical tools by vulnerable populations.

Are there any enabling policies or practices that would facilitate and help advance scientific progress in the area of simpler, accessible diagnostics, particularly for hepatitis B and C?

BLINK: Commitments to fully funded elimination campaigns would make a big difference! Broadly speaking, R&D funding needs to be more sustainable, consistent, and less dependent on time-bound grants. In particular reference to hepatitis B and C, the funding scope needs to be broadened to include implementation. Any product, whether that is a diagnostic or a drug, is meaningless if there's no money to buy it and implement it in a program.

This can be achieved with a model that guarantees upfront purchase if certain product characteristics are met. Scale up is another issue that new products face. Scale is necessary to reach certain cost goals, which leads to purchase commitments and potentially to capital expenditure funding of manufacturing lines.

MSF: The cost of R&D at companies should be delinked from end-product prices and sales volumes. Pooled procurement has been successful in negotiating fairer prices. Support to small- and medium-sized companies to comply with quality and regulatory standards may help improve competition and in breaking monopolies. Expensive [separate service contracts, instrument and consumable procurement] are a barrier for uptake and should be replaced by affordable all-inclusive pricing models.

How can we, as advocates, convince funders or investors to invest in diagnostics using the right to science framework?

BLINK: Anyone who is investing wants to see outcomes. We must transition away from using the right to science as a purely academic exercise to demonstrating its impact. Health economic analyses and their derived conclusions regarding funding needs and mechanisms are useful here.

MSF: The right to science is universal, including the innovations stemming thereof, and should support decisions to fund R&D and making diagnostics tests available to all people. Companies, funders, and governments should bear clear obligations to ensure access to diagnostics, medicines, and vaccines as integral parts of the right to health and the right to science. At the end, theoretical frameworks are only useful when they translate into practical implementations in improving health.

Endnotes

The views and opinions expressed in this article are those of the authors and do not reflect the official policy or position of the company or organization. The interviews have been edited for clarity and brevity, and square brackets were added to define or elaborate a concept.

1. BLINK Diagnostics, based in Germany, was started in 2015 by a team of experienced in vitro diagnostics developers. The company is developing an open-access point-of-care product platform, the BLINK One, a cross-analytical digital multiplexing technology that enables development of ultra-sensitive assays with multiplex and quantitative capabilities. <https://www.blink-dx.com/>.
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TAGline Dedication

We dedicate this edition of TAGline to those lost to the COVID-19 pandemic, including Professor Gita Ramjee. As chief scientific officer at the Aurum Institute and former director of HIV prevention at the South African Medical Research Council, Prof. Ramjee embodied the spirit of the right to science, conducting quality research and championing the implementation of its fruits. She pushed back on inadequate national and global responses based on ideology rather than evidence or human rights, including the U.S.-driven push for “abstinence,” “be faithful,” and “condoms,” or the ABC approach to HIV prevention. We must channel her wisdom and fortitude in responding to the COVID-19 crisis as well as the ongoing HIV, TB, and hepatitis C crises. Only when science and human rights prevail over politics and grandstanding can we mitigate to the fullest extent possible the harms and losses from these pandemics.

SUPPORT TAG

Now in our 28th year, Treatment Action Group advocates for treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, hepatitis C virus, and COVID-19. The progress is palpable, but there’s still much to be done to end these epidemics. We need your support to continue saving lives in 2020.

Make a donation today: treatmentactiongroup.org/support

ABOUT TAG

Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus.

TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

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