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How Gilead is redefining the 'S' in ESG

In Partnership with



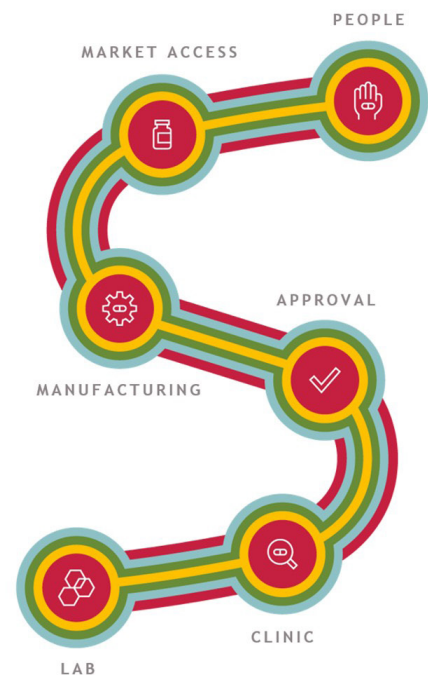
GILEAD



Redefining the “S”

Addressing social needs is central to Gilead’s strategy. Every part of our value chain touches the “S.”

-  HEALTH EQUITY
-  SCIENTIFIC INNOVATION
-  ACCESS



INTRODUCTION

Environmental, Social and Governance (ESG) issues have become increasingly important to investors in the last decade, as investors realized that factors from climate change to access to healthcare and executive compensation could have a material impact on the sustainability of businesses.

Over the past couple of years, ESG has been in a state of flux, particularly in the U.S., where it has become increasingly politicized, with significant pushback from some politicians. Reuters reported in April 2023 that 99 anti-ESG bills had been proposed across 13 states since the start of the year, compared to 39 in the whole of 2022. We have seen a growing divide over the last several years as ESG's true purpose has been diverted from its initial aim as a risk management investing tool.

Despite this, many investors continue to value ESG analysis to help them better understand company priorities, augment their long-term planning, and allocate funds accordingly. Morgan Stanley reported that there was \$3.1 trillion in ESG classified funds under management at the end of June 2023 and its Sustainable (a term typically synonymous with ESG) funds outperformed its traditional funds during the first half of 2023.



ESG DEMONSTRATES ITS VALUE

There are two main narratives around ESG – one says it is part of prudent risk management, and the other says that it reduces returns for investors in favor of pursuing broader social or environmental ambitions. For companies and investors, there is also a geographic divergence occurring. Whereas the U.S. has historically positioned ESG as a voluntary approach to improve the scope and transparency of company disclosures in order to help investors allocate funds, the European Union (EU) has embedded ESG disclosures in regulatory filings, increasing the importance of these topics and disclosures by codifying them into regional and national policies.

For example, the EU's Corporate Sustainability Reporting Directive (CSRD) will require large companies, including virtually all multinational corporations, to report on their material ESG and climate risks. To prepare for and implement these changes, PwC announced in 2021 that it was planning to hire 100,000 employees focused on ESG.

In the U.S., mandatory ESG related disclosures, including a proposed climate disclosure rule, are being assessed by the Securities and Exchange Commission (SEC). More recently, the state of California approved two climate-related reporting statutes, SB 253 and SB 261. The first will require certain public and private entities doing business in California to make public disclosures of their scope 1, 2 and 3 greenhouse gas emissions. The second will require certain public and private entities doing business in California to publicly report their climate-related risks and efforts to address them. These statutes go beyond the current SEC proposed disclosure standards and could affect more than 8,000 companies, according to law firm Dentons.

Despite the views of ESG detractors and the complex regulatory environment both within and outside the U.S., more companies are applying ESG considerations to better inform their company's strategy. And some investors and businesses have been doing so for decades, since before the term ESG existed.

Pharmaceutical company Gilead Sciences is a great example – it has integrated ESG throughout its value chain, as illustrated by:

- \$5 billion annual R&D expense exclusively dedicated to meeting unmet needs in underserved populations.
- \$300M in 2022 corporate philanthropy funding



“AT GILEAD, WE'RE CREATING POSSIBLE AT THE INTERSECTION OF INNOVATION, ACCESS AND HEALTH EQUITY. PRIORITIES LIKE CLINICAL TRIAL DIVERSITY ARE WHAT'S DRIVING OUR SUCCESS AND ALLOWING US TO REDEFINE THE "S" IN ESG. BY GOING BEYOND THE MEDICINES, WE'RE ONE STEP CLOSER TO CREATING A HEALTHIER WORLD FOR EVERYONE”

- Deb Telman, EVP, Corporate Affairs and General Counsel

- More than 30 million patients reached globally through voluntary licensing agreements, across COVID-19, HIV, and hepatitis C therapies.

All of these programs exist because, for Gilead, ESG is not a nice-to-have or a political statement. It is something that is embedded into its value chain and core business operations, and it drives value for the company and the communities it serves.

Companies with a clear purpose and mission are often among those that see the most benefit from ESG analysis. Gilead's vision is to create a healthier world for all people, and it believes that ESG advances its strategic priorities, which are to scientifically innovate to address unmet medical needs and to promote health equity and partnerships in communities it serves.



Pulse of Perseverance, Gilead Foundation grantee

IMPROVING ACCESS TO HEALTHCARE

For the pharmaceutical sector, access to healthcare is the most important aspect of ESG, and Gilead's voluntary licensing program is a leading example. A voluntary license enables select generic manufacturers to manufacture a Gilead branded product for distribution in certain resource limited countries. Gilead provides education and technical training. This arrangement facilitates competition among generic manufacturers to create high quality and low-cost products. "It is a more sustainable model than simply donating medicines, we are instead providing the blueprint," says Andrew Spiegel, Director of ESG Strategy at Gilead. "It's like teaching someone to fish rather than just giving them fish."

Access is made possible by a proactive investment in manufacturing capabilities, supply chain logistics and strategic partnerships in voluntary licensing agreements. At the onset of the COVID-19 pandemic, Gilead did not yet know how safe and effective its investigational medicine was in treating COVID-19, yet still invested \$1B to rapidly scale production while awaiting regulatory approval. Gilead knew that if the drug was approved, it would not have sufficient supplies to meet the demand unless it rapidly scaled manufacturing in

"GILEAD'S RESOURCE-INTENSIVE INVESTMENT IN GLOBAL SUPPLY CHAINS OPTIMIZES FOR UNINTERRUPTED RESPONSE TO GLOBAL PATIENT DEMAND AND PROTECTS PATIENT ACCESS"

- Hemal Shah, Director Public Policy

advance. Ultimately, various regulatory authorities did approve the medicine for patients hospitalized with COVID-19. Gilead went from having 5,000 doses in storage to producing over 1 million doses by the end of 2020. This ramp-up came despite widespread shortages of active pharmaceutical ingredients (APIs) and constrained working conditions. In addition to its own manufacturing efforts, Gilead's voluntary licensing agreements have played a key role in enabling more than 13 million patients around the world to receive the medication to date.



ADDRESSING UNMET NEEDS

Often, for communicable diseases, a treatment exists but may not be reaching the people who need it because of a lack of awareness and a stigma about the disease, which reduces the number of people who come forward for testing. The World Health Organization estimates that up to 300 million people around the world are living with chronic viral hepatitis, and another 37 million are living with HIV. "The scientific community has done miraculous work in their effort to meet these needs. Much of the remaining work lies in educating communities about testing, which therapies are appropriate, and finally access to those therapies," Spiegel explains.

Gilead focuses on scientifically innovating for unmet needs, and also on disease prevention and awareness. "HIV and cancer ... these are massive unmet needs, particularly when there are available therapies to greatly improve the lives of people with these conditions," he adds.

Addressing unmet needs is a conscious choice for pharmaceutical companies, says Sherry Glied, Dean of New York University's Robert F. Wagner Graduate School of Public Service. "Companies can choose to target diseases that most

"GILEAD WAS INSTRUMENTAL IN CHANGING HIV REGIMENS FROM MULTI-PILL 'COCKTAILS' TO A SINGLE TABLET OR ONCE DAILY TREATMENTS. GILEAD CONTINUES TO BE AT THE FOREFRONT OF HIV INNOVATION."

- Jared Baeten, VP Clinical Development

affect high-income people or those that mostly affect those on lower incomes," she points out. "For the good of the world, we should be spending more money on diseases that affect a lot of people who are not rich."

Gilead has always been committed to addressing the social determinants of health and overcoming barriers to care. Through its many global and local partnerships, it strives to advance health equity, diversity in clinical trials and access to

medicines to reduce disparities, advance education among healthcare professionals and support the local communities in which it operates.

There are three aspects to unmet needs, which sometimes overlap. These are:

- difficult to treat diseases
- medical conditions that disproportionately impact underserved communities
- disease areas where front line therapies are either insufficient or burdensome therapy regimens

HIV, for example, was once a disease that met all three of these criteria. The HIV epidemic has moved from a mysterious public health crisis in the 1980s to a disease that the CDC officially aims to eliminate as a public health threat by 2030. Gilead has played an integral role in mitigating its devastation, through significant investment in R&D, ground-breaking scientific work (including several drugs that were designated by the FDA as breakthrough therapies) and a dedication to partnering with communities to reduce the stigma of the disease and overcome barriers to care.

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Gilead sees great potential in tackling the issue of hard-to-follow therapy regimens with another breakthrough treatment, this time for heavily treatment experienced patients with multi-drug resistant HIV. These patients often develop resistance to other HIV therapies after years or decades of existing HIV treatment.

The backbone molecule of this treatment is also being studied as the next generation in HIV prevention dosing regimens. In the 1990s, HIV patients had to take numerous pills each day. Today, once daily medications are available that can either prevent an individual from acquiring HIV or keep their levels of HIV so low as to be undetectable. Gilead’s newest HIV treatment is now being evaluated as an investigational twice-yearly injection to prevent the acquisition of HIV. If approved, this is the type of innovation that has the potential to have



Gilead Employees – Month of Service campaign

real-world effects for people at risk of acquiring HIV and could ultimately pave the way for tens of millions of people to live healthier lives.

Tackling unmet needs is a long-term, ongoing process that begins long before starting to think about access to medicines. It starts with decisions about what pharmaceutical companies want to put their research and development dollars into – and whether those investments will just produce an economic return on investment or also make real world impacts lessening disease burdens in underserved populations.

Meeting unmet needs is thus a conscious strategic decision that must be made by boards, management teams, investors and other stakeholders dedicated to making a healthier world for all people.

ADVANCING HEALTH EQUITY

Related to the issue of unmet needs, but not the same, is the concept of health equity. It is not enough to invest in therapies for unmet needs. There must also be a commitment to health equity. It is worth pointing out that equity is not the same as equality – with equality, everyone gets the same regardless of whether it is what they need, or the treatment is right for them. With a focus on equity, everyone gets what they need, considering an individual's circumstances, the barriers they must overcome and the conditions they face in their daily lives.

It is important to understand that different groups have different needs. For example, 42% of new U.S. HIV diagnoses are among Black people, even though they make up only 13% of the population. In oncology, the mortality rate for multiple myeloma in the U.S. is double for Black individuals compared with white people, while Hispanic people in the U.S. have nearly double the incidence of liver, stomach and cervical cancers compared to white people.

“GILEAD WAS A PIONEER IN CLINICAL TRIAL DIVERSITY AND WE CONTINUE TO LEAD THE WAY. THE PURPOSE 1 & 2 TRIALS FOR HIV PREVENTION ARE SPECIFICALLY DESIGNED TO ENSURE UNDERREPRESENTED COMMUNITIES ARE PART OF THE CLINICAL PROCESS”

- Rashad Burgess, VP Advancing Health & Black Equity

Gilead's acquisition of Kite Pharma in 2017 transformed them into market leaders within hematological malignancy, or blood cancer, where it focused on treatments for those with no or limited options. Kite's focus on cell therapy requires a patient's T-cells to be removed, re-engineered in the lab, and reinfused as treatment. “This approach may sound like science fiction, but it is the key to helping these patients with no or limited treatment options,” Spiegel says.



*Bridget Ndagaano Jjuuko, Executive Director, ACTS 101 Uganda
Yvette Raphael, Executive Director of Advocacy for the Prevention of HIV and AIDS in South Africa*

Gilead then began to focus on cancers that primarily affect populations with an unmet medical need, including Triple Negative Breast Cancer (TNBC), a type of cancer that predominantly affects women of color, as well as HR+/HER2- Breast Cancer. Black women have a breast cancer mortality rate 40% higher than other women. Gilead's innovations in cancer therapy include a medicine that can be used to treat advanced stages of both of these breast cancers, potentially helping these underserved populations. Gilead is investing in research to determine whether it will be effective in treating other types of cancer.

But to ensure health equity, the industry must also commit resources and education to make sure that underserved populations can access the treatments they need. One way to ensure this is to expand the diversity of clinical trials. Gilead was the first company to intentionally include pregnant and lactating people, as well as adolescents, in Phase 3 HIV prevention (PrEP) clinical trials and the first to intentionally include transgender men and gender nonbinary individuals. “Historically, drug trials have targeted white men. Now there is an increased focus on women and different ethnicities. Sex differences are probably more important than ethnicity, but age is the most important aspect of all,” says Stefano Bertozzi, professor of health policy and management at the University of California - Berkeley. “In the past, people under 18 have been ignored until really late in the process.”



PARTNERING WITH COMMUNITIES

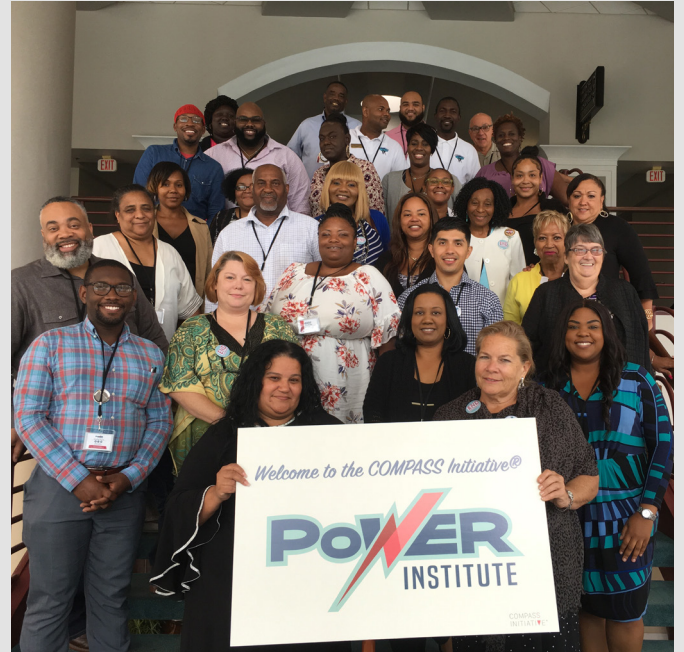
Gilead has a central role in the history of access to innovative medicines in the U.S. and around the world. In employing innovative pricing and access models, Gilead has built meaningful and enduring partnerships with patients, healthcare professionals, NGO's and communities.

This also means working with communities as a partner, above and beyond advocating for Gilead's own products. Gilead funds scholarships, schools, and community programs, as well as promoting de-stigma campaigns so that people living with HIV can live in communities without being defined by their diagnosis.

Healthcare systems are increasingly complex, and treatments can be, too. Patients often struggle to find healthcare providers, access insurance coverage and adhere to therapy regimens, all of which can affect their ability to achieve beneficial health outcomes. To improve access and outcomes, there must be a full understanding of how people interact with the complex healthcare system whose mechanics vary by country. Gilead has taken a holistic, people-centric approach to strengthening health systems and outcomes.

Gilead devotes tens of millions of dollars to testing programs so that people are aware of their conditions. It also provides robust outreach and access programs to help people navigate the processes of health insurance and co pays. In some cases, it offsets the cost of therapies. "Gilead is a leader on prevention and treatment medications, but its commitment goes beyond just producing medications," says Guillermo Chacón, President of the Latino Commission on AIDS and the founder of the Hispanic Health Network. "It has a fantastic track record of supporting community-based organizations and programs to address prevention and cure disparities."

Hispanics are the second-most affected group by HIV, but prevention is a difficult topic, he adds. "Young gay men and transgender individuals are very marginalized and lack access to both prevention services and care. In many places, these populations are in great need, but no one is reaching them.



Power Institute
COMPASS grantees™
(Photo courtesy of Emory University)

Gilead facilitates partnerships with a range of organizations throughout the U.S, working with local health departments, hospitals and clinics and the staff that try to reach these populations."

Another way to make therapy regimens more manageable is to develop treatment options with different dosing regimens. This is something that has happened in HIV care, where multiple pills a day have become one pill, and Gilead's clinical development program aims to reduce the requirement to an injection twice a year.

And access to health goes far beyond delivering the drugs that patients need. There are so many aspects of health that are related to environmental and social factors, and pharmaceutical companies can help to address these by working together with communities and patients.

VOLUNTARY LICENSING

Gilead recognizes the need to make accessible and affordable treatments for all. Voluntary licensing is one of several components of Gilead's access strategy in resource-limited countries. Gilead looks for trusted partners that can produce the relevant drug at scale and high quality.

"Voluntary licensing involves building capacity in low-income countries, rather than leaving them dependent on high-income manufacturers," says Glied. "The social benefit is increased if those countries learn how to manufacture drugs more generally because they are then able to take over more drug production locally."

Intellectual property rights enable voluntary licensing and effective technology transfer. Such collaborative approaches enable therapies to be distributed in countries with significant barriers to healthcare access, which allows underserved populations to live healthier lives. It is also a process that creates more resilient supply chains and wider distribution of manufacturing capabilities. "On HIV, Gilead instituted more aggressive licensing and deals with low- and middle-income countries compared to the rest of the industry," says Bertozzi.

And by working on a partnership basis, rather than simply donating medicines, it creates a knowledge base for producing medicines while enabling the companies that invest billions of dollars in research and development to discover the formulations for new therapies to preserve their intellectual property. "It is in Gilead's interests for a local manufacturer to be producing the drug and knowing that it is a high-quality product rather than a counterfeit," Bertozzi says.

LOOKING AHEAD

With over twenty clinical trials expecting readouts in 2024, including five Phase 3 trials, Gilead enters the year demonstrating their commitment to addressing unmet needs across key therapy areas including HIV, Oncology and COVID-19.

As the ESG landscape continues to evolve, companies like Gilead, whose vision is to "create a healthier world for all",



mothers2mothers
Zeroing In grantee

Bringing a new drug to market can entail testing many thousands of molecules before finding the right one. Gilead's newest HIV treatment, for example, emerged from the testing of more than 4,000 molecules. Once the right molecule has been found, it can take up to a decade of clinical trials before the drug is approved.

will face ongoing expectations to demonstrate how their ESG investments reflect their stated mission and vision.

By centering their efforts in the "S" of ESG, Gilead can demonstrate how the promise of scientific innovation, coupled with person-centric decision making across the value chain, will result in the broad availability of transformative therapies to create a healthier world for all.