

The Pharmaceutical Industry and Access to Health Products

Interrogating the Role of Multinational Companies in Tackling Global Development Challenges

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Summary

Society increasingly calls on business, in particular multinational companies, to contribute to solving global challenges such as poverty, hunger, or the recent pandemic. Many companies and industries have responded positively to these expectations and use a broad set of efforts to work toward objectives such as the United Nations Sustainable Development Goals.

However, research has frequently pointed out that there is limited evidence for multinational companies being effective to this end, as they have to overcome many internal and external hurdles in tackling such development challenges. Thus, uncertainty remains with regard to *how multinational companies can become instrumental in addressing the persistent and global problems we associate with sustainable development*.

This cumulative dissertation explores this question by studying how the multinational pharmaceutical industry has acted upon the challenge of insufficient access to medicines, vaccines, and other health products in low- and middle-income countries. By analyzing how two companies have tried to integrate access objectives into their business, the first empirical paper brings to surface two types of integration efforts that differently enable companies to make progress on the access challenge. It also highlights the strategizing needed for each type of integration to overcome internal and external challenges. The remaining two papers look at the pharmaceutical industry's contributions to the Kenyan response to non-communicable diseases as a case of the growing scale and scope of involvement of multinational companies on the local level. One paper shows that local development actors perceive this as a challenging and risky phenomenon and lays out why and how they engage with companies as development agents regardless. By studying the Kenyan case, the final piece looks more closely at how governance structures may help to ensure that industry-led public health initiatives contribute to development objectives.

Together, these papers contribute to management research by showcasing different pathways through which companies can become instrumental in making progress on development challenges: an internal pathway of integrating social objectives into the business as well as an external pathway of steering corporate initiatives through local actors and governance structures. Finally, it also informs debates in global health research by adding often neglected firm- and country-level perspectives on the growing role of business in global health.

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List of abbreviations

AA	Access Accelerated
ATMI	Access to Medicine Index
CSP	Cross-sector partnership
DCMA	Developing Countries and Market Access Unit (at GSK)
GHP	Global Health Progress database
HF	Healthy Families program (at Novartis)
HIV	Human immunodeficiency virus
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IP	Intellectual property
LDCs	Least-developed countries
LMICs	Low- and middle-income countries
NCDs	Non-communicable diseases
NTDs	Neglected tropical diseases
SDG	Sustainable Development Goals
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TWGs	Technical Working Groups
WHO	World Health Organization

Chapter 1 - Introduction

The COVID-19 pandemic has added fuel to an ongoing debate about the role and responsibility of pharmaceutical and other multinational companies in dealing with pressing societal challenges. In December 2020, less than one year after the first cases of COVID-19 had been reported, the US FDA authorized the first vaccine against the virus. Many saw this as an example for how multinational companies can help to tackle global problems. Even though the development of the vaccine was heavily supported by governments and built on years of publicly funded basic research, it was widely claimed that the speed of developing, testing and scaling-up production and distribution of a vaccine would not have been realized without the organizational processes and resources of private companies (Dolgin, 2021; Irwin, 2020). Accordingly, the pharmaceutical industry, which a 2019 US poll still had identified as being the industry with the worst reputation (J. McCarthy, 2019), received praise for its contribution to solving a global crisis (Armstrong, 2020). In a speech to the G7 in June 2021, for example, US President Joe Biden publicly thanked his “friend”, Pfizer CEO Albert Bourla, for stepping up and acknowledged that the early success of the vaccination campaign “took the full capacity of American companies manufacturing and delivering the vaccines around the clock” (The White House, 2021). Similarly, in Germany, the founders of BioNTech were widely celebrated by media and politicians and received the Federal order of Merit for their contribution to vaccine development (Deutsche Welle, 2021).

The atmosphere quickly shifted, however, once more and more voices pointed out that the inequity in vaccine distribution held back the fight against the pandemic and its consequences. By November 2021, high-income countries like the US or EU member states had vaccinated more than 60% of their populations, while African countries remained at only about 5% (United Nations Secretary General, 2021). UN Secretary General Antonio Guterres complained that “vaccine inequality is a moral outrage that is condemning the world to millions more deaths, and prolonging an economic slowdown that could cost trillions of dollars, hitting the poorest countries hardest of all,” (Crowcroft, 2021). Many started to hold the pharmaceutical companies accountable for this problem. WHO’s Secretary General Dr Tedros Ghebreyesus said this disparity was driven by “greed” of companies prioritizing high-income country customers over improving access in low- and middle-income countries (Helmore, 2021). A large campaign, involving the WHO, governments of hard-hit countries like India and South Africa as well as a broad coalition of civil society organizations, called upon the World Trade Organization to waive patents of originator companies to allow other

manufacturers around the world to produce generic alternatives of the vaccine to expand supplies (’t Hoen, 2020; Teicher, 2021).

The pharmaceutical industry has rejected this idea, arguing that a patent waiver would disincentivize further research and fail to increase access to existing vaccines due to the complexity of manufacturing novel mRNA vaccines without the guidance by originator companies (Nebehay & Burger, 2021). Moreover, industry officials suggested that companies have already invested significantly in improving global access to COVID-19 vaccines (IFPMA, 2021). Even before the launch of vaccination campaigns, a large group of pharmaceutical companies had committed to expanding global access for COVID-19 diagnostics, therapeutics, and vaccines (Life Science Companies and the Bill & Melinda Gates Foundation, 2020). All companies with relevant products in their portfolios acted upon these commitments in different ways (Emanuel et al., 2021): Pfizer and BioNTech claimed to give discounts to middle-income countries on their vaccine and adopt a no-profit sales strategy in low-income countries (Malcher & Pletter, 2021). AstraZeneca and Oxford University entered several licensing agreements, sharing their patent and technology voluntarily with generics manufacturers to increase supply of their vaccine in low-and middle-income countries (LMICs). Both BioNTech and Moderna announced plans to build their own production sites in Sub-Saharan Africa to improve access on the continent in the medium-term (LaHucik, 2021). Yet, doubts remain if those efforts are sufficient to overcome this global access challenge (Kuchler et al., 2021).

This debate about access to COVID-19-related health products is the latest round of a longer fight about the role and responsibility of the multinational pharmaceutical industry in improving access to its products. Since the HIV crisis hit LMICs, especially in Africa, around the turn of the millennium, this topic has regularly flared up in the global health and corporate responsibility discourse. According to the World Health Organization (World Health Organization, 2017), nearly two billion people lack sufficient access to medicines, vaccines or other health products meaning that existing health products are not affordable, available or appropriate for their needs. The United Nations’ Sustainable Development Goal 3 recognizes that access to medicines is a precondition to ensure ‘Healthy Lives and Wellbeing for All’. The lack of access causes preventable human suffering and compromises an individual’s right to health. In addition, it also hinders progress on other challenges such as poverty or education. Moreover, new variants of the COVID-19 virus developing in areas with low vaccination rates have underscored that global welfare depends on universal access to vaccines in all parts of the world.

The pandemic also brought to surface that everybody, including the industry itself, acknowledges that pharmaceutical companies have a role to play in improving access that goes beyond their core business of developing, producing and selling health products. Yet, the ambition in addressing the access challenge varies strongly between companies (Rocha et al., 2020). While some make a credible effort, others appear to treat access initiatives primarily as a public relations tool. Moreover, it is unclear how pharmaceutical companies can best enact their role in creating access to health products given the complexity of the challenge and a diversity in possible approaches (Kong et al., 2019). Thus, concerns exist among scholars and policy-makers that existing access efforts lack impact (Rockers et al., 2017) or may even have negative effects on health outcomes and health governance (Beran et al., 2017; Ruckert & Labonté, 2014; WHO, 2017).

As a contribution to this debate in global health research and practice, my dissertation will study different perspectives on how pharmaceutical companies may become instrumental in making progress on the access challenge in LMICs. It looks both at internal processes of integrating access objectives into the business of companies, as well as interactions between companies, external stakeholders, and health governance systems.

Multinational companies as development actors

Beyond global health, my dissertation also adds to literature on corporate responsibility in management and organization studies by highlighting different pathways through which multinational companies can address persistent and global problems that we associate with sustainable development. (G. George et al., 2016; Kolk et al., 2017; Voegtlin & Scherer, 2019).

Society increasingly calls on business to take on a problem-solving role on the global stage. This is especially reflected in the United Nations Agenda 2030 for Sustainable Development, which represents the most universal and globally adopted set of development challenges. The Agenda 2030 lays strong emphasis on leveraging private sector involvement in implementing its 17 Sustainable Development Goals (SDGs) (Kolk et al., 2017; Scheyvens et al., 2016; United Nations, 2015a, 2015b), highlighting both the special capabilities of the private sector, as well as the need to mobilize more resources. Many companies and industries have responded positively to these expectations and claim to act towards the SDGs, for example by mitigating harmful outcomes of their operations, such as curbing emissions of greenhouse gases, or by proactively developing solutions to make progress on a challenge, including both profit-oriented and philanthropic activities (Kolk et al., 2018; United Nations

Global Compact, 2018). Traditionally, companies focused on charitable social initiatives under the banner of corporate social responsibility and community development (Frynas, 2005; Idemudia, 2011; Muthuri et al., 2012). However, more and more companies try to address development challenges through commercial approaches, e.g. by integrating social objectives into new hybrid business models (Kolk et al., 2014; Prahalad & Hammond, 2002; Seelos & Mair, 2007). Additionally, companies are increasingly engaging in cross-sector partnerships (CSPs) with public sector and civil society organizations to work on development challenges, varying between one-directional philanthropic donations and more integrative, transformative partnerships (Austin & Seitanidi, 2012; Crane & Seitanidi, 2014; Kolk et al., 2008).

However, research has repeatedly highlighted that there is only limited evidence for multinational companies' efforts being effective in making progress on development challenges (Barnett et al., 2020; Blowfield & Dolan, 2010; Frynas, 2005; Vestergaard et al., 2020). In a systematic review of research on CSR initiatives, Barnett and colleagues (2020) found that only a handful of papers have evaluated their outcomes and impact studies do not exist at all yet. Reviewing research on commercial models for making essential products and services available at the 'Bottom of the Pyramid', researchers found mixed results with regard to whether they help to reduce poverty (Kolk et al., 2014). Similarly, despite the large interest in cross-sector partnerships as a tool to address complex challenges, their anticipated benefits have received more attention than the conditions under which these benefits may actually materialize (Austin & Seitanidi, 2012; van Tulder et al., 2016).

In fact, there are many hurdles for companies to make progress on development challenges. For example, research has pointed out that companies sometimes struggle to implement initiatives effectively: they fail to align interventions with needs and priorities of their partners (Idemudia, 2009; Jeppesen & Lund-Thomsen, 2010), rarely harmonize efforts with competitors (Frynas, 2005; Stadtler, 2018), or are too impatient in expecting outcomes (Blowfield & Frynas, 2005; G. George et al., 2016). Scholars have pointed out that their predominant organizing model makes it difficult for companies to focus on challenges external to their core business (Mair & Rathert, 2019; Scherer & Voegtlin, 2018). Even though companies may commit to tackling a specific challenge, initiatives may clash with processes and incentives set up to optimize internal efficiency. Such conflicting demands on the organization may lead to a mere symbolic adoption of new socioenvironmental objectives (Bromley & Powell, 2012; Crilly et al., 2012). Moreover, research has documented that the introduction of such new objectives is often met with resistance from internal actors due to

ideological or cultural differences that limits the extent and pace by which companies act upon them (Hahn et al., 2014; Kok et al., 2019; Soderstrom & Weber, 2020). Beyond internal hurdles, the complexity of most development challenges and the difficulty to assess the outcome of corporate efforts leads companies to develop and sustain ineffective initiatives even if they mean well (Wijen, 2014). In the same vein, past research has pointed out that the effectiveness of a company in addressing development challenges depends on the strength of the supportive institutions and actors in the ecosystem in which it is trying to make a positive change (Krasner & Risse, 2014; Schäferhoff, 2014).

In summary, there is broad agreement that business is needed as an actor for positive change. Yet, in the light of a multitude of different approaches and a broad set of internal and external hurdles, uncertainty remains with regard to how multinational companies can become instrumental in addressing global development challenges. Given its recent relevance, its long history, and strong salience for the industry and its stakeholders, this dissertation will pursue this question in the context of pharmaceutical companies' efforts to improve access to health products in LMICs.

Research approach and structure of the dissertation

At the core of my cumulative dissertation are three independent empirical papers presented in Chapters 4, 5, and 6. These papers look at a set of factors that may enable pharmaceutical companies to contribute to solving the access challenge: how companies integrate access objectives, how local development actors engage with companies on a specific challenge, and how governance systems can shape the effectiveness of corporate involvement. The foundation for these papers is a historical mapping of the pharmaceutical industry's involvement in improving access to health products. In this mapping, I identified two major trends in how companies have enacted access responsibilities which serve as the empirical setting for the other papers. I present this mapping in Chapter 2 alongside a more detailed introduction into the access challenge as well as an overview of the multinational pharmaceutical industry and how it gradually accepted a shared responsibility for access. This chapter draws, in parts, on a handbook chapter written together with Nikolas Rathert and Johanna Mair. Before going into the empirical sections, Chapter 3 reviews existing research on the pharmaceutical industry's role in creating access to health products bringing together management, global health and other disciplines.

The first trend which surfaced in my mapping is that pharmaceutical companies increasingly act upon the access challenge through integrating access objectives into their

business. While companies used to rely on philanthropic donations or activities of corporate foundations that were decoupled from the companies' everyday activities, many have since strived to address access as part of the competitive strategy. However, there is great diversity among companies with regard to their ambition in integrating access: while some are experimenting at limited scale, others try to integrate access objectives throughout large parts of the organization. Moreover, the types of internal access efforts and pathways of integrating access objectives appear very differently across the industry.

In Chapter 4, originally written as a paper in collaboration with Nikolas Rathert and Johanna Mair, I explore this trend of integrating access objectives into the business. We zoom in on the integration efforts of two pharmaceutical companies that were early adopters of access objectives and are perceived as industry leaders in making progress on access to medicines. We use these cases to answer the broader question of *how do integration efforts enable companies to make progress on social problems in light of internal and external challenges?* We identify two types of integration efforts that both companies have been using to varying extent. These types, which we coin as product-level and operation-level integration, differ in the locus of integrating social objectives as well as in the mechanisms for reaching these objectives. We find that these types are exposed differently to the twofold challenge of legitimating internal changes and ensuring external effectiveness. Moreover, we identify two forms of strategizing that companies applied to mitigate the respective challenge emerging for each integration type. Thereby, our study generates a theoretical understanding of the implications of integration heterogeneity for addressing social problems and advances research on the role of integration by specifying the mechanisms, challenges, and forms of strategizing at play as companies increasingly integrate social objectives.

The second trend emerging from my historical mapping in Chapter 2 is a change in the focus of companies' access efforts. After years of focusing on access to vaccines and treatments for infectious or neglected tropical diseases, many companies have shifted or widened their attention to the emerging burden of non-communicable diseases (NCDs) in LMICs such as cancer, diabetes, or cardiovascular conditions. I find that this change of focus is accompanied by companies moving away from uniform global access programs and policies to working on the level of individual LMICs and partnering directly with local actors. In that way, they also go beyond developing and providing products and become increasingly involved in more complex health systems strengthening activities such as training health workers or setting up infrastructure. Thus, they touch upon roles and responsibilities that traditionally used to be in the realm of governments or civil society only. I explore the

implications of this trend in two further empirical chapters that draw on the case of pharmaceutical industry involvement in the Kenyan response to NCDs.

In Chapter 5, I examine *how local development actors in Kenya perceive and respond to this growing industry involvement* in NCDs. I characterize this as a case of companies increasingly acting as development agents (Blowfield & Dolan, 2014) and argue that the voice of local actors has been neglected in an ongoing debate about the merits of this new role for companies. I show that even though most local actors perceive companies as problematic development agents due to past implementation challenges and potential structural risks of their involvement in health, they find themselves to be constrained in their ability to contest and control the growing corporate involvement. Yet, I also bring to surface how local actors navigate within these constraints by following what I refer to as *tempered contestation* in their engagement with companies: Accepting that they have no choice but to work with companies, they apply a set of tactics to make the best out of companies as development agents while gradually trying to expand their room for this contestation.

Chapter 6, a paper written together with Veronika Wirtz and Catherine Karekezi, builds on the insight from the previous chapter that working with multinational companies can incorporate risks of undermining public health efforts if interests of companies and local actors are not fully aligned. We studied how and to what extent LMIC governments can govern industry involvement in development initiatives to mitigate these risks and enable companies to contribute to progress on health problems. To address this, we develop an approach to assess the existence and effectiveness of governance structures that can ensure that industry-led public health initiatives contribute to development. We build a governance assessment tool based on the principles of the Paris Declaration for Aid Effectiveness and other related agreements. By applying it to the case of fighting NCDs in Kenya, we illustrate the viability of this tool for assisting companies and governments alike in defining governance needs for industry-led public health initiatives. Our findings of the existing gaps in Kenya provide example considerations for LMICs seeking to work with companies and showcase how non-industry development partners can support LMICs in strengthening their capacities to govern multinational companies' contributions to development challenges.

Methodologically, while the initial mapping involves some descriptive statistics, the empirical papers rely mostly on qualitative analysis. To this end, I engaged in two major rounds of collecting archival data and conducting a total of 85 semi-structured interviews: This includes a deep dive on the two companies analyzed in Chapter 4 as well as data on the Kenyan NCD response featured in Chapters 5 and 6. More information on data and methods

can be found in each chapter. Moreover, in linking a strong focus on the phenomenon of pharmaceutical industry and the access challenge to the wider debate about the role of multinational companies in addressing development challenges, this dissertation is situated at the intersection of management and global health research. It draws on insights and discussions from both fields, as the literature review in Chapter 3 will demonstrate. It also aims to make contributions to both disciplines in return, which I present in the concluding Chapter 7 together with laying out the limitations of my approach, avenues for further research and implications for practitioners.

Chapter 2 - Mapping Pharmaceutical Industry Involvement in Tackling Access to Health Products

This chapter serves as a foundation for the remaining parts of this dissertation, introducing important concepts and mapping pharmaceutical industry involvement in the global development challenge of improving access to health products in low- and middle-income countries (LMICs). Herein I will first give an overview of this access challenge in more detail and explain who this dissertation refers to when speaking of the multinational pharmaceutical industry. Subsequently, I portray historically how the industry gradually accepted a responsibility for access. Finally, the chapter ends with identifying and showcasing two field-level trends of how companies have enacted this access responsibility over time. I will use these two trends as the empirical setting for the subsequent chapters of this dissertation.

Access to health products as a challenge for sustainable development

The World Health Organization (World Health Organization, 2017) estimates that globally nearly two billion people lack sufficient access to health products. This implies that a large share of people living on our planet cannot benefit from the collective medical advancement made over the last decades. The United Nations' Sustainable Development Goal 3 recognizes that access is a precondition to ensure 'Healthy Lives and Wellbeing for All'. The lack of universal access to medicines or vaccines causes preventable human suffering and compromises an individual's right to health. In addition, it also negatively affects the fulfillment of other SDGs related to, for instance, poverty, education or the empowerment of girls and women: Patients may end up in poverty if essential medicines are not affordable; kids miss out on education if no pediatric formulations of deworming tablets exist; and women continue to die during childbirth if doctors do not have access to treatments for maternal hemorrhage. Recently, the COVID-19 pandemic has demonstrated that humanity's common welfare depends on equal and universal access to vaccines across the globe. As long as the pandemic remains uncontained in some parts of the world, it will continue to affect freedom of movement, cultural exchange, or economic interactions across the entire globe.

One aspect that makes access to health products difficult to tackle is its complex, multi-dimensional nature. The access challenge spans across various upstream and downstream aspects of the health products' value chain (Wirtz et al., 2017). The upstream dimension concerns the research and development of essential health products. For so-called neglected

tropical diseases (NTDs), such as schistosomiasis or lymphatic filariasis¹, often no or only suboptimal treatments exist. For other diseases, existing health products might not be appropriate for use in certain countries. Many products are not suited for use in hot climates, or for specific patient groups such as small children. For instance, even though the treatment for HIV has improved significantly, development of pediatric formulations took much longer. In 1990, an international commission famously described the 10-90 gap showing that only about 10% of health research funding was spent on diseases that caused ca. 90% of global mortality (Commission on Health Research for Development, 1990). Scholars have identified a market failure as the leading cause for this systemic disparity (Trouiller et al., 2002; Yegros-Yegros et al., 2020): The patent-based model for medical research in most countries incentivizes research and development to focus on health products for the most profitable markets. Thus, the financial return on developing yet another cancer treatment is higher than finding a treatment for diseases that are endemic in low- and middle-income countries (LMICs).

The downstream dimension, in contrast, implies a different challenge: while health products exist, patients are not able to access them (Bigdeli et al., 2013). Accessibility and affordability are tightly connected. To realize full access, health products need to be affordable for the patient or health providers. They also need to be locally available and of sufficient quality. The causes for not meeting these criteria vary and are often difficult to isolate. On the one hand, affordability depends on the price of a product. On the other hand, affordability also relates to the income level of an individual or social protection systems in a country. Likewise, products can be unavailable to patients because they have not been registered in a specific country, or because local supply-chains are broken and hospitals are out of stock. Accordingly, ensuring access to health products requires a concerted effort of many actors including health providers, governments, international organizations and pharmaceutical manufacturers. This complexity is also noticeable in the language of SDGs' access-related targets 3.8 and 3.b², which refer to research & development, as well as quality

¹ Two common, sometimes lethal, diseases in tropical countries in Africa and Asia; caused by parasites, often disproportionately affecting marginalized populations.

² SDG 3.8: "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all."

SDG 3.b: "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."

and affordability issues. To discuss what companies can and should do to contribute to improving access, it is helpful to differentiate between those dimensions. Conflating them – as often the case in research and practice -leads to misunderstandings and flawed comparisons. For example, when activists criticize companies for their access performance, companies often respond with highlighting research they do on neglected tropical diseases – even though what activists referred to were issues around pricing.

An overview of the multinational pharmaceutical industry

The focus of this dissertation is on the role of the multinational pharmaceutical industry. By this, I refer to the largest pharmaceutical companies globally that are predominantly relying on a patent-based business model and come from high-income countries – colloquially often described as “Big Pharma”. This is not a stable group of companies, as mergers and acquisitions are frequent in the industry and breakthroughs in drug development can quickly propel smaller biotech startups to the top tier (e.g Moderna and BioNTech during the COVID-19 pandemic). As an indicator for the number of companies belonging to this group, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) had 37 member companies in December 2021. These companies are headquartered in the United States, several European countries such as France, Germany, Switzerland or the UK, as well as in Japan. Independent of the location of their headquarter, all companies are operating and selling their products globally. While many have a footprint in LMICs, high-income countries remain their most important markets from a revenue perspective.

The companies also share a similar business model. At its core, it is based on developing, producing, and selling innovative health products. The main assets are a company’s patents that prohibit competitors from copying and selling similar products in a country where a patent has been filed. To discover patentable health product innovations, companies place a number of high-risk high-reward bets. Traditionally, they invested large amounts into in-house research. However, they increasingly prefer to acquire emerging biotech startups that have already developed a promising drug candidate. No matter if developed inhouse or acquired externally, less than 10% of the promising candidates entering clinical trials will make it to the market (Wong et al., 2019). Yet, once companies successfully bring a product to market, patent protection allows them to sell these products at enormous margins. For example, the US company Gilead initially offered a course of an innovative drug to cure Hepatitis C for USD 84,000 while estimates had production costs at approximately USD 150 (Gorman, 2014). Companies legitimate this with the need to recuperate costs of

failed projects and ensure high returns for investors to continue mobilizing sufficient capital for future drug discovery (Frank & Ginsburg, 2017). Critical voices argue that these arguments are overblown, research is less costly than companies suggest, and companies' drug development is not guided by medical need but by what provides most returns (Medecins Sans Frontieres, 2019a). Instead, critics see big pharma's business model as increasingly relying on marketing incremental innovations, trying to prolong patent protection of successful products and share buybacks to boost stock prices.

I differentiate the so-called originator companies discussed above from the generic pharmaceutical industry, as its business model and industry structure are completely different. Generic companies produce and distribute health products in markets where product patents have expired or are non-existent. In high-income countries and emerging markets, this is typically the case in 10-20 years after market entry depending on when in the development process a patent was filed. Yet, in many low-income countries originator companies do not seek or are not granted patent protection and generics companies can immediately try to develop and supply alternatives. As there is strong competitive pressure without a patent, margins on generic products are very low and the business model relies on scale. To illustrate, five years after its US market entry, the same USD 84,000 Hepatitis C drug mentioned above was offered for less than USD 100 by generic manufacturers in India or Pakistan in 2019 (Barber et al., 2019).

Compared to big pharma, more smaller- and medium-sized enterprises exist and only few companies can compete with originator companies in terms of revenue size. Moreover, the generics industry is more diversified with respect to home country. While many companies also come from the US and Europe, there is a large and growing industry in LMICs. Here, countries like China, India and Bangladesh stand out, but local manufacturers exist throughout the world including in low-income countries of Africa (MacKintosh et al., 2016). Thus, the generics industry plays an important role in tackling the access challenge through providing low-cost alternatives to innovative health products and covering markets that originator companies ignore. Thus, studying how the generics industry can become instrumental in making progress on development challenges provides enough material for a separate dissertation project.

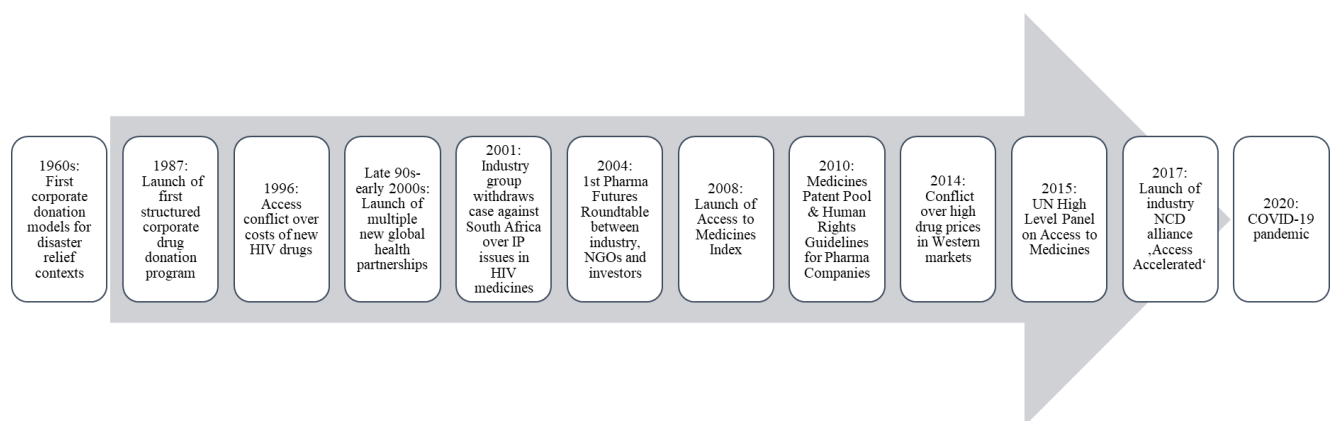
I, however, focus on the role of originator companies for the same reasons that access activists and governments see them as important actors in improving access to health products: First, as research-based companies, they are cornerstones of bringing innovations to the market that can solve existing health problems. As patent holders, they own and control

important aspects of access to these technologies. To illustrate, in a 2017 publication, the Access to Medicine Index³, a biannual ranking of companies' access performance, showed that the twenty leading companies in its scope had 850 products on the market for high-burden diseases endemic in LMICs, and were in the process of developing a further 420 products (Access to Medicine Foundation, 2017). Second, the industry can become an instrumental actor due to its sheer size. A study looking at 35 large pharmaceutical companies found that between 2000 and 2018, they accumulated a revenue of USD 11.5 trillion and a net income of USD 1.7 trillion (Ledley et al., 2020). Thus, they do not only have the technological capability and global reach to address access, but also have significant resources available that could potentially be used for this purpose.

How access became a responsibility of the pharmaceutical industry

The multinational pharmaceutical industry has not always accepted a responsibility for improving access to its products. For a long time, many companies claimed its role stopped at developing and offering health products. Ensuring that these medicines and vaccines reached patients was seen as the job of governments, international organizations, or NGOs. Thus, before going into a more fine-grained analysis of how companies enact access, I will lay out how the industry gradually accepted a responsibility for tackling the access challenge (see Figure 2.1).

Figure 2.1: Selected events around pharmaceutical companies and the access challenge



The emergence of access as an issue for the industry

For most of the 20th century, pharmaceutical companies had few explicit touchpoints with issues discussed in global health. Interactions between international organizations or

³ The Access to Medicine Index is published biannually since 2008 by the Access to Medicine Foundation, an independent non-profit organization funded by governments and foundations.

governments and pharmaceutical companies occurred mostly in form of commercial transactions (Buse & Walt, 2000). Exceptions to this were donations of medical products and medicines for disaster relief which began in the early 1960s and were driven by a few individual companies⁴. From the late 1970s onwards the industry began to transform with the influx of new biotechnology companies and increasing globalization (Malerba & Orsenigo, 2015). As many new products reached the market, the industry became increasingly profitable, but also more exposed to unmet medical need globally. This trend spurred discussions about the responsibilities of multinational companies in a globalizing world and some companies began investing in programs for neglected tropical diseases. Initially, this mostly focused on funding research and development of missing vaccines and treatments (Cone, 1991). Yet, in 1987, the US company Merck & Co also developed the first downstream access program with its donation campaign for ivermectin to fight river-blindness (K. L. Collins, 2004).

Fighting over the responsibility for access

The year 1996 marked a turning point for the relationship of access and the pharmaceutical industry (Trullen & Stevenson, 2006). For the first time, researchers presented a new breakthrough therapy to fight HIV. However, the price of this new combination treatment offered by several multinational companies ranged between USD 12-16,000 a year. This placed it out of reach for patients in LMICs where millions were dying. Thus, immediately, voices in civil society and international organization began calling upon companies to lower prices in order to enable access to these therapies. Unlike in previous discussions around neglected diseases, these demands affected commercially viable products with an immense market potential. Thus, companies were hesitant to act on the access challenge, as they feared that donated or lower cost versions of their products would find their way back into high-income markets and cut into their profits.

Moreover, the HIV crisis further spurred developments perceived by companies as undermining the international intellectual property rights system. The entry into force of the WTO TRIPS agreement in 1995 had brought LMICs to adopt stricter patent laws. The industry had long lobbied for this agreement in order to keep competition from international generics manufacturers at bay (Weissman, 1996). Yet, facing health emergencies with millions of people dying, several countries like Brazil, Thailand or South Africa decided to

⁴ Predecessor companies to what is today Merck & Co as well as GSK launched such programs in 1958 and 1960, respectively.

disregard patents on the new combination therapies and produce medicines locally. Patent-holding companies reacted by getting the US administration to threaten Brazil and Thailand with trade sanctions and a group of 39 companies even sued Nelson Mandela's South African post-apartheid government for circumventing patent laws in 1998. Public outrage over these actions drastically mobilized the emerging access movement and directed its focus on the patent regime as a central hurdle to access ('t Hoen, 2002). As public pressure and outcry intensified, companies began to lose the support of their home country governments and started to make concessions on medicines related to HIV (Trullen & Stevenson, 2006). In 2001, the suing companies withdrew their South African court case and some companies began offering substantial price reductions to LMIC government and international organizations (Dawkins, 2005).

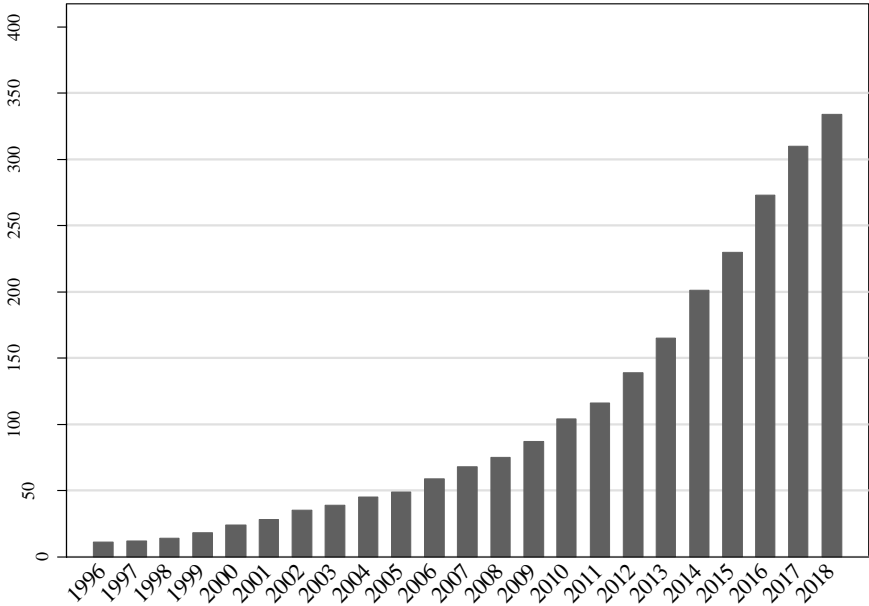
In the debate over HIV medicines activists interfered with the industry's core business for the first time. By questioning the intellectual property rights regime, the access movement of mostly international civil society organizations with the growing support of international organizations and governments threatened the industry's core asset – patent protection. Once the movement had established itself, conflicts over access went beyond HIV. There were similar debates around vaccine prices, access to insulin or cancer care (Medecins Sans Frontieres, 2019b). In 2015, for example, a UN Secretary General High-Level Panel on Access to Medicines shed new light on the conflicts over intellectual property rights. Access also became a political issue in high-income countries, for example in the 2016 US presidential campaign, and NGOs launched notable campaigns against the high price of new drugs like the Hepatitis C treatment Sovaldi or the price hike of existing products such as the EpiPen (The Economist, 2019). Yet, especially in the COVID-19 pandemic these conflicts around access responsibilities took a center stage once again.

Accepting a shared responsibility for access

Despite the contentious nature of the access challenge and ongoing fights over specific issues, the industry gradually accepted a shared responsibility for access (Leisinger, 2005). While in 2002, only two companies had developed a distinct access to medicines policy, more and more companies have since followed suit (Oxfam et al., 2002). The 2021 Access to Medicine Index pointed out that seventeen out of the twenty companies in scope have adopted a clear access strategy that underlines the importance of tackling access for the organization. Representative of this development is a mission statement on the IFPMA website at the end of 2020: “We are deeply engaged in the access to medicines debate to find sustainable solutions

for patients worldwide. To achieve this, we facilitate dialogue and partnership between governments, civil society, and academia to find creative and viable solutions.” It is also reflected in the rising number of industry programs tackling access and other global health challenges as portrayed in Figure 2.2.

Figure 2.2: Total number of IFMPA members' active global health programs per year. Source: GHP database (globalhealthprogress.org), author's own calculations



The external pressure described above certainly helped to get companies to this stage. Yet, stakeholders within and outside the industry also tried to get companies to embrace access as a strategic opportunity. They used the context of the HIV crisis to start thinking about what the access debate implied for companies in the long-term. For instance, in the mid-2000s, actors from the access movement paired up with institutional and social impact investors to create the Pharma Futures Working Group (Tickell, 2004). This group invited pharmaceutical companies to discuss structural responses to access and other conflictual topics that could ensure the long-term value of the industry. NGOs and responsible business activists started to frame access as an issue for corporate strategy and its solution as a win-win opportunity for companies willing to come up with new business models (Oxfam, 2007; Peterson et al., 2012). Moreover, several institutions have been created in the aftermath of the HIV crisis to specifically support companies assuming responsibility for access. For example, the Access to Medicines Index emphasizes best practices in its biannual rankings since 2008 and attempts to create a positive competitive dynamic around access in the industry (Quak et

al., 2019). Founded in 2010, the Medicines Patent Pool tries to overcome conflicts around intellectual property. It acts as a broker for voluntary licenses that allow generics companies to produce cheaper alternatives to patented medicines for certain markets against a licensing fee for patent-holders (Geiger & Gross, 2018).

Two trends in how pharmaceutical companies have enacted access

While most companies have accepted a shared responsibility for access over time, how they have acted upon this responsibility varies substantially. Building on data from the previously mentioned Access to Medicine Index (ATMI) and the Global Health Progress (GHP) database, an industry platform where IFPMA member companies report on their global health initiatives, I will lay out two trends of how corporate enactments of access responsibilities changed over time.

Tackling the access challenge from within the business

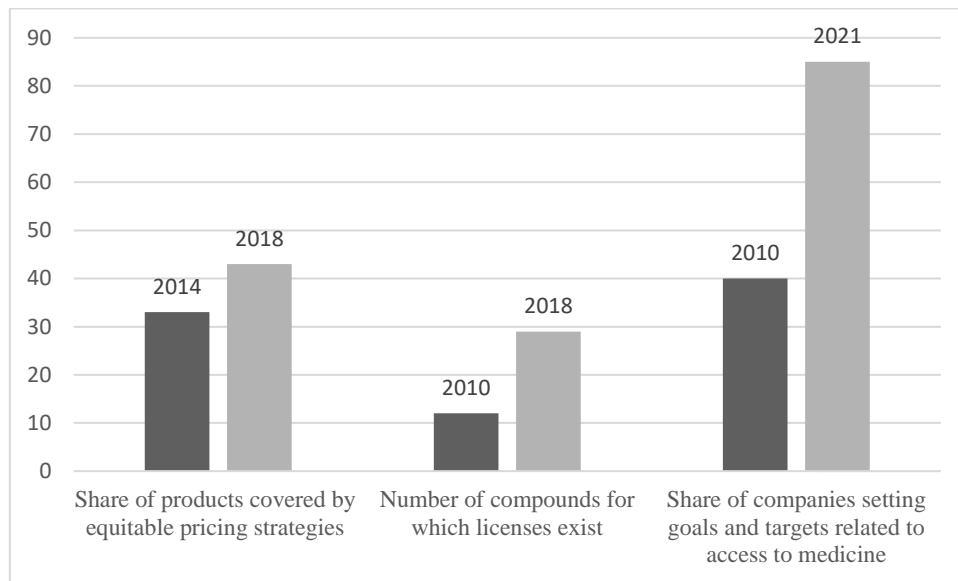
In the early days of enacting access responsibilities, companies engaged in global health and access to medicine efforts on the fringes of the organization. Companies organized their access efforts in a way that decoupled access activities from the business. Early access efforts mostly targeted products for neglected tropical diseases that were part of companies' portfolios but had lost commercial relevance for the companies. Merck's program of donating the antiparasitic medication ivermectin to fight river blindness, for instance, relied on repurposing an established animal health product that had already created a healthy profit for Merck in the years prior (K. L. Collins, 2004). To improve access companies relied on philanthropic donation models or participated in global health partnerships with external organizations. On the side of the companies, they were often implemented by independent corporate foundations or through a central global health unit without involving the more commercial actors within the company. The same applies to research on neglected tropical diseases that was often carved out into special research institutes operating separately without commercial pressure from the remaining business. Thus, these efforts had few touchpoints to the business of companies beyond the specific products they centered on.

Access activists began to criticize such a decoupled approach in the early 2000s, as they considered it insufficient given the scale of the HIV-AIDS crisis. As access issues touched upon products at the center of the business, activists expected the industry to move "beyond philanthropy" and integrate the goal of improving access to medicines more

fundamentally into their organizations (Oxfam et al., 2002). Following this push, companies began this integration process through measures such as tiered pricing or licensing that address access from within the business. Tiered pricing implies charging different prices to different target groups according to their ability to pay (Moon et al., 2011). For companies that meant offering products at lower prices in LMICs than in high-income markets, or making special deals for NGOs or global health partnerships such as Gavi, the vaccine alliance. Often this practice was introduced only for individual products where external pressure to reduce prices was especially high, but many companies have gradually expanded them to wider parts of their portfolio. According to the ATMI, the share of products in scope of the index that is covered by equitable pricing strategies rose from 33% in 2014 to 43% in 2018 (see Figure 2.3).

Licensing offers a strategy for companies to improve the supply of more affordable generic versions of their product without giving up their intellectual property (Outterson & Kesselheim, 2008). They allow and enable selected generics manufacturers to supply an otherwise patent-protected product to specific markets that are often of no commercial interest to the originator company. In return, the licensee pays a royalty fee to the originator company. This practice has mainly been used in the space of HIV but is also slowly expanding to other product areas. Between 2010 and 2018, the number of compounds for which companies have granted licenses increased from 12 to 29, according to the ATMI (Kong et al., 2019). During the response to COVID-19, multiple companies also used licensing as a way to increase global supply of vaccines and other health products. Moreover, some companies went further and tried to develop and implement new hybrid business models within LMICs that aim at creating and tracking social and financial value alike. Such models combine the provision of low-cost products with interventions to ensure that products are available to patients or health providers are able to administer them effectively. While these business models often remained limited in scale, some companies such as Novartis or GSK have experimented with reorganizing entire regional operations to follow a social business approach.

Figure 2.3: Examples for integration progress. Source: ATMI / Kong et al. (2019)



These practices have in common that they allow companies to integrate access objectives into their everyday business. Moreover, they are not decoupled from commercial structures and processes, but involve actors with a traditionally commercial focus such as product managers or business units in LMICs in working towards improving access. However, the level of ambition varies substantially across the industry with regard to the scale and scope of integration. The share of companies setting goals and targets related to access to medicine moved from 40% in 2010 to 85% in 2021, but only 60% of companies have assigned responsibility for access efforts to individuals on the board level (Access to Medicine Foundation, 2021). The percentage of companies in the scope of the ATMI using some kind of equitable pricing strategies had reached 90% by 2018, but only 55% have access strategies covering all therapeutic areas (ibid.). Licensing remains a practice that only few companies pursue at all. Between 2010 and 2021 the share of companies giving out any licenses remained at 35% according to the ATMI.

While some companies are more advanced in some forms of access efforts than others, I find that there are some companies who have been frontrunners in access integration overall (see Table 2.1). Looking at the average ranking of companies in the ATMI over time, you can see that GSK has been leading every single ranking while Novartis and Johnson & Johnson have also ranked high consistently. Some companies, such as Daiichi Sankyo or Astellas have been laggards throughout.

Table 2.1 Rankings in the ATMI over time. Source: ATMI, author's own calculations

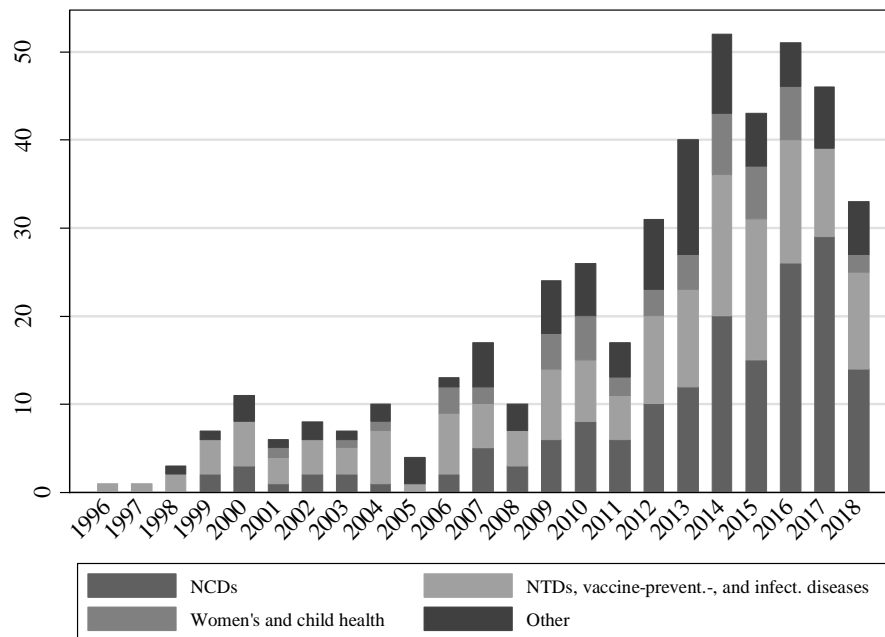
Company name	2021 ranking	2010 ⁵ rank	Average rank	Trend 2010-2021
GSK	1	1	1	0
Novartis	2	3	4	1
Johnson & Johnson	3	9	4	6
Pfizer	4	11	12	7
Sanofi	5	5	6	0
Takeda	6	18	14	12
AstraZeneca	7	7	10	0
Merck KGaA	8	13	9	5
Roche	9	7	10	-2
Novo Nordisk	10	8	6	-2
Eisai	11	16	12	5
Boehringer.-Ingelh.	12	12	14	0
Bayer	13	14	12	1
Astellas	14	19	18	5
Gilead	14	4	9	-10
Merck & Co.	15	2	7	-13
Daiichi Sankyo	16	20	18	4
Abbott / AbbVie	17	10	12	-7
Eli Lilly	18	13	16	-5
BMS	19	15	14	-4

Deepening involvement in local health systems

As a second trend, I observed that the nature of programs through which companies have enacted their access responsibilities has been changing along three interconnected dimensions: Disease-focus, type of strategies applied, and geographical focus. I identify this trend based on an analysis of the programs listed on the GHP database. First, regarding the disease types that companies are addressing in their global health programs, Figure 2.4 shows that while new programs in the early 2000s predominantly addressed *vaccine-preventable-*, *infectious-*, and *neglected tropical diseases*, the share of programs addressing NCDs has been gradually increasing ever since.

⁵ I am starting this overview in 2010, as the first index from 2008 used a slightly different set of companies

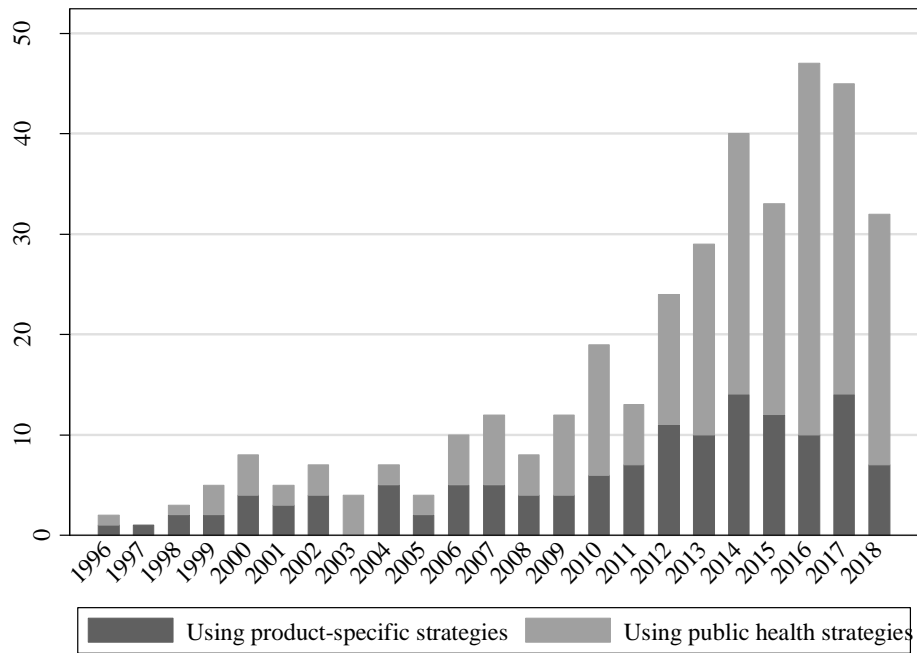
Figure 2.4: Number of new programs by disease-focus. Source: GHP database, author's own calculations



Second, I have summarized the GHP database’s strategy categories⁶ as either product-specific (*supply chain, medicine donation, price scheme, licensing agreements, manufacturing, and product development research*) or more general public health strategies (*Community awareness and linkage to care, health systems strengthening, health service delivery, financing, regulation and legislation*). Programs may use multiple strategies at once, for instance combining donation of cancer products with training oncology nurses (which would fall under health systems strengthening). Yet overall, Figure 2.5 shows that for new programs, the share of programs that used public health strategies has increased over time.

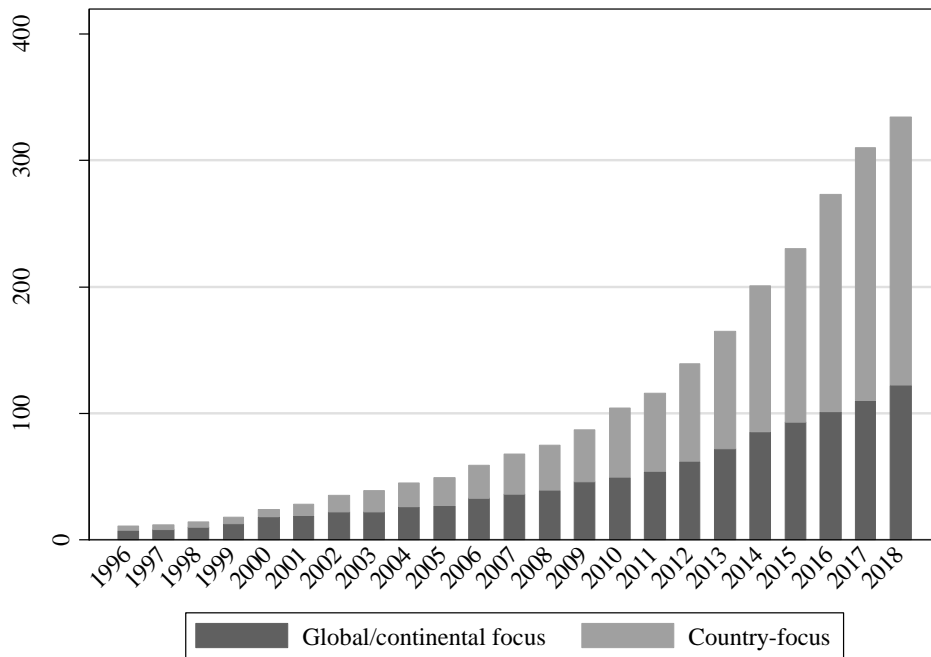
⁶ Companies can tick multiple of these categories when reporting a program on the platform

Figure 2.5: Number of new global health programs by type of strategy applied. Source: GHP database, author's own calculations



Third, I grouped all programs as either having a *country-focus* if they listed a set of specific partner countries (sometimes across multiple continents), or a *global/continental-focus* if the program claimed to cover an entire continent or even had a global commitment. Figure 2.6 demonstrates that the total number of active programs with a *country-focus* has grown faster than those with a *global/continental-focus*.

Figure 2.6: Number of active programs by geographical focus. Source: GHP database, author's own calculations



In total, I find that while companies used to focus on vaccine-preventable-, infectious-, and neglected tropical diseases mainly through product-specific strategies with a global commitment, they increasingly work on non-communicable diseases through localized initiatives that engage more deeply with local health systems beyond product provision. I argue that this reflects developments in the wider access discourse. In the beginning, companies' access efforts were often reactive to stakeholder pressure around a specific product or disease area and in the early 2000s the focus of the global health community was strongly on the HIV crisis and the problem of neglected tropical diseases. The predominant way how companies enacted access responsibilities at this time was through participating in health partnerships on the global level through research, donations or providing products at reduced prices. The responsibility for engaging with country governments and local health systems on broader public health challenges remained with public sector and civil society partners in this context (Buse & Walt, 2000).

Since then, non-communicable diseases such as cancer or diabetes gradually emerged as a new challenge on the global health agenda. In Sub-Saharan Africa alone, the disease burden of NCDs increased by 67% between 1990 and 2017. That stands in contrast to more positive developments around infectious diseases like HIV or Malaria (Gouda et al., 2019). As NCD medicines constitute the core business of most pharmaceutical companies, they also

faced growing pressure to expand access initiatives to this context. Moreover, as more companies began to integrate access objectives and proactively develop access efforts, they often decided to engage in NCDs, as they had both products and expertise to offer in this space. The launch of the industry's 'Access Accelerated' (AA) alliance to tackle NCDs in January 2017 has led to many new initiatives in recent years (Umeh et al., 2020a). However, to engage in NCDs, companies could not rely on a limited role in global health partnerships, as very few international organizations have taken on this topic and companies had to take the lead in setting-up initiatives. Thus, companies developed more industry-led localized interventions working directly with local governments and civil society organizations. Moreover, creating access to treatments for NCDs requires especially strong local health systems. For example, in oncology diagnosing people correctly may require additional technology and many products need to be administered by qualified health workers. Thus, companies had to go beyond reducing prices or making drugs available in new markets and engage in public health and health-systems strengthening activities such as training healthcare workers or setting up diagnostic programs to ensure access to its NCD portfolios.

Outlook

In this chapter I laid down the foundations for the remainder of this dissertation. I have laid out how the industry has gradually accepted a responsibility for tackling the access challenge and shown two trends in how companies have enacted this responsibility. Each observed trend brought up new questions and analytical angles that guided me in the empirical research projects undertaken for this dissertation. First, identifying that companies gradually integrated access responsibilities into their business invites to ask: What made companies move from a decoupled to an integrated approach to access? How did this integration process unfold across different companies and what role did different types of access efforts play? By focusing on two of the industry leaders, Chapter 4 will address these questions. Second, I demonstrated that companies increasingly act through localized initiatives becoming more deeply engaged in country's health systems, particularly in the space of NCDs. Yet, what implications does this new level of involvement have for local actors as well as health governance and how do countries respond to this trend? These are questions that Chapters 5 and 6 provide answers to. Yet, before diving into these empirical chapters, the dissertation will review how past research has studied the interface of the pharmaceutical industry and the access challenge.

Chapter 3 - A review of the literature on the multinational pharmaceutical industry and the access challenge

The relationship between the multinational pharmaceutical industry and the access challenge touches upon a broad range of questions covering corporate social responsibility, corporate organizing, global health governance and politics, ethics, or international development. Thus, before diving into empirically analyzing how companies enact access in Chapters 4-6, I present a systematic review of the literature that has studied this interface in the past. The review brings to surface the importance of bridging and bringing together insights from different disciplines in this context. It shows that past research has already explored different aspects around antecedents, organizing questions and outcomes of the pharmaceutical industry's access efforts. Yet, we are still missing studies that look at what happened inside companies, go beyond individual efforts and trace company engagement with access over time. Similarly, while there is a general lack of studies on the outcomes and impact of growing corporate involvement, this is particularly the case with regard to implications for local health systems and their stakeholders where companies enact their access efforts.

Methods

A first exploratory search on google scholar demonstrated that past research on this topic has been predominantly published in management as well as global health outlets. In terms of scope of the review, I focused on articles that appeared in peer-reviewed journals before April 2021 and excluded other types of publications such as books or reports of international organizations. For global health, I could rely on the "PubMed" database that encompasses most publications in the field. As there is no comparable database for management research, I limited myself to leading journals in this field. Thus, I sampled sixteen leading general management, organization studies and corporate responsibility journals (see Table 3.1).

Table 3.1: Sample included in review

Global Health	Management	Other	Total
Review through PubMed database	Business Ethics Quarterly, Business & Society, Journal of Business Ethics, Academy of Management Journal, Academy of Management Discoveries, Academy of Management Perspectives, Academy of Management Annals, Academy of Management Reviews, Strategic Management Journal, Organization Studies, Organization Science, Administrative Science Quarterly, Journal of Management Studies, Journal of Management, Journal of International Business Studies, human relations	<i>Additional articles found in course of dissertation, published in development studies, sociology, international relations, human rights, or political science journals</i>	
66 articles	27	17	110

For each individual journal, as well as the PubMed database, I used the search terms “pharmaceutical industry” + “access to medicines” as well as “pharmaceutical industry” + “global health”. I did not restrict the search with respect to timespan covered. Yet, on PubMed I limited the review to the first hundred entries. For individual journals, I reviewed all results. In general, I went through titles and abstracts of search results to confirm whether articles were relevant. For example, I excluded articles that focused on the generics pharmaceutical industry, as their business model and position within global health is very different from research-based pharmaceutical companies, or articles that turned out not to have any relationship with access or other global health issues. Moreover, over the course of my dissertation research, I often came across relevant articles that were not captured in my review as they had been published in a journal not excluded in my sample or in a neighboring field such as development studies, sociology or international relations. Adding those pieces, I ended up with a total of 110 papers for further analysis, of which the majority come from the field of global health.

I read each article in detail and made a concise summary of its main messages on the relationship between industry and global health. Accordingly, I tagged each article as speaking about (a) **normative** aspects, (b) **drivers** of industry (non-)activity in global health, (c) description or analysis of industry **activities**, and (d) **outcomes**. Articles could have multiple tags.

Findings

To begin with, the review shows that, overall, the literature discusses all four themes relatively equally (see Table 3.2). The management literature is heavily geared towards discussing normative aspects of industry involvement, which is related to the inclusion of

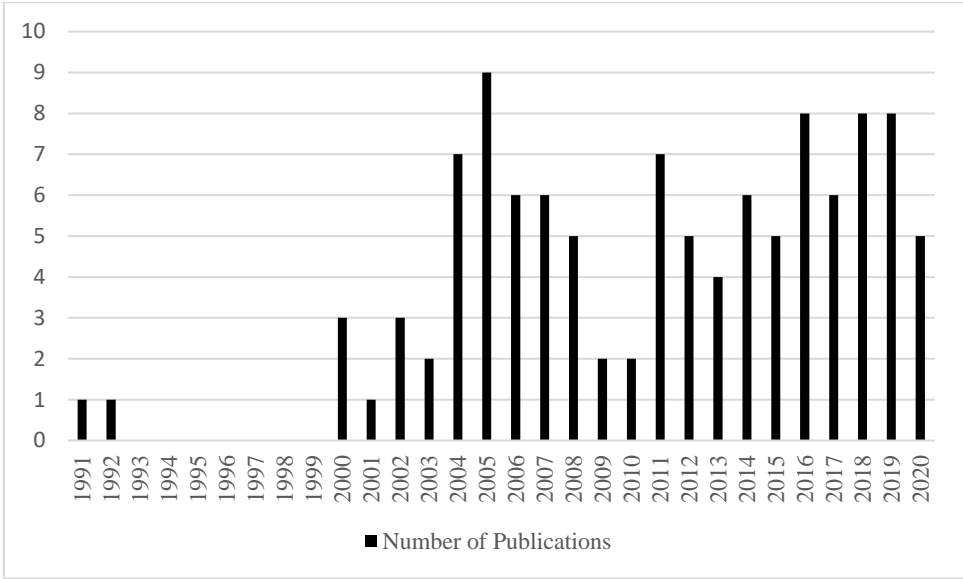
outlets such as Business Ethics Quarterly or Journal of Business Ethics. It also looks more closely at drivers of industry (non)-activity around access than other disciplines. In contrast, research in global health leans more towards analyzing industry activities and its outcomes.

Table 3.2: Papers per category and discipline

Category	Global Health	Management	Other	Total
Normative aspects	7 unique papers / 11% of all papers in this discipline	12 / 44%	3 / 18%	22 / 20%
Drivers	16 / 24%	13 / 48%	6 / 35%	35 / 32%
Activities	46 / 70%	3 / 11%	7 / 41%	56 / 51%
Outcomes	28 / 42%	4 / 15%	3 / 35%	38 / 35%
Total	66 papers	27	17	110

Moreover, looking at Figure 3.1, we can see that – with some exceptions - the topic started to be discussed in research towards the end of the 1990s following the industry’s conflictual role in the HIV pandemic. Subsequently, I will discuss the results for each theme individually.

Figure 3.1: Number of publications over time



Normative aspects

The normative scholarly debate about the access responsibilities of pharmaceutical companies started at the height of the HIV crisis. It originated in the field of bioethics that mostly argued in favor of assigning responsibility to companies for research on neglected diseases (Resnik, 2001) and creating access to existing products (Brock, 2001). Business ethics scholars quickly entered the discussion with a more diverse set of opinions. In one of the seminal articles on the subject in the management literature, Gewertz and Amado (2004) conclude that no moral

obligation exists for companies to act. This minority position was supported at a later stage by (Chang, 2006) and Huebner (2014). However, the majority of scholars made the case that companies have at least a shared responsibility for improving access (R. T. De George, 2005; Wempe, 2009), which they derive from their ownership of intellectual property (Werhane & Gorman, 2005) or from their capacity to act (Dunfee, 2006; Leisinger, 2005, 2009). This line of argument was partially based on parallel deliberations on the right to health and evolving human rights guidelines for pharmaceutical companies (Barbour et al., 2010; Khosla & Hunt, 2009; J.-Y. Lee & Hunt, 2012; Moon, 2013). While this normative debate slowed down in the 2010s, it has recently regained momentum in discussions on the industry's responsibility towards creating access to vaccines and treatments for COVID-19 (Santoro & Shanklin, 2020).

Drivers of corporate (non-activity) in global health

Research has also addressed the question of why companies do or do not engage in access and adjacent global health issues. First, a set of studies focuses on the role of government and the institutional environment in shaping whether companies enact access responsibilities. With respect to research and development, for example, studies explain how policies and market structures disincentivize companies to invest in neglected tropical diseases or antibacterial research and make suggestions for how to solve these issues (G. Martin, 2006; Mrazek & Mossialos, 2003; Trouiller et al., 2002; Viergever, 2013; Yegros-Yegros et al., 2020). Also on the institutional level, Vakili and McGahan (2016) make the case that the WTO agreement of trade-related intellectual property (TRIPS) has contributed to more research on neglected diseases.

Discussing the reasons for the increasing involvement of (pharmaceutical) companies in global public-private partnerships, such as the Global Alliance for Vaccines Initiative (GAVI), scholars argue that the perceived ineffectiveness of governments and international organizations to address health challenges led them to actively involve companies in global health initiatives (Buse & Tanaka, 2011; Buse & Walt, 2000; Ngoasong, 2009; Nishtar, 2004). Turning this argument around, others suggest that it took pressure by governments and international organizations to push companies towards assuming responsibility for contributing to access to medicine initiatives (Flanagan & Whiteman, 2007). Building on this, Doh and Guay (2006) argue that institutional differences between the US and Europe resulted in different expectations towards companies' access commitments.

Moreover, management and sociology scholars have employed a social movement perspective on industry responses to the HIV crisis. Olesen (2006) examines the process of how activists used emotional and strategic elements to make the access challenge resonate with the public and force companies to make concessions. Based on the industry responses to these stakeholder pressures, Dawkins (2005) develops a model of how “issue pacesetters” affect internal management of stakeholder issues. Trullen and Stevenson (2006) use institutional theory to show that companies reacted to social movement pressure that threatened their societal legitimacy. Echoing this line of thought, a study of Novartis’s access program for Glivec in India argues that companies use access programs to protect the legitimacy of their business model (Ecks, 2008).

Finally, research has looked at specific tools meant to shape the institutional environment for companies and enable them to better address access to medicines, for example by showing how benchmarking and transparency can affect corporate access performance (M. Lee & Kohler, 2010), or studying the Access to Medicines Index as a coordination tool for the industry (Quak et al., 2019). In that same vein, Geiger and Gross (2018) analyze how the Medicines Patent Pool as a market-shaping instrument could influence companies’ licensing and collaboration practices in the HIV field. Thus, what is missing with regard to antecedents and drivers are perspectives that take into account firm and micro-level factors. In that space, the study of Girschik (2020) is unique in that it studies the role of internal activists on developing the internal access strategy of a particular company.

Analyzing industry activities

Another group of studies has looked at what companies are doing to address global health challenges and how such efforts are organized. Yet, they differ quite a lot with respect to their perspective and depth of analysis. In global health research, there are multiple qualitative case studies of individual company projects or public-private partnerships that remain fairly descriptive and do not attempt to generalize beyond the cases they cover (K. L. Collins, 2004; Manner et al., 2019; Ramiah & Reich, 2005; Wertheimer et al., 2004). It also appears common for companies and their managers to present and explain their own global health efforts through academic publications (Cone, 1991; Dellepiane & Pagliusi, 2019; Ritter, 2010; Stéphenne, 2011; Witty, 2011).

Similarly, in the early 2000s, many scholars published accounts describing the new phenomenon of global public-private partnerships that slowly became important players in global health and often included pharmaceutical companies (Buse & Walt, 2000; Nishtar,

2004; Reich, 2000; Richter, 2004). Following from this, the analysis of governance arrangements for such industry partnerships became an important element in global health research, for example studying the politics within such partnerships (Buse & Harmer, 2004). Papers in this space raise the importance of principles such as accountability or transparency to improve the effectiveness and legitimacy of partnerships as tools of health governance (Buse & Harmer, 2007; M. H. Martin & Halachmi, 2012; Reich, 2018; Rockers et al., 2018).

Lately, some global health researchers have also looked at the heterogeneity of pharmaceutical companies efforts, specifically with regard to access to medicines. An exploratory study has compared how pharmaceutical companies organize their corporate responsibility efforts in terms of positioning of access responsibilities within the firm or the use of partnerships to address access (Droppert & Bennett, 2015). Another looks more specifically on the sustainability of different types of access strategies (Rocha et al., 2020). Rockers and colleagues also give an overview of which strategies are used by which companies (Rockers et al., 2017), and explore different implementation models for industry programs around non-communicable diseases (Umeh et al., 2020a). Over in the management space, Trullen and Stevenson (2006) provide an analysis of the differences in how companies acted in the HIV crisis and shows its correlation with companies' respective exposure to stakeholder pressures. Still, all in all we know very little about the internal dynamics of how companies organize to address global health challenges.

Outcomes

Finally, research discusses different outcome categories of industry involvement in global health. First, with regard to outcomes on the firm level, studies show how companies have used access and other global health programs to regain legitimacy and improve their reputation (Ecks, 2008; Trullen & Stevenson, 2006). Moreover, in very specific geographical settings, some researchers have also found a positive effect of pharmaceutical companies' corporate social responsibility activities on their financial performance (Malik & Kanwal, 2018; Min et al., 2016).

Second, there are several conceptual articles discussing the impact of increased corporate involvement in global health on global health governance, particularly through the rise of global public-private partnerships. Different authors fear that this development bears structural risks through giving companies more influence in agenda-setting and decision-making, as there is an inherent conflict of interest between commercial and public health interests (Nishtar, 2004; Richter, 2004; Ruckert & Labonté, 2014). For example, Williams

(2012) explains how the development of an industry-inclusive and collaborative global health governance has helped companies to prevent a more regulatory approach to improving access to medicine.

Third, with regard to the actual health outcomes of corporate involvement, the literature provides an unclear picture. In an industry-wide overview Rockers and colleagues show that most corporate access initiatives are lacking any form of social outcome or impact assessment (Rockers et al., 2017). Their systematic evaluation of a single company's access program based on randomized control-trials revealed that the impact of this particular program was weak (Rockers et al., 2019). The only study on societal outcomes of industry responses to a global health challenge in the field of management found that increased corporate attention to a salient challenge, such as a pandemic, can lead to withdrawing resources from other priority but less salient health issues (Arslan & Tarakci, 2020). Additionally, the global health literature provides a number of more descriptive case studies of individual company initiatives (K. L. Collins, 2004; Ramiah & Reich, 2005) or global public-private partnerships (Buckup, 2008; Buse & Tanaka, 2011; Roehrich et al., 2014) that qualitatively discuss their outcomes, but do not represent systematic impact evaluations.

Beyond the program or company level, researchers have studied the theoretical and empirical health effects of specific access tools, such as tiered pricing (Danzon, 2018; Danzon & Towse, 2003; Moon et al., 2011) or voluntary licensing (Outterson & Kesselheim, 2008). Another group conceptually discusses the potential impact of industry partnerships on the health system of partner countries (Beran et al., 2017; Galea & Mckee, 2014; Johnston & Finegood, 2015; Ruckert & Labonté, 2014). For instance, Galea and McKee (2014) argues that well-intended donations of health products can be more of a burden than benefit to weak health systems if the products are difficult to store or distribute. Similarly, facing uncoordinated industry partnerships, health officials end up wasting time on repetitive meetings and reporting and do not get to fulfill their regular duties (Ruckert & Labonté, 2014). To conclude, there is still very limited research about the outcomes of industry involvement on the firm, governance and societal level alike. Especially empirical studies are missing up to now.

Table 3.3: Overview of management, global health and adjacent literature on access and the pharmaceutical industry

Key question	Review results
Do pharma companies have a responsibility to contribute to global health?	<ul style="list-style-type: none"> • Limited responsibility (Gewertz & Amado, 2004; Huebner, 2014; Chang, 2006) • Shared responsibility (R. T. De George, 2005; Dunfee, 2006; Leisinger, 2005; Wempe, 2009) • Strong responsibility (Brock, 2001; J.-Y. Lee & Hunt, 2012; Moon, 2013; Resnik, 2001)
What are drivers of industry (non-)action?	<ul style="list-style-type: none"> • Ineffectiveness of other players creating need for companies to step in (Buse & Tanaka, 2011; Buse & Walt, 2000; Ngoasong, 2009; Nishtar, 2004) • Normative pressures/Role of social movements (Dawkins, 2005; Trullen & Stevenson, 2006; Olesen, 2006) • Government and regulation pushing action (Doh & Guay, 2006; Flanagan & Whiteman, 2007; Vakili & McGahan, 2016) • Institutional structures and policies hindering action (G. Martin, 2006; Mrazek & Mossialos, 2003; Trouiller et al., 2002; Viergever, 2013; Yegros-Yegros et al., 2020) • Role of specific institutions in facilitating corporate efforts (Geiger & Gross, 2018; M. Lee & Kohler, 2010; Quak et al., 2019) • Internal activists (Girschik, 2020)
How do companies address global health challenges?	<ul style="list-style-type: none"> • Global health public-private partnerships (Buse & Walt, 2000; Nishtar, 2004; Reich, 2000; Richter, 2004), with differences in internal governance (Buse & Harmer, 2007; M. H. Martin & Halachmi, 2012; Reich, 2018; Rockers et al., 2018) • Showing heterogeneity of access efforts (Droppert & Bennett, 2015; Rocha et al., 2020; Rockers et al., 2017; Trullen & Stevenson, 2006; Umeh et al., 2020a)
What are outcomes of corporate global health efforts	<ul style="list-style-type: none"> • Outcomes on the firm: Reputation & legitimacy (Ecks, 2008; Trullen & Stevenson, 2006); financial returns (Malik & Kanwal, 2018; Min et al., 2016) • Outcomes on global health governance (Nishtar, 2004; Richter, 2004; Ruckert & Labonté, 2014; Williams, 2012) • Outcomes on societal level: Lack of robust evaluations (Rockers et al., 2017, 2019); Unintended societal outcomes (Arslan & Tarakci, 2020); conceptual discussions on impact of access tools (Danzon, 2018; Danzon & Towse, 2003; Moon et al., 2011; Outterson & Kesselheim, 2008) and health partnerships (Beran et al., 2017; Galea & Mckee, 2014; Johnston & Finegood, 2015; Ruckert & Labonté, 2014)

Conclusion

Taken together (see Table 3.3), the literature review shows that to understand why, how, and with what outcomes the pharmaceutical industry has addressed global health challenges, we need to leverage knowledge across different disciplines. The normative aspects of whether the industry should become active has especially been addressed by business and health ethicists, as well as human rights scholars. There is a broad consensus that companies have at least a shared responsibility. With regard to drivers of corporate action, research has closely looked at the institutional level, particularly in the HIV and R&D context. Much less is known about factors on the organizational and individual level. Moreover, it would be interesting to understand how the drivers might compare across disease areas or over time. The review also identifies important gaps around the organizing aspects of the industry's global health activities. While there have been many single case studies of individual efforts, we are missing insights into the dynamics within companies over time as well as more comparative perspectives. Finally, on the outcome dimension, more rigorous empirical impact assessments are lacking on all levels. Conceptual discussions are especially prevalent with regard to

governance outcomes. Yet, most of these papers address the global level and rarely discuss the impact of rising industry involvement on the national level in low- and middle-income countries. This dissertation may help to patch some of these gaps, but broader research attention, especially from beyond the global health field, is needed to properly understand the relationship of the pharmaceutical industry with access and other global health challenges.

Chapter 4 - Pathways to Progress: Product- and Operation-Level Integration of Social Objectives in the Pharmaceutical Industry

Monitoring by external stakeholders, efforts by internal activists, as well as increasing transparency around corporate behavior have induced companies to adopt and act upon commitments around pressing social problems like climate change, poverty, or pandemics (Girschik, 2020; Haack et al., 2021; Wickert & de Bakker, 2018). In addressing the question of how companies can best address social problems, recent research points to the integration of social objectives into the company's core business is a key enabler for progress (Barnett et al., 2020; Graafland & Smid, 2019; Halme et al., 2020; Hengst et al., 2020). Companies pursue integration, for example, by developing new social business models (Halme et al., 2012), changing commercial practices in developing countries (Girschik, 2020), or adopting ethical tools to deal with responsibility concerns in organizational processes (Ben Khaled & Gond, 2020). Research in this area typically refers to integration as “the inclusion [of social objectives] into the existing competitive strategy, as manifested in an organization's products or services and processes” (Hengst et al., 2020: 246). As such, the effectiveness of integration appears to hinge on legitimating new objectives and the corresponding internal changes to organizational processes (e.g. Bode et al., 2019). Effectively tackling social problems, however, does not only require internal change. In addition, it also depends on how companies are able to intervene in and overcome constraining factors of the social system that sustain a given social problem but are external to the company (Barnett et al., 2020; Mair & Seelos, 2021).

The twofold – internal and external – challenge of integration is evident in the setting of our study: pharmaceutical companies and access to medicines. Pharmaceutical companies can significantly contribute to progress on health problems, but only if people in need have access to the products they offer. Hence, products need to be affordable, locally available, and appropriate for the contexts they are needed in. Internally, this implies that companies might need to overcome short-term thinking and reliance on philanthropic models to improve access such as product donations. Integration efforts critically depend on characteristics and dynamics of the relevant social systems and in the case of access to medicines of public health systems. A lack of health workers administering products or broken supply-chains to get medicines to where they are needed constitute serious challenges for integration. To enable access to medicines, companies therefore need to change business practices and structures

internally as well as address external constraints. Reflecting on our study's context, we therefore conceptualize integration as efforts that address not only internal challenges around the legitimation of new social objectives, but also external challenges related to assessing and acting on system-level limitations that sustain a social problem. We ask: *How do integration efforts enable companies to make progress on social problems in light of internal and external challenges?*

To answer this question, we examine the integration efforts of two pharmaceutical companies that were early adopters of access objectives and are perceived as industry leaders in making progress on access to medicines (Access to Medicine Foundation, 2021). This multiple case analysis allowed us to identify two distinct types of integration efforts common across both organizations. These types – product-level and operation-level integration – differ in the locus of integrating social objectives as well as in the mechanism for enacting these objectives, and thus in how they enable progress on social problems. We find that these efforts address the twofold challenge of integration – internal organizational legitimacy and external effectiveness – differently. In addition, these efforts are associated with distinct forms of strategizing, understood as actions that address the challenges arising from each type of effort. While we find that the types can co-exist throughout a company's integration pathway, we argue that the differences and implications of distinct integration efforts deserve separate analytical and theoretical attention. We thus advance the study of integration by developing a theoretical understanding of the heterogeneity of integration efforts, highlighting the implications of different integration efforts for both means-end decoupling and political dynamics inside organizations as key adverse outcomes of integration. We close with considerations on the portability of our findings to a broader set of industries facing a similar challenge - facilitating access to essential products or services.

Background

Many companies have adopted social objectives, but the resulting corporate social responsibility (CSR) initiatives may not lead to substantial progress on underlying social problems (Halme et al., 2020; Vestergaard et al., 2020; Wright & Nyberg, 2017). Often, this lack of progress has been attributed to a clash between external demands and organizations' internal efficiency, leading to a merely symbolic adoption of social objectives (Crilly et al., 2012; Lim & Tsutsui, 2012). Such forms of policy-practice decoupling, however, may be increasingly rare (Graafland & Smid, 2019). Instead, scholars have argued that increased stakeholder pressure and monitoring in the “audit society” (Power, 1997) have created

economic and reputational incentives to substantively act upon social objectives (e.g. Marquis & Qian, 2014; Bermiss et al., 2014). Recently, several studies have suggested that the integration of social objectives, may allow companies to address social problems in a substantive manner (Hengst et al., 2020). For example, Halme and colleagues (2020) examine 19 European multinationals and find that all cases associated with improvements in social performance also exhibit integration, conceptualized as responsibility considerations in daily organizational practices.

In studying challenges to integration, this research has focused on the resistance within organizations to newly introduced social objectives, as these may clash with other proclaimed goals of the firm, such as profit. Resistance may be rooted in different interpretations of the primary objectives of the organization among different actors (Augustine, 2021; Hengst et al., 2020; Valente, 2012; Weber & Waeger, 2017). A key mechanism by which social objectives engender resistance is through increases in organizational complexity, given the creation of new structures and diversion of resources in the service of social objectives (Bromley & Powell, 2012). As a result, objectives may remain limited in scope and encompass only parts of the organization's activities. Sustainability managers' jurisdictions, for example, may cover a small set of activities of an organization while not extending to other areas that are equally relevant to matters of organizational sustainability (Augustine, 2021). In another example, organizational subsidiaries may enact objectives only if these align with the subsidiary's values and enactment was high within the subsidiary's operating branch. As a result, the reach of social objectives may be confined to a few subunits within large organizations (Jacqueminet, 2020).

A second, though less elaborated challenge revolves around the role of external conditions sustaining a social problem, and how these conditions affect the integration of social objectives. The importance and difficulty of assessing the link between organizational CSR initiatives and social outcomes was previously highlighted by what Bromley and Powell (2012) identify as "means-end decoupling". Under means-end decoupling, CSR initiatives are only weakly linked to intended or desired socio-environmental outcomes. This implies that firms enact initiatives whose effect on outcomes, for example reducing a carbon footprint, may be weak or indeterminate (Wijen, 2014). Such challenges ostensibly manifest in large scale across social and environmental issues. For example, studies document how CSR policies on child labor avoidance or resource reduction often fail to address characteristics of the underlying social problem at hand (Bharadwaj et al., 2020; Stål & Corvellec, 2021). Assessing characteristics of a social problem and the impact of organizational efforts may be

hampered by the causal complexity of the problem that makes establishing the effectiveness of enacting a given objective more difficult, even when integrated into core activities (Wijen, 2014).

Although arguably as important as internal change, how integration relates to external system-level constraints of the social problem is not well understood. Similarly, while the internal legitimation challenges of achieving integration have been documented, our understanding of how integration efforts differ in engendering these challenges likewise remains underdeveloped. Our study seeks to address these questions by centering on differences in *how* companies pursue integration. Conceptual work suggests that integration can indeed be facilitated differently. Yuan et al. (2011), for example, propose seven patterns of integration that differ in how integration efforts displace existing organizational practices, where they are situated within the organization, and who is involved in their development. Other studies differentiate between the depth of integration efforts as being either limited to reducing negative externalities or as alleviating societal challenges through business activities (Halme & Laurila, 2009; Martinuzzi & Krumay, 2013). In this study, we interrogate the potential heterogeneity of integration efforts vis-à-vis the twofold challenge to making progress on social problems.

Setting, Data and Methods

Research setting: Integrating access to medicines

We examine our research question in the context of enabling access to medicines in low- and middle-income countries (LMICs), a social problem affecting nearly two billion people (World Health Organization, 2017). Improving access requires, first, developing relevant health products and, second, making them accessible to all patients who need them (Wirtz et al., 2017). In this paper we focus on the latter aspect and study how research-based multinational pharmaceutical companies seek to make existing products more accessible for patients in LMICs. Starting with the global HIV crisis in the 1990s, civil society actors and governments across the globe began to make pharmaceutical companies responsible for creating access to their recently developed HIV medicines (Olesen, 2006; UN Special Rapporteur on the Right to Health, 2008). They criticized that due to charging high prices and fiercely protecting their intellectual property rights, medicines were not accessible for most patients in low- and middle-income countries. The access movement called on the industry to move “beyond philanthropy” (Oxfam et al., 2002) and integrate access to medicines as a core

objective into their business rather than relying on philanthropic donations or activities of corporate foundations.

Since the 1990s, most companies have devised and adopted access to medicine objectives. The increasing transparency around corporate efforts through civil society monitoring and rankings such as the Access to Medicine Index (Quak et al., 2019) helped to expose the potential decoupling of corporate practices from access policies and to incentivize companies to integrate access to medicine as a social objective into their business. Efforts include licensing patent-protected products to generic manufacturers, changing pricing structures, or developing entirely new business models (Access to Medicine Foundation, 2021). The scale and scope of integration efforts vary considerably among companies (Kong et al., 2019). However, there are open questions around the effectiveness of these different efforts, as impact assessments are very rare (Rockers et al., 2017). As we alluded to earlier, improving access requires changes both within and outside the company. Reducing a product's price, for instance, may have little impact on access if procurement and distribution networks are too weak, if health professionals lack the knowledge and ability to administer the product, or if the product is not available in pharmacies or health centers close to the patients. Thus, the complexity of the access to medicine problem and the differences among pharmaceutical companies in terms of addressing it allow for a highly suitable setting to examine how integration may enable companies to make progress on a social objective.

Case selection

Given our interest in analyzing different integration efforts and generating theory about integration and its internal and external challenges, we opted for a multiple case study design based on two cases of companies widely considered as industry leaders in enacting access policies. Multiple case analysis is well-suited to analyze variation but also similarities between companies facing similar circumstances, for example industry membership or exposure to stakeholder pressure (Eisenhardt & Graebner, 2007). Our cases – GlaxoSmithKline (GSK) and Novartis – constitute critical cases for advancing knowledge on how companies integrate social objectives with the aim to make progress on a social problem. First, both companies were consistently ranked among the ten largest pharmaceutical firms globally during our study period. Their product portfolios include a large share of medicines considered as essential for patients in LMICs. Second, these companies have been among the first to develop and enact access policies (Oxfam et al., 2002) and are still perceived as industry leaders in integrating access to medicines into their business today (Access to

Medicine Foundation, 2021). Despite these similarities, the companies differ considerably in *how* they have pursued integration. The Access to Medicine Index (ATMI), for example, highlights GSK's strong performance around large-scale licensing and tiered pricing deals. In turn, Novartis leads in implementing social business models in LMICs. These differences, their long history with integration, and the perceived industry leadership of these two companies in making progress on access objectives, we argue, constitute an empirical window into how integration efforts may address the twofold challenge of internal legitimation and constraints in the external system.

Data

We collected data from primary and secondary sources. We conducted 37 semi-structured interviews with current and former company representatives at different levels in both organizations as well as with external stakeholders. We also collected archival data from sources such as the biannual ATMI, reports of non-government organizations (NGOs), or media coverage on the topic going back to the year 2000. We present an overview of our data in Table 4.1. We conducted interviews in two phases. In a first exploratory phase, we contacted and interviewed senior commercial and CR managers between November 2018 and April 2019 that we had identified as central protagonists in different stages of the integration process. Initially, we sought to understand the trajectories of individual access efforts, including their emergence, their links to different areas of the organization, and their changes over time. From this exploration, we gained a more nuanced understanding of the role that integration played in both cases.

In a second phase between July and November 2019, we probed our emerging insights in additional interviews with organizational representatives that we identified through our exploratory interviews and archival research. Collecting additional interview data and increasing the diversity among interviewees helped us to avoid potential groupthink among a smaller number of closely involved actors. We followed up with selected interviewees to corroborate insights and validate emerging narratives. In addition, we interviewed several experts from NGOs and the investor community to include an external assessment. We conducted interviews in different constellations of team members and compared notes in debriefing meetings to mitigate interviewer bias. Interviews lasted between 30 and 140 minutes. We obtained the interviewees' consent to recordings, and subsequently transcribed all interviews in their original language of English or German.

Moreover, to assure the validity of retrospective accounts, we tried to understand the motivation or ability of individuals to recount events in a particular way (Golder, 2000; Kipping et al., 2014). Generally, we only discussed events that interviewees directly experienced to avoid speculative accounts. Finally, archival data also helped us to gain an overview of field level developments around access as well as to triangulate facts, events, and activities for each case to develop a detailed overview of companies' integration pathways. These were especially important to better understand earlier events where we could rely less on interviewee accounts.

Table 4.8: Data overview

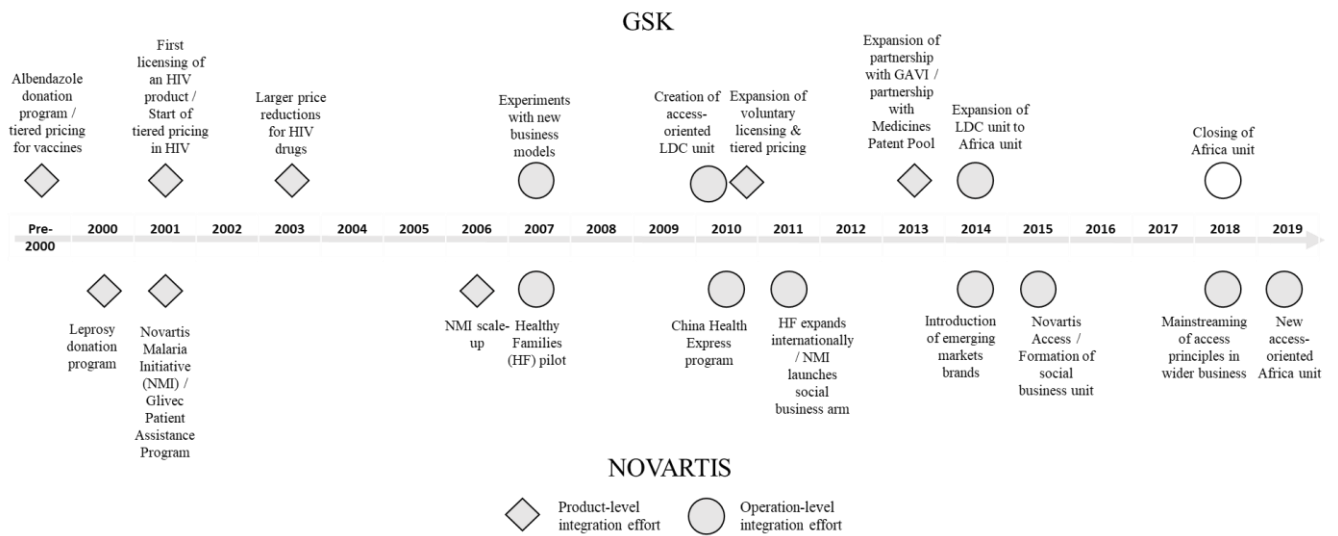
<i>Type of data</i>		Total
GSK		
<i>Interviews (codes assigned to quotes)</i>	<i>Topics covered</i>	14
Senior management of developing countries unit (G1-G5)	Relationship of unit with rest of company, operational challenges, changing nature of the unit	5
Country managers (G6)	Practical implications of integration for business, challenges of implementation	1
Commercial division heads (G7-10)	Background of integration, corporate strategy, top-level involvement, challenges and external influences on process	4
Corporate responsibility, public affairs functions (G11-14)	Relationship with external stakeholders, history of integration process	4
<i>Archival data</i>	<i>Details</i>	248 documents
Company publications	Press releases, annual reports, CSR statements	57
Public statements of company representatives	Interviews, speeches, panel debates	8
Media articles	General and industry publications	161
Case studies	Consulting, NGO, ATMI reports; book chapters; academic papers	23
Novartis		
<i>Interviews</i>	<i>Topics covered</i>	17
Senior management of different integration projects (N1-7)	Project history, relationship with rest of company, operational challenges, dealing with external pressures, top-level involvement	7
Corporate responsibility and global health functions (N8-13)	History of integration efforts, mobilizing support for integration process, struggles over integration, relationship with rest of industry and external stakeholders	6
Senior executives (N14-16)	Views on integration over time, top-level preferences, history, dealing with external pressures	3
Country managers (N17)	Practical implications of integration, development of and struggles over integration efforts in country organizations	1
<i>Archival data</i>	<i>Details</i>	220 documents
Company publications	Press releases, annual reports, CSR statements	77
Public statements of company representatives	Interviews, speeches, panel debates, webinars	8
Media articles	General and industry outlets	108
Case studies	Consulting, NGO, ATMI reports; book chapters; academic papers	27
Field level interviews		
Access campaign representatives (FL1-4)	Relationship between industry and access movement, external assessment of integration in both companies	4
Interviews with responsible investment experts (FL-5-6)	Relationship between investors, companies, and access movement	2

Analytical approach

We analyzed the data collected in an iterative process moving back and forth between our data and literature (Gioia et al., 2013). We proceeded in two analytical steps.

Step 1 - Identifying the locus and mechanism of distinct integration types: First, we took stock of the different means – practices, projects, systems – companies deployed in their approach to integrate access principles into their business (see Figure 4.1). To examine and surface integration pathways we developed detailed timelines for each company. We reviewed GSK’s and Novartis’s annual and corporate responsibility, NGO, and Access to Medicines Index reports to identify efforts that aimed at improvements in the access to companies’ products in LMICs. In line with our research focus, we excluded upstream aspects of access to medicine around research and development of new drugs. Our interview data helped to corroborate these findings, to uncover additional efforts not found in archival data, and to contextualize efforts with respect to genesis and evolution over time. The analysis in this step revealed that integration efforts in both companies could be located at either the level of products or operations. Companies sought to improve access by either changing features of specific products such as price and degree of IP protection, or by integrating access objectives into commercial operations and structures in specific LMICs. This led us to distinguish between *product-level* and *operation-level integration* as a key difference in the *locus* of integration. Subsequently, we strived to understand the mechanism by which each type of integration effort facilitated access to medicines. To that end, we interrogated our data with regard to how efforts were enacted and found a key distinction in how each type involves internal as well as external actors. We grouped these first-order codes into two mechanisms of enacting access: a) external partnerships in the context of product-level integration and b) internal business models in the context of operation-level integration (see Table 4.2). We use these two integration types to inform and guide our further analysis.

Figure 4.1: Integration pathways: mapping of selected integration efforts



Step 2 - Understanding how integration types address internal and external

challenges: Second, as our initial overview of integration timelines had shown that companies aborted and changed efforts multiple times over the years, we examined if and how these efforts were accompanied by and addressed the challenges of integration around internal legitimation and overcoming external constraints that we described earlier. To that end, we engaged in a series of “moves” of coding and categorizing our data (Grodal et al., 2020), gradually diving deeper into emerging insights while being guided by analytical angles derived from the literature.

Probing our data with the two challenges in mind, our analysis of product-level integration efforts surfaced only limited evidence for internal legitimation problems. Instead, we identified that companies relied on external partners to address system-level constraints which we characterized as a *control challenge* over the link between integration efforts and progress on access. We found no such evidence in the case of operation-level integration. For operation-level integration, we observed increases in organizational complexity creating structural and ideological resistance which we refer to as a *legitimation challenge*. Third, building on these insights, we went back to the data on each integration type looking for evidence of how companies approached these two challenges and tried to sustain the distinct integration efforts and their effectiveness over time. This final round of coding brought out differences in supportive strategizing to enable the effective enactment of each integration

type. We find that product-level integration was particularly associated with strategizing at the systems-level, while operation-level integration was accompanied by strategizing at the level of the organization. An overview of all concepts with data exemplars can be found in Table 4.2 below.

Findings

Types of integration

Studying the access efforts of the two companies (see Figure 4.1), we identify differences in what and how they integrate access objectives. Based on this, we derive two types of integration:

Table 4.9: Analytical categories with data exemplars

	Product-level integration	Operation-level integration
<i>Locus of integration</i>	<p><u>Introducing access-oriented business practices on product-level</u></p> <p>Reducing prices of selected medicines <i>Significant price reduction of most of GSK's patented products in Least Developed Countries (Access to Medicine Foundation, 2012)</i></p> <p><i>For leprosy, malaria, and TB, medicines are provided at cost price or free.</i> <i>Novartis has made a commitment to WHO to provide free treatment for all leprosy patients in the world until the disease has been eliminated from every country. Also committed to providing Coartem, its oral fixed-combination anti-malarial product, at cost. In 2006 the average treatment price of Coartem was reduced to \$1 compared with \$1.57 previously. (Oxfam, 2007)</i></p> <p>Sharing intellectual property <i>For Least Developed Countries (LDCs) and Low Income Countries (LICs), GSK will not file patents for its medicines, so as to give clarity and confidence to generic companies seeking to manufacture and supply generic versions of GSK medicines in those countries. For Lower Middle Income Countries (LMICs) generally, GSK will file for patents but will seek to offer and agree licences to allow supplies of generic versions of its medicines for 10 years. (GSK, 2016)</i></p>	<p><u>Disseminating access objectives in operational structures</u></p> <p>Creating new access-oriented business units <i>The DC operating unit: Established in August 2010 – to increase patient access to GSK medicines and vaccines while expanding its presence and helping it build a sustainable business in developing countries (GSK, 2013)</i></p> <p>Assigning access objectives to company's country level actors <i>There are new objectives, not only profitability but also how many people can be reached. That means people lower in the income pyramid should get access to more affordable drugs. The approach is to come up with new commercial models to reach as many people as possible (N5)</i></p>

<p><i>Mechanism to enact access</i></p>	<p><u>External partnerships</u></p> <p>Supply and price agreements with international procurement bodies <i>GSK is a long-standing partner of the Alliance and reserves its lowest prices for GAVI-eligible countries, which can be as low as one-tenth of prices in developed countries. (GSK, 2014)</i></p> <p><i>In 2001, Novartis forged a groundbreaking public private partnership with the WHO and later worked with several other partners such as UNICEF, the United States President’s Malaria Initiative, UNDP, MSF and international procurement agencies to provide Coartem® without profit for use by public health systems in developing countries (Novartis, 2016a)</i></p> <p>Licensing deals with generic manufacturers <i>ViiV Healthcare’s voluntary licensing agreements with the Medicines Patent Pool and Aurobindo Pharma allow generic manufacturers to produce and sell low cost single or fixed dose combination products containing dolutegravir for adults and children in countries with the highest burden of HIV. (GSK, 2021)</i></p> <p>Bypassing company’s country level actors <i>They did not have a role in this program. Products went directly from GSK to WHO and they distribute it. The local GM played no part in that, and they could not have, would be unmanageable. (G12)</i></p> <p><i>In the past, the Malaria Initiative was located in Switzerland...Before, every time there was an issue we had to go to Basel, now much more is managed at the country level. (Chu et al., 2014)</i></p>	<p><u>Internal business models</u></p> <p>Developing social business initiatives in developing countries <i>Novartis Arogya Parivar programme, a sustainable for-profit initiative that has combined access to medicine and the provision of healthcare services for the lowest socio-economic strata in rural areas of India to address locally prevalent diseases (Access to Medicine Foundation, 2012)</i></p> <p>Changing practices of commercial teams in developing countries <i>For example, in Mexico it was how do we work with the government and local health systems to address the critical NCD burden, i.e. Diabetes and bloodpressure, which are rampant. Basically try to grow the business in a way that adds value and increases the 44rogya44bility and affordability of medicines and healthcare in general. (N12)</i></p> <p><i>At the end of the day our GMs, and generally all GMs, they suddenly through a restructure (they were not new people coming in), became part of the unit where there was a dual focus: profitability but with low unit rates (G4)</i></p>
<p><i>Dominant challenges for each integration type</i></p>	<p><u>System-level challenge: maintaining control</u></p> <p>Success of efforts relying on external partners <i>Under this ten-year agreement [with WHO] Novartis manufactured and delivered the drug directly to ministries of health in malaria endemic countries, which then assume responsibility for distribution (Chu et al., 2014)</i></p> <p><i>This allows generic companies to manufacture and supply generic versions of GSK medicines in those countries. (GSK, 2021)</i></p> <p>Limited information on impact <i>It is difficult to estimate the number of patients treated as a result of our preferential pricing agreements, since we do not control healthcare provision (GSK, 2010)</i></p> <p><i>“This decrease is attributed to several measures, including the distribution of long lasting insecticidal nets (LLINs), and targeting high-burden districts with indoor residual spraying (IRS) and effective ACTs”. (Novartis, 2016a)</i></p> <p>Reporting impact of partners as evidence for impact <i>“The achievements of the GAVI Alliance are remarkable with 6 million lives saved since its formation in 2000. At the same time, GSK remains fully committed to supporting GAVI...” (GSK, 2014)</i></p> <p><i>Rwanda adopted the Novartis ACT as first-line therapy in 2006. It reported a significant decline in malaria incidence. (Novartis, 2016b)</i></p>	<p><u>Organization-level challenge: maintaining legitimacy</u></p> <p>Ideological tensions <i>Each time he took that up he was being knocked back by senior leadership. (G5)</i></p> <p><i>At first the units were an enemy of some of the social business efforts. They saw it potentially as cannibalizing their sales. (N15)</i></p> <p>Structural tensions <i>Well, we covered our costs, but still cause complexity in the company. It causes skews in manufacturing, it causes management oversight...all of the mechanics of running these markets. (G6)</i></p> <p><i>Funnily enough, the cost is much higher in organizational terms. It is about the use of management time and bandwidth, than it is about the cost. It makes things quite complicated sometimes. It creates organizational complexity (G1)</i></p>
<p><i>Strategizing in response to challenges</i></p>	<p><u>Strengthening partners in enacting access</u></p> <p>Funding capacity-building to accompany pricing deals <i>Starting in 2006, NMI convened workshops in different parts of SSA. “Through collaborations with NGOs and government partners we have reached over 100,000 health workers and community members without trainings.” (Chu et al., 2014)</i></p>	<p><u>Internal lobbying</u></p> <p>Bottom-up lobbying for integration <i>The Arogya experience helped to show that social business works...being able to show them that Novartis Access would not be a giant black hole (N10)</i></p>

	<p><i>So we agreed through the unit to fund two things: More adequate refrigeration, a cold-chain that keeps the vaccine cold. And secondly more nurse training, so nurses are trained to give the vaccine. These two things enabled us to supply the vaccine probably a year earlier than before. (G2)</i></p> <p>Technical assistance in licensing deals <i>The initiative provides Mylan and Macleods with a financial incentive award from Unitaid via CHAI, as well as the technical expertise of ViiV Healthcare, to catalyze the development, manufacture and supply of generic formulations of pediatric dolutegravir. (Unitaid, 2018)</i></p> <p><u>Steering partners' activities</u></p> <p>Participation in partners' governance <i>The GAVI Alliance, on whose board I have been privileged to serve... (Stéphenne, 2011).</i></p> <p><i>Regular participation of Novartis delegates in Global Fund Board meetings (The Global Fund to Fight AIDS Tuberculosis and Malaria, 2021)</i></p> <p>Participating in cross-sectoral policy fora <i>Speaking today at a European Commission/GAVI Alliance event in Brussels, Sir Andrew Witty, CEO of GSK paid tribute to the GAVI Alliance leadership (GSK, 2014)</i></p>	<p><i>We were asking them to do something extra to this process. That was about advocacy... I went to present to the regulatory group and explain why this was important. (G1)</i></p> <p>Top-down promotion of integration <i>The chair of the supervisory board wanted to do new things...He probably challenged the management to do it (N14)</i></p> <p><i>"If you are in a big company and you are the head of manufacturing, you have 15 big issues going on at any one time...If I did not walk in his office and say 'hey look, I need you to solve this issue with the LDCs in Africa', it would be very hard to get his attention. (G7)</i></p> <p><u>Aligning structures and processes</u></p> <p>Adjusting organizational processes to needs of integration <i>Think through structurally what are the demands that I have to place on manufacturing, supply-chain, finance, local marketing teams (Dorje)</i></p> <p><i>The other thing from manufacturing was the acceptance to have marginal costing...enabling us to win tenders. (G4)</i></p> <p>Aligning incentives of commercial actors <i>We included the access principles as performance management into the objectives of the teams in the countries...It has to be tied to the incentives. (N11)</i></p>
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Product-level integration starts with the company or its stakeholders identifying an access need around a specific product of the company. To address it, the company introduces a specific new practice, such as donations, tiered pricing, or voluntary licensing to the management of this product with the aim to increasing its affordability to patients in need. Access objectives are integrated through centralized access program structures which may draw on certain business functions such as manufacturing or regulatory affairs, but otherwise remain organizationally and financially separated from ground operations in countries of need. Instead, companies form structured partnerships with external organizations such as large-scale supply agreements with multilateral procurement bodies, LMIC governments or licensing agreements with generics manufacturers. Yet, the companies' direct role in access creation stops at the price reduction. To address external constraints to access such as the availability of the product and its uptake in countries of need, companies rely on external organizations and governments distributing their products. Thus, the underlying mechanism to achieve the organizations' access objectives relies on enabling external partners in their work towards better access by providing them with a cheaper supply of health products.

Both companies, for instance, have committed to long-term structured donation programs in the space of neglected tropical diseases following calls by WHO and its partners. These donation programs draw upon corporate resources and business functions but have been run by centralized global health units. GSK also became under pressure by the global

health community to improve access to its HIV treatments in the early 2000s. It initially responded by integrating tiered pricing practices into the management of its HIV portfolio, offering price reductions to WHO, its partners and LMIC governments. Later on, the company started giving out licenses to generics manufacturers to produce low-cost versions of its HIV drugs for sale in LMICs. Thereby, GSK integrated access objectives at the product management level without involving its operations in LMICs and, instead, relying on partners to produce and distribute its products. Another large product-level integration effort revolve around vaccines. The vaccine business of GSK has a long tradition of adjusting its prices to countries' income levels. Since the creation of Gavi, the multilateral vaccine procurement organization, most of GSK's vaccines for LMICs are supplied through this channel. This partnership is managed centrally in the vaccine business but had few touchpoints with GSK's business in recipient countries, as pointed out by this corporate responsibility manager.

They [local teams] did not have a role in this program. Products went directly from GSK to WHO and they distribute it. The local General Manager played no part in that, and they could not have, would be unmanageable. (G12)

Next to the previously mentioned donation program (targeting leprosy), Novartis runs a large product-level integration effort for its antimalarial coartem. When it developed the drug in the 1990s, the company and multiple external stakeholders saw a great potential to improve malaria care and formed a partnership in 2001. Novartis launched its Malaria Initiative, which is a centrally hosted access program that supplies coartem at a no-profit price to WHO and its partner that manage its distribution in endemic countries.

Operation-level integration focuses on integrating access objectives into business activities within LMICs. Instead of introducing new practices to reduce the cost of a drug, the integration of an access objective at the operation level induces organizational actors to develop new business models with commercial practices that address multiple dimensions of access. Therefore, the locus of integration is not a specific product, but a company's regional or country units, making it considerably more decentralized than product-level integration. The tools to address external constraints to access vary across different business models, but overall, they rely much more strongly on the work of internal actors. Rather than enabling external partners, operation-level integration aims at enabling organizational actors to assume full responsibility for diagnosing and overcoming these constraints through commercial operations on the ground.

“There are new objectives, not only profitability but also how many people can be reached. That means people lower in the income pyramid should get access to more

affordable drugs. The approach is to come up with new commercial models to reach more people.” (N5)

To illustrate, Novartis announced in 2019 that it would reorganize its operations in Africa by integrating access objectives alongside financial ones and mandating its local operations to find tailored commercial solutions to improve access to the company’s products in each country. Before this wide-reaching decision, Novartis had already engaged in more scattered operation-level integration efforts throughout the business in LMICs. In 2007, a small team within Novartis India was mandated to develop a new business model that could improve access to medicines in rural areas while securing a sustainable profit. They launched the *Healthy Families* (HF) program building new private sector distribution channels in combination with activities to raise health awareness. HF grew in revenue, broke even in 2010 and expanded to additional countries in 2012. Other country organizations experimented with similar ideas. The China business, for instance, launched the “Health Express” program which borrowed from the HF idea. Moreover, the corporate responsibility department worked with managers in LMICs to develop and sometimes implement new business models that could expand market shares in emerging economies through tackling access challenges. Additionally, in 2014, the company launched the Novartis Access initiative, developing locally adjusted social business models in several countries that combined the provision of a portfolio of drugs against non-communicable diseases at reduced prices with local health systems strengthening activities such as strengthening supply-chains and training healthcare workers. Similarly, in 2009, GSK created a new Developing Countries and Market Access (DCMA) unit that grouped the company’s existing operations in least developed countries (LDCs) and mandated general managers in the respective countries to increase the availability of GSK’s portfolio in their markets, come up with new pricing models, develop localized distribution models and strengthen local health systems by reinvesting 20% of their profits into projects around health worker training, supply-chains or health infrastructure .

Emerging challenges

We have argued that in order to make progress on social problems, integration efforts face a twofold challenge of internal legitimation and overcoming external constraints hindering progress. In this section, we report on how these challenges manifest for each integration type.

Product-level integration: With regard to internal legitimation challenges, we found only limited evidence for tensions caused by product-level integration efforts and increases in organizational complexity induced by integration. The introduction of tiered pricing efforts at

GSK, for example, was accompanied by fears that differentiating prices of HIV drugs would lead to low-priced versions flowing back into high-income markets, delegitimize higher prices in these markets, and negatively affect the established business (Reich, 2002). However, once these initial concerns did not materialize, further tiered pricing efforts were met with less resistance (Yadav, 2010). The Novartis Malaria Initiative also had to deal with organizational complexity as it scaled up and required more management oversight and resources (Chu et al., 2014). Yet, we did not find evidence that it created noticeable internal resistance, partly because the initiative remained organizationally and financially separated from the remaining business. Most organizational actors faced no changes to established practices and did not have to contribute resources to these efforts.

The salience of challenges grounded in external constraints of enacting access to medicine objectives, however, is clearly notable with product-level integration. As described earlier, product-level integration builds on the mechanism of external partnerships to become effective, because reducing a product's price or allowing another company to produce generics does not automatically improve its access for patients. This entails two problems, partner-related issues and impact uncertainty. First, companies depend on the existence and capacity of external partners in order to enact access policies via product-level integration. A GSK manager describes how the inaction of local partners initially limited the impact of product-level integration efforts for HIV products.

We modified the approach, we introduced new pricing policies. We introduced voluntary licensing. It helped to put the company and industry out of the firing line, but it did not help much with access, as IP was never the real problem. Price wasn't even the real problem. It was the fact that the supply-chains were very weak, that governments were in denial. (G14)

Additionally, in some product domains, such as non-communicable diseases, or hard to reach geographical areas, few partners exist whose access work companies could support by providing cheaper medicines. In such circumstances, the potential effectiveness of product-level integration is especially limited.

Second, even when partnerships exist and are functional, companies still face uncertainty about their own impact. This is reflected in how companies officially reported on the impact of their product-level integration effort. In its 2010 corporate responsibility report, for instance, GSK suggests that it is “*difficult to estimate the number of patients treated as a result of our preferential pricing agreements, since we do not control healthcare provision*”. Similarly, in a factsheet on its Malaria Initiative, Novartis admits that the contribution of its

efforts to decreases in Malaria prevalence cannot be singled out amidst a multitude of partners' initiatives. Instead, both companies underline the performance of their external partners such as GAVI or distinct LMIC governments and report it as evidence for a positive impact of corporate product-level integration efforts. Taken together, we identify a challenge of maintaining control over the effectiveness of integration for firms pursuing product-level integration efforts given that they outsource tackling system-level constraints to access. Without control over ensuring and monitoring the impact of their interventions, a resulting means-ends decoupling, where the effect of integration efforts on access outcomes is obscured, may prevent progress on social problems.

Operation-level integration: We find that control challenges are less salient for operation-level integration efforts. While companies may also struggle to come up with effective ways of improving access in the case of operation-level integration, they have more control over the outcomes of their access efforts as they assume responsibility for tackling external constraints and can assess impact more directly. To illustrate, integration efforts are not limited to price reductions, but entail investing in distribution networks, training health professionals or directly signing-up patients for access programs on the ground. Through this, they are less dependent on the work of external actors in reaching their access objectives, as one GSK manager explains:

When big companies make investments in CR area, they are sort of relying on NGOs to tell you what needs doing...but what we felt is that should not be relying on that. We had 700 people in my unit, so what about their expertise? This is a really strong point that we could leverage and utilize our own expertise much better. (G2)

Moreover, engaging the company's local operations in access efforts allows the company to get a better insight into what works and where gaps in effectiveness remain. One way to do that is through the relationships that local operations can establish with local stakeholders. A social business manager at Novartis gave an example how their local involvement allowed them to improve their model of increasing access to NCD care in Ethiopia specifically:

We asked where are gaps, what should we do, what is your opinion? For example, we worked together with the Ethiopian government and local organizations to think how we could decentralize awareness creation around NCDs to make sure that consulting does not only exist in tertiary care hospitals but in the community? (N5)

We also found evidence that Novartis had invested in monitoring the impact of operation-level integration efforts. The company conducted a formal impact assessment for its

Novartis Access program in Kenya, which allowed them to locally adjust the model and close gaps (Rockers et al., 2019). Building on this experience, it also decided to roll-out social impact monitoring throughout the entire access-oriented Africa business unit. In contrast, we find that, compared with product-level integration, operation-level integration efforts create a number of challenges around the legitimation of far-reaching changes to the everyday practices of commercial actors. Structural tensions result from the increasing demand on the various parts of the organization needed to facilitate operation-level integration of access objectives, unlike the more centralized manner of product-level integration. For example, at GSK, new social business models required the product registration department to put in a lot of additional work, or the manufacturing department to flexibly supply small amounts of products that were needed to build up a presence in a small African market. Similarly, using unconventional business practices to expand into markets beyond the urban centers of developing countries opened the company for compliance threats that required more oversight and created costs. Such inherent complexities made operation-level integration an uphill battle in organizations that were trimmed on maximizing profitability.

Moreover, operation-level integration may also create ideological tensions. At Novartis, in the 2000s, the top management was ideologically opposed to operation-level integration. Interviewees argued that *“The CEO had this very old-school mindset: Business and philanthropy are things you should not mix”* (N12). In other cases, it was mid-level management in country organizations that worked against operation-level integration, as they feared that additional access tasks would cut into their profits and thereby into their personal incentives. Managers monitoring the Health Families project explained that the commercial units’ fears *“led to very difficult funding situations for the project, because once it came close to their markets, they would convince the upper management of the regions not to support it”* (N15).

Together, structural and ideological tensions create legitimation challenges for operation-level integration. Ongoing resistance creates a constant pressure that threatens the legitimacy of such efforts on a continuous basis, potentially preventing them from scaling up or even leading to their shut-down, even if they prove effective. At GSK, for instance, access objectives were slowly carved out of the DCMA unit once GSK became under more financial pressure and the tolerance for complexity decreased. If a resistance challenge is unaddressed, companies may be guided by what creates less complexity rather than by what works best to create access.

Strategizing in response to integration challenges

While we have shown that each integration type faces a distinct challenge that can threaten progress toward better access to medicines, we also analyzed how both companies tried to overcome these challenges and maintain the functioning and effectiveness of their integration efforts. We found that each integration type was accompanied by distinct forms of systems-level and organization-level strategizing, mirroring the level at which the challenges occur. We define these forms of strategizing as deliberate actions addressing challenges to integration effort that threaten their effectiveness and/or legitimacy.

System-level strategizing - maintaining control over product-level integration: To ensure that partner organizations address access constraints in LMICs that fall outside the direct scope of product-level integration efforts, we found that both companies tried to actively support their partners in this task through actions that primarily address issues at the system level. They did so in two ways: First, both GSK and Novartis started adding capacity-building programs to their product-level integration efforts to improve their partners' effectiveness in addressing access constraints external to the company. Starting in 2006, for instance, the Novartis Malaria initiative began to work together with NGOs and governments to host workshops training the heads of national malaria programs and local health workers in Sub-Saharan Africa to improve the uptake and use of the supplied antimalarials (Chu et al., 2014). Similarly, after realizing that licensing alone did not directly improve access to the licensed product, GSK started to work more closely together with selected generics manufacturers, supported them with technology transfers and guided them through regulatory approvals (Access to Medicine Foundation, 2010). Still, these backup initiatives were also implemented through the organizationally differentiated access program units and did not involve local operations and other business actors.

The second approach that we identified was that both companies found opportunities to become involved in steering partners' activities to ensure that partnerships remained effective. They could do so through joining governance bodies of global health partnerships that played a leading role in creating access to the products at the center of companies' efforts. Thereby, they could monitor if working through these partnerships still contributed to companies' access goals and even steer partner activities in the desired direction. Multiple presidents of GSK's vaccine business, for instance, have sat on the board of Gavi, the Vaccine Alliance, while Novartis Malaria representatives regularly participate in board meetings of the Global Fund to Fight AIDS, Malaria and Tuberculosis. Moreover, both companies actively participated in disease-specific coordination bodies to stay in contact with the broader set of

actors and align the contributions of their product-level integration efforts to activities of other actors. GSK's management, for instance, would regularly join cross-sectoral discussion fora around vaccines and HIV topics and Novartis would equally be present in many conferences on malaria or leprosy where the focus of its product-level integration efforts lies.

Organization-level strategizing - maintaining legitimacy of operation-level integration: We also identified two ways through which supporters of operation-level integration sought to reduce the structural and ideological tensions around this type of integration. In this case, strategizing took place on the organization-level. For one, we found that operation-level integration was accompanied by top-down and bottom-up lobbying efforts. By trying to change attitudes of individuals towards operation-level integration, supporters wanted to broaden the coalition behind this type of integration. At Novartis, proponents of operation-level integration consisting of a few individuals in business units as well as the corporate responsibility department began by convincing company leadership of the merits of their Healthy Families pilot program by inviting them for field visits and sharing promising data. Subsequently, they tried to sensitize the wider organization for the business opportunities and strategic relevance of operation-level integration. For example, in 2010, the CR and HR department jointly developed an Entrepreneurial Leadership Program that exposed mid- to senior-level managers to public health challenges and tasked them to develop new commercial models for such problems.

The leadership development program helped to change mindsets, build skillsets and develop their toolkits to become our champions (N12)

Building and sharing positive experiences with pilot projects helped supporters of operation-level integration at Novartis. When they proposed to roll-out Novartis Access as a social business model for non-communicable diseases, they could use the Healthy Families case to show “*that Novartis Access would not be a giant black hole (N10)*”. At GSK, we also saw that integration advocates, including top management, invested a lot of time to keep up internal support for integration by explaining their needs transparently to affected organization members and communicating broadly about the progress made around access integration:

We were asking them to do something extra to this process. That was about advocacy... For instance, I went to present to the regulatory group and explain why this was important. (G1)

Once company leadership became supportive of operation-level integration efforts, they also engaged in aligning organizational processes and structures to reduce structural

tensions. For example, at Novartis, the CEO of the pharma business agreed to centrally pick up the costs of the Healthy Families project to reduce conflicts between financial and social objectives for commercial managers in the India business. At GSK, the head of the emerging markets business explained how they would help to align organizational processes with the needs of the new DCMA unit, for example working with the manufacturing department to prioritize deliveries for African country units and introduce a different way of internal costing that would make it easier for access-oriented business models to become financially sustainable. Similarly, representatives from both companies explained that, in the areas where operation-level integration should take place, it was important to align the personal financial incentives of general managers with the new access objectives of their units to prioritize this new mandate for traditionally commercial actors. This has become an important element of the rollout of Novartis's latest access strategy which strengthened operation-level integration efforts.

We included the access principles as performance management into the objectives of the teams in the countries...It has to be tied to the incentives. (N11)

A model of integration

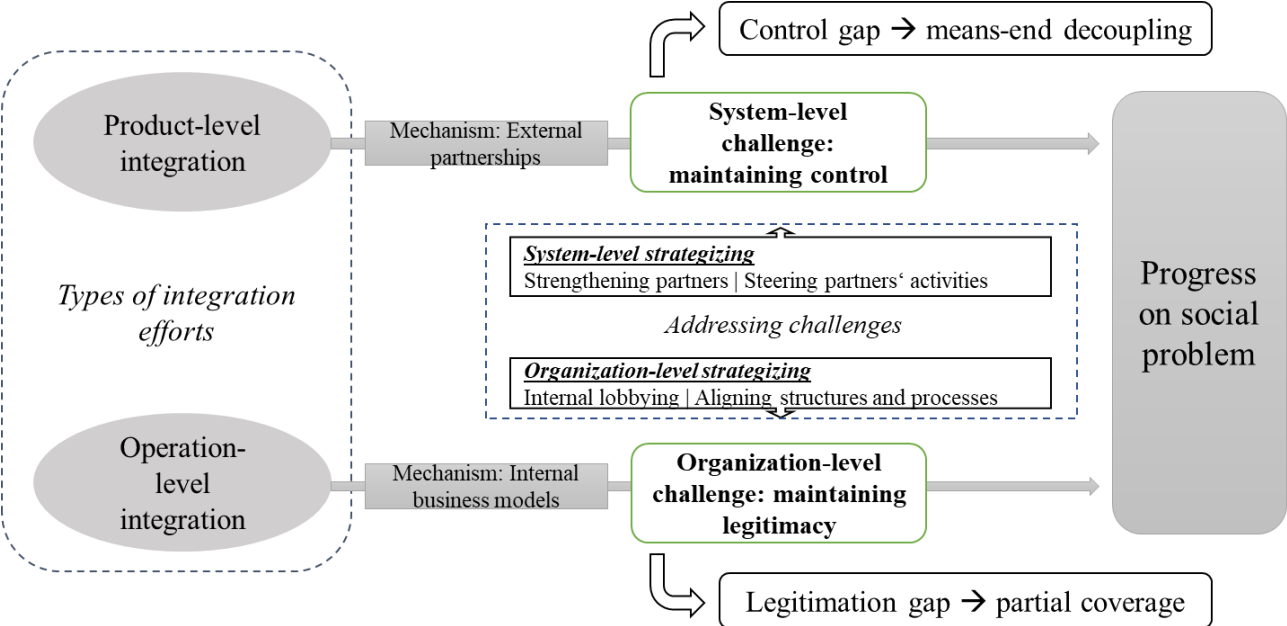
Figure 4.2 visually summarizes how integration efforts enable a company to make progress on a social problem. This model builds on the twofold challenge of integration that is at the core of our study: a need for change to internal processes and structures in line with a social objective, as well as tackling system-level conditions external to the company that sustain the social problem at hand. We identify two types of integrations efforts that facilitate progress on a social problem. While both types can co-exist in the integration pathway of a company they are analytically and theoretically distinct. We find that these two types differ in their locus of integration and their mechanism to enact a social objective. These differences between the two types are associated with distinct challenges that can limit integration's effectiveness, but also with distinct strategizing efforts that can be adopted in response.

Product-level integration rests on changes to features of individual products in combination with external partnerships to address the social objective. With product-level integration, companies minimize internal legitimation concerns while relying on partner organizations to overcome external constraints. As a result, this type of effort is more at risk to induce system-level challenges of assessing, monitoring, and ultimately controlling how and whether an effort can be linked to improvements on the ground. For this type of integration effort, means-end decoupling – a state of (un)knowingly sustaining ineffective

integration efforts – represents a real concern. Companies can support product-level integration through strategizing on the systems-level, which includes strengthening partners and getting involved in the governance of the system to strengthen and assess the effect of partnerships.

Operation-level integration, in turn, relies on in-house efforts of altering and developing business models. As the mechanism for enacting access involves various changes to established organizational structures and processes beyond product features, it induces a pronounced challenge for organizational actors to maintain the legitimacy of these efforts internally. Our model highlights the structural and ideological resistance against operation-level integration that can lead to a legitimation gap and result in the partial coverage of integration across the company’s product or activity portfolio. Such challenges can be addressed through strategizing efforts at the organizational level involving internal lobbying as well as the alignment of social objectives with structures and processes.

Figure 4.2: A model of integration efforts for progress on social problems



Discussion and conclusion

Our findings extend existing knowledge on how the integration of social objectives enables progress on social problems (Halme et al., 2020) by opening a discussion on the heterogeneity of integration efforts. Our paper offers novel analytical insights by linking integration types to their associated challenges and forms of strategizing and offers theoretical insights on the dynamics of integration. Our findings contribute to existing research and conversations in

literatures on business and society in three ways: 1) they expose the heterogeneity of integration efforts; 2) they allow for relating conversation between research on integration and means-end decoupling; and 3) they highlight the contingent role of organizational political dynamics in integration efforts.

First, research has suggested that integration constitutes a key enabler for companies to become effective in addressing social problems, including those perpetuated by companies themselves (Halme et al., 2020; Mair & Rathert, 2019). Yet, this literature has so far largely focused on the antecedents and processes of enabling integration as a whole (Halme et al., 2012; Hengst et al., 2020; Soderstrom & Weber, 2020), while our understanding of the arguably crucial link between different integration efforts and social problems has remained outside the scope of this work. These studies largely share the assumption that substantial alignment of internal processes vis-a-vis a social objective will enable the organization to make progress. Our paper, in turn, situates integration as efforts to address the twofold challenge of legitimating internal changes while overcoming external systemic conditions that sustain complex social problems. We then provide a conceptual model of how integration efforts can achieve this in different ways, based on two analytical markers – locus and change mechanism – that bring empirical insights to a largely conceptual debate about integration heterogeneity (Halme & Laurila, 2009; Yuan et al., 2011). These findings call for future research to study the prevalence of either type of integration effort across a wider sample of companies and industries, as each type may have different implications for the extent to which companies can contribute to addressing specific social problems. Although the efforts we identify in this study can indeed co-exist throughout a company's integration pathway, some problems may call for situating integration at the locus of operations, rather than products, for example in addressing forced labor (Caruana et al., 2021). Thus, research may also study the conditions under which we see each type emerge and link these conditions to both intended and unintended consequences for the problem at hand.

Second, we clarify how integration efforts may overcome or avoid means-end decoupling, often considered pervasive in corporate social and environmental efforts (Bromley & Powell, 2012; Wijen, 2014). We first document means-end decoupling as a threat arising in particular for companies pursuing product-level integration efforts. Yet our findings also show a pathway of how such adverse consequences may be avoided by explaining how companies may strengthen and co-govern the ecosystem of partners around a social problem. While other work has explored how organizations live with and sustain means-end decoupling (Dick & Coule, 2020; Stål & Corvellec, 2021), we develop a theoretical understanding of the

circumstances and ways through which organizations can minimize the chances of this occurring - arguably a crucial task for companies that seek to address social problems substantively. Future research may focus in greater depth on the strategies that companies can draw on to sustain this collaborative governance and avoid a state of means-end decoupling. Here, there are opportunities for extending research on cross-sector partnerships and the issues that participants in such partnerships face, for example maintaining inclusiveness and efficiency (Henry et al., 2020). In facilitating integration through external partners, such issues could conceivably become salient, or new issues around how to adequately assess progress may arise.

Third, in examining the challenge of partial coverage of social objectives across a company's portfolio of products and activities induced by limited legitimacy of such objectives, our study also speaks to recent interest around the political organizational dynamics around sustainability (Soderstrom & Weber, 2020), linking to a scholarly tradition of seeing organizations as political arenas (Bower, 1970; March, 1962; Weber & Waeger, 2017). In line with this political perspective, we document bottom-up and top-down lobbying at play in integration efforts (Alt & Craig, 2016a; Chin et al., 2013; Girschik, 2020; Howard-Grenville, 2007; Wickert & de Bakker, 2018). We extend this line of research by showing that the salience of political tactics is linked to a specific locus and mechanism of integration. Consequently, we gain a better understanding of when integration may spark internal legitimation concerns, and when it may not. In examining the nexus of political strategies and types of integration efforts, however, our study has focused less on the differences between organizational polities that may enable such strategies in the first place. As a fruitful avenue for future research, answering these questions may therefore draw on research designs comparing organizations in terms of, for example, the extent of goal alignment and centralized control (Weber & Waeger, 2017), and how changes to the organizational polity over time impact political strategies.

Arguably, the generalizability of our theorizing integration efforts might be limited by potential idiosyncrasies of the problem faced and addressed by the companies in our study – access to medicines. The integration types identified in this paper may not perfectly match how companies address environmental problems, for instance. Nevertheless, the insight that integration's potential for making progress on social problems must be seen in light of internal legitimation problems *and* external systemic constraints may help to better understand how internal and external advocates can address a broad array of complex societal problems beyond our specific case. Moreover, enabling access to essential products and services is in

fact a problem and objective for many different companies beyond the pharmaceutical industry. Financial service providers as well as energy and technology companies all offer products and services that could help to make progress on social problems if only people had sufficient access to them (Ault & Spicer, 2014; Seelos & Mair, 2007). We therefore argue that the underlying elements of the two integration types and their associated challenges and maintenance strategies identified for access to medicines appear similarly in other industries, making our findings around integration relevant for future studies on a wide array of corporate access efforts.

Chapter 5 - “Work with the devil you know...”: How local development actors respond to the increasing role of companies as development agents

Non-communicable diseases (NCDs) such as cancer or diabetes kill 32 million people in low- and middle-income countries (LMICs) each year (WHO, 2018). In Sub-Saharan Africa, the disease burden of NCDs has risen by 67% between 1990 and 2017 – in contrast to more positive progress on many other health indicators (Gouda et al., 2019). While traditional bi- and multilateral donors still shy away from tackling this challenge, multinational pharmaceutical companies have begun to fill this gap by launching an increasing number of programs and initiatives aiming at reducing the NCD burden of LMICs (Kulkarni et al., 2020). As a result, the industry has become the main development partner for many governments and non-governmental organizations in this space, providing access to medicines, building capacities, delivering services, and even supporting policy development.

The growing industry involvement in the NCD response is representative of a wider trend in the international development arena to increasingly rely on multinational companies to tackle development challenges (Kolk & van Tulder, 2010). This perspective has been taken up in many international agreements and national development policies since the Millennium Development Goals (Kolk et al., 2008). The passing of the UN Agenda 2030 has reemphasized the ambition of countries and international organizations to work with and through the private sector to achieve the Sustainable Development Goals (Kolk et al., 2017; Scheyvens et al., 2016; United Nations, 2015b).

Overall, multinational companies have responded positively to this growing demand, and many try to develop initiatives to contribute to reaching development goals (United Nations Global Compact, 2018). Thus, companies increasingly act as ‘development agents’ (Blowfield & Dolan, 2014). This implies that they no longer treat positive impact on development goals as an indirect side-product of their commercial activity. Instead, they invest their own capital with the intention to directly address development challenges and can be held accountable for development outcomes. Therefore, they go beyond defensively fixing social or environmental problems in their supply-chain as responses to stakeholder pressure and proactively assume responsibility for addressing development goals (Kramer & Kania, 2006).

However, while international development actors and multinational companies seem to embrace the idea of companies as development agents, little is known about the perspective of local actors in low- and middle-income countries on this trend. As scholars have pointed

out before, research at the intersection of corporate responsibility and development has often neglected to give room to voices of local stakeholders and beneficiaries of corporate efforts (Idemudia, 2011; Prieto-Carrón et al., 2006).

This is especially surprising as the merits of companies as development agents are contested. On the one hand, both practitioners and scholars suggest that companies can bring different capacities and additional resources to the table to solve problems that require multi-sectoral approaches (Kolk & van Tulder, 2010; Selsky & Parker, 2005; United Nations Global Compact, 2018). On the other hand, since the early 2000s, business and development research has repeatedly pointed out that there is – at best - only anecdotal evidence to support the assumed positive effect of multinational companies acting as development agents (Blowfield & Dolan, 2010; Frynas, 2005; Kolk et al., 2014; Vestergaard et al., 2020). In contrast, many scholars have even argued that the increasing reliance on companies as development agents bears substantial risks as it consolidates corporate power in global governance and prevents governments from addressing root causes of poverty (Banerjee, 2008, 2018; Chatterjee, 2016; Ozkazanc-Pan, 2019; Reed & Reed, 2009; Utting & Zammit, 2009). Thus, in the light of this debate, this paper aims to explore *how local development actors perceive and respond to the increasing role of companies as development agents*.

The paper tries to address this question in the context of the multinational pharmaceutical industry's role in the fight against NCDs in Kenya – a setting with especially high scale and scope of corporate involvement. Based on the analysis of 30 interviews with local actors in government, civil society and the health sector, I shed light on the contradictions that local actors have to deal with. Even though most perceive companies as problematic development agents, they find themselves to be constrained in their ability to regulate and limit the growing corporate involvement. By analyzing how stakeholders navigate within these constraints, I identify a set of tactics that I refer to as *tempered contestation*. Accepting that their room to openly contest the growing corporate involvement is limited, they first try to make the best out of a fait-accompli by steering corporate involvement, and second, they try to gradually expand the room for contestation.

As a result, this paper makes two main contributions. First, by adding voices of local development actors to the debate over the merits of companies as development agents, it offers a realist position to a mostly normative and Manichean discourse. Local actors neither romanticize nor reject corporate involvement but see it as a necessary evil imposed on them by decisions beyond their realm of control. Second, identifying tempered contestation as a response of local actors expands existing research on stakeholder responses to problematic

corporate behavior (Barnett, 2014; Frooman, 1999). The paper shows how stakeholders act if they do not have the agency to stop associating with companies and have to resort to less direct forms of contestation (Harrison & Wicks, 2021).

Literature review

Debating the merits of companies as ‘development agents’

In the 1980s and 90s business was predominantly seen as a passive ‘development tool’ (Blowfield & Dolan, 2014). Development actors like the World Bank promoted the poverty-reducing promises of investments, privatization, and job creation. Similarly, companies could indirectly contribute to development through the products and services they offer. To describe the phenomenon of companies becoming more proactive in development, Blowfield and Dolan (2014) put forward the perspective of business as a development *agent* as opposed to a tool. They lay out three criteria in their differentiation. First, companies need to make investments towards an expected development benefit, rather than seeking impact as a secondary outcome. Second, initiatives need to give primacy to the beneficiaries when considering different stakeholder interests. Third, companies can be held accountable for development outcomes, implying that they must make an effort to ensure their initiatives actually contribute to making progress on an issue. These perspectives can include a range of different corporate approaches to development, including commercial approaches, by developing social business models (Kolk et al., 2014; Prahalad & Hammond, 2002) or philanthropic initiatives under the banner of corporate social responsibility (Frynas, 2005; Idemudia, 2011; Muthuri et al., 2012). Similarly, they incorporate both the independent corporate initiatives that business and development research has widely studied in the context of mining companies’ community development programs (Campbell, 2012; Ite, 2007) as well as the increasing number of cross-sector partnerships (CSPs) with public sector and civil society organizations (Crane & Seitanidi, 2014; Kolk et al., 2008).

For all of the approaches introduced above, researchers have pointed out time and time again that the empirical support for the positive impact of companies as development agents is not conclusive (Kolk et al., 2018; Kolk & van Tulder, 2010; Vestergaard et al., 2020), whether looking at commercial “Bottom of the Pyramid” initiatives (Kolk et al., 2014) or emerging cross-sector partnerships (van Tulder et al., 2016). The business and development literature discusses two sets of arguments supporting a more skeptical outlook on corporate involvement in development. First, it identifies different *implementation challenges* that explain why for-profit companies might struggle to create impact more than other

development agents. Second, a more critical perspective argues that involving companies as development agents introduces *structural risks* that may even exacerbate certain development challenges.

Starting with *implementation challenges*, the tendency of companies to think about the “business case” for corporate responsibility (Shabana & Carroll, 2010) or “shared value” (Porter & Kramer, 2002, 2011) bears the risk that the issues companies seek to address, or the tools they offer, do not align with local priorities (Banerjee, 2008; Blowfield, 2012; Frynas, 2008; Ite, 2007; Kolk et al., 2008). Rather than developing programs based on stakeholder demands and needs, companies have often made the mistake of launching supply-driven initiatives derived from their strategic interest and expertise (Idemudia, 2009; Jeppesen & Lund-Thomsen, 2010). Another challenge for companies is coordinating – not to mention collaborating - with other companies, as they prefer not to share the reputational or networking returns from development initiatives (Frynas, 2005; Stadler, 2018). In contexts where multiple companies operate, this leads to inefficiencies and duplications of efforts. Moreover, management research has demonstrated that multinational companies driven by expectations of capital markets suffer from short-termism in their decision-making (Marginson & McAuly, 2008). This can also be a challenge for companies as development agents since creating development impact often requires longer timespans than companies are used to (Blowfield & Frynas, 2005; G. George et al., 2016). Finally, Frynas (2005) points out that multinational companies often simply lack the experience and in-house capacity to develop and implement their own initiatives. While partnering might be a way out of this conundrum, different authors have demonstrated that the impact of CSPs is often undermined by tensions between companies and partners due to conflicting organizational logics and cultures (Berger et al., 2004; Gray & Purdy, 2014; Selsky & Parker, 2005).

Concerning more *structural risks* of companies as development agents, many scholars see voluntary corporate initiatives as supporting a neoliberal development agenda that reproduces rather than solves many social and environmental issues (Chatterjee, 2016; Reed & Reed, 2009; Scheyvens et al., 2016; Soederberg, 2007). By treating companies as the solution rather than the problem, corporate power in global and national governance is consolidated (Banerjee, 2008, 2018). According to some authors, this gives a false impression of the role of corporations in development and discredits the drive to tame corporate wrongdoing through legally binding approaches (Idemudia, 2011; Newell, 2008). Moreover, it may create further dependency in many LMICs where it legitimizes government inertia to

address development issues and crowds out more structural interventions (Frynas, 2005; Kolk et al., 2018; Utting & Zammit, 2009).

Understanding local responses to companies as development agents

Even though the academic literature widely questions the merits of companies as development agents, we know only little about how present this perspective is among local actors in LMICs that may affect or be affected by progress on local development objectives. Scholars have criticized that research at the intersection of business and development has neglected to give voice to companies' partners and beneficiaries in LMICs about their experiences with corporate development initiatives (Idemudia, 2011; Jamali & Sidani, 2011; Mitra, 2012). However, the few empirical studies that exist indicate that there seems to be a dissonance between local actors' increasing cooperation with companies and their perception of the merits of companies as development agents. For example, beneficiaries of oil and mining companies' community development programs criticize that the gains from such programs are outweighed by the damages created through ongoing problematic extraction processes (Adanhounme, 2011; Idemudia, 2009). Other studies showed that local actors involved in CSR activities oppose these programs after experiencing unintended negative consequences (De Neve, 2012; Khan & Lund-Thomsen, 2011; Tran & Jeppesen, 2016). In several cases, actors in LMICs also voiced a more structural critique in that they see CSR initiatives as part of a larger neoliberal or imperialist development approach (Adanhounme, 2011; Khan et al., 2010). Yet, these studies say little about how this dissonance comes about and how local actors deal with it.

From stakeholder theory, we know that external stakeholders of a firm may not openly contest corporate behavior that they perceive as problematic for several reasons (Barnett, 2014; Rowley & Moldoveanu, 2003). Interest-based approaches argue that even if stakeholders find it in their interest to react to corporate actions, they may not have sufficient resources to do so (Jenkins & Perrow, 1977; J. D. McCarthy & Zald, 1977). Cognitive perspectives (Barnett, 2014) argue that stakeholders' reactions to perceived corporate misconduct are moderated by the perceived opportunity costs and expected impact on changing future behavior. However, as Harrison and Wicks (2020) point out, these perspectives generally assume that stakeholders are free in their decision whether to stop associating with a company whose behavior they consider as problematic. Thus, we have a limited understanding of stakeholder responses in contexts where stakeholder agency is limited. As a rare but important exception, merging stakeholder with resource dependence

theory, Frooman (1999) suggests that stakeholders who are dependent on a company's resources resort to more indirect ways of responding to problematic corporate behavior such as attaching conditions to an ongoing cooperation.

While some have tried to empirically explore these indirect influence strategies (Hendry, 2005; Hoque et al., 2016; Lin et al., 2019), they all approach them as stakeholder reactions to individual acts of corporate wrongdoing and irresponsibility, trying to improve specific corporate behavior. In contrast, I seek to understand how local actors perceive the changing societal role of companies in development and how that affects actors' overall engagement with this new role. Additionally, stakeholder theory understands stakeholders as "any group or individual who can affect or is affected by the achievement of the organization's objectives" (Freeman, 1984). However, my focus lies on those that can affect or are affected by the achievement of a specific development objective. To avoid this misunderstanding, I prefer to speak of "local actors" rather than stakeholders in this article. Thus, while it helps to inform my analysis, its firm-centric perspective prevents me from drawing more fundamentally on stakeholder theory in answering these questions.

Methods

Case selection and setting

To analyze how local stakeholders deal with the contradictions around involving companies as development agents, I turn to an exploratory single case study of the Kenyan response to the rising threat of non-communicable diseases (Yin, 1994). A single-case study allowed me to engage closely with a diverse set of local development actors and understand their perspectives in detail. I chose the Kenyan NCD response as an extreme and therefore unusually revelatory case (Eisenhardt & Graebner, 2007; Siggelkow, 2007), as the industry's involvement is especially large in scale and scope. This far-reaching involvement suggests that most local actors will have been exposed to companies as development agents and were forced to evaluate and form a position on this involvement.

Non-communicable diseases (NCDs) like cancer, diabetes or cardiovascular conditions have become a major public health threat for LMICs, with 32 million people dying each year (WHO, 2018). In Sub-Saharan Africa alone, the disease burden of NCDs increased by 67% between 1990 and 2017 (Gouda et al., 2019). Kenya has been hit especially hard. In 2017, NCDs have been responsible for 38% of all deaths in the country (Institute for Health Metrics and Evaluation, 2017). In recent years, the Kenyan government has started addressing this challenge and developed both a NCD strategy as well as several disease-specific

programs. Yet, their implementation is limited by a shortage of domestic funds and capacities. Especially on the county level, to which Kenya's decentralized constitution grants fiscal, political and operational responsibility for health services (McCollum et al., 2018), resources are very low. Moreover, most established development partners like high-income country governments or philanthropic foundations still shy away from funding NCD programs due to their high complexity and resource needs, as well as NCDs' stigma as "lifestyle diseases" of richer segments of the population (Heller et al., 2019; Nugent, 2016; Reubi et al., 2016). In contrast, the transnational pharmaceutical industry has assumed a leading role in tackling the rise of NCDs in Kenya and other LMICs (Nugent & Feigl, 2010).

While some companies have developed industry-led NCD initiatives since the early 2000s, the number has grown rapidly in recent years, especially as the launch of the Access Accelerated (AA) alliance in January 2017 reinforced industry commitment (Umeh et al., 2020a). AA is an industry alliance of more than twenty pharmaceutical companies together with World Bank, PATH and other international organizations to improve NCD care. This umbrella partnership engages in its own projects, but also serves as a coordination and standard-setting mechanism for companies' independent initiatives. Kenya is the country with the largest number of industry-led NCD initiatives. In 2020, Access Accelerated listed 27 individual industry-led NCD initiatives by 11 different pharmaceutical companies in Kenya—more than twice as many as in any other country globally.

These programs differ from traditional global health partnerships like GAVI or the Global Fund (Buse & Walt, 2000) in that they are not driven by countries or international organizations, but "designed and co-financed by companies and companies take responsibility and credit for them" (Rockers et al., 2018). They vary strongly with regards to their implementation structures (Umeh et al., 2020a). Some programs are more integrative cross-sectoral partnerships (Austin & Seitanidi, 2012) with their own governance structures, while other initiatives are made up of a number of independent transactional agreements between the company and different partners.

Pharmaceutical companies contribute to the Kenyan NCD response in three areas. First, several companies have developed access programs for selected NCD products. These programs include donation (e.g. Novartis's GIPAP program for imatinib) or price-reduction (e.g. Roche's Empower partnership including trastuzumab) models for high-cost oncology products for which generic or biosimilar options are hardly accessible in Kenya. Beyond oncology, access programs also include originator versions of more basic products like hypertensives (e.g. Astra Zeneca's Healthy Hearts Africa) or insulin (e.g. Novo Nordisk's

Changing Diabetes in Children). For these product categories, generic alternatives are available, but access programs often offer better quality at lower prices.

Second, companies contribute to capacity-building and service delivery in the health system. This may include funding the training of healthcare workers or investments into infrastructure as well as activities that directly deal with patients, such as health education, screening or even treatment services (Laing et al., 2019). Most of this takes place as part of formal industry-led initiatives, which often combine the product access strategies discussed above with flanking measures in the health system (Kulkarni et al., 2020). Yet, local non-governmental organizations (NGOs), health professionals and public sector bodies also directly approach companies with ad-hoc funding requests for their own activities.

Finally, the pharmaceutical industry has played a major role in funding and contributing to the development and dissemination of NCD policies and guidelines. This began in 2010 with the National Diabetes Policy receiving support from the Novo Nordisk-funded World Diabetes Foundation (Shiroya et al., 2019). Subsequently, it became the norm that pharmaceutical companies fund NCD policy processes either proactively as part of companies' NCD initiatives or based on requests from the government. For example, Astra Zeneca financed the creation of a hypertension management protocol in 2015. In 2017, the National Cancer Control Strategy specifically acknowledged support by Takeda, Roche and Merck whose logos were even printed on the back of the document. The financial support did sometimes, but not always, involve company participation in developing the content of the respective outputs. Company representatives have been members of technical working groups (TWGs) and contributed to the writing and review of documents such as diabetes or cancer control strategies in the past.

As NCD medicines constitute the core business of many pharmaceutical companies (Access to Medicine Foundation, 2018), companies have expertise and products to contribute to LMICs' NCD response. However, it also implies that these initiatives can be part of companies' commercial strategy for its NCD business in emerging markets by creating the enabling environment needed for future sales of their products and establish a local presence and reputation. Given the resulting tensions between commercial and public health interests as well as the large scale and scope of corporate involvement, the Kenyan NCD response is a rich setting to explore how local actors perceive and deal with companies as development agents.

Data

To uncover attitudes of local development actors, this paper primarily draws on interviews with individuals and organizations in the Kenyan NCD space which are supported by an analysis of archival data. For the purpose of this paper, interviewees came from all sectors. Yet, I excluded local representatives of international organizations or donors in my analysis as their relationship with the industry usually goes beyond the Kenyan NCD context. Data collection proceeded in two phases. Between June and December 2019, I gathered mostly archival data on the Kenyan response to NCDs (government documents, reports by international organizations or donors, academic articles etc.), as well as reports by AA and companies themselves about industry activities in the country. I also extracted the Access Observatory, a monitoring platform connected to AA, data for Kenya to analyze which companies were working on which issues with which partners and strategies. Moreover, I was able to conduct four preparatory open-ended exploratory interviews with industry and development experts at this early stage of data collection. Based on this, I conducted a mapping of local actors to guide the selection of interviewees for a research stay in Nairobi, Kenya, between January and March 2020. It showed that all major organizations involved in NCDs had been exposed to companies as development agents either through direct partnerships or through participation in industry-sponsored activities or events.

In total, I conducted 30 interviews with representatives of federal and county government bodies, local civil society, local pharmaceutical industry, as well as health professionals (Table 5.1). Questions touched upon the history of industry involvement in the Kenyan NCD response, interviewees' personal experiences of working with companies, their perceptions of benefits and risks and, if applicable, their strategies to deal with these risks. Those interviewees who did not bring up any risks themselves, I confronted with more critical accounts from other interviews in order to probe their attitudes. Moreover, I also conducted 18 additional interviews with representatives of the multinational pharmaceutical industry and international development organizations operating in the Kenyan NCD space. These interviews helped me to better understand selected industry-led NCD initiatives and corroborate the narratives of local actors about their interactions with companies.

Interviews lasted between 26 and 103 minutes. Subsequently, I transcribed all interviews from their original language to either English or German. I also had the opportunity to join different public and private events around NCDs like the NCD Alliance's annual membership meeting and accompanying the Kenya Network of Cancer Organizations to the national World Cancer Day commemoration event in rural Kenya. These events helped

me to observe how local actors talked about industry involvement outside of formal interview situations. After each of these events I noted down an extensive summary of my observations and conversations. Additionally, I recorded selected statements in the media or as captured on video during public events. Moreover, at the end of every week during my stay in Kenya, I wrote up detailed notes on preliminary insights and resulting follow-up questions. Together, these memos helped me to sharpen the direction of my interviews over time. Thus, I talked to several interviewees twice to follow-up on insights I obtained during data collection.

I obtained the interviewees' consent to recordings following directions given by the ethics review of Strathmore University's Institutional Review Board (SU-IERC0574/19). I have assured interviewees of remaining anonymous. Thus, when using quotes, I will not use names of individuals or organizations and only refer to the interviewee's sector.

Table 5.10: Overview of interviews

Sector	Organizations	Number of interviews:
<i>Local development actors</i>		30
Public sector	Ministry of Health Department of NCDs, National Cancer Institute, Pharmacy and Poisons Board, County Ministry of Health Meru & Machakos Counties	8
Civil society	NCD Alliance Kenya, Kenya Network of Cancer Organizations, Christian Health Association Kenya, Kenya Hospice and Palliative Care Association, Amref, Kenya Red Cross Society, Doctors Without Borders Kenya, Beyond Zero Campaign, Beth Mugo Cancer Foundation, Women for Cancer	15
Health sector	Kenya Cardiac Society, Kenya Society for Hematology and Oncology, Nairobi Hospital, Meru Teaching and Referral Hospital, International Cancer Institute	5
Private sector	Biodeal Laboratories, Villgro Africa	2
<i>Multinational companies and other development agents</i>		18
Companies and industry associations	Kenya Association of Pharmaceutical Industries, Takeda, Novartis, Roche, Merck, Medtronics, Access Accelerated, Kenya Healthcare Federation	12
International donors	World Bank, WHO, GIZ, Development Partners in Health Kenya, UN SDG Partnership Platform	6

Data analysis

As a foundation for my data analysis, I reviewed archival data such as the Access Observatory's reports of corporate programs and transcripts of my interviews to obtain a clear overview of the role that the industry plays in the Kenyan NCD response. Based on that I identified the previously discussed areas of corporate involvement: product provision, capacity-building and service delivery, as well as policy development. Subsequently, I proceeded to analyzing local development actors' perceptions of companies as development

agents in several steps. First, drawing on the pattern described in the literature review, I used the categories of *benefits*, *implementation challenges*, and *structural risks* of corporate involvement for a first round of coding transcripts. I ended up with 31 unique codes that I refined into 13 empirical themes grouped under the three categories derived from the literature (see Table 5.3 below). As a next step, I looked at how these perceptions differed among different actors and across the three areas of corporate involvement. While there was some diversity in perceptions, the majority had very ambivalent perceptions of the merits of companies as development agents. Across all areas of involvement, they saw benefits as well as challenges and risks of working with companies.

Subsequently, I engaged in a second round of coding interviews to understand how actors react to and deal with the challenges and risks they perceive. As a result, I noticed that despite perceptions of companies as problematic development agents, nobody suggested that these normative reasons stop them from cooperating with companies or urge them to reduce their involvement in the future. Instead, I found that all interviewees called for an expansion or continuation of corporate involvement. My coding brought out three factors that local actors reported as limiting them in their ability to contest the growing corporate involvement. This led me to identify the image of a constrained contestation space that local actors have to navigate. At the same time, my analysis also surfaced a number of tactics which local actors used to engage with companies within this space and make the best out of having to work with companies as development agents. Thus, to contrast with the lack of open contestation and describe how local actors try to find a middle-ground between conforming and rebelling against companies as development agents, I grouped these strategies as *tempered contestation*. For both the coding of benefits, challenges, and risks as well as for tempered contestation, I present data tables in the findings section.

Finally, throughout this process I made sure to test narratives and emerging themes with academic peers as well as with the interviewees themselves. For example, I organized a webinar presenting preliminary results at the end of 2020 to which all interviewees were invited. This helped me to refine the classification of local actors' assessments and responses to companies acting as development agents.

Findings

Perceptions of industry involvement in the NCD response

This section presents local actors' perceptions of companies as development agents following the structure described above. Across all areas of involvement – product provision, capacity-

building and service delivery, as well as policy development - they raised both benefits of working with companies as well as implementation challenges and structural risks that are summarized in Table 5.2.

Table 5.2: Overview - benefits, challenges and risks

Category	Interviewee perspectives	Example quotes
Benefits	Improving access to medicines	It's really good that pharma is now investing into access programs, because some of their products were way out of affordability for most of the people in Sub Saharan Africa (Interview #10, civil society)
	Financial support for NCD-related activities and investments	We really appreciate the support we were able to get from the pharma companies among other partners to ensure that we have guidelines and protocols, that we were able to do capacity building and even technical support sometimes, activities. (Interview #15, public sector)
	Expertise in NCD issues	New technologies, access to medicines, research capabilities, what you get from clinical trials, this push for patient-centered care, doing genetic studies. The people in AA have a lot to offer, not only money but expertise (Interview #19, civil society)
	Internal capacity-building	They've also provided links to like-minded organizations locally and internationally. Yeah, they've guided us and given us like extensive knowledge when it comes to oncology matters and all that. (Interview #20, civil society)
Implementation challenges	Commercial interests → misalignment with health priorities, ill-designed programs	I would say, from, from an investment perspective, it's probably not the wisest decision to really invest too much on a drug at best solves maximum 15% of your problems. (Interview #12, public sector)
	Competitiveness → lack of coordination	They have indicators around access. Then many also want to brand themselves... So they usually don't play well together. (Interview #19, civil society)
	Short-termism → lack of sustainability, commitment issues	It ended very abruptly, my guess is that pharmaceutical companies are always restructuring and changing strategy. So my thinking is it was just a change of strategy. They felt, okay, I think we've done enough... (Interview #28, health sector)
	Inexperience → ill-designed programs	I want to be frank with you: A lot of fellas in the private sector who want to do program work don't really know what they are saying...Because the way they want to do it... They need to listen to the people on the ground more than talk (Interview #11, civil society)
Structural risks	Gaining undue influence over policymakers and regulators	And it is our job to make sure that decisions remain patient-centered and not industry-centered. Cause when industry is supporting something, it should not mean that they will get a big deal. (Interview #5, civil society)
	Undermining legitimacy of policy processes	It is about perceptions. And I have been involved in some of these strategies, and I know for sure that they were not influenced. But as soon as you put the brand there, it is about perceptions. You cannot tell people, 'you know, those guys only put their logo, they had nothing to do with content'. (Interview #5, civil society)
	Shaping development agenda (towards treatment and vertical approaches)	the industry really drives this agenda shaping - mostly because we are a very heavily donor-driven economy. And unfortunately, that informs our decisions. It is about he who pays the piper...(Interview #10, civil society)
	Crowd out government action and regulatory solutions	I think also that one of the other issues is that when the access programs come in, the government takes a back seat. Instead of treating it as a time, an opportunity to get the systems in place, as the programs evolve, you can take more ownership. I know they tried that with the counties. Some counties are more proactive than others and are more willing to commit funds to sustain aspects of the programs (Interview #7, civil society)
	Goal conflicts	They really undercut us on some medicines to a degree that they will also lose money. Quite strange to be fair, but of course government comes to us and asks why we cannot offer the same price...In the long-term you block chances for local industry development. (Interview #3, private sector)

Benefits: All local development actors stated that there are benefits to involving companies in the NCD response. The majority perceived the provision of health products as the most important contribution of companies to the NCD response. Government actors pointed out that cost of treatment remains the most important barrier to access, specifically in oncology. Thus, they see a benefit in corporate access programs to lower prices for patients and government alike and make sure that products are available throughout the country.

One of the biggest barriers for access in this country is cost, and so we want to engage with the companies to see how we can start addressing the costs of treatment. (Interview #12, public sector)

Moreover, both civil society organizations as well as government bodies highly valued the financial support that they have received from companies for their NCD-related activities around capacity-building, service-delivery and even policy development. Beyond financial support, companies could also contribute with their expertise around issues like strengthening supply-chains or the use of specialized health products. Some individuals in smaller NGOs also mentioned that accessing scientific expertise and international networks through corporate partnerships helped to develop their organizational capacities more fundamentally.

Implementation challenges: While acknowledging that they have benefited from working with the pharmaceutical industry in the past, all but six interviewees perceived companies as problematic development agents due to their commercial nature. Collectively, they identified four features of companies that can result in implementation challenges undermining the impact of industry-led initiatives or even exacerbating problems: misaligned interests, competitiveness, short-termism and inexperience (see Table 5.2). These challenges appeared across all areas of involvement, potentially limiting the impact of access programs and broader capacity-building and service delivery initiatives alike.

First, interviewees argued that due to companies' strategic interest and growing business case thinking in development, their ideas for NCD initiatives have sometimes not well aligned with local structures and priorities. Rather than adjusting to local demands, companies have pushed through their own interests in several cases. An often-cited example was an oncology access program wherein the company insisted on a central product delivery strategy that was at odds with the government's decentralized county-based procurement system. This prevented the initiative from developing impact until the company realized its mistake and revamped its strategy. Misalignment might also weaken the equity orientation in public health. Stakeholders complained that rather than trying to find solutions for areas with

the most pressing need, companies often pilot their initiatives in counties that offer the easiest implementation conditions or best commercial potential. Similarly, interviewees suggested that some counties responded to corporate offers and spent its limited resources on cost-sharing access programs even though the product offered could not be considered a priority item from a cost-effectiveness perspective.

I would say, from, from an investment perspective, it's probably not the wisest decision to really invest too much on a drug at best solves maximum 15% of your problems.
(Interview #12, public sector)

Second, many local development actors – and also industry representatives themselves - pointed out that the competitive nature of companies prevents them from properly coordinating, let alone cooperating, in their initiatives. They experienced companies not wanting to share the spotlight and resulting gains in reputation or stronger networks. Others argued that companies are simply not used to intra-industry collaboration due to rivalries and competition in the commercial sphere. Once many companies move into the same disease area or county, this creates a challenge for local stakeholders to steer existing initiatives and implies a waste of limited resources if every companies holds their own consultation meetings or requires independent reporting procedures.

I thought instead of strengthening the system, we were actually weakening the system as we were repeating those access programs in the very same way every day.
(Statement during Access Accelerated event at World Health Assembly 71, public sector)

Interviewees identify another challenge in companies' preference for the short-term. This includes that that companies seem to prefer quick results as well as frequently change their management structures and people. Stakeholders reported that this leads to changing corporate priorities on the global level and may cause companies to dishonor their local commitments. They specifically referred to a large cardiovascular initiative that surprisingly terminated its capacity-building and service delivery activities, sowing more doubt about the stability and true intention of industry initiatives. Interviewees also observed that short-termism leads companies to favor certain types of interventions that allow them to show off short-term outcomes without thinking about the sustainability of such measures. An NGO representative, for instance, complained about one company's preference for mass health screening events without having a strategy to help patients who were found to suffer from a disease.

Truly speaking, pharma companies are a bit impatient...They like to see quick results. You want to take Panadol and the pain goes away. You want to invest like this, and tomorrow you want to see people going to hospitals. It does not work like that.

(Interview #11, civil society)

Finally, multiple interviewees pointed out that the limited experience of companies as development agents undermines their effectiveness in designing initiatives. As many local organizations and staff members are new to this role, they simply lack skills in developing and implementing social programs. While most companies seem to balance this out by hiring people from the development sector or building on expertise of their partner organizations, some companies fail to do so. As a result, they end up insisting on ineffective strategies, choose the wrong partners or have wrong expectations about costs or timeframes to create impact.

I want to be frank with you: A lot of fellas in the private sector who want to do program work, don't really know what they are saying... They need to listen to the people on the ground more than talk

(Interview #11, civil society)

Structural risks: A group of seven interviewees went beyond critiquing implementation challenges and pointed out the structural risks inherent in the large scale and scope of working with companies as development agents: Even though individual corporate initiatives may have a positive impact, these stakeholders considered the increasing reliance on companies as threatening to progress in Kenya's NCD response. Again, these risks span across all areas of corporate involvement.

First, interviewees were afraid that acting as development agents allows companies to build networks and enhance their reputation, thereby gaining undue influence over policy-makers, regulatory agencies and health professionals. The core assumption driving this perception is that while corporate and public health interests can be aligned in limited project-specific settings, there will be instances where social and commercial objectives are at odds. Interviewees believe that companies' fundamental profit orientation will overrule any social concerns if companies are forced to make a choice. Thus, if their influence allows them to shape a decision to their favor, companies will take that opportunity and influence legislation processes, regulatory decisions or prescription behavior.

When industries invest in something, they want something to come out of it. It is business. They want to sell more medication, making sure there is a bigger market for their products. (Interview #16, civil society)

Moreover, local actors also brought up more indirect pathways through which increasing corporate involvement could harm the NCD response without assuming malicious intent on the side of the companies. For one, they see an especially great risk of involving companies in the space of policy or guideline development. Interviewees saw the mere potential for corporate influence as harmful to the legitimacy of policy processes, as it sows doubt about the objectivity of official documents among the wider public.

It is about perceptions. And I have been involved in some of these strategies, and I know for sure that they were not influenced. But as soon as you put the brand there, it is about perceptions. You cannot tell people, 'you know, those guys only put their logo, they had nothing to do with content'. (Interview #5, civil society)

Additionally, interviewees raised the risk that the reliance on corporate funding inadvertently shapes the NCD agenda in an undesirable way from a public health perspective. For example, stakeholders worried that the reliance on corporate funding distorts the balance between prevention and treatment. Even though patients have a right to treatment, prevention is more cost-effective for a resource-constrained health system such as Kenya. Yet, given their interest and expertise in curative approaches to NCDs, companies focus on treatment-related interventions, such as training healthcare workers on diagnostics and disease management. Civil society representatives feared that this could draw public sector and NGOs priorities into this direction as they adapt their activities to funding possibilities.

When the company came, it was one of the first projects dealing with NCDs, but they were not considering a public health sort of approach. They were not willing to spare some resources to deal with prevention. They wanted us to just focus upstream on diagnosing people and putting them on treatment. In that sense they can derail a government. Especially those who are just getting the entrance into NCDs. (Interview #28, health sector)

Similarly, relying on voluntary industry-led initiatives can also discourage government to pursue more systemic and regulatory solutions, especially with regards to improving access to medicines. NGO representatives, for example, worried that corporate access initiatives take away the pressure from government to pursue routes like using the flexibilities of the TRIPS agreement for better access to affordable generics or speeding up regulatory approval of biosimilar alternatives to expensive originator cancer drugs. With increasing dependency on companies, government might fear to lose the support of originator companies if they engage in too much generics-friendly policy.

We think, for instance, that this country is not using the TRIPS flexibilities as we should, making patent-protected medicines available to our patients...and if nobody is pushing that, the industry is happy. Or registering of new molecules, the licensing of generics or biosimilars, they are fighting a great deal that those things are kept out of the market for as long as they can. (Interview #5, civil society)

Finally, relying on access initiatives may also stand in conflict with other health policy goals. To improve health security and strengthen industrialization alike, Kenya has committed to building its own generic pharmaceutical manufacturing capacity and increasing the share of locally sourced health products (MacKintosh et al., 2018). Local companies increasingly supply NCD-related products to the public sector, specifically for cardiovascular diseases. Thus, local manufacturers complain that access programs are distorting tender markets by offering artificially low prices. As a result, they undermine the long-term goal of building a sustainable generics manufacturing capacity for more short-term access gains.

They really undercut us on some medicines to a degree that they will also lose money. Quite strange to be fair, but of course government comes to us and asks why we cannot offer the same price... (Interview #3, private sector)

Responding to the growing role of companies as development agents

In the previous section, I demonstrated that most Kenyan NCD actors had an ambivalent perception of the merits of companies as development agents. Even though they identify some potential benefits, they questioned the impact of corporate efforts and pointed out how strong corporate involvement could structurally weaken the Kenyan NCD response in the future. There was some diversity across actors with respect to the degree of this assessment and their resulting preferences for the level of corporate involvement. Only six representatives of smaller NGOs and county governments saw no shortcomings in working with companies. Yet, the majority, especially civil society, but also most government actors, stated that they would prefer a smaller, more traditional role for companies in the NCD response, focusing more on improving access to their products. In the other areas, capacity-building, service delivery and policy development, most would prefer working with traditional development partners given the implementation challenges and risks around greater corporate involvement. Next, I will analyze if and how these perceptions of and normative preferences towards the scale and scope of corporate involvement shaped how local actors engage with the growing role of companies as development agents in practice.

A dissonance between normative perceptions and engagement in practice: To begin, I found that the diversity in their preferences towards the role of companies in development did not lead to substantial differences in how local actors dealt with the growing corporate involvement in practice. Their actual engagement with companies appears detached from their nuances in normative perceptions. Nobody fundamentally opposed the growing involvement of companies as development agents or openly contested corporate involvement in specific areas. Even the most critical actors suggested to continue working with pharmaceutical companies - not only around access to products, but also in other areas - despite the challenges and risks they identified and their normative preferences towards the role of companies in development.

The reason that I find for this dissonance between perceptions of companies as problematic development agents and expanding engagement in practice is that actors consider their space to contest corporate involvement to be strongly limited. The constraints of this contestation space are threefold (see Figure 5.1 below): First, local actors stated that in the face of millions suffering from NCDs in Kenya, they feel an urgency and pressure to make progress on this challenge. Discussing the merits of companies as development agents, one cancer advocate pointed out to me that they need to use any funding they can get and do not have the option to be picky.

When you come from the Western world you don't even appreciate the gap...A pap smear is such a privilege. People usually don't die of cervical cancer in the West. They don't. It is only in Africa. So to cut a long story short, you need to really understand why we needed all those players...Please look at it from my perspective. (Interview #9, civil society)

The second constraint for contestation lies in the challenge to find alternative funding. On the one hand, government funds are limited and actors from all sectors rely on mobilizing external resources. Yet on the other hand, established donors in Kenya and beyond are hesitant to invest in NCD-related programs. This includes bilateral donors, multilateral organizations or large foundations. Globally, only 1-2% of global health financing is directed towards fighting the rise of NCDs (Allen, 2017).

We have a big problem with funding. Globally, not just us; all the other hospices, all associations have a funding problems. There is no money in NCDs. There is nothing like PEPFAR money for HIV. Most of the organizations struggling with NCDs are struggling with funding. (Interview #17, civil society)

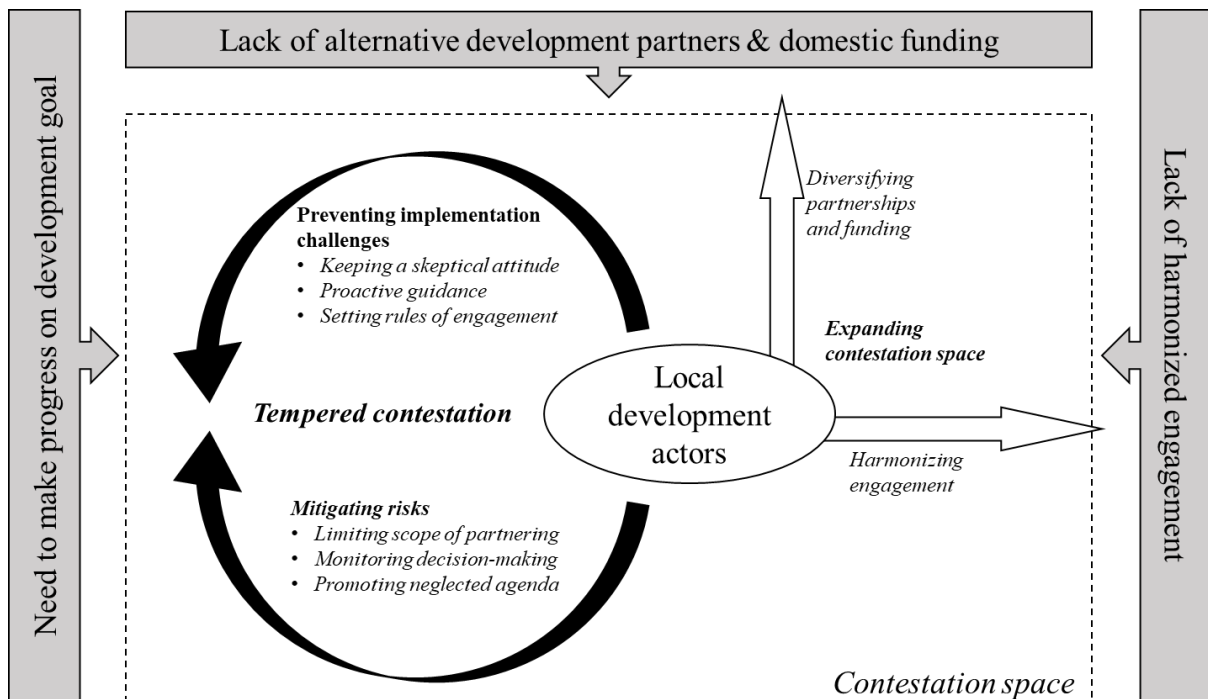
Finally, local actors also mentioned that a lack of a harmonized approach towards companies as development agents limited their ability to openly contest and criticize specific practices and areas of corporate involvement. Government officials reported that even if they spoke out against an industry project, companies have used their connections to higher offices to get their projects approved or moved to another county which did not bring up such concerns. Similarly, civil society representatives pointed out how the competition among NGOs has prevented them from openly voicing their concerns. They feared that if they had too many conditions and expectations for how companies should act, they would stop working with them and select a different partner.

The moment someone tells you, 'no', you wonder, 'how much do I push?' They may decide to go and use a different organization... (Interview #28, health sector)

Thus, I find that many local actors have decided to work with companies out of necessity but not necessarily out of choice. They see no alternatives but to enter industry partnerships even if they see challenges or risks and to “*work with the devil you know*” (Interview #5, civil society). Given the scale of the NCD challenge, everybody considered it unethical to reject immediate gains through industry-led programs for ideological preferences towards the role of corporations in society or fear of potential risks in the future. A government official described this conundrum well:

We don't have dedicated funding for some of these programs...we don't have much opportunity. So you might as well take this limited funding, e.g. for an awareness program...even if you know that the bigger objective is to push products for the industry. I would say the cancer space is also a victim of circumstances. (Interview #12, public sector)

Figure 5.2: Navigating in a constrained contestation space



Tempered contestation to navigate the constrained contestation space

Even though local development actors are not completely free to act upon their normative preferences towards the level of corporate involvement in the NCD response, I found that the widespread recognition of challenges and risks still affected how most actors engaged with companies in practice. As they acknowledge their constraints, they use the remaining space for what I call *tempered contestation* (see Figure 5.1 and Table 5.3). Local development actors accepted that they cannot fundamentally contest the growing corporate involvement. Instead, they applied different tactics to improve its outcomes from within the system while simultaneously trying to expand the contestation space. Thereby, they could navigate the middle ground and keep a balance between conforming with and rebelling against the growing role of companies as development agents.

Preventing implementation challenges: One set of tempered contestation tactics involves changes to partnering behavior with the aim to prevent the known implementation challenges from appearing and limiting the development impact of joint interventions. A common tactic that I identified in this regard was *keeping a skeptical attitude*. Both NGO and government actors underlined that despite all trust-building by industry players, they enter new industry partnerships with past bad experiences in mind. They mentioned that they do not give companies the benefit of the doubt. In contrast, they proactively evaluate and try to understand what hidden corporate interests could be beyond health objectives and how

companies could profit from this cooperation. Industry representatives mentioned that this attitude has made partnering processes very time-consuming and complicated. Yet, given the multiple negative experiences that local actors made, skepticism serves as a protection from unwanted surprises.

We just have to be more cautious in dealing with them: make sure we read the fine print, get lawyers even to review whatever MoUs or contracts that you sign so that you also don't leave any loopholes on your side. (Interview #28, health sector)

Second, having experienced implementation challenges in past industry projects, local development actors have developed a good understanding of how they can help companies to avoid these problems. Thus, I found that local actors engage in *proactive guidance* to help companies develop more appropriate initiatives and implement them effectively. This tactic builds on the understanding that some companies are indeed interested to prioritize public health needs over commercial interests but may need support in putting this ambition into practice. Local actors may sometimes be in the position to compensate for shortcomings of companies, e.g. in harmonizing initiatives with other industry players or developing an effective implementation structure for industry-led projects. In that regard, government officials explained that they have frequently approached companies willing to launch a new initiative with technical support and guidance on where and with whom to work best. To this end, government has also put in place supportive governance structures such as permanent technical working groups that companies can consult for advice on how to develop better programs. NGO representatives also gave multiple examples of how they have proactively guided companies in developing and implementing their initiatives. For instance, interviewees explained how they helped introducing companies to county-level decision makers in order to improve and expand a previously unsuccessful access initiative.

They did not fully understand the intricacies of government and the county system...So I challenged them and asked "why don't you see how you can work with the governors' spouses to ensure that the health system within those counties fits what you are doing?" (Interview #23, civil society)

Third, to prevent implementation challenges, government and several civil society organizations have set *rules of engagement* which they communicate to companies seeking a cooperation. While there are no formal laws or regulation, government officials stated that they expect companies to follow a number of guidelines in developing industry-led NCD initiatives. For example, they require companies to involve public sector and civil society actors closely in the selection of issue areas or implementation partners and ask them not to

build parallel structures in the health system. Similarly, it was an important condition for most people I spoke to that any initiatives would always respect state-of-the-art science and follow internationally recognized medical guidelines in trainings or information campaigns.

Mitigating structural risks: A second group of tempered contestation tactics that I observed aims at the structural risks that local actors saw in corporate involvement and seeks to mitigate the potential negative impact on the NCD response. First, while local actors felt that the overall level of corporate involvement could not be reduced, some decided to *limit the scope* of partnering and rule out selected practices which they considered to implicate especially large potential for conflicts of interests. For example, both government and civil society actors underlined that they would never directly promote a company's products towards patients even if they were part of an access program. Moreover, as I explained above, it used to be common practice that company representatives not only financed policy development but would join technical working groups to contribute to and discuss NCD policies and guidelines. While government has still received corporate funding to host policy workshops when I gathered data for this paper in 2020, civil society organizations had successfully lobbied to exclude companies from joining and taking part in such forums. Thus, local actors accept larger corporate influence in the NCD space as a price to pay for accessing corporate resources but try to make it more difficult for companies to abuse this influence by shaping the underlying rules and modalities of the NCD response.

For some while, companies were part of these Technical Working Groups until the Inter-Sectoral Coordination Committee was formed, and through the NCD Alliance Kenya, some people pushed and said, 'we don't want them to be part of TWGs,' and now currently they are not. (Interview #16, civil society)

Moreover, civil society representatives have argued that they see it as their job to watch over policy makers and regulators in the NCD space to ensure that decision-making remains focused on patients and does not respond to industry interests. Thus, by closely *monitoring decision-making* in the NCD space, NGOs try to mitigate the risks of increasing corporate influence following from stronger corporate involvement as development agents. Yet, this watchdog function of civil society may also be constrained by their growing dependence on industry funding.

Finally, acknowledging that industry-led initiatives will hardly push for issues and strategies that do not align with companies' own strategic interests, some civil society stakeholders explained that, together with government, they try *balancing the agenda*. They try to ensure that company preferences not derail the strategic direction of the Kenyan NCD

response. NGO and government actors proactively raise issues and approaches in discussions over the country’s NCD strategy that have not received corporate support and are thereby falling behind in implementation. This includes advocating for faster entry of generics and biosimilar products as well as making sure that prevention is not forgotten in the NCD response even though corporate funding mostly covers treatment-related approaches.

The last strategy had a big emphasis on treatment. So in drafting a new one we're looking across, making sure that it's both prevention and treatment, palliative care, rehabilitation survivorship... (Interview #29, civil society)

Table 5.3: Overview – tempered contestation

Tempered contestation tactics		Example quotes
Preventing implementation challenges	Keeping a skeptical attitude	We just have to be more cautious dealing with them: make sure we read the fine print, get lawyers even to review whatever MoUs or contracts that you sign so that you also don't leave any loopholes on your side. (Interview #28, health sector)
	Proactive guidance	They did not fully understand the intricacies of government and the county system...So I challenged them and asked ‘why don’t you see how you can work with the governors’ spouses to ensure that the health system within those counties fits what you are doing?’ (Interview #23, civil society)
	Setting rules of engagement	First, let there be a full understanding of the scope of the engagement. Number two, we need to ensure that whatever is happening whether on national or sub national level is aligned to overall priorities for us in the health sector. (Interview #12, public sector) We have various technical working groups they should work with. This group will look at your idea. Then they can present their finding to the main NCD coordination committee. If the idea is adopted, the same will be passed on to the Cabinet Secretary for adoption or rejection. (Interview #21, public sector)
Mitigating structural risks	Limiting scope of partnering	Through the NCDAK some people pushed and said we don’t want them to be part of TWGs, and now currently they are not. (Interview # 16, civil society)
	Monitoring decision-makers	And it is our job to make sure that decisions remain patient-centered and not industry-centered. (Interview #5, civil society)
	Balancing agenda	The last strategy had a big emphasis on treatment. So in drafting a new one we're looking across, making sure that it's both prevention and treatment, palliative care, rehabilitation survivorship... (Interview #29, civil society)
Expanding contestation space	Diversifying partnerships and funding	Slowly we are diversifying to not be so dependent on Access Accelerated. We are aware of the conflicts and try to manage them. (Interview #16, civil society)
	Harmonizing engagement	We should have come together and negotiated as a group. We would have had a lot of advantage, seeing that we were the biggest partners in Kenya! If they did not work with us, they would have had no one to work with. So we would have just come together say this is our demands – as a group. As opposed to dealing with us separately. (Interview #28, health sector)

Expanding the contestation space: A group of local development actors acknowledged that the reliance on industry funding and the lack of a harmonized engagement approach do not only limit the degree to which contestation is possible but also constrains the impact of the tempered contestation tactics that were available to them. For example, with

respect to rule-setting, government officials worried that companies often use their connections to higher offices to go around currently existing rules if they consider them to go against their interests. Similarly, even though local stakeholders try to proactively guide companies, they complained about some companies ignoring their advice.

To improve the impact of tempered contestation and enable local actors to get closer to their normative preferences towards the level of corporate involvement in the NCD response, I found that local actors follow two approaches. First, stakeholders in NCDs increasingly come together to discuss how to best work with the pharmaceutical industry and harmonize their engagement. Federal government representatives explained that they are in discussion with county officials and members of civil society to develop a wider partnership framework for public-private cooperation in healthcare that should codify and harmonize rules and processes. This could help to keep companies from profiting from a fragmentation in local actors' engagement approaches. Moreover, civil society also appears to harmonize its position and response towards companies across organizations. In their 2020 annual planning meeting, which I was allowed to attend, the civil society's sectoral association, the NCD Alliance Kenya, decided to form a technical working group dedicated to this end. Civil society groups have realized that if they work together, they have the power to set conditions for corporate involvement, as companies have an inherent interest in developing and implementing their initiatives but need local partners to make progress.

We should come together and negotiate as a group. We would have had a lot of advantage, seeing that we were the biggest partners in Kenya! If they do not work with us, they have no one to work with. So we would have just come together say this is our demands – as a group. As opposed to dealing with us separately. (Interview #28, health sector)

Second, stakeholders have realized that they need to diversify their partnership structure to increase the contestation space and improve corporate involvement in the NCD response. It is easier to set and insist on boundaries and rules in working with companies if you are not completely dependent on their resources. Thus, local actor expressed that they actively look for funding beyond the pharmaceutical industry. For example, civil society groups explained how they engage with and try to learn from other groups such as the HIV community on how to build a broader support base. Moreover, both NGOs and public sector officials mentioned that they continuously lobby international donors to increase their involvement in the space of NCDs and work with the Ministry of Finance to allocate more funding to the NCD response.

Slowly we are diversifying to not be so dependent on Access Accelerated. We are aware of the conflicts and try to manage them. (Interview #16, civil society)

Discussion and conclusion

By examining how Kenyan actors with a stake in the country's response to NCDs perceive and respond to the growing involvement of multinational pharmaceutical companies, this paper makes two contributions. First, it amplifies the voices of LMICs' local development actors in the debate over the merits of companies taking on the role of development agents (Blowfield & Dolan, 2014). Listening to the people who regularly work with companies in tackling development challenge helps to go beyond an often Manichean scholarly discourse falling into camps of either underlining the promise of corporate involvement (Porter & Kramer, 2011; Prahalad, 2004) or highlighting its downsides and risks (Banerjee, 2018; Blowfield & Frynas, 2005). This paper shows that while most local actors broadly share critical perspectives on companies as development agents, they do not consider themselves free to act upon their normative stances and cannot contest or limit the growing corporate involvement due to the urgency of the development challenge, missing alternative funding sources and a lack of harmonization in how they interact with companies. Thus, local actors don't romanticize corporate involvement, but see it as a necessary evil - a fait accompli imposed on them by decisions of traditional donors and their local government not to fund the needed interventions. They see the challenges and risks of working with companies but are not free to put the cursor on what the role of companies should be in working towards their development objective.

The paper makes a second contribution by adding to and expanding perspectives in stakeholder theory on why and how stakeholders contest corporate behavior that they perceive as problematic (Barnett, 2014; Frooman, 1999; Rowley & Moldoveanu, 2003). While my findings mirror arguments around resource-dependence (Frooman, 1999) and high opportunity costs (Barnett, 2014) as limiting open contestation, the paper offers a more fine-grained understanding of the more indirect or, as I call it, tempered contestation tactics that stakeholders can use to act upon their concerns instead. Through these tactics they could shape how corporate involvement manifested in practice even though they had little influence over its scale and scope. In that way, the paper responds to a call for exploring how stakeholders react to perceived harmful corporate behavior if they do not have the agency to stop associating with the company (Harrison & Wicks, 2021). Despite these links to stakeholder theory, my study also highlights how its firm-centric perspective limits its

applicability to this context: Existing accounts have always treated stakeholder strategies as reactions to specific corporate behavior. Yet, in centering on actors with a relationship to a specific social issue rather than on stakeholders of a specific firm, this paper looks at stakeholder responses to a changing societal role of the company rather than to specific corporate acts. Even if actors' normative stances on the role of companies are somewhat rooted in their experiences of corporate behavior, the herein described response of tempered contestation does not describe how actors react to individual companies in specific situations, but how they approach corporate involvement in general. Thus, I second past suggestions that stakeholder theory may profit from taking a broader perspective on who it refers to as stakeholders and how these stakeholders may shape how companies behave in society (Tashman & Raelin, 2013).

These contributions are limited, however, by the types of stakeholders that I managed to interview as part of my research. They mostly represented people who were directly working with companies and rarely involved executive level representatives in civil society or senior level decision-makers in government. Involving those groups in future research would allow for an even more holistic approach and allow to compare attitudes across hierarchical levels. Similarly, the generalizability of the findings is somewhat limited given that the paper only looked at one case. However, I believe that insights such as the limited contestation space and the resulting response of tempered contestation could also emerge from similar cases. The exact tactics one can observe may differ across countries and development challenges though. As I assume that the trend towards more companies acting as development agents will gradually bring up more contexts with a high degree of corporate involvement, it will be interesting for future research to adopt a comparative perspective. Future studies could also build on the insights gathered here and explore in more detail how Kenya and other countries could best govern industry involvement to make sure that companies can become effective development agents.

Finally, I want to highlight several implications for development practice. As donor governments and international organizations increasingly rely on companies to step in and contribute to solving sustainable development challenges, they appear to buy into the promise of companies as development agents. While some may acknowledge that risks of corporate involvement exist, they argue that LMICs are free to make their own decisions if they want to work with companies and make suggestions on how LMIC governments can govern corporate involvement to mitigate risks and make the best of it (Beisheim et al., 2018; Galea & McKee, 2014; WHO, 2017). Yet, this requires that local stakeholders have the agency to openly

discuss the limits and conditions of corporate involvement. This paper has shown that local development actors often do not have the freedom to do that in a context like the Kenyan NCD challenge, where the power balance is strongly tilted towards the companies. As a result, the societal debate over if, how, and to what extent to work with companies in development is cut short. Thus, even if they subscribe to the promise of companies as development agents themselves, traditional donors should not concede entire issue areas to multinational companies to allow local development actors the space to contest and limit corporate involvement in development if they perceive its challenges and risks as too high. Similarly, LMIC governments should be wary of relying too strongly on companies as a way to avoid assigning domestic resources to a development challenge. Finally, in areas like NCDs where the role of companies has already increased significantly, established donors should at least support local actors in implementing their tempered contestation tactics. This could involve, for instance, working with governments and other local actors to harmonize their engagement with companies as development agents and set-up a strong governance framework to guide and regulate corporate involvement.

Chapter 6 - Governing industry involvement in the non-communicable disease response in Kenya

Transnational corporations, including those in the pharmaceutical industry, have gradually been taking on more proactive roles in national-level development, acting as development partners with governments and non-governmental organizations (NGOs) in many low- and middle-income countries (LMICs) (Blowfield & Dolan, 2014; Crane & Seitanidi, 2014; Kolk & van Tulder, 2010). Especially the passing of the UN Agenda 2030 has again emphasized the ambition of countries and international organizations to work with and through the private sector to achieve the Sustainable Development Goals (Kolk et al., 2017; Scheyvens et al., 2016; United Nations, 2015b). Both practitioners and scholars suggest that companies can bring different capacities and additional resources to the table to solve problems that require multi-sectoral approaches (Kolk & van Tulder, 2010; Selsky & Parker, 2005; United Nations Global Compact, 2018).

In global health, the number of access-to-medicines and other global health initiatives involving pharmaceutical companies or their foundations has significantly increased in recent years (Rockers et al., 2017). Pharmaceutical companies have taken on especially strong roles as development partners for LMICs addressing non-communicable diseases (NCDs) (Allen, 2017). The industry has both expertise and strategic interests in supporting LMIC's NCD response, as medicines for NCDs constitute the core business of many pharmaceutical companies (Access to Medicine Foundation, 2018). Most other global health donors are still shying away from NCDs and continue to focus on other health challenges (Nugent, 2016).

Research on the role of business in development has repeatedly pointed out that there is – at best - only anecdotal evidence to support the assumed positive effect of multinational companies acting as development agents (Blowfield & Dolan, 2010; Frynas, 2005; Kolk et al., 2014; Vestergaard et al., 2020). Thus, global health scholars and policymakers are divided over the desirability of the growing involvement of pharmaceutical and other companies in public health efforts in LMICs. Some perceive it as an opportunity to tap into additional resources and expertise (T. Collins et al., 2018; Nishtar, 2004). Those with more critical perspectives are concerned that companies use their involvement to gain more influence in global health governance (Richter, 2004; Ruckert & Labonté, 2014). Critics have also identified risks of industry involvement in countries' health systems (Clarke et al., 2019; WHO, 2017): because corporate interests do not necessarily align with public health

priorities, corporate development initiatives may lead to undesirable diversion of limited local resources. Corporations might also gain undue influence through these activities that they could later use to steer future decision-making to their own advantage. To address these concerns, advocates have suggested that it is important for LMICs' governments to actively steer and regulate private sector involvement (Clarke et al., 2019; T. Collins et al., 2018; WHO, 2017). The World Health Organization (WHO) has developed a checklist for governments dealing with corporate access to medicines initiatives (WHO, 2017)—however, gaps remain in understanding the extent to which this or other proposed structures and processes for stronger governance have been adopted by countries.

Thus, this paper asks: how and to what extent can LMIC governments govern industry involvement in development initiatives? What challenges do governments face, and what lessons can we derive from their current efforts? The paper begins by reviewing the principles for governance of health and development initiatives that we integrated into an assessment tool. We then use the tool to focus on the case of Kenya, which has been a leader among LMICs in experimenting with industry involvement in responding to the expanding challenge of NCDs. Through this, the paper aims to assess the degree to which the Kenyan government has already implemented governance structures and processes to promote the effectiveness of pharmaceutical corporations' involvement in the NCD response. It highlights some of the challenges this effort has faced and derives lessons from Kenya's experience for other countries dealing with a growing number of industry-led programs.

The Paris Declaration on Aid Effectiveness as a governance framework

In 2005, more than 100 donor and aid-receiving countries, as well as major international NGOs and multilateral institutions, agreed on the Paris Declaration on Aid Effectiveness (OECD, 2008), which lays out a set of five partnership principles for development: *country ownership* of development efforts, *alignment* with local systems and priorities, *harmonization* among initiatives, *managing for results*, and mutual *accountability*. The 2008 Accra Agenda for Action (OECD, 2008) affirmed these principles and added *stakeholder inclusivity* as a sixth element. While the effectiveness of donor aid also depends on other factors, many of which are case- or country-specific, these principles represent a set of necessary or enabling conditions and rights-based norms.

The Paris Declaration is the leading framework on how to conduct development cooperation. The Paris Declaration does not explicitly address the private sector, but there is no reason to assume that its principles would be less valid for corporations when they act as

development partners (Glösenberg et al., 2019). International global health donors further committed to a sector-specific application of these principles in the 2007 International Health Partnership (Holzscheiter, 2011). In 2016, IHP evolved into the UHC2030 coalition, whose “Global Compact” also directly refers to the Paris Declaration (UHC 2030, 2018).

There is an established practice of referring to these principles in academic work that analyzes and evaluates corporate global health efforts (Buse & Harmer, 2007; Clarke et al., 2019; Rockers et al., 2018; Ruckert & Labonté, 2014; Umeh et al., 2020a). Recent actions to lay out guidelines for the pharmaceutical industry’s global health efforts, such as the WHO policy brief or the partnership principles of the industry’s Access Accelerated alliance, also build on the Paris Declaration (Access Accelerated, 2019; WHO, 2017). Table 6.1 shows how the guiding principles are presented in these different documents, from the general aid effectiveness agenda to the specific case of NCDs. The column on the far-right offers several examples of why following aid principles is not necessarily in companies’ interests. These include concerns about the costs involved in collaboration processes, losing control of corporate resources, and being forced to act against their own profit-making interests. Given potential inconveniences and conflicts of interest, governments cannot rely on companies’ adherence to established, but voluntary, principles in international aid.

Table 6.1: Aid effectiveness principles and potential challenges

Principle	Universal	Health, in general	Health, industry initiatives		Potential challenges for industry as development partner
	Paris Declaration & Accra Agenda for Action (2005/2008) (OECD, 2008)	UHC 2030 Global Compact (2018) (UHC 2030, 2018)	WHO Policy Brief for governments (2017) (WHO, 2017)	Access Accelerated guiding principles for industry (2019) (Access Accelerated, 2019)	
Program strategy Alignment	“Donors base their overall support on partner countries’ national development strategies, institutions and procedures”	“All partners should ensure their efforts are evidence-based and align with national priorities and policies”	“Ensuring that initiatives abide by all national regulations; align with national health plans and other development plans and goals”	“Align with government priorities and support national efforts to build sustainable access to NCD prevention, treatment and care services”	<ul style="list-style-type: none"> • Corporate strategic interests might not align with country priorities. • Preference for creating parallel company-controlled structures, over investing in adapting and improving existing systems.

<i>Harmonization</i>	“Donors’ actions are more harmonized, transparent and collectively effective.”	“Ensure coordination and alignment of health system strengthening efforts at global, regional and country levels and appropriate linkages with other sectors.”	“Harmonization and coordination with existing programs and future initiatives should also take place to avoid duplication”	“Build a collaborative network of member companies, partner organizations, and other key stakeholders to share knowledge and support a more coordinated collective response to NCDs”	<ul style="list-style-type: none"> • Competition among companies for reputation and influence may impede willingness or ability to coordinate. • Harmonization can be more costly and slower than independent action. 	
	<p>“Donors commit to respect partner country leadership and help strengthen their capacity to exercise it.”</p> <p>“All partners - including donors, foundations and civil society - participate fully”</p>	“Making health systems everybody’s business – with engagement of citizens, communities, civil society and private sector”	“Decision-making should be open to the public and include NGOs and other non-governmental stakeholders.”	“Foster collaboration and open communication with local stakeholders at all stages of program development, execution and evaluation”	<ul style="list-style-type: none"> • Thorough stakeholder involvement requires additional time, investment, and complexity. • Giving away control and influence can jeopardize any preconceived ideas and priorities for engagement. 	
<i>Program implementation</i>	<i>Managing by results</i>	“Developing countries and donors shift focus to development results and results get measured.”	“Accountability for results”	“Process for monitoring and evaluation has been established”	“Apply appropriate monitoring and evaluation processes to understand how a program is contributing to its stated goal(s), including improved health, and broadly share learnings from successes and challenges”	<ul style="list-style-type: none"> • Substantial investment of financial and management resources that many corporations are not willing to make.
	<i>Accountability</i>	“Enhance mutual accountability and transparency in the use of development resources”	“All partners should...recognise their accountability to people and communities.”	“Have strong mechanisms to ensure financial, performance, and public accountability”	“Establish accountability measures, manage expectations, and build mutual understanding”	<ul style="list-style-type: none"> • Fear the reputational effects of reporting negative results. • Fear of sharing information considered proprietary.

Pharmaceutical industry-led NCD initiatives in Kenya

With 27 individual corporate programs by 11 different pharmaceutical companies running in January 2020, Kenya was the country with the greatest number of industry-led NCD programs, according to the monitoring platform Access Observatory (www.accessobservatory.org). Industry-led programs have explicit social goals and are often structured as cross-sector partnerships between companies, NGOs, and government agencies (Crane & Seitanidi, 2014). Yet, they differ from more traditional global health partnerships (Buse & Walt, 2000) in that they are “designed and co-financed by companies and companies take responsibility and credit for them” (Rockers et al., 2018). While most companies work through their Kenyan business or their in-house corporate responsibility department, two of the eleven companies primarily work through their corporate foundations. Even though

foundations are technically independent, in this paper, we treat them as extensions of their mother companies, as companies take credit for their work and corporate executives usually lead the foundations' governance. In Kenya, industry-led programs were mainly focused on cancer care, diabetes, and cardiovascular diseases. While some programs were primarily providing access to health products, the majority also involved elements of strengthening or providing health services, such as supporting health worker training, sponsoring screening campaigns and even development of policy and guidelines (Laing et al., 2019).

The international pharmaceutical industry has always had a large footprint in Kenya. Many companies have established their regional offices in the country, which constitutes one of Africa's most promising growth markets, works as a regional logistics hub, and has a market-friendly political system. The launch of Access Accelerated (AA) in January 2017 reinforced industry involvement in Kenya's NCD response. AA is an industry-led alliance of more than twenty pharmaceutical companies collaborating with the World Bank, PATH, NCD Alliance, City Cancer Challenge, World Heart Federation, and RTI International to improve NCD care. AA engages in its own projects as well as serving as a coordination and standard-setting mechanism for industry-led NCD initiatives. In 2018, AA selected Kenya to be one of two pilot countries for deeper industry involvement in the NCD response.

Similar to global trends, NCDs have recently increased in political relevance in Kenya. The first NCD policy to be developed in Kenya was the National Diabetes Strategy in 2010, supported by the World Diabetes Foundation (WDF), which is funded by the company Novo Nordisk (Shiroya et al., 2019). With increasing NCD prevalence and disease burden, more civil society organizations began pushing for NCDs, especially cancer, to be taken seriously (Morgan et al., 2018). As a result of this attention and ongoing advocacy, various national NCD policies and legislative documents have been developed (Kenya Ministry of Health, 2010, 2015, 2017, 2019a). However, implementation of the policies has been inconsistent. It differs by county, as Kenya's devolved constitution grants fiscal, political and operational responsibility for health services to county-level governments (McCollum et al., 2018). Further, there is a persistent lack of available resources for NCD services. Only a few development partners have thus far engaged in the NCD response, and domestic funding for health remains too limited to cover the necessary budgets. In the face of the growing public health need, and in light of the lack of available resources, national- and county-level actors turned to pharmaceutical companies as possible development partners in the Kenyan NCD response.

In line with the devolution process and the “Kenya Health Policy 2014-2030” (Kenya Ministry of Health, 2014), the Kenyan government has been working on improving governance structures and processes to manage health sector partnerships. Most notably, the Ministry of Health, with support from WHO, is currently developing a new “Kenya Health Sector Partnership and Coordination Framework” (Kenya Ministry of Health, 2019b), which aims to guide management of all types of partnerships, including with NGOs and the private sector, as well as with bilateral and international donors. This remains an ongoing process, and thus far has not primarily focused on industry-led programs.

Methods

Data collection

To assess how Kenya has implemented governance structure and processes for industry-led NCD programs, this paper builds on data that were collected from primary and secondary sources in two phases. Between June and December 2019, we collected gray literature (including government documents, reports by international organizations or donors, academic articles) on the Kenyan response to NCDs; we also gathered reports from AA and the pharmaceutical companies about industry activities in the country. We captured existing stakeholder statements about industry-led NCD initiatives that we found in online news media and in videos of public events such as NCD stakeholder forums and panel discussions available on YouTube. We also extracted the Access Observatory’s data for Kenya to get an overview of which companies were working on which issues, and with which partners and strategies.

Based on the findings from that phase of data collection, we mapped stakeholders to identify organizations involved in the NCD space. Following a snowball sampling strategy, we started interviewing existing contacts within these organizations and asked them for links to other stakeholders. In total, we conducted 48 semi-structured interviews with stakeholders from five sectors: the public sector (national and county government agencies and ministries); the private sector (transnational and local pharmaceutical companies, industry associations); civil society (patient and disease advocacy organizations, NGOs); international organizations (donor agencies, UN agencies); and the health sector (medical professional associations, health service delivery institutions). All interviewees were either directly managing projects involving pharmaceutical companies or held senior management positions in their respective organizations. The interviewees’ organizations are listed in Table 6.2. The interviews, which were recorded, lasted between 26 and 103 minutes. Subsequently, we transcribed all

interviews. We obtained the interviewees’ consent to record their interviews and assured them that they would remain anonymous. Thus, quotes are not attributed to names, job titles, or organizations, but only refer to the interviewee’s sector (government, health services, civil society, pharmaceutical industry). The project underwent ethics review by Strathmore University’s Institutional Review Board (SU-IERC0574/19).

Table 6.11: Overview of interviewees by sector

Sector	Organizations	Number
Public sector	Machakos County Ministry of Health, Meru County Ministry of Health, National Ministry of Health Department of NCDs, National Cancer Institute, Pharmacy and Poisons Board,	8
Civil society	Amref, Beyond Zero Campaign, Beth Mugo Cancer Foundation, Christian Health Association Kenya, Doctors Without Borders Kenya, Kenya Hospice and Palliative Care Association, Kenya Network of Cancer Organizations, Kenya Red Cross Society, NCD Alliance Kenya, Women for Cancer	15
Health sector	International Cancer Institute, Kenya Cardiac Society, Kenya Society for Hematology and Oncology, Meru Teaching and Referral Hospital, Nairobi Hospital	5
Private sector	Access Accelerated, Biodeal Laboratories, Kenya Association of Pharmaceutical Industries, Kenya Healthcare Federation, Merck, Medtronics, Novartis, Roche, Takeda,	14
International organizations	Development Partners in Health Kenya, GIZ, WHO, World Bank, UN SDG Partnership Platform	6
	Total number of interviews conducted:	48

Data analysis

While different tools exist to assess the internal governance of individual programs and partnerships (Buse & Harmer, 2007; Umeh et al., 2020b), we did not find any framework to study the overarching governance of involving industry-led NCD programs in the health system. Thus, we developed an assessment tool based on the principles of the Paris Declaration. Our goal was to identify a set of governance elements that governments could put in place to shape how companies adhere to these principles. In this framework we grouped the principles of *alignment* and *harmonization* together, as both affect the design of program strategies. *Management by results* and *accountability* were analyzed together as benchmarks for governing program implementation. Finally, *ownership* and *stakeholder inclusion* were included as cross-cutting procedural principles, highlighting the roles that governments and affected groups should play in deciding about strategy as well as being involved in program implementation.

We identified both *regulatory* and *enabling* elements (Beisheim & Simon, 2015). Regulatory elements are rules and norms about how corporations design and govern programs. These could be either formalized in policies or guidelines or just exist as informal norms. Regulatory elements have sanction mechanisms for non-compliance—these may be

formal or informal, such as refusing to grant permission for program activities, withdrawing public resources, or damaging a company’s reputation. Enabling elements are any activities or structures that make it easier for corporations to adhere to the principles, such as provision of public data for needs assessments, or conducting stakeholder forums that corporations could use for better harmonization. In sum, country governance frameworks can shape the adherence of companies to the guiding principles in two ways: turning guiding principles into enforceable local rules and norms, and by assisting companies to set their programs up according to the principles.

Our selection of governance elements for assessment draws on three sources: First, on thoughts about governance frameworks for cross-sector partnerships (Beisheim et al., 2018; Beisheim & Simon, 2015). Second, we adopted suggestions made by the WHO for country responses to incorporate access to medicine initiatives which we described in the introduction and Table 6.1. Third, we identified relevant governance elements from the draft “Kenyan Health Sector Partnership and Coordination Framework” (Kenya Ministry of Health, 2019b), which remained under review at the time of writing. We assigned each element to a single principle of the Paris Declaration for parsimony’s sake, even though some may be associated to multiple principles. Review meetings, for example, are certainly both important for *managing by results* and *accountability* alike.

Table 6.3 presents an overview of the assessment tool. The left column lists the Paris Declaration Partnership principles. The next column includes the regulatory and enabling elements as described above. The column furthest on the right lays out how each governance element can shape adherence to a given principle and as well as questions to assess a specific case. We used the assessment questions to code our interview transcripts with the help of the software MAXQDA and to review archival data in order to obtain answers to each individual question of our framework. If interviewees had conflicting perspectives on a question, we corroborated accounts through additional interviews or document review and report these nuances in the results section.

Table 6.12: Assessment tool

Partnership principles	Governance elements	Rationale for how element shapes adherence	Assessment questions
Cross-cutting Program strategy	Regulation	Stating and implementing the government’s expectations about designing program strategy (e.g. outlining requirements for needs assessments or stakeholder involvement)	<ul style="list-style-type: none"> Do formal policies or legislation exist that regulate program design? If not, do clearly stated informal norms exist of what government expects from companies in this regard? In how far are these rules or norms backed up with sanctions to enforce compliance?

	Alignment	Direct government support	Assisting companies in aligning with country priorities	<ul style="list-style-type: none"> Does government support program design processes with public resources (staff time, funds etc.)? 	
		Provision of strategies and policies	Identifying a government strategy with which companies can align their programs	<ul style="list-style-type: none"> Do sector strategies exist for companies to align with? Is this information accessible for companies? 	
		Provision of data	Finding or generating data so companies can assess needs and align accordingly	<ul style="list-style-type: none"> Does government provide data (e.g., on NCD prevalence and health system capacities) for needs assessments? Is this information accessible for companies? 	
	Harmonization	Mechanisms for information sharing among partners	Sharing knowledge about stakeholders' activities to enable harmonization	<ul style="list-style-type: none"> Does a registry of active NCD programs exist for better harmonization? Is it complete and updated regularly? Can companies access this information? Does government host an exchange structure for partners to plan jointly? Is it open for companies? 	
	Ownership and stakeholder involvement	Structures for stakeholder engagement	Identifying and participating in existing engagement structures makes it easier for companies to broadly consult stakeholders	<ul style="list-style-type: none"> Does the government host stakeholder engagement structures? Do companies have access to them? 	
	Program implementation	Cross-cutting	Regulation	Stating and implementing government expectations regarding the design of program governance (e.g., outlining requirements for representation on governance boards or M&E systems)	<ul style="list-style-type: none"> Do formal policies or legislation exist that regulate program governance? If not, do clearly stated informal norms exist of what government expects from companies in this regard? In how far are these rules or norms backed up with sanctions to enforce compliance?
		Managing by results	Results framework	Guiding companies in setting up M&E systems	<ul style="list-style-type: none"> Does the government provide a unified results framework that companies can build on?
		Accountability	Reporting structures	Offering platform for reporting results and creating transparency	<ul style="list-style-type: none"> Does the government provide a public reporting framework where results can be shared transparently?
			Government oversight	Accountability through participation in governance structures of individual programs	<ul style="list-style-type: none"> Does government join governance structures of corporate programs?
Review meetings			Providing space for companies to broadly present and discuss results	<ul style="list-style-type: none"> Does government host regular review meetings where companies can report on progress? 	

Findings

Partnership principles in program strategy

Kenya's National NCD Strategy 2015-2020 (Kenya Ministry of Health, 2015) underlines a need for cross-sector partnerships, but it does not specify expectations about how partnerships develop their strategies. Although there are no formal policies or laws guiding the design of industry-led NCD programs, informal local norms exist that govern how companies should act if they intend to launch a NCD program (see Table 6.4 below for a summary). In our interviews, representatives of the national government clearly stated their demands for strong government ownership, including expecting to be consulted on any corporate activities that are linked to the health system. One industry representative recognized this:

We strongly engaged with the NCD department in the Ministry of Health. Together we came up with a good approach. They were of the mindset of wanting to work with pharma in improving NCD care. Their only request was to not create parallel health

systems and align well. If we kept them informed about anything we did, they would be happy to work alongside us. (Interview #31, industry representative)

As the quote alludes to, technical experts in the public sector explicitly demanded that companies developed programs that aligned with local priorities and systems. Since companies often rely on the public health infrastructure for the implementation of their programs or need to cooperate with regulatory bodies, the government has leverage opportunities to pressure the companies to meet its expectations.

However, the degree of government representatives' insistence on its norms can vary on a case-by-case basis. According to other accounts, norms have at times been undermined. A civil society representative, for instance, asserted that high-level political leaders sometimes agree to companies' preferences before technical experts were consulted.

Companies will not come and negotiate with the Ministry's NCD division. They go to a higher office. Then, the project is brought to you as an order from above. So, in as much as on the technical level you are able to give these inputs and set conditions for when you are coming to do a NCD project, this is the biggest challenge. (Interview #29, civil society representative)

Misalignments between corporate and public health interests have produced huge inefficiencies in programming. For example, in one case a company prohibited an NGO from using funds provided to screen for diabetes to also screen for cardiovascular conditions, as the company was only interested in diabetes. However, government and civil society were often hesitant to push companies on adhering to partnership principles, as they fear the loss of corporate support.

So when they said, 'no these are our priorities at the moment, 'we had to make a decision and say, 'Okay, it's better to focus on something than nothing.' I think we just agreed to give in...It's just that we felt that maybe if we asked for too much they might decide to go elsewhere. (Interview #44, civil society representative)

For companies that are willing to ensure the alignment of their programs with national priorities, a broad set of national policies and disease-specific strategies exist and are easily accessible. However, on the county level priorities are less clear. While county development plans broadly address the health sector, few counties have laid out specific plans related to NCDs. Moreover, interviewees reported that it is difficult to get access to reliable data on disease prevalence and health systems capacities, making it difficult to understand the needs. Publicly provided data are incomplete in many cases; in other counties, the data simply do not exist:

The information system is also what we lack...we don't have a sufficient data registry on cancer that's national. So decisions are being made on emotional grounds.

(Interview #21, civil society representative).

Data availability is gradually improving, but some interviewees expressed concern that growing pressure to protect patient data more strictly might make it more difficult for non-state actors to access data in the future.

We need to point out that some companies voluntarily pushed for strong alignment of their programs with local priorities. One company for instance, invested time and resources into a bottom-up approach of developing a program improving cancer care. It invited stakeholders from different sectors for several meetings to discuss about priorities, intervention strategies and possible partners who now also lead and oversee the program's implementation. In some cases, such companies were also able to build on ad-hoc support from the government to achieve alignment. Interviewees reported that the national Ministry of Health assigned technical staff to help develop program strategies, for example by advising on the selection of counties in which to operate:

We engaged with the Ministry of Health at high level who then cascaded it down and appointed a team to work with us. (Interview #16, industry representative).

The NCD division of the Ministry of Health has grown substantially; however, it still has limited human and financial resources when compared with other divisions in the Ministry. Thus, it could not assist the growing number of potential industry partners approaching it for support on an ad-hoc basis. In order to deal with limited resources, and to empower local stakeholders, the NCD division works closely with civil society organizations on governance of the sector. To this end, the NCD Strategy of 2015 proposed the creation of an NCD Interagency Coordinating Committee and various technical working groups (TWGs) on specific themes. Government representatives explained that companies are expected to submit their program ideas to the relevant TWG, thereby ensuring alignment and stakeholder involvement at the same time. However, the potential effectiveness of this structure has been undermined by budgetary constraints and frequent leadership changes in the Ministry of Health. While several TWGs have become operational, companies relied on their own networks for stakeholder engagement in previous years.

We selected the key players that we worked with at the time. Yet I was not sure if we got all the right and necessary stakeholders back then. Since then we did a lot of rejigging. (Interview #31, industry representative)

The Kenyan government has regularly called on companies to invest more in harmonization among their initiatives—this represents another informal norm. Many interviewees including government representatives complained publicly about inefficiencies that result from companies’ unwillingness to collaborate effectively.

Everyone wants exclusivity, but I say: “The other company came last week and had almost the same program as you. Since you are not competing would you be able to partner so we use the same platform?” (Public statement, government representative (Access Accelerated, 2018))

Despite its calls, the government provides only limited support for harmonization. For example, there is no public registry of ongoing programs addressing NCDs. This makes it harder for potential new partners to obtain an overview of which actors are already working, in which counties, and on what issues. Government representatives also mentioned that initiatives are sometimes launched without their knowledge, especially when partners either go to the county level or decide to fund NGO activities directly.

I think that quite a number fall through the cracks and the Ministry also gets to know about them after private sector players have already engaged with the counties or facilities. (Interview #24, government representative)

In 2018, the national government and the international NGO PATH undertook a stakeholder mapping exercise that was supposed to be the foundation of a standing oversight platform. Several interviewees noted that this effort missed many initiatives and has not been regularly updated. These gaps are partially remedied by the existence of the Access Observatory, a database of programs financed by Access Accelerated (Kulkarni et al., 2020). However, the information listed in the Observatory is neither detailed enough for harmonization at the county level, nor does it include non-corporate NCD programs. Moreover, several interviewees suggested that the platform is not well-known among Kenyan stakeholders.

The government could improve harmonization by hosting regular joint planning forums with partners working on NCDs. We found a successful example of such a government-led multi-stakeholder NCD forum in the Kenyan cancer space – albeit without industry participation (Morgan et al., 2018). The TWGs of the NCD Interagency Coordinating Committee are providing such a platform in some disease areas, too. The Kenyan government has also hosted several broad NCD stakeholder meetings with the support of Access Accelerated; however, according to interviewees the conferences did not incorporate joint planning or coordination exercises and mainly had a representative function.

Understanding the dynamic and bringing people together, to have a conversation and to agree on the direction and on the implementation model—Access Accelerated currently has not done this very well. Everyone comes to the platform and showcases what they're doing differently and nothing is coordinated to exploit each other's strengths and competences. (Interview #1, industry representative)

Beyond government, international organizations and major donors meet regularly at the Development Partners in Health roundtable for the purpose of harmonizing their programs. However, the roundtable has not yet put NCDs on its agenda. Further, it does not recognize corporations as development partners. Thus, companies cannot participate in its meetings. Moreover, we have found that - in some counties - existing multi-stakeholder consortia are assuming the role of ensuring harmonization and alignment of industry-led NCD initiatives. For example, the Academic Model for Providing Healthcare (AMPATH), a strategic partnership between Moi University, Moi Teaching and Referral Hospital and a group of North American and European Universities led by University of Indiana originally known for its HIV programs, has helped multiple pharmaceutical companies to develop and implement NCD initiatives in line with local needs, as well as harmonizing their corporate partners' activities (Access Accelerated, 2019; Mercer et al., 2018). Similarly, the “Blueprint for Innovative Healthcare Access” consortium of healthcare providers and NGOs tries to coordinate among multiple industry partners willing to launch NCD programs and points them to needs and gaps in the counties where it operates.

We look for partners to come in and help with the gaps that we are experiencing. (Interview #34, civil society representative)

Table 6.13: Kenya Results: Program strategy

Partnership principles	Governance elements	Assessment questions	Assessment of the situation in Kenya
Program strategy	Cross-cutting Regulation	Do formal policies or legislation exist that regulate program design?	<ul style="list-style-type: none"> No formal rules or laws existed at the time of the research. The health sector partnership framework was under development.
		<p>If not, do clearly stated informal norms exist of what government expects from companies in this regard?</p> <p>In how far are these rules or norms backed up with sanctions to enforce compliance?</p>	<ul style="list-style-type: none"> Government expects to be consulted on programs that interact with the health system. Government and civil society expect companies to use NCD technical working groups for stakeholder consultation. Only informal sanctions are currently in place to pressure companies into meeting government expectations (e.g. through non-cooperation or withholding licenses).
Alignment	Direct government support	Does government support program design processes with public resources (staff time, funds etc.)?	<ul style="list-style-type: none"> MoH assigns technical teams to support program development. MoH lacks sufficient capacity to do this for all industry-led programs.

Provision of strategies and policies	Do sector strategies exist for companies to align with?	<ul style="list-style-type: none"> • A broad set of policies and strategies are in place at national level. • County development plans do not always exist and are often not costed. 	
	Is this information accessible for companies?	<ul style="list-style-type: none"> • Existing strategies are publicly accessible. • A complete and easily database is not available. 	
Provision of data	Does government provide data (e.g. on NCD prevalence and health system capacities) for needs assessments?	<ul style="list-style-type: none"> • Publicly available data are not always complete or updated. 	
	Is this information accessible for companies?	<ul style="list-style-type: none"> • Health data are only partially accessible, but companies were able to work with KEMRI for better access to data in some cases. 	
Harmonization	Mechanisms for information sharing among partners	Does a registry of existing NCD programs exist for better harmonization?	<ul style="list-style-type: none"> • The government conducted a mapping exercise in 2018 and results are available by request; beyond that, a government registry is not available. • Access Observatory (AO) exists as a privately funded alternative
		Is it complete and updated regularly?	<ul style="list-style-type: none"> • The 2018 mapping was not comprehensive and remained a one-off project. • AO is also not comprehensive. It is updated annually, but its future depends on AA's continued funding.
		Can companies access this information?	<ul style="list-style-type: none"> • The AO is publicly accessible. • The 2018 mapping information was not published, but could be provided on request.
		Does government host an exchange structure for partners to plan jointly?	<ul style="list-style-type: none"> • There is no regular public structure. There was a private initiative: AA country team hosted two large-scale networking meetings. • The Development Partners in Health Roundtable is the leading coordination platform in the health sector where partners meet on a regular basis.
		Is it open for companies?	<ul style="list-style-type: none"> • AA/MoH meetings were company-focused. • Existing donors have thus far neglected NCDs and do not accept corporations as development partners. Thus, the Roundtable has yet to invite corporations to its meetings.
		Does the government host stakeholder engagement structures?	<ul style="list-style-type: none"> • An NCD Interagency Coordinating Committee and different technical working groups (TWGs) on specific NCD themes include various stakeholders. • The TWG structure was only established effectively in 2019. Meetings are still irregular.
Ownership and stakeholder involvement	Structures for stakeholder engagement	Do companies have access to them?	<ul style="list-style-type: none"> • Companies can make use of these TWGs to discuss the design of their NCD programs, but are not full members.

Partnership principles in program implementation

As summarized in Table 6.5, we found no laws or rules regulate how corporate programs should govern the programs they implement. Interviewees said that the public sector does not strongly promote monitoring and evaluation frameworks, nor does it place a high priority on their development. Thus, there are also no informal norms that could nudge companies towards adherence to the principle of managing by results.

The government did not give us clear requirements on reporting. There were some local standard things that local partners know and many were already collecting that information. (Interview #31, industry representative)

Programs that deliver health services, including screening, diagnosing or treating patients, are bound by local regulations to report on basic indicators - such as the number of cases of a specific disease treated - to the general Kenyan health information system. Yet, company representatives explained that the existing public health information system mostly

captures output indicators. It is not sufficiently elaborate to inform a unified results framework that could guide outcome-oriented management for more complex NCD programs. To fill this gap, companies can draw on a repository of logic models and indicators offered by the Access Observatory, but some have resorted to independently developing their own results management frameworks. Moreover, in some cases, prominent implementing partners, for example the previously mentioned AMPATH consortium in Western Kenya, may push companies to install ambitious monitoring and evaluation systems in their NCD initiatives (Johnson et al., 2018; Mercer et al., 2018).

We identified very few norms, either formal or informal, regarding accountability. Government representatives stated in interviews that they wanted companies to respect their leadership and to inform them about and invite them to any activities related to the public sector, such as capacity development for public sector health workers or the dissemination of health management guidelines.

We do it in partnership with them. We would be very cross with them when they did the training without our involvement. (Interview #24, government representative)

Beyond that, however, there seemed to be no expectations regarding reporting modalities, transparency, or involving government and stakeholders in decision-making and oversight bodies. If invited by companies, government representatives agreed to join oversight or advisory bodies of programs with formal governance structures. However, government representatives explained that they do not have the capacity to be closely involved in individually monitoring all industry-led programs.

In terms of government monitoring, it is not an organized space. But it can only happen if there are functional technical working groups. Now there is the National Cancer Institute, but it is yet to be fully commissioned. (Interview #21, civil society representative)

Neither national nor county governments offer many supportive structures for companies proactively seeking to ensure accountability. No public reporting platform exists that companies could use to share their results and create transparency. Thus far, companies aiming to be publicly accountable use either the Access Observatory or their own websites for that purpose. However, most of the Kenyan stakeholders interviewed reported that they rarely used these channels to inform themselves about companies' activities. Accountability could also be supported through regular progress review meetings with local stakeholders. However, these opportunities remain very limited. Some county governments do organize regular stakeholder meetings on health or even specifically on NCDs, during which implementing

partners report on their activities and results. However, the frequency and quality of these forums varies widely from county to county.

In some counties, like in Kericho, the county calls meetings. Probably because of this one guy at a hospital who was really enthusiastic about the program. He made sure we had a quarterly meeting for a World Diabetes Foundation program. Very rigid quarterly meetings. They are important. Some counties do it, others don't. (Interview #23, civil society representative)

These meetings are supposed to take place in each county on a regular basis as part of the general health governance system, but county governments generally depend on donor funding to support them. Moreover, the pharmaceutical companies are rarely actively involved, although they may be represented by their implementing partners. In some counties, interviewees were unaware of the corporate involvement in local NCD programs, as they only dealt with implementing partners that did not actively disclose their corporate funding.

When we started the program, the company was not part of it. All I knew is that of course this NGO has some heavy funding and maybe they were looking for counties where they could work. They never told me where their funding was coming from. (Interview #40, county government representative)

On the national level, NCD-specific learning and exchange forums involving corporations have taken place irregularly. In 2018 and 2019, national forums were hosted by the Ministry of Health in collaboration with the NCD Alliance Kenya, funded by Access Accelerated. Previous meetings also depended on donor funding preventing those meetings to function as an independent and regular accountability structure. With the outbreak of the COVID-19 pandemic, national NCD forums have been interrupted.

Table 6.14: Kenya Results: Program governance

Partnership principles	Governance elements	Assessment questions	Assessment of the situation in Kenya
Program governance	Cross-cutting Regulation	Do formal policies or legislation exist that regulate program governance?	<ul style="list-style-type: none"> No rules exist addressing either internal accountability structures for industry-led programs or in how and how often they must report progress to the government. Only programs that use health service delivery strategies, such as screening, diagnosing or treating patients, are bound by local regulation to report on basic output indicators to the Kenyan health information system.
		If not, do clearly stated informal norms exist of what government expects from companies in this regard?	<ul style="list-style-type: none"> Weak norms exist. The public sector does not push strongly for M&E frameworks for programs and puts little priority on their development. The only clear expectation is respect of government ownership, as shown by informing and inviting government representatives to events that relate to public sector responsibilities.

		In how far are these rules or norms backed up with sanctions to enforce compliance?	<ul style="list-style-type: none"> • There are informal sanctions in place.
Managing by results	Results framework	Does the government provide a unified results framework that companies can build on?	<ul style="list-style-type: none"> • The existing country-wide health information system is not sufficient to guide the design of M&E frameworks. • Access Observatory (AO) has a repository of logic models and indicators for companies as a private alternative.
	Reporting structures	Does the government provide a public reporting framework where results can be shared transparently?	<ul style="list-style-type: none"> • No official platform exists for Kenya. • AO allows companies to transparently report progress of their programs but it is not widely known or used in Kenya.
Accountability	Government oversight	Does government join governance structures of corporate programs?	<ul style="list-style-type: none"> • If invited, government representatives attend progress review meetings or sit on governance boards of programs. • However, government participation may be limited by staff capacities.
	Review meetings	Does government host regular review meetings where companies can report on progress?	<ul style="list-style-type: none"> • A few platforms exist for stakeholder exchanges. Some county-level governments organize regular stakeholder meetings. • The frequency and quality of county-level meetings vary. • Companies are rarely actively involved in such meetings. More often, companies are represented by their implementing partners. • Nationally, NCD-specific learning and exchange forums have taken place twice, through AA in cooperation with the MoH, but no permanent structure exists.

Discussion

Our study examined how Kenya is approaching the challenge of governing industry-led NCD initiatives. We seek to contribute to an understanding of how countries can assure that industry-led public health initiatives adhere to partnership principles and become an effective development tool. Kenya provided an apt study setting given the large number of industry-led initiatives being implemented there.

We identified several governance features in use to steer industry-led programs in Kenya: Informal norms exist to guide companies that intend to launch a NCD program. Structures, such as TWGs and stakeholder forums, are in place at the national level and in some counties—these can make it easier for companies to adhere to partnership principles while taking the onus off them to organize to convene stakeholders. This indicates that Kenya has already made important strides to address the challenges related to involving the industry in its NCD response. Once finalized, the Kenya Health Sector Partnership and Coordination Framework currently in development will provide additional tools to further strengthen the governing of industry-led initiatives (Kenya Ministry of Health, 2019b). Another promising governance initiative that interviewees reported is underway is the government’s effort to strengthen the NCD Interagency Coordinating Committee by tasking it with the implementation and governance of an upcoming National Strategy for Prevention and Control of NCDs 2021-2025 which is yet to be published. Other LMICs aiming to work more closely

with the pharmaceutical industry in their NCD response may find Kenya's existing governance approaches informative.

However, many gaps still exist in Kenya's approach to governance of industry-led health programming. At a minimum, these gaps could undermine the effectiveness of industry-led programs in fully contributing to the country's NCD response. More problematically, they could have negative effects on the health system if poorly designed programs use up limited resources. The first gap is the lack of formal regulation or other official benchmarks to guide program strategies and governance. In the absence of formal guidance, companies can interpret partnership principles on a case-by-case basis and to their own advantage. Although the government has clear, if informal, expectations regarding alignment, harmonization, and ownership, no informal norms exist for accountability and results management. One possible explanation for this gap is a fear of government and civil society partners that regulation would deter companies from further investments in the NCD programs that are filling a need in Kenya. However, stakeholders may be underestimating the importance that the companies place on such programs, which form a key part of corporate non-market strategies by building up networks, improving corporate reputations, and creating an enabling environment for future commercial gains (Mellahi et al., 2016). As a future growth market for the pharmaceutical industry (Holt et al., 2015), Kenya is highly relevant to many companies. Thus, we anticipate that companies would be likely to follow any regulations imposed—indeed, they might welcome more guidance on the government's expectations. Interviewees pointed to positive experiences in some other countries, notably Rwanda, where the government has been more proactive in steering and setting conditions for industry involvement.

Second, while the public sector is trying to expand enabling governance practices, many are not yet functioning well. The existing ad-hoc support for program design varies widely. Currently, the government, both nationally and in many counties, has not allocated resources to uphold and sufficiently finance permanent and robust structures that companies and other partners could utilize for better adherence to partnership principles. For example, stakeholder forums are supposed to be held regularly on the county level according to health governance regulations, but rarely take place. Instead, most enabling governance structures are currently provided by non-governmental actors, such as the accountability function of the Access Observatory (Kulkarni et al., 2020). Still, privately supported governance function could also only partially steer industry-led NCD initiatives. While important implementing partners such as AMPATH that work with multiple companies have leverage and expertise to

shape strategy and implementation of corporate programs, these are only present in some counties or disease areas. National-level structures such as Access Accelerated and the Development Partners in Health roundtable are missing opportunities to promote harmonization. It is notable that while the traditional donors for health are not significantly supporting NCD interventions, they are also not coordinating or harmonizing with the industry players that are filling that gap.

Third, we want to specifically highlight the limited availability of epidemiological and health service data as a cross-cutting factor undermining coordination among stakeholders—this is a challenge that extends beyond just governing industry-led programs. Building up data repositories has been a factor for success in other areas of global health. For example, national governments have closely coordinated with external agencies to expand data collection and use in, for example, both HIV (UNAIDS, 2021) and malnutrition (WHO, 2021). Expanding collection of and access to data will also be a key element for better governance of the NCD sphere.

Many interviewees recognized the existing gaps in regulating and enabling governance and expressed support for closing them. Kenya has a window of opportunity to use this current stakeholder support to develop and implement stronger governance of industry-led public health programs. Traditional development donors could play a more active role by supporting Kenya and other countries on this path, for instance by contributing to ongoing efforts around the UN Sustainable Development Goals (SDG) Partnership Platform (United Nations, 2018). For such efforts to succeed, companies must be willing to cooperate and stop circumventing established processes, for example by using ties to high-level political leaders who make exceptions for them (Yu & Lee, 2021).

In addition to making recommendations specific to the Kenyan NCD context, this paper presents a tool for assessing national governance of other industry-led public health programs. While many scholars have argued for better governance of private sector involvement in public health, these calls lack specificity about what they imply for countries (Clarke et al., 2019; Galea & Mckee, 2014). Similarly, previous work analyzing country-level implementation of the Paris Declaration has ignored the roles of corporations as development partners (OECD, 2012), while focusing on specific aspects such as donor coordination (Sundewall et al., 2009). While we developed the assessment tool for the case of pharmaceutical industry-led NCD programs, it could easily be adapted for use either in other sectors in public health or with other industries.

Limitations

Our assessment tool sought to integrate principles of aid effectiveness with perspectives on governance of corporate initiatives in a new way. Therefore, we could not adopt an existing validated framework. We do not claim that the proposed framework and tool are complete. Instead, we propose this tool as a starting point for further use, discussion, and development. For example, we focused only on how industry-led programs can be governed for effectiveness. Governance processes might also address other concerns, such as how to decide the degree to which a national health system is willing to work with industry-led programs in the first place.

The application of our assessment tool to the Kenyan NCD context was limited by the available data. As the local governance system is dynamic, official documents were often outdated or incomplete. Thus, we had to draw on interview accounts to expand the picture. While we tried to triangulate insights across interviews and by feeding preliminary results back to experts, we might have missed some relevant information.

Conclusion

This paper presented an assessment tool to study how a country governs pharmaceutical industry-led public health programs, which are growing in number—especially in LMICs. By using the tool to examine the case of the Kenyan NCD response, we generated insight into how normative calls for stronger country-level governance are being implemented. Other countries with growing pharmaceutical companies' involvement in their NCD response may learn from Kenya about formulating clear rules of engagement and creating a supportive environment. For Kenya, these findings could contribute to the forthcoming health partnership framework and implementation of the new strategy for prevention and control of NCDs 2021-2025

The study highlights that LMIC governments face multiple challenges in developing and implementing comprehensive and functioning governance systems that can regulate and steer industry-led programs in public health. If traditional donors continue to provide only limited support to address NCDs, and as corporations become more active in working towards the SDGs, countries require support to strengthen the regulatory and enabling structures that can assure that industry-led programs become an effective development tool.

Chapter 7: Conclusion and outlook

In this dissertation, I explored how pharmaceutical companies enact their responsibility for creating access to health products and how external actors and systems interact with companies in the process. I showed that this is a generative setting to better understand how multinational companies become instrumental in addressing the persistent and global problems we associate with sustainable development. Throughout this dissertation I built on and linked insights from both management and global health research. Thus, in this concluding section, I will present an overview of contributions to both fields. Moreover, I will lay out the limitations of this project and derive an agenda for future research on this topic. Finally, the dissertation will end with a number of implications for development policy-makers and practitioners as well as managers in companies willing to contribute to tackling development challenges.

Contributions to management research

To management research, the dissertation contributes the thorough interrogation of a specific industry's approach to a specific societal challenge - starting on the field level and adding insights into organizational processes, stakeholder interactions, and governance questions. By zooming in on two trends in how companies enacted access responsibilities I lay out internal as well as external pathways of how companies can become instrumental in making progress on a development challenge.

The internal pathways, as reflected in Chapter 4, refer to different internal efforts of companies trying to become more effective in addressing a societal challenge. Together with Nikolas Rathert and Johanna Mair, I explore how integrating social objectives into the business may enable companies to enact social responsibilities substantively in contrast to decoupled approaches that were and are still widespread in many industries (Crilly et al., 2012; Halme et al., 2020). While past research on integration has largely focused on the antecedents and processes of enabling integration (Halme et al. 2012; Hengst et al. 2020; Soderstrom and Weber 2020), we identify two integration efforts varying in the locus of integrating social objectives as well as their mechanism in enacting them and specify their link to progress on the social problem at hand. Moreover, we extend existing literature by considering that companies do not only have to overcome internal legitimation challenges that keep integration efforts limited in scale and scope, but must also ensure that efforts overcome external systemic conditions sustaining complex social problems. In analyzing how

companies deal with the legitimation challenge, we extend insights into political strategies to overcome internal resistance to socioenvironmental efforts (Alt & Craig, 2016b; Chin et al., 2013; Girschik, 2020; Howard-Grenville, 2007; Wickert & de Bakker, 2018). Additionally, we contribute to literature on means-end decoupling (Bromley & Powell 2012; Wijen 2014) by showcasing ways for companies to address external constraints around ensuring and monitoring effectiveness and avoid sustaining futile efforts.

Moreover, the dissertation discusses external pathways of enabling companies to make progress on a development challenge. It does so by shifting the focus away from what companies are doing, towards how local stakeholders and governance systems interact with companies to ensure that they become effective development agents. First, Chapter 5 expands existing knowledge on the shortcomings and risks of growing corporate involvement in development (Blowfield & Dolan, 2014) by amplifying the experiences and attitudes of local development actors towards this trend. The chapter also brings to surface different strategies by which these local actors try to mitigate risks and prevent implementation challenges from occurring. As a result, it also contributes to perspectives in stakeholder theory that have tried to understand why and how stakeholders react to corporate behavior that they perceive as problematic (Barnett, 2014; Frooman, 1999; Rowley & Moldoveanu, 2003). Building on these insights, together with Veronika Wirtz and Catherine Karekezi, in Chapter 6 we propose a set of governance elements that LMICs can put in place to steer corporate involvement in public health and ensure that industry-led initiatives are developed and implemented in respect of aid effectiveness principles. While this chapter has a strong global health focus it also helps answering questions discussed in management research. For instance, by analyzing what the Kenyan government does to steer industry initiatives, it informs debates on the role of governments in overseeing and steering corporate responsibility efforts (Gond et al., 2011; Knudsen & Moon, 2017; Schneider & Scherer, 2019). It also answers a call to focus more strongly on the societal rather than internal governance of social partnerships with the private sector (Crane, 2010).

As a final, more general remark, my dissertation shows that studying how the pharmaceutical industry acts upon the access challenge provides a rich setting to pursue a broad array of questions in management theory. By engaging in a deep dive on an individual industry and challenge, I also take seriously the observation that we need to pay attention to context and idiosyncratic features of an industry when researching how multinational companies address sustainable development challenges (Voegtlin & Scherer, 2019).

Contributions to global health research

As the literature review in Chapter 3 demonstrated, the role of the pharmaceutical industry has already received much scrutiny in global health research. Yet, I argue that this dissertation advances existing perspectives in three ways.

First, despite the industry's central position and importance in the global health discourse, global health research has often lacked nuance and treated the pharmaceutical industry as a unitary actor when discussing its role in tackling specific challenges or its influence on global health politics. Thus, by mapping how companies enact access and showcasing two industry trends in Chapter 2, my dissertation adds to a small set of literature that tries to differentiate more strongly with regard to how access responsibilities are enacted across companies and over time (Droppert & Bennett, 2015; Rocha et al., 2020; Rockers et al., 2017). Yet, the bigger contribution, in my eyes, lies in the intra-company perspective offered in Chapter 4. Global health research treats companies as a black box and rarely pays attention to the internal processes behind corporate actions. By zooming in on two companies and trying to understand how their access efforts developed, how they are organized internally, and which challenges they have to overcome, this dissertation may help to better understand the motivation, ability and limitations of the pharmaceutical industry to play a role in tackling access and other global health issues.

Second, global health research has paid increasing attention to NCDs as an emerging threat for LMICs. The majority of these studies has focused on describing and analyzing the dimensions of this problem (e.g Gouda et al. 2019). Yet, there is a growing literature on the politics behind the NCD challenge and how different actors and factors shape the global and national level responses (Heller et al., 2019; Nugent, 2016; Reubi et al., 2016; Shiroya et al., 2019). Here, the dissertation contributes by highlighting the previously underexplored role of the pharmaceutical industry and showcases its dimensions and potential implications in the context of Kenya. While some comments in the literature had pointed out concerns over this trend (Beran et al., 2017), Chapter 5 builds on that and provides an overview of the implementation challenges and structural risks of growing industry involvement that are rooted in the perceptions of local actors working with pharmaceutical companies on the NCD challenge.

Third, the dissertation contributes to a long-lasting debate in global health about the governance of public-private partnerships. Yet, while past studies have often looked more closely at the internal governance arrangement of specific health partnerships (Buse & Harmer, 2007; M. H. Martin & Halachmi, 2012; Reich, 2018; Rockers et al., 2018), Chapter 6

focuses on the societal governance of such partnerships. While some scholars have already argued for better governance of private sector involvement in public health (Clarke et al., 2019; Galea & Mckee, 2014), these calls lack specificity about how countries could approach this challenge. By drawing on established aid effectiveness principles, Chapter 6 provides a more structured approach to this question.

Gaps, limitations, and an agenda for future research

This dissertation attempted to shed light on the nexus between pharmaceutical companies and the access challenge from different perspectives. Yet, the research process brought up many additional questions and interesting empirical puzzles that could not be covered in this project – either due to limited space or because of limitations in its approach and available data. These form key opportunities for further research, especially on the field- and firm-level.

Field-level perspectives

First, Chapter 2 gave a rough overview of the relationship between the access challenge and the wider industry on the field-level, which can be seen as a community of organizations interacting with one another in both consenting and conflicting ways over issues, ideas and material interests (Fligstein, 2013; Hoffman, 1999; Zietsma et al., 2017). Thus, especially the frequent and close interactions between the industry and access to medicines as a movement provide promising opportunities that this dissertation could not pursue further. A field perspective would allow us to capture how events and actors jointly shape the ways in which firms confront a societal challenge. Scholars have pointed out that there is need for more longitudinal field-level analysis to better understand how change in corporate practices towards societal challenges unfolds over longer time periods (Fligstein, 2013; Zietsma et al., 2017).

One observation that merits further exploration is the diversity in field-level sources of change. The onset of increasing conflict over the role of the pharmaceutical industry in global health suggests an exogenous impetus (i.e. the HIV crisis) with real consequences for how firms interpreted their responsibility that is markedly different from earlier and also later periods. It could be interesting to study how the shock of the COVID-19 pandemic compares to that. Moreover, once field reform took place, we can observe endogenous sources such as industry working groups on access (Tickell, 2004) or networks of internal change makers at play. Thus, these observations invite to theorize and reconcile distinct visions of how fields

can experience change both from within and without, and that change can be both disruptive and gradual (Fligstein, 2013; Zietsma et al., 2017).

Additionally, a field perspective allows for a better understanding of the diverse means by which internal and external actors can push companies to act upon development challenges. In the case of access, this included protests and framing, the use of indices, unilateral firm actions or cross-sector collaboration. Clearly, emerging conventions such as the industry's Access Accelerated alliance constitute a substantively different mechanism from the Access to Medicine Index that set off competitive dynamics over access-related firm practices (Leblebici et al. 1991; Sauder 2008). Resulting from this are intriguing questions: how are these strategies linked to ensuing change in corporate practices and collective action? And to what extent are strategies transferrable across different subdomains of the access field (e.g., neglected tropical diseases vs. HIV; see e.g., Wang & Soule 2012)?

Finally, a longitudinal analysis at the field level opens avenues for studying the emergence and change of field ideologies, 'the coherent system of ideas and beliefs' (Hehenberger et al. 2019: 1673) that underpins industries and issue fields. Such belief systems are in flux over time, variably supported or challenged by exogenous and endogenous events and strategies discussed above. In the case of access, as the initial opposition against access responsibilities gave way to a more collaborative and integrated approach in the industry, the contours of a new field ideology have become apparent. Future research could examine the discursive and material changes that accompany a change in field ideology, but also pay attention to which ideas become sidelined or survive in the periphery (Hehenberger et al. 2019; Schneiberg 2007). For example, although new collaborative forms to improve access, e.g. by granting voluntary licenses, have been expanding in past years, the more conflictual ideology still exists as notable in the fight over patents throughout the COVID-19 pandemic.

Firm-level perspectives

The dissertation has highlighted the heterogeneity of access efforts and how they differently enable companies to make progress on their social objectives. Yet, there are other aspects on the firm level that deserve more attention in the future. For one, the observed differences in terms of ambition and type of initiatives would allow us to understand the antecedents for corporate action on SDGs more generally. For example, studies could look at how differences between the institutional environments of companies' home or host countries affect the selection of corporate social initiatives (Campbell et al. 2012; Rathert 2016). Moreover, in the case of the pharmaceutical industry, firms display considerable variation in product portfolios,

footprints in emerging markets, or firm structure. The Access to Medicine Index suggests that companies with a higher number of products of the WHO's essential medicines list in portfolio also perform better in the index. Thus, it would be interesting to study how firm characteristics may impact the composition of initiatives making up a firm's approach to a global challenge (Jackson & Rathert, 2017; Jacqueminet, 2020). Additionally, as access has become a board level issue, studying differences and variation among initiatives could be of interest to upper echelon scholarship. Different backgrounds and world views of executives are likely to shape the ambition and types of corporate social initiatives such as access (Gupta et al. 2017; Hambrick and Mason 1984). Future studies could go beyond the case-study approach applied in this dissertation and use quantitative methods to analyze causal factors and antecedents across the whole industry.

In studying internal processes around enacting access in Chapter 4, we observed and highlighted the internal politics of companies trying to act on challenges beyond the core business. Thereby, we identified an opportunity to build on canonical organization theories that consider organizations as political spaces (Bower 1970; March 1962; Selznick 1949) or refine the open polity approach that considers the interplay between internal politics and external demands (Weber et al. 2009; Weber and Waeger 2017; Zald 2005). Yet, as we engaged in a retrospective analysis of the developments in GSK and Novartis, we did not have the chance to fully capture these dynamics as they played out and analyze them at the necessary level of granularity. Future studies could follow-up on this agenda by applying in-situ research designs. For example, one observation I made was the importance of corporate change agents pushing internally for more ambitious access strategies. Thus, I see opportunities to study the tactics of middle managers and other actors driving transformation towards sustainable business that builds on and extends the growing literature on CSR intrapreneurship and issue-selling (Alt and Craig 2016; Halme et al. 2012).

Finally, to study how companies can become instrumental in tackling development, this dissertation focused on better understanding enablers of effectiveness such as the integration of social objectives or companies' adherence to principles of aid effectiveness. Yet, the validity of these factors enabling companies to make progress on development challenges is founded on observations in past literature, conceptual ideas and perceptions of local development actors. Future research could help to verify the effectiveness of these enablers empirically by, first, identifying successful companies or individual initiatives though actually measuring outcomes and social impact and, second, analyzing which factors were determinants of effectiveness. This corresponds to a recent call for more targeted, small-

data research on the design of successful corporate responsibility initiatives (Barnett et al., 2020). Mirroring impact evaluation in development economics, this requires close collaboration between researchers and companies in designing initiatives and integrating measurements of progress from the start. The pharmaceutical industry could be a promising context for such research given its growing interest for monitoring impact of its initiatives (Nusser et al., 2018; Rockers et al., 2018, 2019).

Insights for practitioners

While I laid out contributions for research and theory above, the question of how companies can become instrumental in addressing development challenges is also highly relevant for practitioners. As explained in the introduction, there is increasing demand by governments and international organizations for companies to get involved in tackling these challenges and growing interest on the side of companies to respond to these calls. Thus, my dissertation will close with summarizing implications both for policy-makers and non-industry development actors as well as companies willing to contribute to progress on socioenvironmental problems.

Implications for policy-makers and development practitioners

Development policy-makers both in donor and recipient countries have increasingly assigned a greater role to multinational companies in tackling development challenges. From personal experience of working in development cooperation as well as observations throughout collecting data for this dissertation, I noted that corporate involvement is sometimes treated as an end in itself rather than as a means to make progress. At the same time, there has been much backlash against this trend, especially from civil society groups, claiming that companies abuse this involvement for profiteering instead of contributing to solving the societal problems at hand. The insights from this dissertation may help both camps to develop a more nuanced approach to this debate. While I highlight the potential for companies to become effective development agents and show that some companies appear to make an honest effort (see Chapter 4), the dissertation also suggests for development practitioners to be cautious in dealing with companies and to be aware of the potential downsides and limits (especially in Chapters 5 and 6).

In practice, this implies paying more attention to the modalities of involving multinational companies in development practice. For example, both donors and local development actors should invest in understanding the ambition and motivation of companies whose efforts they consider supporting or with whom they want to partner. The mapping in

Chapter 2 highlighted the diversity across and within companies in this regard. Working with a company that still decouples its efforts from its everyday business may be less likely to be fruitful given that internal support for development efforts could be weak and priorities shift quickly. Similarly, some internal actors may have a stronger position and better resource base than others. Thus, the sustainability and scalability of joint efforts depends strongly on which company you work with or who your partner is internally.

To illustrate, in my previous position as a development advisor for a public sector agency, I was in contact with a pharmaceutical company that wanted to launch a new access initiative in Kenya and needed advice. Our funders had asked us to work more closely with the industry in general and the proposed project appeared promising. Thus, we invested considerable time in advising the company and even initiated a partnership for an expansion to another country. During my PhD research a couple of years later, I had the opportunity to better understand the genesis, motivation and internal structures behind this project. Only then I realized that its ties to the overarching access and commercial strategies were weak and it had little support internally. Thus, I was not surprised when I learnt that the company stopped its and left the project to falter despite initial promises of long-term engagement and sustainability. This experience shows that there is merit in carefully understanding internal dynamics behind a company initiative before engaging in a partnership.

Moreover, development practitioners should consider introducing more conditionality to corporate involvement. Companies do not become engaged in addressing development challenges only out of goodwill and charity. Critics are right in that companies' development efforts can help them to enter new markets and improve their long-run competitiveness. The more socioenvironmental objectives become integrated into commercial strategies, the more hybrid efforts that simultaneously pursue development and business objectives become the norm. Given the potential for conflicting interests, there is a case for traditional development actors, specifically in LMICs, to put in place norms for corporate involvement ensuring the primacy of development objectives in developing and implementing industry-led initiatives. At the same time, as Chapter 6 suggested, they can support well-meaning companies in following these norms by setting up and sustaining enabling governance structures and processes. Donor countries and organizations should support LMICs in building and running such governance frameworks and make sure that their support for corporate initiatives is tied to companies adhering to local norms.

Finally, there are two structural issues concerning growing corporate involvement that development practitioners should keep in mind. First, as Chapter 5 showed for the space of

NCDs, it becomes difficult to regulate and steer the role of companies if local development actors are completely dependent on their resources. Thus, donors and LMIC governments should not leave entire development challenges for the private sector to solve and, instead, try to balance the role of companies where it becomes too dominant. Second, a growing number of voluntary corporate efforts to address development challenges should not stop governments from considering and implementing regulatory solutions to align companies' activities with development objectives. Even though many companies make credible efforts to contribute to progress, priorities can shift quickly with changing leadership or emerging financial pressures. Additionally, as the dissertation also highlighted, most companies still have a long way to go to become instrumental in making progress on development challenges. The threat of crowding out regulatory solutions through voluntary efforts is noticeable in the debate over equitable access to COVID-19 vaccines: Industry spokespeople and political supporters argue that forcing companies to share patents is not needed, as companies are already doing enough to secure sufficient global supply. Yet, others have pointed out that these voluntary efforts would not have developed as quickly without the discussion around a patent waiver. Thus, the threat of regulatory interventions alone can be an important tool for governments.

Implications for corporate managers

This dissertation also provides insights for managers within multinational companies who are willing to tackle development challenges. They are most pertinent for the pharmaceutical industry, but will hold at least partially in other sectors, too. First, Chapter 4 may guide internal change makers to conceptualize and strategize how to best integrate social objectives into the everyday business activities of the company. It underscores that it is important to pay attention to the differences in available tools and how they would function in the context that you find yourself in. For example, to improve access to essential products and services managers need to consider whether they can achieve their objectives through a model of providing products through external partnerships or whether they need to build internal structures and programs in LMICs.

The chapter also highlights what managers need to look out for in the design and implementation of integration efforts. For one, it showcases that internal changes are likely to induce internal political quarrels. Managers may want to identify where established interests will be hurt and where existing structures clash with new demands for the organization. Anticipating these problems will help to scale faster and create more sustainable and effective initiatives. Second, when relying on external partnerships to minimize internal changes,

company managers should be aware that these partners may need help addressing external systemic hurdles that limit access. Thus, companies may need to go beyond just providing products or other resources and get more actively involved in such partnerships by engaging in capacity-building or co-governing to ensure the effectiveness of joint efforts. In both cases, it remains important to measure actual impact and adapt your efforts according to the results. Even in the case of Novartis, where internal change makers tried to address many of the internal and external challenges discussed in the chapter, they had to recalibrate an important access effort after an early assessment found little social impact (Rockers et al., 2019).

Chapters 5 and 6 serve as a reminder for managers in charge of corporate development efforts that local needs and preferences should take a center stage in developing and implementing initiatives. If there are norms, structures, and processes in place to guide corporate involvement, companies should follow them to ensure the legitimacy of corporate efforts. This may require them to get used to a different style of working, such as harmonizing initiatives with competitors or accepting that social outcomes take more time to materialize than commercial success. Several of well-meaning company managers that I interviewed for this dissertation told me that sometimes they try to go around demands by local development actors or ignored required participatory processes believing to know better how to make progress on development objectives. However, these good intentions rarely led to better results. Often initiatives got stuck due to missing cooperation or even resistance by local actors who felt disrespected and the overall trust in companies as development agents decreased. Thus, in trying to become instrumental in tackling development challenges, companies should be careful not to impose their efforts on unwilling beneficiaries.

All in all, this dissertation has shown that after years of discussing the “if” of corporate involvement in development, it is necessary to pay more attention to the question of “how” this can best be done. The pharmaceutical industry’s role in improving access to health products has always been a case in point, but the COVID-19 pandemic has drastically underlined how important it is to find good answers to this question quickly.

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Annex: list of pre-publications

This cumulative dissertation is made up of several chapters that have either already been published or are still undergoing a review process at the time of submission.

Parts of Chapter 2, 3 and 7: Bündler, T., Rathert, N., Mair, J. (in print). Understanding firm- and field-level change toward sustainable development: insights from the pharmaceutical industry and access to medicines 1960–2020. In: George, G., Haas, M.R., Joshi, H., McGahan, A.M. and Tracey, P. *Handbook on the Business of Sustainability: The Organization, Implementation, and Practice of Sustainable Growth*. Edward Elgar Publishing.

Chapter 4: Bündler, T., Rathert, N., Mair, J. (in review). Pathways to Progress: Product- and Operation-Level Integration of Social Objectives in the Pharmaceutical Industry. Submitted to *Business and Society* in December 2021.

Chapter 5: Bündler, T. “Work with the devil you know...” How local development actors respond to the increasing role of companies as development agents. *To be submitted*

Chapter 6: Bündler, T., Karekezi, C., & Wirtz, V.J. (2021). Governing industry involvement in the non-communicable disease response in Kenya. *Globalization and Health*, 17. doi.org/10.1186/s12992-021-00776-3