Confronting the Contagion:
Cuba's Response to the SARS-CoV-2 Virus

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Abstract

Much has been said about the structure of the Cuban biotechnology sector in development literature. The collaborative and integrated structure of the Cuban sector has facilitated development and widespread distribution of Cuban vaccines for decades. There is some research on the Cuban biotechnology sector in the context of the COVID-19 pandemic, in which the transmission of the SARS-CoV-2 virus has been rampant. However, there is little analysis into its collaborative and integrated structure, and its effect on the development of five Cuban vaccines against the virus. In the historical analysis that is provided in this thesis, the origin and evolution of the Cuban sector was examined, which has brought forth the collaborative and integrated elements of the structure. A comparative analysis of biotechnology sectors between Cuba and the United States has demonstrated a stark discrepancy in their respective structures and in the amount of the population that has been vaccinated. This thesis finds that the collaborative and integrated structure of the Cuban biotechnology sector has facilitated the effective and efficient development and distribution of vaccines against the SARS-CoV-2 virus.

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List of Abbreviations

COVID-19	Coronavirus disease 2019
CIGB	Centre for Genetic Engineering and Biotechnology
CIM	Centre for Molecular Immunology
CIE	Centre of Immunoassay
CNEURO	Cuban Neuroscience Centre
CNIC	National Centre for Scientific Research
CECMED	Centre for State Control of Drugs, Equipment and Medical Devices
DPT-HB	Diphtheria, pertussis, tetanus, and hepatitis B; tetravalent vaccine
FDA	United States Food and Drug Administration
GDP	Gross Domestic Product
HIV	Human immunodeficiency virus
IFV	Finlay Institute
ICID	Central Institute for Digital Research
IP	Intellectual property
MINSAP	Ministry of Public Health
OWS	Operation Warp Speed
PHEIC	Public Health Emergency of International Concern
RT-PCR	Real-time polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
RBD	Receptor-binding domain
WHO	World Health Organisation

WHSP	West Havana Scientific Pole

Introduction

The Cuban healthcare system is astonishing. According to the Right to Health, the Cuban state is responsible for ensuring access to healthcare and maintains a high quality, universal and preventative healthcare system (De Vos, 2005). The guarantee to healthcare is maintained in the Cuban medical biotechnology sector[1], which develops and distributes vaccines to the population (Mola et al., 2006). Over time the sector has evolved into a collaborative and integrated structure composed of over twenty biotechnology institutions, which has facilitated the development and distribution of an array of Cuban vaccines against prevalent illnesses like hepatitis B, and a tetravalent vaccine against diphtheria, tetanus, pertussis, and hepatitis B (DPT-HB) (Mola et al., 2006); the sector has facilitated development and distribution of Cuban vaccines domestically and abroad (Kirk, 2015).

The Cuban biotechnology sector has facilitated this collaborative and integrated approach again throughout the COVID-19 pandemic, in which the Cuban sector has developed five vaccines against the SARS-CoV-2 virus[2] (Aguilar-Guerra et al., 2021). At the time of writing, 87.7% of the Cuban population has been vaccinated with two doses of SOBERANA 02 and a

[1] The focus of this thesis is on the development of vaccines within the medical biotechnology sector.
[2] The term "SARS-CoV-2" is used in direct reference to the virus whereas "COVID-19" refers to the period of the pandemic.

third dose of SOBERANA PLUS, or a three-dose scheme of ABDALA[3] (Our World in Data, 2022). Conversely, 65.8% of the population in the United States has been vaccinated with a two-dose scheme[4] (Our World in Data, 2022). The United States has purchased its vaccines against the SARS-CoV-2 virus from various private biotechnology companies like Pfizer-BioNTech and Moderna Incorporated (Powell et al., 2021), as opposed to the Cuban approach, which has developed and distributed its vaccines within its collaborative and integrated structure. The stark difference in the percentage of vaccinated population between Cuba and the United States is indicative of the discrepancy in structures between both country's biotechnology sectors. This thesis will argue that the collaborative and integrated structure of the Cuban biotechnology sector has facilitated effective and efficient development and distribution of Cuban vaccines against the SARS-CoV-2 virus amidst the COVID-19 pandemic.

Literature Review

The Cuban Healthcare System

The Cuban healthcare system has been examined extensively in both its domestic context and its relationship with the developing world. The system is founded on revolutionary leader Fidel Castro's initial philosophy that science a pillar of national societal development and, this philosophy has held over time, which is exemplified through the preventative approach to healthcare (Baracca & Franconi, 2016; De Vos, 2005; Kirk, 2015). Many of the early analyses of the Cuban approach to healthcare have been critical of the philosophy on which the system sits

[3] The name SOBERANA is a Spanish word that translates to "sovereignty" in English, which has been given to three of the Cuban vaccines– FINLAY-FR-1, FINLAY-FR-2 and FINLAY-FR-1A. The name ABDALA is in reference to Cuban independence leader José Martí, which has been given to Cuban vaccine CIGB-66.
[4] Having completed the appropriate scheme of vaccine doses is defined as having "full vaccination" status. This definition is dependant on the region being examined. In Cuba, this is a three-dose scheme.

(Brotherton, 2012), whereas recent analyses have focused on the evolution of the healthcare system and the structures that maintain its preventative nature, and in particular, the Cuban biotechnology sector (De Vos, 2005; Feinsilver, 1993; Graber, 2018; Reid-Henry, 2008, 2010; Yaffe, 2020). Emphasis has been placed on the system's successes, despite the 60-year-old United States embargo on Cuba, which has impeded a substantial amount of trade for Cuba (Feinsilver, 1993; Yaffe, 2020).

The Cuban Biotechnology Sector

Existing research has focused on the structure of the Cuban biotechnology sector and the biotechnology institutions that form the sector. The collaborative nature of the sector is seen most clearly in the close spatial organisation of biotechnology institutions west of the capital Havana (Baracca & Franconi, 2016; Mola et al., 2006; Núñez et al., 2011; Reid-Henry, 2008). The collaborative nature is nurtured by centralised funding from the Cuban state for biotechnology development, which has removed the sector from privatisation and its inherent competitive nature between institutions (Baracca & Franconi, 2016; BioCubaFarma, 2018; De Vos, 2005; Gómez, 2008; Gorry, 2020; Reid-Henry, 2007, 2008; Núñez et al., 2011; Mola et al., 2006). Baracca and Franconi (2016) have commended the centralisation of the sector by pointing out the Cuban state's commitment to invest in the biotechnology sector. Given the country's limited resources, the state's investment into the biotechnology sector — which does not produce short-term results considering the extensive scientific processes — demonstrates the continuity of its long-term commitment to high quality, universal and preventative healthcare (Baracca & Franconi, 2016). Mola, Silva, Acevedo, Buxadó, Aguilera and Herrera (2006) have examined the integrated structure of development and distribution in the sector's respective biotechnology institutions, with particular interest in the Centre for Genetic Engineering and Biotechnology (CIGB)[5] (Mola et al., 2006). These authors have highlighted the sector's integrated "full-cycle" production, which refers to a closed-cycle of development and distribution of vaccines through the respective commercial arm of various biotechnology institutions (Mola et al., 2006). Although the Cuban biotechnology sector has been analysed at length over time, there are gaps in knowledge pertaining to the sector in the context of its role in confronting the COVID-19 pandemic.

The Cuban Biotechnology Sector and the SARS-CoV-2 Virus

There has been a substantial amount of research on the Cuban healthcare system's response to the COVID-19 pandemic as well as the response by the Cuban biotechnology sector specifically. However, the healthcare system and the biotechnology sector have been examined particularly in consideration of their close collaborative relationship with the Cuban national regulatory body and the Cuban Ministry of Public Health (MINSAP) (Aguilar-Guerra et al., 2021; Riverol, 2020). Inasmuch as there is relevant and recent research on the Cuban response to the COVID-19 pandemic, there is little research that pertains to the collaborative and integrated structure of the Cuban biotechnology sector in the context of the SARS-CoV-2 virus, and the Cuban approach to dealing with the COVID-19 pandemic. This thesis will argue that the collaborative and integrated structure of the Cuban biotechnology sector has facilitated the safe, effective and efficient development and distribution of Cuban vaccines against the SARS-CoV-2 virus during the COVID-19 pandemic.

[5] The Spanish abbreviations of the Cuban institutions are used in this thesis.

Purpose of Research

The SARS-CoV-2 virus has ravaged populations, and due at least in part to the already-existing overarching ideologies pertaining to the role of the state in maintaining healthcare systems, the virus, and the nature of the COVID-19 pandemic have dealt substantial blows to public health systems in both developing and industrialised countries. The discrepancy in percentage of the vaccinated population between Cuba and the United States warrants analysis into the Cuban biotechnology sector. Particularly, it seems that the privatised structure that is prevalent in the United States and among industrialised countries in the Global North did not sufficiently facilitate the development and distribution of vaccines, a situation which warrants further examination into the collaborative and integrated structure of the Cuban biotechnology sector. This thesis will strengthen established research on the Cuban biotechnology sector by situating it within the context of the SARS-CoV-2 virus during the COVID-19 pandemic, constructing a more holistic understanding of the sector and of the Cuban response to the COVID-19 pandemic.

Methodology

This thesis provides an historical analysis that draws on academic literature, government reports and media sources on the Cuban biotechnology sector to analyse in detail the fundamental components of the collaborative and integrative structure of the sector. A qualitative analysis of processes within the biotechnology sector during the COVID-19 pandemic will underscore the sector's distinct characteristics and demonstrate their respective roles in the development of five[6] Cuban vaccines against the SARS-CoV-2 virus. In addition, a comparison

[6] This thesis focuses on four of the five, because they are the most developed and widely distributed of the Cuban vaccines against the SARS-CoV-2 virus.

between Cuba and the United States of respective healthcare and biotechnology structures is used to underscore the success of the development and distribution within the Cuban biotechnology sector. Appropriate background context is necessary to situate Cuba in the contemporary global arena.

Background

Cuba is unique in many ways. The country has developed a socialist political economy after the 1959 Revolution, and this has been relatively maintained over time (Yaffe, 2020). The health of the population is of primary importance to the Cuban state, a commitment which dates to the early days of the Revolution. As a result, it is of no surprise that the Cuban healthcare system has developed significant capabilities over time and is among one of the best in the developing world (Kirk, 2015; Reid-Henry, 2010). The state's commitment to healthcare since the early days of revolutionary Cuba has been maintained in an integrated system of public health that includes primary, secondary and tertiary care, as well as the development and distribution of medicines, and a national regulatory body (Kirk, 2015). Its basic commitment is to provide high quality, universal, and preventative healthcare free-of-charge to the Cuban population (De Vos, 2005; Kirk, 2015; Más-Bermejo et al., 2021; Yaffe, 2020). Throughout the revolutionary period, healthcare in Cuba has evolved expansively despite a 60-year-old embargo imposed by the United States.

As a consequence of the embargo imposed on Cuba by the United States, the state faces significant difficulty in obtaining necessities for the population, like foodstuffs, medical supplies, and spare parts for machinery (Yaffe, 2020). Even so, the state has managed to preserve its commitment to healthcare ratified in the 1976 Constitution, wherein the centralised control of the market and guaranteed access to education and healthcare were principal elements (Yaffe, 2020). To demonstrate where Cuban development is situated in the global arena, development indicators in education and health are worth considering, since they constitute a useful background for a holistic analysis of the emphasis on scientific knowledge, and the significance of the Cuban biotechnology sector in the context of the COVID-19 pandemic.

Situating Cuba in The Global Arena: Indicators of Development

Data that pertain to education and health are principal indicators of development because they highlight significant human advances that go beyond economic data– which in many cases are not pertinent to meaningful development (Sen, 1999). Given the restrictions on trade, focusing solely on economic development in Cuba would present what seems to be sub-par development, ignoring the significant advances in education and healthcare since the 1959 Revolution. These key contributors to any meaningful development have to be taken into consideration.

Education. In the immediate revolutionary period, the state initiated a national literacy campaign, a campaign which reduced illiteracy from 23% to 3% (Baracca & Franconi, 2016; Blackburn-Dwyer, 2016), The right to education was subsequently guaranteed in the 1976 Constitution (Yaffe, 2020). By 2012 99.8% of the Cuban population between the ages of fifteen and twenty-four were considered literate (World Bank, 2021). In 2010, government spending on education as a percentage of Gross Domestic Product (GDP) in Cuba was 12.8%, whereas for all North America in the same year, government spending on education was 5.3% (World Bank, 2021a). Although these indicators have not been updated by the World Bank for several years, they are indicative of the state's continual maintenance of this provision.

Health. The state’s commitment to healthcare can be appreciated through some basic indicators of health. For example, the infant mortality rate in 2019 was 5.1 deaths per 1000 live births (World Bank, n.d.). Life expectancy at birth for males and females (as of 2019) was 77 and 81 years of age, respectively (World Bank, 2019; World Bank, 2019a). Life expectancy at birth in 2019 is almost directly on par with that of the United States (World Bank, 2019; World Bank, 2019a). Furthermore, incidence of the human immunodeficiency virus (HIV) per 1000 uninfected people between the ages of fifteen and forty-nine is on par with that of the United States and the world average (World Bank n.d.a).

Indicators of health and development in Cuba are useful to situate the country’s development within the contemporary global arena. These are also useful to provide a baseline understanding of the island at the time the SARS-CoV-2 virus began to circulate and the declaration of a pandemic in early 2020.

Contemporary Cuba and the Emergence of SARS-CoV-2

The approach employed by Cuba to the COVID-19 pandemic illustrated the state’s commitment to healthcare, and in particular the widespread use of vaccines. On 30 January 2020 the World Health Organisation (WHO) declared a Public Health Emergency of International Concern (PHEIC) (Horton, 2021). The PHEIC indicates an unusual or unexpected circumstance that could pose problems for public health and could extend beyond state borders (Horton, 2021). The declaration had followed the concern from scientists about the newly emerging SARS-CoV-2 virus, especially because its characteristics were not yet known. The virus resulted in policies for social distancing, mandated masks, and months-long nationwide lockdowns in many countries, a process which had especially adverse impacts on marginalised groups within every country (Horton, 2021). The first confirmed case in Cuba of the SARS-CoV-2 virus was on 11 March 2020 (Powell et al., 2021), which was the same day the WHO officially declared the transmission of the virus a pandemic; the period since then is referred to as the COVID-19 pandemic (Horton, 2021). Although the virus's characteristics were widely unconfirmed at the time, the Cuban state had long been prepared for the COVID-19 pandemic.

In January 2020, the Cuban state established the Plan for Coronavirus Prevention and Control, which included the Temporary National Working Group to Fight COVID-19. The Plan, which was particularly focused on directing public health, addressed policies for governance, ensured equity in response to cases, and directed allocation of resources for vaccine research to biotechnology institutions (Más-Bermejo et al., 2021). The Temporary National Working Group to Fight COVID-19 was formed of research specialists, academics, healthcare representatives and state officials, and was split into different councils (Más-Bermejo et al., 2021). The Plan called for the mobilisation of the councils, which were stationed within different levels of key government organisations and in different provinces and regions of the country (Más-Bermejo et al., 2021). The councils were to coordinate public health measures by promoting the appropriate information and ensuring the adherence to social distancing measures, as well as ensuring consistent door-to-door check-ups regardless of whether a case was detected. This meant that the councils were constantly aware of the circumstances in their respective regions (Más-Bermejo et al., 2021; Riverol, 2020). In the same month, the Plan called for an appropriate level of surveillance at ports of entry, and in January 2020 personnel were trained on how to respond to detected cases (Riverol, 2020). The Plan was critical for the Cuban state to develop an understanding of the severity and breadth of the virus, both in the domestic and international contexts (Más-Bermejo et al., 2021). The councils were immediately mobilised following the first detected case on 11 March 2020 (Más-Bermejo et al., 2021).

It is necessary to ensure that there are appropriate methods of case detection, contact tracing and isolation (Horton, 2021). By March 2020, incidence[7] of the virus had increased to around fifty new cases daily (Our World in Data, 2022a), wherein real-time polymerase chain reaction (RT-PCR) tests were being used for case detection (Más-Bermejo et al., 2021). Following a single protocol in every region for the provision of case detection, first- and second-degree contacts of each confirmed case were required to isolate in new facilities that were constructed separately from existing hospitals and health facilities (Más-Bermejo et al., 2021). Once they were found to be negative for the virus, individuals were to remain quarantined at home for an additional fourteen days under further consistent surveillance by their respective family medical doctor and their council (Más-Bermejo et al., 2021).

[7] Incidence is measured by daily new confirmed cases of the virus.

In sum, the nationwide Plan for Coronavirus Prevention and Control and the Temporary National Working Group to Fight COVID-19 illustrated the Cuban state's level of commitment to public health. Since January 2020 and even before the WHO declared a PHEIC, The Plan and Temporary National Working Group to Fight COVID-19 served as a foundation for Cuba's response to the SARS-CoV-2 virus, which propped up the necessary measures to control the virus. The single protocol employed by the councils to manage cases of the virus granted equitable response to the population, which was maintained by the Temporary National Working Group to Fight COVID-19. The Plan ensured equity in the healthcare system's response to cases by addressing appropriate policies and directed the allocation of resources for vaccine development, a strategy which was helpful in the early stages of research into the virus (Más-Bermejo et al., 2021). An historical analysis of the Cuban biotechnology sector is provided in the following chapter to bring forth the elements that illustrate the collaborative and integrative structure of the sector, which facilitated the effective and efficient development and distribution of vaccines against the SARS-CoV-2 virus.

Chapter One: The Origin and Evolution of the Cuban Biotechnology Sector

The international biotechnology market is extremely lucrative with vast profits available to the manufacturers of key pharmaceutical products (Brody, 2006). However, this is not a driving factor in the Cuban state's development of the biotechnology sector. The sector is funded by the Cuban state, and it has been integrated into the healthcare system, which has resulted in prioritisation of Cuba's domestic health needs rather than potential profits resulting from the export of products (Mola et al., 2006). As such, collaboration between biotechnology institutions, as opposed to competition, has been a unique factor of the sector. Collaboration between biotechnology institutions is expressed in the sector's close spatial organisation at the West Havana Scientific Pole (WHSP), wherein institutions are in close proximity to others and their researchers are encouraged to share findings amongst each other (Mola et al., 2006). In addition to collaborative research and development at the WHSP, commercialisation for distribution of products has been integrated within biotechnology institutions and has resulted in full-cycle production (Baracca & Franconi, 2016; BioCubaFarma, 2018; Mola et al., 2006; Reid-Henry, 2008). Although the biotechnology sector includes an array of products, this thesis focuses on development and distribution of vaccines.

The Cuban approach to research and development in the biotechnology sector is distinct from those found in industrialised countries. The collaborative and integrated structure is central to the Cuban biotechnology sector. As noted above, there is a large body of literature that has examined the Cuban biotechnology sector and its distinct elements. The historical analysis offered in the following pages of this thesis will analyse the basic elements of this collaborative and integrated structure of the Cuban biotechnology sector, which is crucial for analysis within the context of the COVID-19 pandemic.

Vision and Philosophy of Fidel Castro

The Cuban biotechnology sector has been critical to the development of Cuban healthcare since its establishment. Its initial inception is traced to the importance placed on science by Fidel Castro in the immediate post-Revolution period as a means of improving societal development, as it was outlined by Castro (Feinsilver, 1993). In 1960, Castro declared:

> The future of our country must necessarily be a future of men of science, it must be of men of thought, because it is precisely what we are sowing the most; what we are sowing the most are opportunities for intelligence (Castro, 1960, para. 3).

Declaring science as a pillar of long-term development is common discourse in developing countries with a basic socialist philosophy. It has been said that socialist ideologies analyse development from a “scientific” approach and are able to make rational development goals, thus serving to legitimise the state (Feinsilver, 1993). Following this declaration, Castro continued to provide support for the development of a fundamental scientific culture (Baracca & Franconi, 2016).

An initial large-scale reduction of illiteracy by the revolutionary Cuban state campaign in 1961 provided the base for the government's reform of education (Baracca & Franconi, 2016). The 1962 Higher Education Reform Law included the provision of free enrolment for eligible students (Baracca & Franconi, 2016). This was critical because it sanctioned the establishment of several post-secondary schools and subsequent training of scientific researchers, which propelled the development of a modern scientific system (Baracca & Franconi, 2016). For one year upon graduation, graduates of medical schools provided services for rural communities (Kirk, 2015). This was advantageous for the later construction of health facilities in rural regions — community polyclinics — and for widespread distribution of vaccines (Ambrón et al., 2018; Feinsilver, 1993; Kirk, 2015). The early Cuban state’s conceptualisation of health and medicine was developing into its model based upon universal and preventative care (Ambrón et al., 2018). At the same time, Castro proposed an institution that would support the growing number of research activities and institutions, a process which eventually led to the founding of the National Centre for Scientific Research (CNIC) in 1965 (Baracca & Franconi, 2016). This institution would carry out significant research in biological sciences (Baracca & Franconi, 2016). The dedication of the Cuban state to the long-term societal development of Cuba is exemplified by the importance placed on science and its significance for long-term development.

During the 1970s, the move toward building capacities in scientific research continued, and other institutions specifically related to biotechnology were established (Baracca & Franconi, 2016; Cárdenas, 2009). The research areas of different institutions became coordinated and complemented each other, coming to form the current structure of the sector (Gorry, 2020). However, the growing complexity and number of institutions required a better organised structure which led to a more centralised spatial organisation of the biotechnology structure (Baracca & Franconi, 2016). The biotechnology sector became more connected with the priorities of Cuban development following the creation of the Biological Front in 1981 (Baracca & Franconi, 2016; Cárdenas, 2009; Mola et al., 2006).

The Biological Front was implemented to better coordinate the institutions of research in biology and was to ensure and maintain a strong link between scientific development and the country's economy (Baracca & Franconi, 2016). With access to the highest levels of the Cuban state, and therefore with greater access to resources, the objective of the Biological Front was to accumulate the necessary information and technology and to utilise products that were developed through the sector (Baracca & Franconi, 2016; Mola et al., 2006; Reid-Henry, 2008). Developing biotechnology products through the domestic sector would further decrease the reliance on industrialised countries to import products needed to treat disease and illnesses, and therefore offered significant benefits for the Cuban state (Feinsilver, 1993). The Biological Front introduced the concept of "full-cycle" production, in which products are researched, produced, and commercialised as a result of the coordinated efforts of several centres (Baracca & Franconi, 2016; Mola et al., 2006; Reid-Henry, 2008). This system of full-cycle production is discussed in detail in this chapter. Although the Biological Front was the crux of the biotechnology sector's establishment, Cuba had already eradicated many prevalent diseases with vaccines prior to the formation of this integrated approach.

First Campaign Against Vaccine-Preventable Diseases

In 1962, the infant biotechnology sector focused its energy in dealing with common conditions such as whooping cough, neonatal tetanus, tetanus, and diphtheria, all of which have since been eradicated thanks to Cuban vaccines (Ambrón et al., 2018). In addition to the eradication of such prevalent diseases, Cuban vaccines have successfully eradicated measles, mumps, meningitis following mumps and tubercular meningitis among several other VPDs (Ambrón et al., 2018). Although not eradicated, over time the Cuban sector also intervened in the incidence of hepatitis B, meningococcal B and C, and typhoid fever through the utilisation of Cuban vaccines (Ambrón et al., 2018). Since its inception, the biotechnology sector has produced an extensive list of developed vaccines that have been approved for utilisation by the Cuban national regulatory body (Mola et al., 2006).

In addition to eradicating or lowering incidence of the most prevalent vaccine-preventable diseases since the establishment of its biotechnology sector, Cuba produces most its official childhood vaccination medicines (Ambrón et al., 2018). Vaccines that protect against hepatitis B, severe forms of tuberculosis and meningococcal B and C are applied to children before their first birthday, among other vaccines that are utilised throughout youth and adolescent years of age (Ambrón et al., 2018). In addition to those developed for children, a vaccine has been developed to treat diabetic foot ulcers of individuals that are at risk of amputation (Mola et al., 2006). CimaVax-EGF is a novelty vaccine developed by the CIGB (Mola et al., 2006). In addition to the vaccines themselves, Cuba maintains a successful national immunisation program that has been supported both by the primary healthcare system and the participation of mass organisations in the community (Ambrón et al., 2018). The success that has been exemplified by the biotechnology sector demonstrates the abilities and the capacities of its established processes and regulations that are present within the sector.

The adequacy of the national immunisation program and concurrent campaigns conducted by public health and community polyclinics dating back to the earliest days of the revolutionary process demonstrate the ongoing and consistent political commitment to science and high quality, universal, and preventative healthcare by the Cuban state. In addition, it demonstrates the willingness of the domestic population to receive Cuban vaccines. Over time, the biotechnology sector of Cuba has evolved extensively. However, which of its elements form its collaborative and integrated structure?

Elements of The Contemporary Biotechnology Sector

After establishing the importance of the development of science and the establishment of the Biological Front, the WHSP was formed. The WHSP is composed of dozens of institutions dedicated to development and distribution of biotechnology products (Baracca & Franconi, 2016; Núñez et al., 2011; Mola et al., 2006; Reid-Henry, 2008). Within the Pole are Cuba's biotechnology institutions, which have respectively integrated all aspects of production, including the commercialisation of developed products (Baracca & Franconi, 2016; Núñez et al., 2011; Mola et al., 2006; Reid-Henry, 2008). It is not only the origin and evolution of the sector that render the Cuban biotechnology sector different from those of the Global North, but also the elements that form its whole.

The West Havana Scientific Pole

The spatial organisation of Cuba's biotechnology sector is distinct, and is located West of Havana (Feinsilver, 1993; Kirk, 2015). Comprising dozens of scientific institutions — including biotechnology's most important research centres such as the CIGB and the Finlay Institute (IFV) — the WHSP is a massive integrated complex of institutions that are devoted to biotechnology (Baracca & Franconi, 2016). Over time, the Cuban state has invested billions of dollars into the cluster (Baracca & Franconi, 2016; Kirk, 2015; Mola et al., 2006). This close spatial organisation within Havana has been advantageous to the biotechnology sector, and the development and distribution of vaccines; it has allowed for collaboration within development processes, improved communication and exchange of information, and subsequently reduced competition for profit through funding by the Cuban state (Mola et al., 2006; Reid-Henry, 2008).

Integration has been a primary component of the biotechnology sector within the WHSP and has guided collaboration between the institutions. As such, each institute has dealt with respective areas of focus (Mola et al., 2006). It is also important, and unique, to see the process in which they exchange information and findings amongst each other; this has been deemed successful in the past by scholars and personnel within the field (Ambrón et al., 2018; Baracca & Franconi, 2016; Gómez, 2008; Gorry, 2020; Mola et al., 2006; Reid-Henry, 2008). In 1997, a study between two primary institutions within the biotechnology sector, the CIGB and the IFV, led to the development of a combined vaccine against DPT-HB (Expósito et al., 2006). In carrying out their respective responsibilities, the partnership between the CIGB and IFV facilitated rapid development and later manufacturing of the vaccine (Expósito et al., 2006). The CIGB and IFV obtained approval for their vaccine against DPT-HB in 2004 (Mola et al., 2006). This vaccine is amongst many that were developed and approved throughout the early to mid-2000s (Mola et al., 2006). This successful partnership in production is due at least in part to the collaborative and integrated nature of the institutions within the sector. The particular focus of primary institutions of the Cuban biotechnology sector is discussed later in this chapter.

Major Institutions Within the Biotechnology Sector and How They Interact

There is one central state organisation that acts as an umbrella for all research and development activities carried out at the diverse research institutes. Created in 2012, the state-owned conglomerate BioCubaFarma has overseen various biotechnology institutions with different responsibilities in the sector (Gorry, 2020). Through coordinating projects within the sector at the WHSP, BioCubaFarma has produced high quality vaccines that comply with international standards of proper clinical and manufacturing processes despite severe financial limitations for decades (BioCubaFarma, 2018; Gorry, 2020; Mola et al., 2006). In the institute's effort to coordinate development between many institutions, BioCubaFarma has developed a large list of successful biotechnology products (BioCubaFarma, 2018). A network of thirty-four institutions is located under the BioCubaFarma umbrella (BioCubaFarma, 2018). Its core consists of eight institutions: the CIGB, the Centre for Molecular Immunology (CIM), the IFV, the Centre of Immunoassay (CIE), the Neurosciences Centre (CNEURO), the CNIC, the Central Institute for Digital Research (ICID) and FARMACUBA (BioCubaFarma, 2018). This thesis focuses on three of them, since they are the most notable ones that came into play during the COVID-19 pandemic. The CIGB, the IFV and the CIM are integral to the Cuban biotechnology sector (BioCubaFarma, 2018; Mola et al., 2006).

Within the biotechnology sector, the CIGB is considered the leading institution (Mola et al., 2006). It has been responsible for the development and distribution of both prophylactic and therapeutic vaccines, including therapeutic molecules such as peptides, proteins and monoclonal antibodies that are important to vaccine development (BioCubaFarma, 2018). Specialists from this key institution have been tasked with forming a supervisory body, collaborating, and overseeing a particular research project within the CIGB (BioCubaFarma, 2018). These supervisory groups have focused their attention on specific research projects in biomedicine, agricultural biotechnology, technological development, and clinical trials (BioCubaFarma, 2018). Similarly, the CIGB maintains a unit to oversee collaborative projects at both the national and international scale in consideration of pertinent global regulations (BioCubaFarma, 2018). This has been particularly useful for exporting biotechnology products and for creating bilateral and multilateral agreements with other countries (Gómez, 2008).

The CIGB is Cuba's top exporter of Cuban biotechnology to the rest of Latin America and the world (BioCubaFarma, 2018). Products that have been produced have resulted from development processes within the CIGB have had an immensely positive impact on public health in Cuba (Mola et al., 2006). For example, the institute has several approved biotechnology products for use, including a vaccine against the hepatitis B virus (Mola et al., 2006; Pentón-Arias & Aguilar-Rubido, 2021), which has been utilised by other countries and biotechnology institutions around the world (Mola et al., 2006). This analysis of the CIGB's embedded and successful processes, and the widespread success of its products, exemplify a strong element of the Cuban biotechnology sector. It also shows that the necessary technical capacities, regulations, and processes have been in place for decades (Gorry, 2020). In addition to the CIGB, the IFV is a distinguished institution for the development of vaccines (Gorry, 2020).

Like the CIGB, the IFV is a distinguished institute specialising in vaccine development (BioCubaFarma, 2018). The IFV is responsible for coordinating development and distribution of products in immunology, molecular biology, and microbiology for the development of vaccines. In addition, the IFV is tasked with research of fermentation processes which is necessary for production of vaccines (BioCubaFarma, 2018). Like its counterparts within the BioCubaFarma umbrella, products developed and manufactured by the IFV have been embraced by other scientists and institutions globally. Particularly notable among IFV-developed products, is the success and widespread implementation of the world's first vaccine against serogroup B meningococcus in 1989 (Gorry, 2020). The institute developed several other products, including a vaccine against typhoid fever (Azze et al., 2003). In processes of production there are certified plants for manufacturing vaccines, and they conform to international standards (Gorry, 2020). These plants are operated by both the IFV and the CIM, which is another key institution in the WHSP (Gorry, 2020). Analysis of the IFV demonstrates extensive and successful background in vaccine development within the Cuban biotechnology sector and large-scale manufacturing of vaccines for decades.

The CIM has been a primary contributor to the biotechnology sector since 1991 (Gorry, 2020). Focusing on cancer immunotherapy, the institute specialises in molecular vaccines specifically for cancer treatment (BioCubaFarma, 2018). This institute is significant for the development of products related to diagnosis and treatment of diseases connected with the immune system (BioCubaFarma, 2018), and can produce recombinant proteins that are crucial to the development of many vaccines at a large-scale for many years (Gorry, 2020). In addition, the CIM shares a common element with the CIGB and IFV among other biotechnology institutions– the right to commercialisation of biotechnology products is extended to commercial arms of respective institutions and has been termed “full-cycle” production (BioCubaFarma, 2018; Mola et al., 2006). The CIGB, the IFV and the CIM have different commercial arms– Heber Biotec SA, Vacunas Finlay SA and CIMAB SA, respectively (WHO et al., 2015). The commercial element is significant for contributing to the national economy and for the distribution of vaccines that have been developed in the Cuban biotechnology sector.

Full-Cycle Production

Full-cycle production refers to an integrated research-development-commercialisation approach, which streamlines the process of development and distribution of products

(BioCubaFarma, 2018; Cárdenas, 2009). In Cuba, the right to commercialisation of developed biotechnology products is extended to the commercial arms of respective biotechnology institutions (Mola et al., 2006). The full-cycle method of production protects the Cuban biotechnology market by sharing the IP patent instead of selling it to companies for manufacturing (Mola et al., 2006). The CIGB, the IFV and the CIM have different commercial arms– Heber Biotec SA, Vacunas Finlay SA and CIMAB SA, respectively (WHO et al., 2015). The commercial element is significant for protecting the national economy and for the distribution of vaccines that have been developed in the Cuban biotechnology sector because while each of these institutions develop and commercialise their own products, all funding for the research and development is provided by the state and all profit from the sales revert to the state, which in turn provides funding to the institutes for further research (BioCubaFarma, 2018).

This integrated approach to developed products was an explicit decision by the Cuban state (Baracca & Franconi, 2016). In consideration of the importance placed by the Cuban state on science for long-term development, biotechnology production has been seen as a tool for medical sovereignty in Cuba (Baracca & Franconi, 2016). Owing to the full-cycle method of production, the country is not reliant on imported biotechnology products (Baracca & Franconi, 2016). This is a significant process for the distribution of biotechnology products. In particular, the ever-common neoliberal competition for profit in the international market has had immense impacts on health systems and resulted in many problems regarding intellectual property (IP) policies (Baracca & Franconi, 2016; Gómez, 2008). The method has expanded the sale of Cuban biotechnology products to markets in other countries whilst maintaining its ongoing position in the Cuban domestic market (Mola et al., 2006). The full-cycle method is a key element of the Cuban biotechnology sector.

In short, the importance placed on scientific development by Fidel Castro in the earliest days of the revolutionary process facilitated the development of the Cuban biotechnology sector. The early and subsequent large-scale reduction of illiteracy in 1961 and educational reforms were foundational for Cuba's early healthcare service delivery and the development of Cuba's modern scientific system. The centralisation of the biotechnology sector at the WHSP is crucial for collaboration between institutions. This examination into the integrated processes of development and commercialisation in respective institutions has brought forth the importance of full-cycle production in the Cuban biotechnology sector and shown its success domestically and globally over time. The contemporary structure of the Cuban biotechnology sector therefore clearly established and was thus able to respond rapidly to the need for vaccines against the SARS-CoV-2 virus.

Chapter Two: Bracing for Impact and Confronting the Contagion

The Cuban biotechnology sector was long prepared for the SARS-CoV-2 virus. This chapter will analyse the policies brought into action by the Plan for Coronavirus Prevention and Control and the processes that were undertaken by the CIGB, IFV and the CIM. This analysis will analyse the collaborative and integrated structure of the Cuban biotechnology sector in the context of the COVID-19 pandemic, and the development and distribution of Cuban vaccines against the SARS-CoV-2 virus.

Initial Response in Cuba

On 30 January 2020 the WHO declared the SARS-CoV-2 virus a PHEIC (Horton, 2021). The first case of the SARS-CoV-2 virus was on 11 March 2020 (Galbán-García & Más-Bermejo, 2020; Más-Bermejo et al., 2021; Powell et al., 2021). On the same day, the WHO formally declared the transmission of the virus to be of pandemic status (Horton, 2021). However, Cuba was prepared for the pandemic months before the country's first detected case. In January 2020, the Cuban state organised and prepared the Plan for Coronavirus Prevention and Control, which detailed policies for monitoring of the virus[8], delivery of healthcare services and allocation of resources for the development of vaccines against the virus (Más-Bermejo et al., 2021). The Plan was composed by academics, specialists from universities and scientific research institutions, and representatives from other areas of healthcare (Más-Bermejo et al., 2021). In the Plan, an already-existing nationwide protocol for healthcare service delivery was included, which has underscored the state's continual upholding of equity in healthcare (Más-Bermejo et al., 2021), even amidst the unfolding pandemic. The Plan set out the Temporary National Working Group for COVID-19, a group which was mobilised for the detection and supervision of patients, once the first case was detected (Galbán-García & Más-Bermejo, 2020; Más-Bermejo et al., 2021; Powell et al., 2021).

The Temporary National Working Group for COVID-19 contained the Innovation Committee, which specifically coordinated the Cuban biotechnology sector (Aguilar-Guerra & Gorry, 2021). Once the Temporary National Working Group for COVID-19 was mobilised in March 2020, several actions were taken within the biotechnology sector (Más-Bermejo et al.,

[8] These included measures for contact tracing, isolation, and detection of cases.

2021). The Plan and Innovation Committee sanctioned research for the development of prophylactic vaccines, a preventative form of vaccine, which introduce antigens into the body to raise immunity against a virus (Aguilar-Guerra & Gorry, 2021; Pentón-Arias & Aguilar-Rubido, 2021). In accordance with the policies detailed in the Plan and by the Innovation Committee, the WHSP's key institutions CIGB, the IFV and the CIM, rapidly developed five vaccines for trials against the SARS-CoV-2 virus.

Cuban Vaccines Against the SARS-CoV-2 Virus

Development of the SOBERANA Vaccines

Initial research on the SARS-CoV-2 virus by the Innovation Committee and others within the Cuban biotechnology sector prompted the development of subunit protein vaccines, which are prophylactic vaccines (Aguilar-Guerra & Gorry, 2021). These vaccines require the production of proteins (antigens) for the receptor-binding domain (RBD) which are needed to bind to the SARS-CoV-2 spike and will trigger an immune response to the virus and build immunity against it (Aguilar-Guerra & Gorry, 2021). Given its extensive experience in the development of products used for diagnosis and treatment of diseases related to the immune system, the CIM was responsible for research and development of the RBD (Aguilar-Guerra & Gorry, 2021). The IFV worked alongside the CIM in the development process for the RBD as it initiated the conjugation of the RBD to tetanus toxoid (Toledo-Romani et al., 2021). Together, the CIM and IFV produced the necessary components to develop the subunit protein vaccine. A result of this process between the CIM and the IFV was the vaccine SOBERANA 01, and resulting from findings in phases I and II of clinical trials was SOBERANA 02 (Aguilar-Guerra & Gorry, 2021).

SOBERANA 02 began its phases I and II of clinical trials in October 2020 (Gorry, 2020). A third variation of the SOBERANA vaccine, SOBERANA PLUS, was developed and entered its phases I and II of clinical trials parallel to SOBERANA 02 (Gorry, 2020). Once completed, phases I and II of clinical trials concluded that SOBERANA 02 was safe and tolerated in adults aged 19-80, while an additional third dose of SOBERANA PLUS would increase the immune response (Toledo-Romani et al., 2021); this became the scheme for vaccination with SOBERANA 02 and SOBERANA PLUS. The success of these initial phases of clinical trials allowed for further investigation in the final phase of clinical trials (Toledo-Romani et al., 2021).

The final phase of clinical trials for the SOBERANA 02 and SOBERANA PLUS vaccination trials began in March 2021 (Marsh, 2021). Although detected cases of the virus were rising in Cuba at this time due to an influx of tourism — which is discussed later in this chapter – – the country was not experiencing a large enough outbreak to produce sufficient data on the SOBERANA vaccines (Marsh, 2021). As such, phase III of clinical trials was conducted with thousands of volunteers in Havana, and in Iran by virtue of the Cuban biotechnology sector's full-cycle method of production (Marsh, 2021). The use of Cuban vaccines in Iran is discussed later in this chapter. Following phase III of clinical trials, SOBERANA 02 was found to be 91.2% effective against the virus when followed by a third dose of SOBERANA PLUS (Aguilar-Guerra et al., 2021). The CIM and the IFV made substantial progress in the development of subunit protein vaccines against the SARS-CoV-2 virus. In addition, however, the CIGB developed another– ABDALA.

Development of the ABDALA Vaccine

The CIGB began research and development for another subunit protein vaccine parallel to the CIM and IFV (Hernándes-Bernal et al., 2021). The CIGB produced a recombinant protein in a kind of yeast for the RBD and was conjugated to alumina to trigger an immune response (Hernándes-Bernal et al., 2021). Phases I and II of clinical trials were conducted in July 2020 for the vaccine, which was named ABDALA (WHO, 2021). Phases I and II concluded that the ABDALA vaccine was safe and tolerated in individuals aged 19-80 and three doses of ABDALA were effective (Hernándes-Bernal et al., 2021). The success of the initial phases of clinical trials warranted further probing in phase III of clinical trials (Hernándes-Bernal et al., 2021).

Parallel to the phase III of clinical trials for the SOBERANA vaccines, the phase III of clinical trials for the ABDALA vaccine began in March 2021, in which several thousand volunteers took part in its final phase (Fariñas, 2021). It was concluded that ABDALA was 92.28% effective against the SARS-CoV-2 virus if three doses were given (Hernándes-Bernal et al., 2021). The clinical trials have also concluded that the ABDALA vaccine was able to produce comparable levels of antibodies to the mRNA vaccine developed by Pfizer-BioNTech (Hernándes-Bernal et al., 2021), which is a private biotechnology company of the Global North. Once all phases were complete, the three-dose scheme of SOBERANA 02 with SOBERANA PLUS and that of ABDALA were approved for emergency use by the Centre for State Control of Drugs, Equipment and Medical Devices (CECMED) in July and August 2021, respectively (CECMED, 2021). This approval is required for the distribution of vaccines (Aguilar-Guerra et al., 2021).

Distribution of Cuban Vaccines

The distribution of Cuban vaccines against the SARS-CoV-2 virus began in phase III of clinical trials for SOBERANA 02 and SOBERANA PLUS. Owing to the full-cycle method of production, Iran was granted the IP patent to produce Cuban vaccines in March 2021 by the commercial arm of the IFV– Vacunas Finlay SA (Marsh, 2021). This was a significant event for both countries. Cuba was not experiencing a large enough outbreak of the virus to accumulate data for phase III of clinical trials for the SOBERANA vaccines, and Iran needed vaccines for its own population (Marsh, 2021). The shared IP patent for SOBERANA 02 and SOBERANA PLUS meant that Iran was able to manufacture the Cuban vaccines under a different name, and they have been commercialised as PastoCovac and PastoCovac Plus (Marsh, 2021). As well, Cuban vaccines were distributed in Vietnam, where the government imported millions of doses of the ABDALA vaccine and granted it approval for emergency use in September 2021 (Nga, 2021). The IP patent was shared with Vietnam shortly after (Nga, 2021). The full-cycle method of production facilitated widespread distribution of Cuban vaccines abroad. These processes were beneficial to the Cuban economy because development and distribution for vaccines are funded by the state, and by sharing the IP patents rather than selling them, the positions of the Cuban vaccines were maintained in Cuba's national market. Even in the early development of the SOBERANA vaccines, the full-cycle method of production facilitated widespread distribution of vaccines against the SARS-CoV-2 virus.

In Cuba, Cuban vaccines have been distributed across the island. At the time of writing in April 2022,.7% of the population has been fully vaccinated with three doses (Our World in Data, 2022). This is a stark comparison to the United States who, at the same time, has vaccinated just

65.8% of its population with two doses of its respective vaccines (Our World in Data, 2022). Although the Cuban biotechnology sector has facilitated widespread efficient and effective development and distribution of Cuban vaccines against the SARS-CoV-2 virus, the sector has come up against challenges at various stages of the COVID-19 pandemic.

Challenges

Sanctions Affecting the Cuban Economy

At the end of 2020, then-President of the United States Donald Trump imposed new sanctions on Cuba, which impacted the national economy (Al Jazeera, 2020). In September 2020 Trump banned imports of different Cuban products, such as rum and cigars, and prohibited citizens of the United States from staying at property owned by the Cuban state (Al Jazeera, 2020). Later in November 2020, the former president placed additional sanctions on Cuba, a process which blacklisted a Cuban firm that processed remittances from Cubans living abroad (Augustin, 2020). These sanctions limited the flow of capital into the Cuban economy and stopped a major source of funding from the Cuban diaspora, which was particularly concerning as the COVID-19 pandemic has exacerbated existing economic concerns for every country. This blow to the Cuban economy resulted in the state's decision to permit tourism into the country beginning in December 2020 despite the global lack of vaccines against the SARS-CoV-2 virus (Acosta, 2021). Consequently, incidence of the SARS-CoV-2 virus increased significantly on the island since December 2020 (Our World in Data, 2022a).

The number of cases in Cuba rose dramatically between December 2020 and the summertime months of 2021 (Our World in Data, 2022a). Prior to this period, Cuba had been successful in containing the virus and had seen less than sixty new cases per day (see Appendix A) (Our World in Data, 2022a), which was due to the stringent monitoring of cases as detailed in the Plan and mobilisation of the Temporary National Working Group for COVID-19. The number of daily new cases rose steeply, and Cuba eventually began counting over eight thousand new cases a day (Our World in Data, 2022a). Insofar as the recorded number of cases per day rose steeply, the number of daily new cases decreased steeply by mid-September 2021 as Cuban vaccines had been approved for emergency use by the CECMED by late-August 2021 and were being distributed to the Cuban population (Our World in Data, 2022a). At the time of writing, the number of daily new cases is relatively low at around eight hundred (Our World in Data, 2022a). It is important to note that the number of daily new cases globally has been rising due in part to the omicron variant of the SARS-CoV-2 virus, which was first detected in South Africa (Our World in Data, 2022b). Not only has widespread distribution of Cuban vaccines reduced the incidence of the SARS-CoV-2 virus, but the case-fatality rate[9] has remained steady since September 2021 (see Appendix B) (Our World in Data, 2022c). Although high incidence of the virus in Cuba has been reduced significantly at the time of writing owing to Cuban vaccines, the country faced some difficulty in obtaining the resources that are necessary for distributing vaccines.

Shortage of Syringes

The global increase in vaccines against the SARS-CoV-2 virus meant syringes were in high demand to administer doses of newly developed vaccines, and vaccination against the virus often required more than one syringe per person within a given population to achieve "full

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[9] The case-fatality rate relies on the number of confirmed cases and reflects the context at a particular time in a particular area.

vaccination" status (Nicoll, 2021). Cuba was unable to obtain a sufficient number of syringes to vaccinate the whole population for the three doses required to complete the scheme (Nicoll, 2021). The shortage was due to the global increase in vaccination, the required three-dose scheme, and the United States embargo on Cuba (Nicoll, 2021). Global solidarity organisations, such as Global Health Partners and other non-governmental organisations, rallied to allocate syringes for Cuba through donation schemes (Nicoll, 2021). Following donations of syringes for Cuba, calls for donations of supplies for vaccination ended. Despite the widespread success and distribution of Cuba's effective vaccines, the Cuban biotechnology sector was faced with criticism regarding some decisions that were made within the sector throughout the pandemic.

Criticism

Critics of the Cuban vaccines have pointed out the lack of peer-reviewed data resulting from the clinical trials of both the SOBERANA candidates and ABDALA. The available data collected and analysed by Cuban scientists have not been peer reviewed, although they have been published online. The available data have been collected and put together by Cuban scientists and has been utilised by other countries such as Iran and Vietnam, which have both undertaken production and distribution of the vaccines (Marsh, 2021). Insofar as there is a lack in peer-reviewed data resulting from the clinical trials, there are no known anti-vaccination counterargument resulting from distribution of the Cuban vaccines on the island. Despite the lack of peer-reviewed data, the CIGB formally applied for the WHO prequalification process on 25 January 2022 (Taylor, 2022). Approval of Cuban vaccines in the prequalification process signifies that the institution has met international quality standards for vaccine development, which the CIGB has been granted for past developments (Augustin, 2022).

In summary, the Cuban state was prepared for the COVID-19 pandemic long before it was declared by the WHO. The Plan for Coronavirus Prevention and Control ensured stringent measures for monitoring of the virus, delivery of healthcare services and allocation of resources for the development of vaccines against the virus (Más-Bermejo et al., 2021). The Temporary National Working Group for COVID-19 contained the Innovation Committee, which sanctioned research for the development of subunit protein vaccines against the SARS-CoV-2 virus. The research and development of Cuban vaccines were undertaken by the WHSP's key institutions –– the CIGB, IFV and CIM — which followed a collaborative approach during the vaccine development processes. This collaboration facilitated the effective and efficient development of vaccines because the processes were divided among the institution's respective specialised areas of research and development, thus facilitating rapid development of several vaccines against the virus. The successful distribution of the Cuban vaccines is also exemplified in the comparison of the total percentage of the population who has been vaccinated between Cuba and the United States, as is analysed in further detail in next chapter.

Chapter Three: The Proof is in the Pudding

The structure of the biotechnology sector in the United States is noticeably different in comparison to that of Cuba. Over the course of the COVID-19 pandemic, the United States funded eight private biotechnology companies to develop and distribute vaccines against the SARS-CoV-2 virus through a public-private partnership. Although the biotechnology sector of the United States has been able to develop and distribute vaccines against the virus, it has not done so effectively or efficiently at an appropriate scale. The comparison that is provided in this chapter serves as a valuable contrast to the approach used by Cuba in its own management of the COVID-19 pandemic and development of vaccines against the virus. Analysis of the United States' model is important to contrast the sector's ability to successfully develop and distribute vaccines and provides a rationale for an alternative structure. The following pages provide an examination into the structure of the healthcare system and consequently the biotechnology sector in the United States. This is necessary to situate it within the context of the COVID-19 pandemic and to bring forth an analysis of the processes that were undertaken through the public-private partnership for the development of vaccines against the SARS-CoV-2 virus (United States Department of Health and Human Services, 2020).

Broad Overview of the Structure of Healthcare in the United States

The structure of the healthcare system in the United States is decentralised (Powell et al., 2021). As such, the individual state-level governments are responsible for maintaining the healthcare services within their respective states (Powell et al., 2021); this is a stark difference to the healthcare system of Cuba. Access to healthcare services is acquired through insurance programs such as Medicaid or Medicare, which are offered by the federal or state government (Powell et al., 2021). However, healthcare insurance programs are most often acquired through employment benefits. In this way, access to healthcare services is largely dependant on employment status and is not guaranteed (Powell et al., 2021). Since healthcare services are maintained at the state-level and access to insurance programs is largely dependant on employment status, there is large discrepancy in healthcare between individual states (Powell et al., 2021). The decentralised and inaccessible nature of the healthcare system in the United States is reflected in its biotechnology sector.

Development and Distribution within the Contemporary United States' Biotechnology Sector

The biotechnology sector of the United States consists of individual privatised companies (Brody, 2006). Private companies are driven by the accumulation of profit and can be traded on the stock market (Brody, 2006). As such, they are responsible for sourcing investment capital and investing it into the development of their products, which incentivises competition for development between individual companies (Brody, 2006). The biotechnology companies found in the United States sector are not concentrated in one locality, but rather they have been dispersed across the country and are unable to make use of the collaboration that is possible within a close spatial organisation– such as the WHSP in Cuba. In addition, the United States has imported a significant amount of biotechnology products from foreign institutions to make up for what cannot be sufficiently developed and distributed domestically (Brody, 2006).

The permission to manufacture a product is granted by the patent, which is extended by federal IP agencies to the company that has developed the given product (Brody, 2006). Since patents limit the manufacturing of biotechnology products to a single company — and their manufacturing capacities (Brody, 2006) — widespread distribution of needed vaccines cannot be facilitated effectively or efficiently in the contemporary structure of the United States biotechnology sector. In the context of the COVID-19 pandemic, this structure intensified the high mortality rates caused by the SARS-CoV-2 virus because of the prolonged research and development processes within individual biotechnology companies, and the inability to facilitate widespread distribution.

The United States' Biotechnology Sector amidst the COVID-19 Pandemic

The federal government of the United States arranged measures to mitigate[10] the SARS-CoV-2 virus a few days after the WHO declared the virus to be of pandemic status on 11 March 2020 (Horton, 2021). These included methods for contact-tracing, isolation, and case detection–although these varied widely by state (Powell et al., 2021). Not long after these provisions were put in place the United States experienced a slight decrease in the average number of cases and many states pulled back their measures to mitigate the virus, which had the adverse effect and caused the number of cases to increase (Powell et al., 2021). The need for vaccines against the SARS-CoV-2 virus was clear.

On 15 May 2020, the federal government announced Operation Warp Speed (OWS), whereby billions of dollars of funding were allocated through a public-private partnership between the federal government and private biotechnology companies (United States Department of Health and Human Services, 2020). These companies were to develop a vaccine against the SARS-CoV-2 virus. The OWS outlined specific targets that included federal support for large-scale manufacturing capacity and support from the United States Food and Drug Administration (FDA) in phases of clinical trials to expedite the development and distribution of vaccines against the virus (United States Department of Health and Human Services, 2020). Eight

[10] This is opposed to the preventative approach taken in Cuba.

companies were chosen to receive funding by August 2020, whereas Cuban institutions had already entered phases I and II of clinical trials (United States Department of Health and Human Services, 2020).

Two vaccines were developed by two of the eight different companies and have been most widely distributed in the United States following the emergency approval for their use granted by the FDA in December 2020– these are from Moderna Incorporated and Pfizer-BioNTech (FDA, n.d.). However, the latter has been scrutinised in various instances over comments that were made by the company's executives, which pertained to the funding that was received; executives had inconsistently both confirmed and denied at different times that funding had been accepted from the federal government of the United States and the OWS (Athey, 2020). This likely had an adverse effect on vaccine distribution in general in the United States, considering the prominent anti-vaccination counterargument in the Global North amidst the COVID-19 pandemic. At the time of writing, the United States has vaccinated 65.8% of its population with two doses of its respective vaccines, which is far below the percentage of the vaccinated population in Cuba (Our World in Data, 2022).

Ultimately, the decentralised structure of the healthcare system in the United States intensified the mortality rate caused by the SARS-CoV-2 virus because of the prolonged research and development processes within individual private biotechnology companies, and the inability to facilitate widespread distribution. Since the federal government of the United States did not initiate measures to prevent the SARS-CoV-2 virus until after the pandemic status was declared by the WHO in March 2020, the research and development of vaccines against the virus were delayed until mid-May 2020, while the CIGB, the IFV and the CIM were already conducting phases I and II of clinical trials for the Cuban vaccines. The public-private partnership between the federal government and biotechnology companies was only collaborative insofar as the funding was provided because the vaccines were patented by the private biotechnology companies. Furthermore, the inconsistent discourse regarding the funding of development that were made by executives from the company Pfizer-BioNTech likely contributed to anti-vaccination counterargument, which have been most prominent in the Global North. At the time of writing, the percentage of the population that is vaccinated in the United States is far below that of Cuba, despite the emergency approval for the Moderna Incorporated and Pfizer-BioNTech vaccines that was granted by the FDA in December 2020 (Our World in Data, 2022).

Conclusion: The Next Wave

The structure of the Cuban biotechnology sector is collaborative, integrated, based on the Cuban preventative and equitable healthcare system and, during the COVID-19 pandemic, it has proven itself to be resilient. This thesis has shown that the collaborative and integrated structure of the Cuban biotechnology sector facilitated the effective and efficient development and distribution of Cuban vaccines against the SARS-CoV-2 virus. Collaboration at the WHSP between the CIGB, the IFV and the CIM was efficient because it facilitated rapid development of vaccines against the virus, all of which were found to be effective in the prevention of the virus (Hernándes-Bernal et al., 2021; Toledo-Romani et al., 2021). Effective development was also exemplified in the sharp decline in cases (after the noticeable increase in December 2020) following the emergency approval of Cuban vaccines. The integrated full-cycle method of production facilitated efficient distribution of Cuban vaccines because the country was able to share the patent of Cuban vaccines for production and commercialisation with Iran to accumulate sufficient data for clinical trials. In addition, the full-cycle method facilitated effective distribution of Cuban vaccines, with the result that the majority of the domestic population has been vaccinated with three doses– a stark contrast with the situation in the United States. The structure of the Cuban sector is unique, and it was especially advantageous throughout the COVID-19 pandemic.

The advantage of the Cuban model for the development and distribution of biotechnology products is its collaborative, integrated, preventative, and equitable nature– this cannot be said for that of the United States and other industrialised countries of the Global North. The Cuban model offers an alternative to the Global North's prominent model for production of biotechnology products, — which lacks the collaborative and integrated structure of the Cuban model — and prioritises the accumulation of private profit and incentivises competition between companies. This model had consequences for the United States during the COVID-19 pandemic because research for vaccines was delayed for months following the declaration of a pandemic due to insufficient allocation of resources, and their development was facilitated by private companies. The public-private partnership was not able to facilitate widespread distribution because of the restrictive parenting scheme. This contrast is especially important considering the mortality rate of the SARS-CoV-2 virus, and the volatile nature of the COVID-19 pandemic. The advantages of the Cuban model extend beyond the Global North to the Global South.

Due in part to the lack of a developed biotechnology sector, other developing countries in the Global South have not been able to produce homegrown vaccines against the SARS-CoV-2 virus. However, the Cuban model offers benefits to countries of the Global South, given the patent-sharing scheme of respective commercial arms, which facilitated production and commercialisation of Cuban vaccines for distribution in both Iran and Vietnam during the COVID-19 pandemic. The Cuban model not only extends its benefits, but the structure is advantageous for biotechnology production in other countries because of its resilience to the volatile circumstances of the pandemic. This is particularly beneficial to developing countries, which are often unable to mitigate public health crises due to a lack of available capital or insufficient allocation of resources.

Although it is likely difficult to do so without significant reform within the respective political economy, this structure of biotechnology development and distribution should be utilised elsewhere. Further research may be necessary to determine the extent to which this unique structure of the Cuban biotechnology sector has influenced the willingness of a population to receive the vaccination scheme in consideration of the anti-vaccination counterargument that has been prominent in the Global North. The virus itself and the nature of the COVID-19 pandemic have had substantial and lethal consequences for populations and healthcare systems globally, a situation which indicates a need for improved structures of healthcare and of biotechnology to prevent further transmission of this virus, and those that are likely to come.

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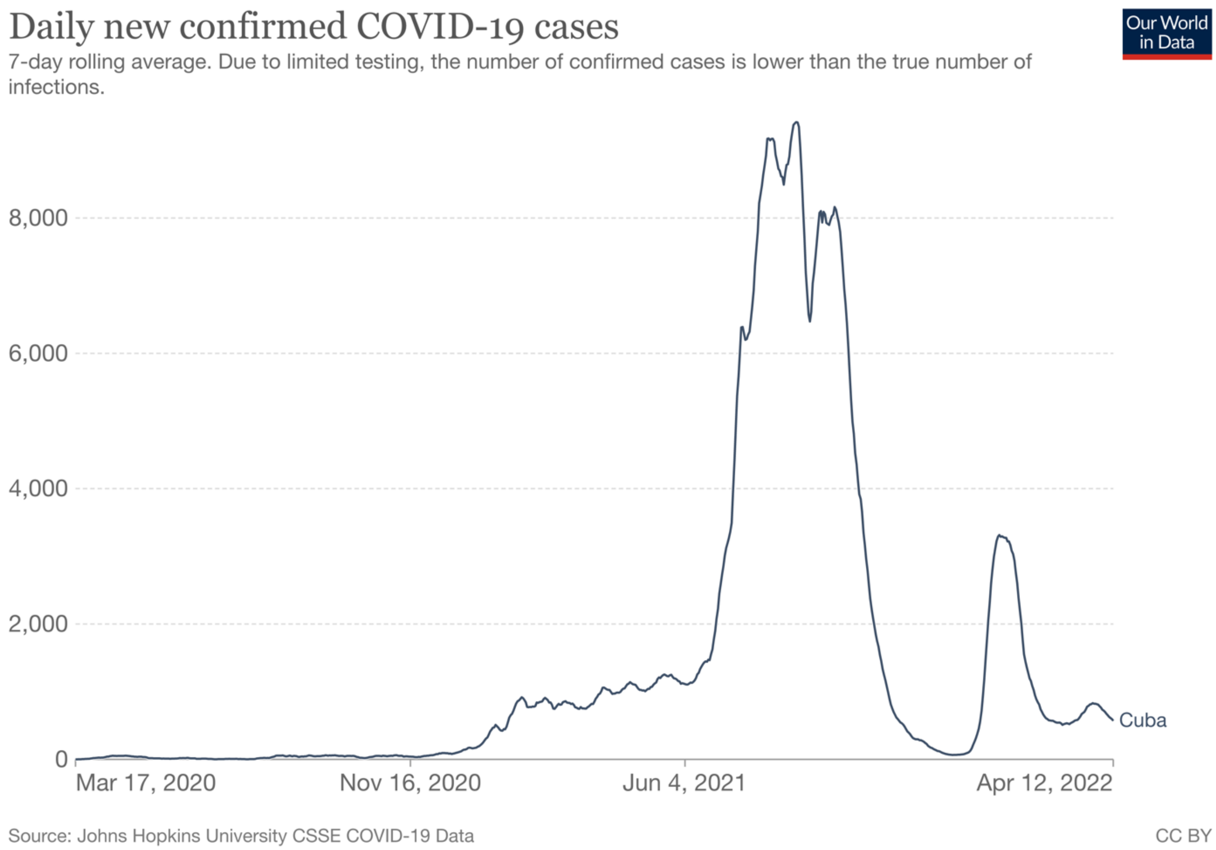
Appendix A



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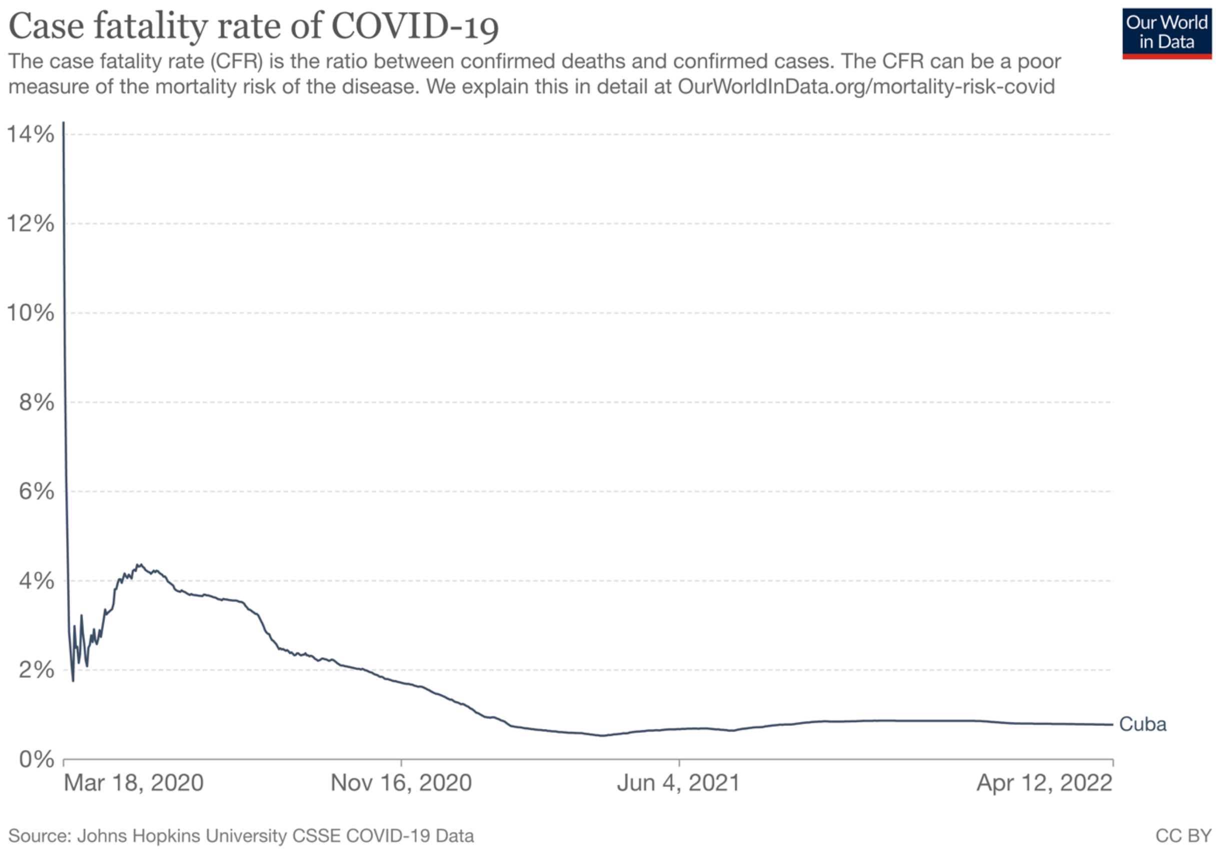
Appendix B



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