A ROAD LESS TRAVELED:

AN ANALYSIS OF CUBA'S UNIQUE MODEL FOR BIOTECHNOLOGY

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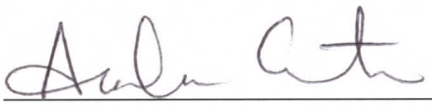
APPROVED: 

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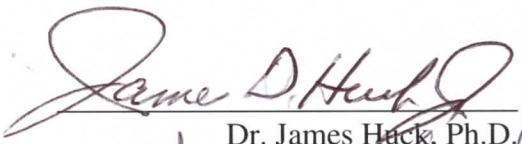

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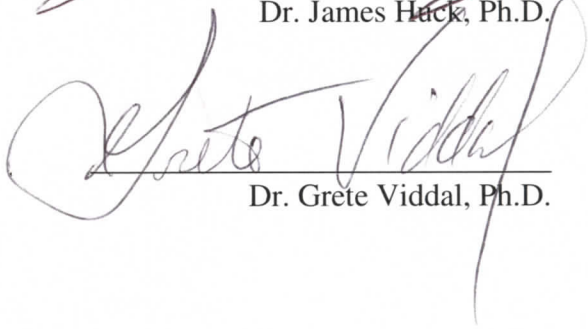

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Preface

"Para ser cubano, tú tienes que preservar la cultura del cubano. Me molesta mucho cuando hablan de cultura y se están refiriendo a lo artístico y literario. […] Sí, lo artístico y lo literario es parte de la cultura, pero cultura es qué cosa comemos, cómo nos la comemos, cómo caminamos, qué idioma hablamos, cómo vestimos, cómo enamoramos, cómo hacemos el amor... ¡Parte de ser independiente es no tener dependencia de otro país! Sí. Tú, para tener la tecnología que tenemos, [tendrías] que inventar mucho."

In June of 2016, in the stifling heat of Havana summer, Dr. Francisco Rojas Ochoa spoke these words as we shared a coffee at the National School of Public Health. This was the scrambled but heart-felt commentary he provided to prelude his analysis of Cuba's biotechnological development. That afternoon, the school's kitchen had only one cup of coffee left and in a very Cuban demonstration of solidarity he told me: *"pa' los dos"*. Rojas Ochoa is a renowned public health specialist, the founder of Cuba's first maternity home, and a member of the first delegation of medical students to bring healthcare to rural Cuba in 1960. He described to me in this interview, how ten of the thirteen vaccines that make up the national immunizations program are manufactured in Cuba—independently of the production processes in other countries. For him, what promulgates this independence is the protection of Cuba's style of healthcare. He believes that autonomy is derived from preserving Cuban healthcare, and by extension, Cuban biotechnology's freedom to remain *Cuban*.

At the time of this interview I did not trace the connection of his words to my own research on biotechnology—mostly because I had not fully undertaken it yet. But after months of my own engagement with the literature on the sector, I uncovered new meaning and new depth to his words. In an age when technology and science are

advancing at exorbitant rates, and both capital and intellectual exchange defy borders to produce highly specialized medicine, in an increasingly globalized neoliberal economy, it is easy for a nation to lose its cultural identity the further it incorporates itself into this system.

This past summer I was part of the first delegation of US students traveling to Cuba on federal grant dollars since the instatement of the embargo over fifty years ago. Although my research project was concerned with a different area of Cuban healthcare, being in Havana brought me into the realm of the country's biotechnology industry. I visited the Centro de Inmunología Molecular (CIM), Cuba's production epicenter for drugs and vaccines. Here I learned about the center's history and viewed its labs and research facilities, which enlisted my curiosity in the country's radical approach to biotechnology. This visit, my conversations with healthcare scholars in Havana, and my independent investigation set in motion this project.

Introduction

My research project investigates the emergence of Cuba's unique biotechnology sector. It analyzes the industry's trajectory from its early development to its current state under the specific political and economic circumstances that shaped it. Throughout this paper I develop one argument—comprising two parts—and venture a prognosis for the future of Cuban biotechnology. The argument I present is predicated on the premise that Cuba's model is an alternative model for biotechnology to those currently present in the US and many European countries. The Cuban model deviates from these models in that the industry is nationalized. Unlike systems in the West where biotechnology is fragmented and serves both public and private interests, in Cuba biotechnology is unified under the control of the state.

First, I contend that two factors were decisive for the development of Cuba's alternative model for biotechnology—and that the combination of these two factors is necessary for preserving the industry's alternative character. The first fundamental component is the state's unwavering control of the industry.

This permits all Cubans to hold equal equity in the industry, making them both the target population after which treatments are modeled, and shareholders in all profits the industry garners. In this sense, nationalization actively creates the conditions that distance the industry from those of other western countries. From research investment decisions to drug development and marketing, every facet of Cuban biotechnology is

dictated by the medical needs of the population. Whereas this factor determines the character of the Cuban biotechnology sector, the second decisive factor serves more to preserve it through a protectionist stance.

The post-1990s US trade embargo on Cuba, imposed through the Helms Burton and Torricelli Acts, is the second factor fundamental to maintaining the industry's "alternativism". Unlike state ownership—which essentially determines the functions of Cuban biotechnology—the embargo serves to keep these functions in place. It shelters the industry from powerful external pressures that could destabilize and ultimately compromise the industry's character. Essentially the embargo excludes Cuba's biotechnology institutions from aggressively for-profit markets in the West, thus holding the industry to its promise of producing socialized products. The embargo's critical part in maintaining the industry's unique nature reminds us of the need to situate the Cuban industry in its real-world context wherein it is subject to the demands of capital in an increasingly globalized and neoliberal marketplace.

Proceeding chronologically, the first chapter examines how state-ownership shaped and established the industry's "alternativism". The second chapter looks at how the embargo affected the kinds of trade-ventures the industry engaged in and how it shaped Cuban biotechnology's relationship with the global industry—ultimately demonstrating its protective impact.

In the final chapter, I explore the latest phase in the industry's history, which is characterized by the relaxation of the embargo, one of the necessary factors for Cuba's nationalized industry. The loosening of embargo regulations combined with President Raul Castro's eagerness to foment economic growth through economic reform, have

directly informed the goals and motivations of Cuban biotechnology. By analyzing current events, including a newly established pharmaceutical collaboration with the US, I argue that Cuba's alternative model is slowly taking on a new form. The final chapter seeks to shed light on how new developments might impact the future of Cuba's biotechnology, potentially changing its unique character.

Methods and Literature Review

Before addressing my research methods and discussing the relevant literature to this topic, I would like to briefly define biotechnology. Biotechnology is a scientific field that employs the genetic engineering of living organisms or their components to produce commercial products for specific uses in agriculture, food production, and medicine (UN Convention on Biological Diversity, Art. 2). Related and overlapping fields include genomics, applied immunology, and the development of pharmaceutical therapies. One of Cuba's most renowned scientists claimed that biotechnology's defining characteristic is that it is a *production* process (Davila, 2006:52.) The types of products that most concern this thesis are vaccines, prophylactics, and other medical therapies.

To conduct this research I used mainly archival methods and limited ethnographic methods. The bulk of my research is based on an analysis of secondary literature that originates primarily from the fields of anthropology and history and also includes a review of judicial and government documents, as well as sociological, economic, and political analyses. Most of the sources informing this thesis were derived from searches in Tulane's Tilton Memorial Library's databases, as well as ProQuest, JStor, Google Scholar, SciELO, MEDICC Review, and Infomed. Spanish language databases provided

critical in-country information on the progression of specific biotech institutions early in the industry's development. Additionally, they provided key articles on the development of Cuban drugs and their clinical processes. This information was instrumental in tracing Cuban drug development as it rejected or acquiesced to international standards of efficacy and ethicality. In this thesis I include information from one interview with an official public health informant from 2016 to supplement my analysis of published works and to introduce an individualized perspective from within the country. I personally transcribed this interview.

Scholars from several fields contribute to the conversation on biotechnology with insights from within their disciplines. Though the field's practice might be grounded in the hard sciences its implications are inextricable from the political, legal, social, and economic. Because biotechnology has broader implications than mere technological development, the industry necessitates an analysis from the fields of anthropology, history, political science, economy, law, and public health. Biotechnology's increasingly global nature implies that the legal frameworks that establish what is permissible or reprimandable in terms of the creation, production, and sale of medicine are applied across national borders. National and international law has arisen alongside biotechnology, shaping and complicating a multiplicity of conflicting definitions on what is "acceptable" conduct.

Intellectual property law and patent law bear directly on the accessibility of biotech, and regulatory law informs the industry's activities on local and global levels. While the existing literature on this subject originates from multiple disciplines, this thesis draws primarily from socio-political and anthropological analyses from the

following scholars: Simon Reid-Henry, Julie Feinsilver, P. Sean Brotheron, and Kaushik Sunder Rajan. Each of these authors contributes a unique disciplinary perspective and while they do not necessarily share a common discourse, when put in conversation with one another, they produce a more complete picture of contemporary Cuban biotech today. While Feinsilver is interested in the economic ramifications of the industry both in terms of the cost to the Cuban state and the revenues it produced for it, Brotherton has a greater preoccupation with the industry's role as an extension of public health care and medical internationalism. Brotherton and Reid-Henry rely on early data gathered by Feinsilver in the 90s to develop their own analyses. Because national fiscal information is difficult to obtain from the Cuban state, Feinsilver became a pioneer in establishing some of the early figures demonstrating the impacts of the industry. She provides not only the hard numbers for the Cuban state's investment in and returns from the industry but also describes its establishment as a medical leader in the global south. While Feinsilver tells the story of development through an economic lens, she and Brotherton focus on biotech's ties to Cuba's preventionist healthcare goals, and Reid-Henry devotes his attention to the industry's development in Cuba and the challenges it faced.

Kaushik Sunder Rajan differs from the other scholars prioritized in this thesis in two ways. The first is that his research does not directly address Cuba. He is a biologist and anthropologist interested in biotechnology in India and the global south in general. The second is that he provides an overtly theoretical analysis on the subject. While the other authors are focused on providing a descriptive landscape, Sunder Rajan imbues his descriptions with a primarily Marxist and Foucauldian understanding of the way in which biotech is articulated under different conditions. Because biotech is a heavily capitalized

branch of science/healthcare, understanding Sunder Rajan's contexualization of these extractive processes in their larger globalized, neoliberal, and even neocolonial narratives is pivotal to reading this thesis.

Also critically influential to this project are the findings made by geographer Simon Reid-Henry in his work *The Cuban Cure* (2010). Reid-Henry spent several years in Cuba leading up to the publication of his book where he took on the audacious task of compiling the authoritative history of the emergence of Cuban biotech and its current characteristics. His research led him to a number of conclusions but his primary message is this: biotechnology in Cuba is an alternative model to the industry's capitalist articulations around the world. Scholars like Brotherton, Feinsilver, and Sunder Rajan would agree with this claim, although I would include that biotech in other countries such as Egypt, India, and Vietnam in the global south have also been described as alternatives to the capitalist model (Thorsteinsdóttir et al., 2004). In exploring the rise and development of the sector, Reid-Henry sheds light on the specific processes of Cuba's approach and seeks to understand what there is to learn from local articulations of biotechnology in a world whose economy is so globalized. Also consequential to this thesis are Agustín Lage Dávila and Cori Hayden's work on the knowledge economy in Cuba, and patents, IPR, and open forum debates in the US respectively.

In a nod to Reid-Henry's theory on Cuba's alternative model, my research seeks to identify the factors that contributed to this occurrence. What this research adds to conversations about biotechnology in Cuba is an analysis of the conditions necessary for the socialized production of medical products to persist. I contend that Cuba's position on the periphery of for-profit of biotechnology combined with the country's national

monopoly on the industry have created the necessary conditions for the proliferation of a socialized model for biotechnology.

Chapter 1 of this thesis chronologically explores the development of Cuba's biotechnology industry. I address the specific ways in which the industry's socialized model functions through an exploration of its drug developments and the establishment of key research and development (R&D) institutions. This chapter seeks to identify how the relationship between the government and the industry has steered research towards national health needs and the nationalization of profits.

Chapter 2 is concerned with the second factor that I argue was critical to the protection of Cuba's socialized model for biotechnology: the embargo. In this chapter I address the specific legislation that blocked Cuba out of trading markets for biotechnology supplies and sales (the Torricelli and Helms-Burton Acts). I describe how in the 1990s, this legislation had the effect of incentivizing Cuba to produce the drugs and vaccines it could no longer buy from the US, and subsequently how it protected Cuba from trading in destabilizing and aggressively for-profit markets. Finally, I address how the embargo shapes Cuba's status within the globalized biotechnology marketplace today and allows it to bypass many of the regulations imposed by international trade organizations.

Chapter 3 provides insights into how contemporaneous events might influence the future of Cuban biotechnology and how its unique model might be affected. I address the political and economic developments occurring both in Cuba with Raul Castro's implementation of mixed-market policies, and in the US with the easing of embargo regulations. Tracing the ways these changes are shaping the context for Cuban

biotechnology facilitates an understanding of the industry's future direction. Finally, this chapter looks at a current medical trade venture between Cuba and the US and addresses some of the voices within the US pharmaceutical industry who speculate about investing in Cuba.

Chapter One: The Development of Nationalized Biotechnology

Introduction

This chapter opens with a brief historical contextualization of Cuba's healthcare and medical education sectors and how they developed throughout the country. The development of these sectors was critical to the development of Cuban biotechnology twenty years later, primarily because they trained the doctors and scientists who would go on to work in biotechnology. These industries also laid the groundwork for Cuba's socialized biotech model. The next section addresses Cuba's early inroads into the field with interferon research, followed by a section on the establishment of Cuba's core biotechnology institutions. Then I explore the concept of *do-ability* and Cuba's approach to cancer research followed by a section on Cuba's development of the first meningitis B vaccine—product of the industry's commitment to finding solutions to national health epidemics. Finally, this chapter concludes by addressing some counterpoints and by examining Cuban biotechnology in its global context.

Healthcare and Education for *Cubanos*, Not Just *Habaneros*: Reforms that Informed the Purpose of Cuban Biotechnology

To preface the emergence of biotechnology in Cuba, I will briefly recount the origins of the country's public healthcare sector. In order to understand the motives for national investment in biotechnology the reader should have a basic knowledge of the country's attitudes toward public healthcare and medical education.

Following five years of guerrilla warfare, in 1959 the 26 of July movement succeeded in deposing Fulgencio Batista. At that time, Cuba lacked an articulated public healthcare system. Doctors practiced medicine independently and those who practiced for the state were relegated almost entirely to Havana. Dr. Francisco Rojas Ochoa—physician, academic and retired Public Health director of Camagüey province, put it this way,

> There are two different situations, one in the city and major towns, and one in the countryside […]. In rural areas there are no health services, state or private. The revolutionary government began to worry about these people because the war was fought mostly by peasants and [the revolutionaries] saw how bad their conditions were. (F. Rojas Ochoa, personal communication, July 13, 2016)

One of the first reforms made by the new government was to carry out *misiones de campo* whereby doctors were sent to work in communities outside of Havana and as far away as Holguín and Santiago de Cuba provinces. The premise of these missions was to assess the health needs of Cubans throughout the country and treat the most preventable, as well as the most life-threatening diseases. The first attempt at this failed however, because doctors were not willing to leave their established clienteles and the comforts of the city. The new administration would have to propose a strategy to incentivize rural medical campaigns and implement a culture of solidarity where there had previously been no pretext for socialized medicine.

It seized the opportunity to expand healthcare with the first class of medical graduates. During the last years of the dictatorship, the school of medicine in Havana was closed down and when it was re-opened under President Castro, he implemented a law for the graduates of 1960—law no. 723, “Servicio Médico Social Rural”. The statute ruled that students would have to spend six months working in a rural community if they

wanted to go on to work in the country's public health sector. This meant that any student who aspired to work in a public hospital, polyclinic, or family doctor's office would have to comply. While the law was not compulsory, it brought the majority of medical graduate students to heel. Over the years, the program successfully eradicated some of the most critical diseases of poverty in the country (García, 1996[10]).

Programs like "Servicio Médico Social Rural" were not embraced by many doctors or even many residents in Havana, however. The abrupt and vehement shift towards a consideration of the entire island's health needs unearthed a wave of resistance from the capital. Formerly, the national gaze had not wandered outside of city limits. Wealthy Cubans living in the capital experienced health indicators resembling those of higher income countries in the 1950s, while rural Cubans lacked the tools for basic hygiene such as plumbing, clean water, or even simple latrines (Perez, 2008:8). The vastly different lives of Cubans in the rest of the country included experiencing dismal quality of life from childhood to old age due to easily treatable diseases. Among these diarrhea, scabies, small pox, hemorrhagic conjunctivitis, leptospirosis, malnourishment, intestinal parasites, and sexually transmitted diseases (Ochoa & Pardo, 1997:804).

Those who owned the means of healthcare-production in Cuba at the time were the owners of large and profitable medical clinics, the members of *mutualistas* (mutual benefit societies), and the physicians themselves who, without a system for progressive financing, charged out-of-pocket for their services. The threat of losing their assets set in motion a chain of emigrations that would continue throughout the 1960s leaving Cuba with 3,433 doctors, half of the physicians it had in 1960 (Brotherton, 2011:478). The emphasis on dismantling the *mutualista* and private healthcare systems in the country was

materialized, at least symbolically, with inauguration of the law on "Servício Medico Social Rural". This law was a first step in establishing the "Sistema Nacional de Salud" (SNS), Cuba's country-wide public healthcare system.

Those in medical school at the time had a decision to make. One option was to join the ranks of new and inexperienced doctors in a clumsy, poorly organized, and understaffed national healthcare project—in which resources were limited and infrastructural complexities had not yet been resolved. Or join in what was becoming a culture of emigration for Cuba, and flee to the US, Puerto Rico, or Spain to pursue greater financial opportunity. Ambivalence, financial restraint, or commitment to revolutionary values, were some of the motivations that grounded these students, making them the forerunners of the Sistema Nacional de Salud (SNS), Cuba's first public healthcare system.

Rojas Ochoa's experience as one of the first doctors to practice medicine in the countryside is symbolic because as a young medical student, he represents the first generation of Cubans who begun to understand disease as a social problem and not just an individual condition of the body. Coming face to face with Cuba's national health problems constituted a shift in the educational paradigm for medical students who were not only being compelled to conceive of medicine differently but also to expand the audience of their labor from wealthy *Habaneros* to all Cubans. The belief that doctors alone could cure the preventable diseases of the country was replaced by the idea that poverty was the prevailing factor in disease and that improving healthcare would have to occur contemporaneously with improving social conditions (Brotherton, 2012).

Along with these changes, the government carried out a development in the extension of its scientific and medical education that would include the whole country. An educational reform was put into effect in 1962 founding the second school of medicine (after the one in Havana) in Santiago de Cuba and the third in Santa Clara by 1966 (García, 1996). By 1971, 30% of all university students were medical students (Brotherton, 2011:478).

As access to medical education was expaned to students in the rest of the country, Cubans in their own communities gained the tools to improve their local health outcomes. In 1976, medicine and other sciences developed independent branches from academia to create their own centers for technical learning (García, 1996). One such institution was the National Center for Scientific Research (CNIC), the pioneering research-training center that predates biotechnology. Established in 1965, the center graduated more than 32,000 experts in various fields over the course of 45 years (Mendoza, 2011). Many scientist working in biotechnology were also medical doctors. With the advent of research-training in the various areas of biotechnology came the first wave of doctor-scientists who introduced a pointedly social approach to the founding institutions of Cuban biotech. Establishing research-oriented infrastructure was a core objective of the Revolutionary government from early on in its administration. However it did not divert its full financial attention to the sector until a viable healthcare system was established throughout the country (Reid-Henry, 2010:31).

Centralized networks of polyclinics and arose alongside the country's expanding medical educational system. Cubans throughout the country began receiving care administered by doctor-nurse teams and gained access to an array of primary healthcare

services including dentistry, psychology, optometry, gynecology, geriatric care, pediatric care, and maternity care. The evolution of Cuba's community-based healthcare system signified a shift away from underfunded and overrun medical outposts in the 1960s, to an organized network of facilities that succeeded in raising national standards of living and improving health indicators across socioeconomic backgrounds. By 1976 the country counted on 344 fully staffed polyclinics and 140 rural medical outposts—a well-equipped system that would be protected and grown through state funding over the years, despite economic hardship (Brotherton, 2012:69). In 1984, the Ministry of Public Health launched the *Programa del Médico y Enfermera de la Familia* (MEF). This program called for family physician and nurse teams to live and work in the communities they serve in small clinics known as *consultorios*. By 2009 the MEF included 34,261 physicians and oversaw 100 percent of the Cuban population (Brotherton, 2011:481). Acting as an intermediary between the community and the local polyclinic, the MEF provides a closer relationship between doctors and their patients in a way that ensures continuity of care (Brotherton, 2011).

As Cuba eradicated most of the country's infectious diseases and the disease landscape changed towards increasingly chronic health problems such as cancer and heart disease (in the late 1980s and 90s), the science behind medicine also adapted its objectives to meet these challenges. If prevention was instrumental to the elimination of infectious diseases, more imaginative and expensive recourses would be necessary to find cures for Cuba's chronic diseases. And so in 1973, the Deputy Ministry of Teaching and Scientific Research was created as a branch of the Ministry of Public Health followed by the establishment of the National Council of Science and Technology (CNCT) in 1974.

The creation of these centers signaled a repositioning of Cuba's priorities towards innovation, over simply the provision of healthcare (Reid-Henry, 2010:31).

The Making of Cuban Biotechnology: How Collective Needs Benefit from Collective Ownership and The Role of Interferon

Biotechnology in Cuba arose alongside biotech in the more industrialized nations of the Western hemisphere. The US and a few European countries were the first to begin exploring the field, and Cuba precociously joined their ranks at a time when very few industrialized nations had biotechnology on their radar. Unlike the US and European biotechnology though, Cuban biotechnology was motivated by more than just an impetus to advance medicine. It was motivated by crisis. The US embargo (beginning with the 1990s sanctions imposed by Helms-Burton and Torricelli) induced a total collapse of the country's medical supply chain. And despite the government's continued investment in the SNS, drug shortages obstructed the healthcare system's ability to provide care (Brotherton, 2012).

Cuba's dependence on US medical supplies was still distressingly prominent in the early 1990s. Even today, most of the world depends on the pharmaceutical products of the US and handful of other countries—although many nations now count on local sectors for the production of generic drugs (Davila, 2006:52). In Cuba's case however, the flow of medical products from the US was abruptly severed in the early 1990s. In a matter of months Cubans lost access to prescriptions, over the counter medicines, and the supplies necessary to provide surgeries. The country's fledgling biotechnology sector was suddenly under immense pressure to fill the gaping void in drugs and medical supplies

left by the US (Presno Labrador & Sansó Soberat, 2004; Gorry, 2004). Thus, the development of Cuba's biotechnology industry was if not borne out of, then certainly accelerated, by the US embargo.

Biotechnology emerged as a discipline in the US and Europe in 1970s through a combination of factors; mainly government funded university research, private investors, and the right political actors to ensure an amenable set of regulations for patenting living matter. Early developments in human vaccines created exciting prospects both for medicine and for capital, putting the field at the forefront of global political consciousness. The US and Finland were the first to make advances in the field but by the mid-1980s, other countries also began creating their own sectors. Early on, Cuba took steps to invest in the facilities, technology, and information necessary to cultivate its own sector. At its outset, early experimentation with biotechnology seemed like a natural step for the revolutionary government who had, since 1959 placed science and medicine at the forefront of Cuban development (Reid-Henry, 2010:3-10). But while the path of Western biotechnology lead to economies of excess, in Cuba, the advent of the 1990s US sanctions threw its still underdeveloped biotech economy into a crisis of scarcity.

In instances of national disaster, a government's response is only as efficient as its ability to mobilize its industries. At the outbreak of the medical crisis, Cuba's response was to solicit aid from humanitarian organizations (such as People-to-People) and to import pirated and generic versions of US products (Feinsilver, 1992). But greater reforms took place internally. Throughout the late 1980s and 1990s the State Council set in motion an overhaul of biotechnology that would soon capacitate the industry to cast a much wider net to meet Cubans' basic medical needs. This response could not have been

induced without collective ownership of the industry. It was ultimately the state's uncompromising jurisdiction over the biotechnology's processes that gave way to reforms that would benefit the majority.

It was not always obvious that Cuba would rely on itself for vaccines, drugs, and medical supplies, though. The country could have easily continued to purchase most of its basic pharmaceuticals from the US and aimed its biotech research towards other areas. But after the onset of the strictest embargo regulations, the biotechnology sector would be elevated to a rank similar to the country's public healthcare system (Reid-Henry, 2010). The industry became primarily accountable to the needs of the population, prioritizing the timely development of treatments and cures for diseases afflicting the masses. The industry's accountability to society is an indispensible component of what renders it "alternative" to Western biotechnology.

Before the onset of the 1990s sanctions, however, the government had invested in a drug thought capable of curing cancer, interferon. Interferon was at the vanguard of the biotechnology industry internationally in the late seventies and early eighties (Reid-Henry, 2010:45-49). The State Council purchased machinery to process the drug and sent groups of scientists to study in international labs where interferon research was conducted. Natural interferons are signaling proteins released by certain cells in the body in response to the presence of pathogens, or as part of an immune response to viral infection. When processed they can reduce the growth of cancerous cells (Fensterl & Sen, 2009). The two groups of Cuban scientists who were sent to receive interferon research-training abroad would go on to found the country's first biotechnology institutions (Reid-Henry, 2010). Interferon research effectively set in motion the nation's first drug-

production operation and set a precedent for the kind of investigation that would be conducted for decades to come.

As the Cubans processed interferon they learned about their own capacities. They grappled with issues of strategy and resource management, and found exceedingly creative applications for the drug (interferon was instrumental to the development of Cuba's hepatitis B vaccine (Reid Henry, 2010:46). Biologist Pedro López Saura, director of clinical trials with interferon noted, "Interferon served for all our methodological development: the first cloning, the first expression, the first fermentation, but then we applied it elsewhere, in growth factor, or the hepatitis B vaccine […] [Our interests] were now directed at wider issues, above all questions of genetic engineering" (Reid Henry, 2010:46).

Interferon was a one-size fits all drug, with seemly limitless possibilities for the kind of research it could impact. It was in this style that Cuba modeled its entire approach to biotechnology—to do more with less, to find answers within the existing research, and to pursue results from the locally available material. Going against the grain of the other industries' tendencies to reach for the cutting edge, Cuba discovered how to innovate using the hand it was dealt (Reid-Henry, 2010:23-46).

Two research centers in particular were at the vanguard of interferon manipulation in the late 1970s. One was M. D. Anderson Hospital in Houston and Kari Cantell's lab in Helsinki (Jiménez, 2011). In the shadow of moderate embargo restrictions, Anderson Hospital founder and cancer specialist Dr. Ralph Clark and President Castro struck up what would become a high profile friendship in 1980 (Jiménez, 2011). This personal encounter wherein the two men shared a fondness for

each other—and a fondness for humanitarian values within medicine—was the open door through which Cubans gained access to exclusive networks of biotechnology research. This allegiance between Fidel and Clark is characteristic of the Cuban model. And it illustrates the depth of the state's involvement in the direction of the industry. Because Cuban biotechnology is inextricable from the social and political, those willing to aid the Cubans were most often proponents of the same values as the revolutionary government (Reid-Henry, 2010:14-18).

The exchange between Clark and Fidel would thereafter prompt the American cancer specialist to host two Cuban researchers for training at Anderson's facilities, doctors Victoria Ramírez and Manuel Limonta. Clark further aided the Cubans by pointing them towards Finnish researcher Kari Cantell. In Helsinki in 1981, another group was sent to accelerate their research with interferon and gain the skills needed to launch their own operations back home (Feinsilver, 1992:83, Reid-Henry, 2010:12-18). A team of six doctors, two of which were also biochemists, was sent to Cantell's lab where he showed them the techniques involved in the process of mass production and purification of interferon. The Finnish scientist viewed interferon as a resource to be shared. He defied the commonplace practice of patenting his technique by instead generously divulging the specifics of his process to those interested (Lindenmann, 1998:845). In this collaboration as well, the personal and political was inextricable from the Cubans' relationship with Cantell. And the government's involvement in securing the deal and the materials the researchers would need to initiate their own operation in Havana demonstrated its heavy-handed involvement. Later on Cantell's purification technique was patented by the president of the American Cancer Society who set up a US

company that produced and sold purified interferons at double the price of Cantell's (Lindenmann, 1998:845).

With Cantell's advice and the necessary state funding, the Cuban group created its first biotechnology lab in a converted villa dubbed "House No. 149". In just a few weeks Cuba was producing large quantities of purified interferon (Reid-Henry, 2010:16). However, those amounts were not enough. Cantell's method alone did not produce high enough quantities for clinical purposes. This posed a problem because the state's entire impetus for investment hinged upon interferon's eventual use in clinical treatment. Quickly though, molecular biologist Luis Herrera and other Cuban researchers were able to develop their own method for cloning interferon and in 1984 they produced "a second-generation interferon, recombinant alpha-2b, cloned in yeast" (Reid-Henry, 2010:47). Despite Cuba's late arrival to the scene, it was able to overcome the scientific hurdle of insufficient interferon production and advanced to the testing phase whence it became the first country to apply interferon in clinical trials (Reid-Henry, 2010:54).

Outside of Cuba, the vibrant work once undertaken on interferon began to wane, as did the excitement surrounding its potential. Before much had been proven, scientists had envisioned it as a miracle drug whose inherent properties, if harnessed correctly, would be capable of *curing* a disease as complex as cancer (De la Fuente, 2001:905). When in the US and Finland it became evident that interferon would not live up to that lofty goal, they abandoned it and moved on to exploring other compounds. Cubans, on the other hand, recycled this research and moved forward using different techniques from those previously employed. Despite not becoming a blockbuster drug, interferon led the Cubans to greater discoveries in the field of genetics and ultimately to the production of

vaccines (Reid-Henry, 2010:17-8). Engineering creative solutions out of limited resources is another characteristic that sets Cuba apart in the global industry. Scientists' ability to innovate with a fraction of what is available to biotech industries in foreign countries is both a product of necessity and a sign of quality education in Cuba.

Cuba's interferon story is illustrative of this innovation because it shows how the country took a low-cost drug which was deemed ineffective by a majority of foreign researchers, and with a fraction of what other nations had invested in cancer research over the years, was able to develop products that contribute to the control and prevention of cancer. Cuba now has head, neck, and lung cancer vaccines in advanced stages of R&D—with its lung cancer vaccine being administered both nationally and to thousands of European patients (Almendrala, 2016).

The timing of interferon's arrival in Cuba is also consequential to the story of Cuba's biotechnology development. It occurred when the harshest embargo regulations of the 1990s had not yet been imposed and it was possible for Cuba to engage freely with both the US and Finnish biotechnology sectors (Gorry, 2004). The local interferon project would have been rendered impossible without the resources and training it received from the US and Finland. It was these early inroads established in the 1980s that fundamentally capacitated Cuba for future research beyond interferon. Because biotechnology was only just emerging as a field of research in the US and Europe at the time, Cuba's contact with these epicenters provided the critical impetus it needed to undertake its own operations. The window of opportunity for international exchange of resources and ideas quickly closed after 1992 when US congress passed the Torricelli

Act. But by that point, Cuba had already made substantial discoveries (Reid-Henry, 2010:19-22, 38-39).

Industry in Motion: The Biological Front and The Scientific Pole

Upon the return to Cuba of the scientists sent to Helsinki, researchers and government administrators alike were filled with a sense of possibility. The government's idealistic objective of becoming a powerhouse for science and technology was actually coming into focus. In the weeks that followed, the government would create a highly enfranchised organization called the Biological Front. It was created in the very Cuban style of generating experimental bureaucratic entities whose powers are not founded in any constitutional legitimacy but that are designed to expedite development according to its own agenda. Being governed by science directors and policymakers, and having direct access to the State Council, the Biological Front was not reticent to use its newly acquired power. Between 1981 and 1989 the Biological Front poured one billion dollars into the biotechnology industry, establishing an infrastructure involving multiple research and production facilities, processing plants, and the equipment, information sharing, and raw materials necessary for institutional ventures that would eclipse the interferon project (Reid-Henry, 2010:50-1; Davila, 2006:52).

The biotech industry was also growing in brainpower. Universities and technical schools founded across the country in the 1970s began graduating students at rates that would have been unimaginable under the country's pre-Revolutionary, Havana-centered higher-education system. Cubans were increasingly gravitating towards careers in the medical and scientific field, as evidence by the following data. As early as 1986, Cuba

counted on almost 40,000 scientific workers, one for every 282 people on the island. Over half of these workers were involved in biotechnology research and half of them were under the age of 35. The percentage of women scientists employed in Cuba rose above rates in the UK in similar institutions. And over the years, female scientists in Cuba surpassed rates in other Latin American countries as well (Reid-Henry, 2010:70; Reardon, 2016:602). The biotechnology industry also employed several groups of students who had not yet earned a Master's degree. Nonetheless, more seasoned directors empowered students to be in charge of their own projects and their own labs (Reid-Henry, 2010:70). This investment to educate a critical mass of scientists through intense application in the field is an important quality of what renders Cuba's model for biotechnology alternative. The Biological Front prioritized resources for the education of these students and ultimately expedited the creation of a generation of biotechnologists. The mobilization of these educational funds, which capacitated the industry with critical brainpower over a short period of time, is the direct result of the nationalization of biotechnology. The state's ability to make unified decisions and to invest, quickly and resolutely, in the training of researchers is what propelled the industry forward.

Another characteristic of the Cuban model, which is both "alternative" and significant to its expedited development, is its culture of improvisation. This is evident in the industry's willingness to apply untested methods to interferon in attempts to achieve relevant results. And also in its flexible conduct when it allowed inexperienced students to have exceeding autonomy over their own research in hopes of achieving greater levels of innovation (Reid-Henry, 2010:70).

Throughout the 1980s and 90s the Biological Front invested in the creation of Cuba's foundational research institutes. These centers were built in a cluster at the Western periphery of Havana. They were built in an imitation of "science parks" which are found in the US, Japan, and Europe. The area was created to localize resources and promote collaboration between institutes. Biomaterial suppliers, educational institutes, and production facilities are some of the composite parts of Havana's "Scientific Pole". However unlike the science parks in the US that usually represent a handful of companies working under one area of research, the Scientific Pole comprises the majority of Cuba's biotechnology industry whose institutes are dedicated to a multitude of research areas (Reid-Henry, 2010:56-7). While science parks in the US vie for profits alongside others in the industry, the Scientific Pole is bereft of this kind of competition due to the lack of influence of private capital. One of the ways that the Scientific Pole stands out as characteristically Cuban is that it also provides housing for several thousands of the scientists that it employs. Social services such as daycare for children are also available. By providing these services, the Pole seeks to foster collaboration between scientists from different institutes and provide unified objectives instead of individualism in each institute (Reid-Henry, 2010:77). Again, this facet of Cuban biotechnology is representative of how the social and the communal are inextricable from the medical and the scientific.

Simon Reid-Henry identifies two significant motivations for the clustering of the Scientific Pole in Havana. The first has to do with the State's desire to foment collective problem solving through information sharing across industries. By placing all of the industry's institutions in close proximity, and adding the community component of

shared living, a greater sense of personal commitment to common medical goals is fostered. Secondly, and more importantly, he argues that this decision originates from the state's desire to retain political control over scientific processes (Reid-Henry, 2010:67-9).

Cuban biotechnology's centralized geography allowed the state to retain its gaze over the industry and allowed it to maintain a close involvement in its processes. Close proximity between federal administrators and the directors of the Pole's institutes is key because it solicits a perpetual conversation on the status and direction of research. This dynamic acts as a check on the industry's commitment to national health objectives (Reid-Henry, 2010:67-9).

In US and European systems of biotechnology, this dynamic has no place. This is primarily because biotechnology industries in these countries do not answer primarily to the state, rather they respond to a mixed market economy and are not necessarily tied to national healthcare responsibilities. In Cuba, government ministers and members of the Political Bureau of the Party regularly attended the Scientific Pole's meetings and, the former director of the Scientific Pole, José Miyar Barrueco, was also one of Fidel's closest advisors (Reid-Henry, 2010:58-9).

The CIGB, CIM, and Cuba's Cancer Drugs

The Biological Front made its first major investment in 1986, when it founded Cuba's flagship institution, the Center for Genetic Engineering and Biotechnology (CIGB). The center received an initial $25 million dollars and over the next few years would receive an additional $100 million from the government. While hugely significant for the island, these figures pale in comparison to what a center of a similar status might

have cost in the US. The CIGB is the perfect representation of Cuba's low-cost, high return model because despite its limited resources the center punched high above its weight. It is considered the grandfather institution of Cuban biotechnology and is responsible for the R&D of most of the products sold, traded, or donated to its allies in the middle and low-income countries (Feinsilver, 1992:87-90; World Bank, 2016).

Internally, the CIGB comprises several sets of research groups, working in different areas such as: cell genetics, proteins, hormones, vaccines, diagnostic kits, restriction enzymes, and quality control. The center's facilities and administration are structured in a way that expedite full-cycle production, and to this end the State Council allocates funds for specialized technology such as massive spectrometers, automatic sequencers, electron microscopes, and DNA synthesizers. These measures in particular helped equip the CIGB for research oriented towards the development of pharmaceuticals, immunodiagnostics, and vaccines (Reid-Henry, 2010:53; Evenson, 2007).

In 1991, the CIGB established Heber Biotech, S. A., a subsidiary company with exclusive rights to market the CIGB's products. Along with CIMAB, a similar marketing subsidiary for Cuba's molecular immunology center, these entities are the only ones allowed to sell molecules and engage in international joint ventures on behalf of the entire industry (Evenson, 2007:9). These subsidiaries wings of Cuba's R&D institutions are peculiar precisely because they are integrated into the same centers where drug testing and production occur.

This model contrasts that of the US, the UK, and others wherein there is "upstream" research, and "downstream" production and sales, which constitute two

different economies (Sunder Rajan, 2012:343; Reid-Henry, 2010). Within these systems biotechnology discovery and production originate from several sources such as start-ups, academic institutions, and sometimes from within pharmaceutical companies. These producers have to then convince pharmaceutical companies of the potential of their molecule in order for them to purchase the rights to it. Subsequently, if the drug passes the necessary clinical and regulatory trials, the pharmaceutical companies must advertise and sell the drug to the public (Sunder Rajan, 2012). Operating independently from state control results in a much more complex and even convoluted system wherein an inherent mistrust arises between the industry and regulatory agencies. The separation between molecule discovery, production, and marketing—combined with the uncertainty introduced by considerations of cost-benefit for the companies, sparse R&D funding, speculative markets, high costs of development, patent cliffs, and long public health approval waiting-times—make for a splintered industry that faces aggressive obstacles to efficiency and innovation (LaMattina, 2012; Sunder Rajan, 2012:323). Unlike Cuba's state-owned marketing branch, the multiplicity of factors that influence a biotechnology company's ability to bring a drug to market in countries like the US and UK, may ultimately cause this system to become unresponsive to the healthcare needs of the population.

Alongside the CIGB, the other institution that is equally prominent in the Scientific Pole is the Center for Molecular Immunology (CIM), which became operational a few years after the CIGB in 1990 but didn't officially open its doors until 1994. While the CIGB's research orientation spans a diversity of fields, the CIM is primarily focused on cancer research. Its main orientation is towards the development of

monoclonal antibodies, and more recently, research on epidermal growth factors (EGF). Cuba's particular interest within the field of the diagnosis and treatment of cancer is in immunotherapy (Evenson, 2007:9).

It is easy to see why the Cubans would be inclined to explore immunotherapy. As I describe later on, it is an area of cancer research that finds ways to harness natural immune functions to prevent or halt the growth of tumors. It is not only more affordable than surgery (to remove tumors) because it is non-invasive, but it also seeks to attack cancer before it fully develops. Cuba's investment in preventive medicine within biotechnology is a logical extension of its preventive tactics within its healthcare system.

The CIM, as well as all of Cuba's biotechnology industry, is guided by the notion of *do-ability*, a term that has both practical and economic repercussions and constitutes an aspect of its "alternativism". In the practical sense, Cuba is dedicated to investing in resources that can be utilized for several purposes. Monoclonal antibodies and interferon research, for example, share the property of being useful for jump-starting several kinds of research (Reid-Henry, 2010:98). The other practical aspect of *do-ability* is Cuba's dedication to achieving set goals, whether that be creating a diagnostic kit or producing a vaccine, the industry works in unison to achieve concrete ends. In theory, achieving a tangible product appears like a logical goal for any biotechnology industry regardless of the country. But systems of biotechnology that are subject to market demands experience greater obstacles. Companies in these systems are in competition with one another and are always tethered to their own budgets and financial considerations. In places where state control over the industry is weak, these processes become convoluted and valuable molecules that could turn into useful medicine get stranded somewhere along the research

to market pipeline (LaMattina, 2012). Divisions between the private sector and the state can also lead to higher waiting times for products to receive clearance that they are safe to use for the public. This could be due to the minimal participation of the state throughout the R&D process (Sunder Rajan, 2012). In Cuba the government is involved at every step, meaning there is a greater exchange of information throughout the process of discovery and testing. There is also an impetus on the part of the government to expedite bringing drugs to market—a condition that may not be as salient in countries where the government acts as a regulator rather than a partner. In terms of the economic aspects of *do-ability*, for Cuba, the maximum return on a medical investment seems to be the creation of a product that serves a pressing public health need, regardless of whether or not it garners international revenues. In systems of for-profit medicine, however, where the community is both the patient and the client, success is contingent on the product's marketability and its ability to reproduce profits, in addition to its ability to serve a public health need. This condition shapes the motives behind the type of medicine that is produced in these systems of biotech and leads to an overemphasis on treatments over cures.

By the aforementioned understanding of *do-ability*, the CIM's dedication to immunotherapy in cancer research poses a query. Only in the last few decades has immunotherapy become part of treating some types of cancer. Immunotherapy is considered to be an area of treatment that supplements individualized treatments, such as surgery, radiation, or chemotherapy, which are more proactive approaches for removing cancer (American Cancer Society, 2016; A. Vigh, personal communication, December 6, 2016). What renders immunotherapy more tedious than other approaches is the fact that

the immune system naturally recognizes cancerous cells as the body's own. These cells can progress unobstructed because they are overlooked as a threat to the body (A. Vigh, personal communication, December 6, 2016). The problem that Cuban researchers set out to resolve was how to trigger an immune response that blocks cancerous cells or inhibits their growth. If it were possible to fight cancer from within, through the manipulation of immune responses, this method would lower the need for invasive, painful, and costly procedures that constitute the usual cancer treatments today (Reid-Henry, 2010:96-100). But as Stephen Hall points out in *The Cuban Cure* (2010), owing to the fact that immunotherapy was not considered as viable as other alternatives by specialists in the US and Europe, Cuba was locked out of billion-dollar cancer research funds that were available to groups working on more mainstream areas of cancer research (p. 97). Returning to the principle of *do-ability*, when we consider that there are cancer treatments that are more widely researched and more widely implemented than immunotherapy, it appears as though the Cubans were diverging from this commitment by exploring an area that was potentially unsound. However, intrinsic to the idea of *do-ability* is affordability and mainstream cancer therapies are costly. Not only this, but they are also overly oriented towards the removal of advanced tumors instead of tumor-prevention.

In the US, it is the cancer patient and their insurance company that absorb the cost of chemotherapy and tumor-removal surgeries. In Cuba, however, the state is responsible for these therapies. Under the country's single-payer structure the state is acting in its own financial interests when it invests in the development of cures and treatments that are preventive and inexpensive. Still, cancer is notoriously complex and the CIM had to be willing to risk time and funds to investigate the processes of different cancers in the body

before attempting to manipulate cellular and immune responses (Reid-Henry, 2010:90-99). It took several years before bioscientists arrived at meaningful results, but as a result of these decisions, today Cuba boasts of several cancer drugs that are in mid-to-late stages of development. The industry also created its own cancer imaging technology (Thorsteinsdóttir et al., 2004). An essential do-able component of Cuba's cancer drugs is that they are a one-for-all solution. Certainly individualized cancer treatment is still necessary but by learning to manipulate immune responses to prevent cancer growth the CIM's scientists are able to target these specific responses in all patients. Cuba's decision to invest in this particular kind of long-term cancer research hinged upon the structure of its preventive healthcare model. Whence most infectious diseases were mitigated, chronic diseases became the leading causes of death on the island. Cancer accounts for most deaths among people under the age of 65 in Cuba and is the second cause of death for people over 65 (Reid-Henry, 2010:96). As we will see later on, the country also had other motivations for investing in cancer research.

Three drugs in particular represent the crowning achievements of the CIM's immunotherapy efforts. These are Nimotuzumab, Racotumomab, and CimaVax. Cuba's position within foreign biotechnology markets shifted with the release of these drugs. While Cuba had previously distinguished itself in the field, it is important to note that these cancer drugs were at the forefront of its appeal and they solidified the country's status as a capable biotech manufacturer (Reid-Henry, 2010; Almendrala, 2016).

The first drug, Nimotuzumab, was patented by the CIM in 1999 for the treatment of head and neck tumors. It is currently an option for patients in a few countries, not including the US, for the treatment of squamous cell carcinomas. Scientists believe it

could have greater potential than what has already been discovered (Ramakrishnan et al., 2009). The second, Racotumomab, is in phase two and three trials in Cuba and is a drug that targets a molecule believed to exist on all cancer cells. Cuban and US researchers agree that the drug could eventually become effective against solid tumors that arise from diseases like lung, breast, prostate and colon cancer, as well as on certain blood cancers (Lee, 2016). The third drug is CimaVax—the CIM's leading cancer vaccine in terms of its efficacy and its significance to the most common type of cancer in men (lung cancer). CimaVax works by reducing the growth of tumors in patients who are at-risk for developing lung cancer a second time. The term vaccine can be misleading though, because unlike Cuba's vaccines for meningitis, tetanus, or polio, CimaVax does not prevent lung cancer from occurring. The way it functions is by inducing an immune response that neutralizes a growth factor circulating in the blood of lung cancer patients that has been linked with tumor growth. CimaVax essentially starves the tumor of the necessary growth factor, inhibiting the spread of lung cancer. While it may not eliminate tumors, it prevents their growth with minimal toxicity to the patient. The vaccine allows patients to live several months, and even years, longer than current treatments with good quality of life. CimaVax passed all clinical trial phases and is marketed in Cuba, the UK, and a few other countries. 5,000 patients have been treated with it worldwide; 1,000 of these being in Cuba (Lee, 2016). As specialist Dr. Kelvin Lee remarks, right now CimaVax is most relevant for lung cancer survivors at risk for relapse, but it has the potential to lead to further discovery in the way of treatments and cures for all cancers (2016).

Cancer drugs are having a different effect for Cuba's biotech economy than the usual products that the industry has a history of marketing. While most of Cuba's products are sold to lower income countries—due to their appeal to affordability and infectious diseases—the advent of Cuba's cancer drugs has brought the country under the spotlight of more lucrative world markets where diseases like cancer are lucrative and lacking in innovative approaches (Reid-Henry, 2010:94-102). The Cuban industry stands to benefit financially from cancer drug partnerships with Canadian and, more recently US entities (Evenson, 2007; Roswell Park, 2016). CIM director Agustín Lage Dávila explains that the country has historically been cautious when dealing with these kinds of external markets because the state seeks to "avoid giving the relationships between the biotech industry and [Cuba's] health care system a market character" (2006: 54-55). Scientists like Dávila caution against incentivizing biotechnology research and development for the purpose of exportation because the greater the incentive to export, the greater the incentive to create sell-able drugs. Nonetheless, Dávila argues that from its outset the biotechnology industry recognized that exportation would be a precondition to its viability because the fixed costs of R&D and quality control are too high to be covered by the domestic market (2006: 54-56). Additionally, it had always been part of the state's objective to produce national wealth through biotech sales. In the chapter two I explore how embargo regulations are currently affecting Cuba's status as an "exporter" within the global biotech marketplace and in chapter three I return to CimaVax and its role in spearheading trade relations with the US.

Cubans First: The Finlay Institute and Va-Mengoc-BC

Of the core institutions comprising the Scientific Pole, the Finlay Institute, established in 1987, has the greatest focus on the development of human vaccines. It is a task that it undertakes in large part with its sister institution, the CIGB. The history of the Finlay Institute's creation differs from those of the other centers, and an analysis of its role can provide distinct insights into the ideological imperatives of Cuba's alternative biotechnology sector.

Many factors affect the orientation of Cuba's socialized biotechnology industry. Some of these are related to national health needs and others are aimed to profit generation. Julie Feinsilver provides much of the research on Cuba's internationalism, demonstrating the mechanism whereby the country uses biotechnology sales to grow its national revenues while simultaneously acting as a socialized biotechnology provider to countries in need (147-153:1993). These elements greatly influence the types of institutions created and decisions regarding which projects to invest in. The government (assessed by science advisors) is carefully selective with its funds, and, as exemplified by the multi-purpose interferon and monoclonal antibody projects, aims to maximize gains (social and financial) from their limited investments. Constitutive of Cuban biotech, therefore, are long-term projects such as cancer-treatment and the creation of medical products that are easily marketable, such as AIDS diagnostic kits. But the spontaneous circumstances spurring the creation of the Finlay Institute reveal another aspect of Cuban biotech's priorities. Despite considerations of value generation, when a national health crisis arises, the sector can be mobilized to respond to the immediate needs of the Cuban population.

The Finlay Institute was created during the height of a meningitis B epidemic that swept the country in the mid 1980s. Meningitis B is a bacterial infection that affects the lining of the brain and spinal cord and can lead to infections of the blood. Meningitis B and C strands can also cause high fevers and severe headaches as well as eventual neurological impairment (CDC, 2016). When public health interventions failed to assuage the crisis affecting thousands, state officials, the MINSAP, and the Biological Front convened to decide on a course of action involving the creation of a vaccine to halt the epidemic. Multi-pronged approaches to dealing with disease outbreak are par for the course in countries with the proper infrastructure. But, in addition to the possible course of action taken in many countries, Cuba enlists the efforts of its biotechnology sector (Reid-Henry, 2010:67-100). The fact that the government can call on the rapid mobilization of scientists to develop medical solutions to public health crises is one of the fundamental features that renders Cuban biotechnology "alternative" and differentiates it from its counterparts in the US and Europe.

In countries where the state does not have a monopoly on biotechnology, the industry answers to the demands of investors and often to entirely more complex systems of management. For this reason, a national campaign to develop a vaccine for a disease like meningitis B—regardless or not of an outbreak—would likely be ignored by producers in the US and other countries. Even in Cuba meningitis was not originally prioritized. Both nationally and internationally the disease was viewed as posing a relatively low threat, until suddenly it had a significant impact in Cuba. The case of the meningitis B epidemic leading to the creation of the Finlay Institute demonstrates the specifically Cuban phenomenon whereby the very institutions that comprise the

biotechnology sector are the product of the illnesses that affect Cubans. Recalling Rojas Ochoas words, what keeps Cuban biotechnology operating in an alternative fashion is its freedom to remain *Cuban*.

The history of the development of Cuba's meningitis BC vaccine is also illustrative of Cuba's biotechnology model in this era. Scientists at the institute were successful in producing, testing, and clinically applying their drug across age groups to eradicate the meningitis epidemic in Cuba. The vaccine even attained a level of efficacy that made it marketable to Cuba's usual partners as well as to other foreign countries (Feinsilver, 1993:134-147). The development of Va-Mengoc-BC inadvertently demonstrates how Cuba's investment in finding a cure for an illness deemed "un-lucrative" eventually generated national revenues because they were the only country that produced this product.

The first signs of the outbreak were recorded in 1976 with the incidence eventually increasing by 50%. The serotypes that were predominantly affected by the outbreak were groups C (50% of recorded cases) and B (35%) and the most affected age group was 10 to 14 year olds, followed by infants under one year old (Padrón et al., 2007). The incidence remained relatively low in 1978 and 1979 with 1.8 cases per 100,000 people and 5.6 cases per 100,000 people respectively (Rojas Ochoa, 2005). The early stage of the epidemic was mitigated when the MINSAP imported a French vaccine that attained 80% coverage. However, a resurgence of meningitis occurred in Cubans with blood group B—which would later prove to be the most resilient strain to target with a vaccine. With rising rates of infections and fatalities, the disease continued to take its toll on the population. By 1984 there were 14 reported cases of meningitis B per 100,000

people (Aledo & Viloria, 2004). Meningitis was declared a major health problem when death rates in infants surpassed 120 per 100,000 infants. This was one of the more significant factors that prompted the government to create the Finlay Institute soliciting the help from director Concepción Campa Huergo and a small group of scientists from existing centers. Together they worked to develop a vaccine strong enough to terminate the serogroup B variant (Reid-Henry, 2010:65).

The drug produced was a combined recombinant meningitis B and C vaccine called Va-Mengoc-BC. In the spirit of solidarity with clinical trial patients, and perhaps in an effort to demonstrate her confidence in the vaccine, director Campa Huergo tested it first by injecting herself and her children. This is a practice undertaken by several Cuban scientists who absorbed the risks associated with an untested vaccine, symbolizes their rejection of the superior status associated with scientists (Reid-Henry, 2010:63-65).

Concepción Campa Huergo remembers telling Fidel Castro that her lab needed an ultracentrifuge, which costs around $70,000. After listening to her plan, Castro said she would need ten (Starr, 2004). Continuing in the State Council's tradition of setting priorities differently than other countries, the Finlay Institute received the necessary materials to produce enough quantity of the vaccine for clinical trials. As with all biotechnology producers in Cuba, the institute drew volunteers through the state-run hospital system. Va-Mengoc-BC attained high levels of efficacy under randomized control trials—the "gold standard" of clinical trial methods (Evans, 1998).

> A massive double-blind experiment with vaccinated and placebo groups of more than 100,000 students between the age of 10-14 years [was conducted]. Following this, the group tried vaccinating 250,000 young people with the VA-MENGOC-BC vaccine and recorded 95 percent efficacy over all, with 97 percent in the 3 months to 6 years group. (Reid-Henry, 2010:65)

Upon confirmation of the drug's clinical safety, MINSAP administered it to three million Cubans between 1989-1990 in all provinces where meningitis outbreaks were recorded. It would later be reported that no severe reactions occurred, and one of the most severe epidemics in recent Cuban history had been practically eradicated (Reid-Henry, 2010: 66). The speed with which the vaccine was developed, tested, and mass administered would be a difficult achievement for any biotechnology sector. A process that in this case took 2 years in Cuba, could take up to 15 years in the US under current pipeline-to-market protocols (LaMattina, 2012). A number of factors contribute to Cuba's ability to accomplish feats like this. The most critical one, perhaps, is the sense of urgency instilled in the sector by virtue of being under the jurisdiction of MINSAP. Despite the country's notorious reputation for bureaucratic inefficiencies in other sectors like agriculture, the Cuban biotechnology system is designed to expedite medical discoveries and bring its products to market with minimal delay.

The creation of Va-Mengoc-BC marked a milestone for Cuban biotechnology in the global sphere because it was the first successful vaccine against meningitis B ever developed. The vaccine's commercial success was instrumental in turning biotechnology into one of the country's leading export industries by catalyzing some of Cuba's first medical trading ventures with other Latin American countries (Feinsilver, 1992:94-95). It is also worth noting that Norway was working on its own meningitis B vaccine at the same time as Cuba. The two countries exchanged critical information throughout the process but ultimately Cuba's three-shot vaccine achieved higher efficacy than Norway's two-shot vaccine (Plahte, 2009; Reid-Henry, 2010:67).

Cost considerations played an important role in Norway's decision to attempt a two-shot solution. This serves to highlight Cuba's intensive focus on biotechnology wherein cost considerations were counteracted by non-financial motivations for success. Va-Mengoc-BC was nationally patented in 1989 and today it is protected by 3 patents in 20 countries (Padrón et al., 2007). Upon its commercialization, the World Intellectual Property Organization awarded the vaccine the medal for innovation and in 2001 the World Health Organization endorsed its application globally (Mendoza, 2011).

In the end Cuba was able to benefit from its substantive investment in the highly effective vaccine. In 1990 and 1991 Cuba sold millions of dollars worth of Va-Mengoc-BC to Brazil, and in a not a-typical demonstration of solidarity, the Cuban government reduced the price-per-dose by $1 at the request of the Brazilian minister of public health (Feinsilver, 1992:93). In a similar demonstration of internationalism, Cuba traded its vaccine with Uruguay for food and goods and, for a limited time, even donated it. Today over 55 million doses have been administered in Cuba and internationally. The vaccine exported to several countries in Latin America and, through a licensing agreement with Glaxo-Smith-Klein, has been distributed in Europe and North America (Fortner, 2007; Evenson, 2007). Only in 2014 did the US create its own version of the meningitis B vaccine, leaving thousands of patients to suffer in the meantime while the Cuban drug stagnated in US clinical trials (CDC, 2016). Apparently the US pharmaceutical system was left unchanged by this experience because when Cuba created Heberprot-P a treatment to prevent deeply damaging foot ulcers in type 1 diabetics in 2006, the US was one of the few countries that did little to expedite its arrival. As a result of these ongoing delays, to date tens of thousands of diabetics have had limbs amputated due to ulcers that

could have been treated by this drug that reduces the need for amputation by more than 70% (Almendrala, 2016; Keck, 2016). At the time of writing, the drug is still not available to patients in the US spurring healthcare professionals and public health officials to complain about the slow pace of approval and marketing of Cuban drugs in the US.

Counterpoints, Global Pressures and Developing Contexts, and Conclusions

A couple of issues occurring contemporaneously with the rise of Cuban biotechnology are worthy of analysis. They serve to nuance our understanding of the sector's rise to prominence and call into question the motives of the state in creating a biotechnology industry that prioritized national needs and the needs of developing countries. The first issue regards the prolific government investment the industry received over many decades, despite national economic challenges. The second concerns key administrative changes that occurred within the industry following the Soviet collapse.

To view the Cuban biotechnology industry's development in the light of the State Council's generous spending on biotechnology we must consider the socio-political events occurring in Cuba contemporaneously. As the government poured close to $100 million into the industry from 1990 to 1991, the country was undergoing a severe economic shock brought about by the collapse of the Soviet Union and the subsequent loss of Soviet subsidies (Feinsilver, 1992). Over half of the country's food imports were depleted and, at the height of Cuba's fiscal retrenchment, the state was unable to provide such critical basic needs as potable water (due to the lack of chlorine) leading to a series of severe public health problems. A sharp decline in oil imports led to cuts in

transportation services. Rolling blackouts affected the livelihood of millions and Cubans could no longer cook or refrigerate their food properly. Nutritional deficiencies contributed to widespread cases of neuropathy causing thousands of Cubans to temporarily lose their vision. A record drop in per-capita daily food consumption during "Special Period in Time of Peace"—as designated by Fidel Castro in the 1990s—showed that people went from the consumption of 3,100 calories in 1989 to less than 1,800 in 1993 (Brotherton, 2011:483; PAHO, 2001).

These years were characterized by pervasive human suffering, increased policing and repression, and governmental ineptitude manifested in an inability to resolve major public health problems effectively. Although the deep despair evident both in Havana and throughout the island during this period bespoke the urgency of the situation, it was never accompanied by even a momentary divestment from biotechnology to address more immediate needs.

Julie Feinsilver examines these social conditions in her work on biotechnology development and bookends her essay by arguing that, "because [the problems resulting from the Special Period] require hard-currency imports, the export of biotechnology […] becomes more important as a means of paying for socioeconomic development and meeting basic human needs" (1992:81-82). She endorses on behalf of the state's decision to continue full steam ahead with biotech investment but in doing so seems to disregard, or at least underappreciate, the fact that this process will take time to show a return while Cubans are quite literally starving in the short-term. The decision regarding the allotment of Cuba's budgetary resources during this period seems unambiguous to most observers.

The immediate health needs of the population are clearly more pressing than the distant prospect of treating cancer—particularly under Cuba's brand of socialist healthcare.

This leads us to another point then, on the state's incentive to continue investing in biotechnology in spite of prolonged social anguish. The State Council was beholden to another interest: the desire to present an image of modernity to the rest of the world—particularly to the US and Europe. This desire permeated much of Fidel Castro's administration and had both a moral dimension—demonstrating their advanced humanitarianism by exporting medical doctors abroad—and a technical/empirical one manifested in their ability to compete with the biotechnology of wealthier nations by developing a competitive industry themselves (Feinsilver, 2010:97).

The second criticism addressed here revolves around the industry's administrative changes of the mid 1990s that were also related to the socio-economic changes brought about by the Special Period. One researcher from the CIGB spoke out about the issue when he published an article in the prestigious science journal *Nature* titled "Wine to Vinegar—the fall of Cuba's biotechnology" (2001). Although several of his predictions of a bleak future for Cuban biotechnology proved wrong, José de la Fuente represents the dissenting voices of some exiled scientists when he addressed certain issues with Cuban biotechnology. De la Fuente's grievances are reflected, to a lesser extent, by other researchers, including vehement advocates of the Cuban industry like Agustín Lage Dávila. Two things are emphasized in De la Fuente's article: a loss of creative autonomy for scientists, and a brain drain resulting from low wages (caused in part by the implementation of a dual-currency system). He argues that the instability resulting from the economic crisis led to paranoia and governmental distrust of those working in the

biotech industry. According to De la Fuente, research centers lost the possibility of deciding internal policy, even for small things. Furthermore, he argues that the instatement of a dual currency system in 1994 caused prices of basic goods to increase, making other industries such as tourism more appealing for employment to Cubans with the capacity to become scientists (De la Fuente, 2001).

These criticisms, albeit dubious, serve to highlight two weak spots in the State Council's management of biotechnology. First, at a time when millions of dollars were being invested in the biotech industry, it could be argued that some of those funds should have been earmarked for higher wages for scientists in order to halt the brain drain into the tourism sector. Second, it reveals the fine line that divides state control and state encroachment on public industries. When directors of biotechnology centers lose authority over their projects and become suspects of political dissent, the state loses credibility as a partner and the industry's production process is threatened. Trust and accountability are essential components to the success of this kind of model for biotechnology—precisely because the state is so embedded in the industry's mechanisms. As an industry of the state, those working within it should share in the core values and objectives of the industry's pre-determined mission—but not necessarily anything beyond that. So when scientists and directors are scrutinized and stripped of their scientific autonomy because they might disagree with certain aspects of political life, the state is essentially disenfranchising them from their role as innovators and slowing down the process of biotechnology development. This is perhaps an inherent tendency of the authoritarian component of the Cuban model, which creates the potential for mutiny on the part of its workers. It should be stated however, that many years have passed since De

la Fuente's outcry and although Cuban internal affairs of this sort tend to be difficult to uncover, the biotech industry has continued to innovate, signaling that creative autonomy has, in significant measure, been restored. While I argue that the Cuban government's heightened involvement in the genesis and oversight of the industry is what protects the industry's "alternative" modus operandi (vis-à-vis biotechnology in the other nations), I do not mean that this is inherent to Cuba's *dictatorial* state model.

In the same way that healthcare is nationalized in most democratic countries worldwide, it is possible to envision biotechnology receiving a similar treatment under democratic administrations. Healthcare serves as a useful foil to biotechnology because through it we can analyze how certain ethical expectations are bound to some industries but not to others. In Cuba, just as in democratic countries like Canada, Norway, Portugal, or the UK—healthcare is expected to be a public good. It has reached a status where, in most cases, it is a constitutionally protected public service, collectively funded and responsible to national needs. Universal healthcare occupies a space in these national imaginaries as a system whose sole purpose is to provide services that protect and improve citizens' health. In these societies, then, why are the same expectations not applied to biotechnology? Certainly the two industries are interdependent and the products of biotechnology are indispensable to healthcare.

In the field of biotechnology, the question of who should own the means of production has been highly contested. In his book *Biocapital: The Constitution of Postgenomic Life*, Kaushik Sunder Rajan explores the "frictioned terrains" on which biotechnology emerged. He argues that the drift towards corporatization has hardly been "natural or inevitable", but rather a highly disputed battleground between researchers and

corporations (2006:4). Despite the efforts to publicize databases and protect the collectivization of information on DNA sequencing and molecule libraries, the general trend over the course of 30 years has favored the privatization of knowledge and has led "towards more corporate forms and contexts of research" (2006:4).

Today, the capturing of biotechnology by private interests is propagated through an intricate global system that is unwavering in its rules and in its enforcement of intellectual property (IP) laws. This global system defines and dominates biotechnology markets and imposes sanctions on nations who defy IP law. This pressure creates a kind of gravitational pull that makes it exceptionally difficult for states to develop industries that stand in opposition to for-profit biotechnology. In fact, the pressure is so pervasive that it is assumed as standard for countries to ascribe to the mainstream model (Sunder Rajan, 2012). Cuba is certainly not immune to these pressures and we will most likely see as Cuba's industry progresses into the 21st century that the increasing global reach of IP law will have an impact on Cuba's trade. The more advanced Cuban biotechnology becomes, the more tendency there is for it to insert itself into lucrative foreign markets. However, the government is unwilling to re-write its state-centered patent legislation or renounce trading with its partner countries who disregard IP laws—two conditions that global legislation seeks to regulate (Reid-Henry, 2010:115-127).

In the opening pages of his book, Sunder Rajan writes, "capitalism is triumphantly acknowledged today as having defeated alternative economic formations" (2006:3). With this he is making a powerful statement about how for-profit biotechnology, similarly to capitalism, has become a global phenomenon and now constitutes the only accepted style of biotechnology production. Poorer countries were able to reject this model more easily

in the past when regulations were not yet so globalized and pervasive. These countries recognized that they were at a global disadvantage if they imitated US and European models—for example, in the adoption of patent laws. For them, not only was the prospect of paying lofty sums for these patented drugs untenable, but also the resource intensive demands of developing a European-like biotechnology sector served as a natural barrier to any such attempts (Sunder-Rajan, 2012).

It is important to situate Cuba in its global context as a nation whose biotechnology industry is somewhere in between that of lower income and higher income countries. Investigating some of the impacts that global hegemonic forces have had on the biotechnology industries of lower income countries can help to identify the sorts of pressures Cuba may be subjected to (World Bank, 2016). Much like Cuba, nations like Egypt and India initially founded their biotechnology industries on the production of generics, blatantly disregarding Western patents (Abdelgafar et al., 2004; Sunder Rajan, 2012). Over the years however, the structures that held these models in place—namely governments sympathetic to providing affordable pharmaceuticals to their populations—began eroding. Particularly evident in India's case, the change of government to a US-friendly administration led to a stripping of the industry's foundational institutions and the implementation of a new biotechnology sector with a very different production focus (Sunder Rajan, 2012).

In Cuba, centralized federal power extends significant protection to its socialized model for biotechnology. However, other mechanisms exist to ensure the proliferation of socialized biotechnology in both in Cuba and in democratic countries (who inherently do not have the same centralized state power as Cuba). As long as the socialization of

biotechnology is protected by a constitutional document that is legitimate and respected, then socialized biotechnology can exist in any country regardless of whether it is a democracy or an authoritarian government. Nonetheless, the establishment of non-for-profit biotechnology industries in today's vehemently for-profit international climate is difficult for many nations.

The Cuban case is unique because the revolutionary government integrated science and medicine into the core of its national mission for development and sovereignty. One of the fundamental steps the state took to accomplish this was to take and active role in the research decisions and financial needs of the industry at every step of the process. Also to ban the creation of pharmaceutical retailers to ensure that investment was routed into research for the creation of medicine for human diseases (instead of being diverted to other areas, like "blockbuster life-style" drugs that we see in Western markets) (Reid-Henry, 2010). Cuba also averted the pressure to "profitize" its biotechnology industry by making sure that those within the Party be avid defenders of the country's revolutionary principles and nationalistic ideology. Additionally, it had to ensure that those within the State Council agreed on the purpose of biotechnology. Also inherent to the success of the Cuban model are the characteristics mentioned throughout this chapter: the industry's strategy of recycling research and applying different approaches to its interferon investigation, its willingness to improvise in the use of limited resources, the Biological Front's investment in educating a critical mass of scientists, and the industry's emphasis on *doability* all along the research to production pipeline.

Thus, it becomes evident that several supports simultaneously bolster the Cuban model for biotechnology and the system relies on much more than the capacity of its institutions. As Simon Reid-Henry argues, "the relationship between science and government [in Cuba] is just as important as the efficacy of its clinical trials […]" (2010:104). It is this relationship that ensures that science is harnessed for the advancement of citizens' health setting Cuba's biotechnology industry apart from most of the developed world. The government acts as an insurer of national well being reminding the industry that all Cubans are its collective owners and that both the products and the profits derived from them are to benefit them as the natural shareholders.

Chapter Two: The Protection of Nationalized Biotechnology

Introduction

The second part of this paper aims to shed light on the *external* factors that influence the viability of Cuba's alternative model for biotechnology. Primarily, this chapter traces the US trade embargo's protective effects on Cuba—both from aggressively for-profit markets and from the influence of predatory global policies. While the embargo was, and continues to be avowedly detrimental for Cuba, some of its sanctions had a protective impact on Cuba's socialist, altruistic, and nationalistic biotechnology industry. By forcibly barring the Cuban industry from unregulated exposure to vehemently for-profit markets, I argue that the embargo was a central component to preserving and boosting Cuba's alternative model for biotechnology.

While the embargo certainly hindered Cuban trade with the US and Europe (by barring Cuban commerce with all US-affiliated companies), Cuba was far from cut off from foreign markets. As protocols arose to regulate and standardize biotechnology production internationally, Cuba acquiesced and adapted to several of these norms. A shift in the country's marketing objectives from the 1980s to the 1990s incentivized the biotechnology industry to develop more exportable products. In order to increase its biotechnology exports without international scrutiny, Cuba would have to adhere to certain international standards and grapple with different conceptions of property and production. This was somewhat welcomed by the administration considering its

enthusiastic desire to appear modern to the rest of the world. Although many international trade protocols were disputed by Cuba, others like the standardization of ethical clinical trials were whole-heartedly embraced (Reid-Henry, 2010:109-118). To better analyze how the Cuban industry adapted to, and interacted with foreign systems of biotechnology, it is imperative to explore some of the mechanisms of these foreign systems. Similarly, in order to better situate Cuba in terms of its trading capabilities and objectives, it is essential to examine how the embargo helped shaped these.

In this chapter I will analyze the embargo legislation responsible for blocking Cuba out of certain biotechnology markets. These restrictions came in waves and had far-reaching implications, as not only did they isolate the island from the US but also from most foreign trading partners. Then I go on to describe the embargo's effect on certain US companies seeking to conduct trade with Cuba as well as the impact that multinational pharmaceutical companies have in countries with developing biotech industries—with particular focus on India (as a potential example of how these pressures could affect Cuba). Then I describe the kinds of partnerships that Cuba developed which were permissible under embargo restrictions. I examine Cuba's joint-development venture with York Medical Canada: a small non-US affiliated company that endorsed and strengthened Cuba's alternative model for biotechnology. In the final section, I analyze the impact of intellectual property regimes on biotechnology markets and position Cuba within these developments. And finally, I define The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and describe Simon Reid-Henry's term "Regulatory Overstretch" in order to analyze the protective impact that the embargo had

on blurring Cuba's status as a country that does not have to entirely comply with TRIPS standards (Reid-Henry:2010, 127).

Preface to Torricelli and Helms-Burton

In 1960, John F. Kennedy declared a trade embargo on Cuba, mandating a freeze on all US exports to the island excluding food and medicine. Two years later these measures were expanded to bar all Cuban imports, and the Foreign Assistance Act was amended to prohibit the deployment of US aid to any country that provides assistance to Cuba. The US did this in response to Cuba's nationalization of American-owned Cuban oil refineries (Hufbauer et al., 2011). However, these sanctions were more or less unenforced for the next three decades and remained at the discretion of the US executive branch. Until the 1990s, Cuba relied almost entirely on its import economy, which was intimately tied to the US. In addition to importing many of its food products, the country also imported almost all of its drugs and medical products from the US (Feinsilver, 1993).

The US officially claims that it upholds the embargo due to the Cuban government's refusal to move toward "democratization and greater respect for human rights", but it also asserts that it holds $6 billion worth of financial claims against Cuba for US property that was nationalized after the revolution (Torricelli Act, 1992). These lingering financial claims highlight the US's lack of acknowledgement for its colonial legacy on the island and demonstrate a continued imperialistic attitude towards the country. Despite international repudiation for its unfair sanctions, the United States embargo against Cuba continues to be the most enduring trade embargo in modern

history. While several statutes enforce the embargo's various sanctions, two pieces of legislation in particular played an instrumental role in shutting Cuba out of western biotechnology markets. These were the Torricelli Bill—also known as the "Cuban Democracy Act"—and the Helms-Burton Act, or "Cuban Liberty and Democratic Solidarity Act" (Hufbauer et al., 2011; Rojas Ochoa & López Pardo, 1997).

The Torricelli Act

In 1992, Congress passed the Torricelli Bill, which severely obstructed trade between foreign (but US-affiliated) companies and Cuba (Drain & Berry, 2010). In previous years, many sanctions against Cuba had remained dormant but the Bush Administration would revive them by implementing a ban on subsidiary corporations (based in third countries) from trading or investing in Cuba (Mesa Lago & Perez López, 2013:13). The measure was successful. After just one year of the bill's enforcement, a majority of US subsidiary companies severed their business transactions with Cuba—leaving the country with extreme shortages of critical goods (Lamrani, 2013:32).

The ramifications of the Torricelli Act for Cuba's biotechnology industry were also devastating. This was in part due to the rise in international conglomerates. Pressures to consolidate smaller foreign supply companies into large multinationals effectively disenfranchised Cuba's previous trade partners from proliferating these deals. Ismael Clark, president of the Cuban Academy of Sciences, stated "you would have a supplier for several years, and suddenly you would get a letter from the company saying, 'We can't supply you anymore because our firm was bought by an American transnational'" (Starr, 2004). Prior to Torricelli, Cuba imported $719 million USD worth of goods

annually from US subsidiary companies, 90% of which was food and medicines (Drain & Berry, 2010). To make up for these losses, as well as for those created by the loss of Soviet subsidies, Cuba desperately sought trading partnerships with companies unaffiliated with the US, and found them through South-South collaborations with Latin American countries and with China, Vietnam, Angola, Iran, Algeria and others (Feinsilver, 2010). The aid needed to fill the void left by the US and its affiliates (and by the Soviet Bloc) did not arrive immediately however, and Cuba plunged into an overwhelming economic crisis. Several years would pass before international business partnerships came to full fruition—but when they did, many of them were with other socialist nations, and they became the kind of political-economic bonds that the embargo sought to undermine but in fact strengthened.

Most notably perhaps is Cuba's longstanding trade and barter deal with socialist Venezuela wherein Cuba provides doctors and medical products to Venezuela since 2003 in exchange for petroleum. In other non-traditional forms of exchange Cuba also accepted food and other products as payment for biotech products, like the in case of socialist Uruguay (Reid-Henry, 2010:118).

The Helms-Burton Act and Ineffective International Pushback

In 1996, with the onset of the Clinton administration, came the passing of the most stringent piece of legislation on the embargo: the Helms-Burton Act. The Act did not introduce so many new sanctions as is it did embolden the old. Helms-Burton strengthened the measures introduced by the Torricelli Act by closing important legislative loopholes.

Certain national interests sought to further penalize national and foreign companies from trading with Cuba and they accomplished this when Congress passed the Helms-Burton Act. The law would provide fewer loopholes for US and subsidiary companies and would restrict the president's authority to bypass sanctions in unprecedented ways (Lamrani, 2013). In basic terms, Helms-Burton codified all standards, regulations, and presidential orders passed since 1962, thereby elevating to rank of law an entire arsenal of measures against Cuba (Lamrani, 2013:34).

Overnight the act emboldened the US's anti-Cuba stance and did so irrevocably. The bill's instatement was met with widespread dismay from corporations (including pharmaceutical companies), non-governmental organizations, and the US electorate. Behind the bill were the two senators Jesse Helms and Dan Burton and the Cuban-American National Foundation (CANF), a wealthy political action committee spearheaded by Cuban-Americans in Florida (Roy, 2000). Specialist Joaquín Roy explains that the group was modeled after the influential American-Israeli Political Action Committee (AIPAC) and that it was sponsored in large part by a Cuban-American father and son duo with a collective net worth of around $586 million (2000:204).

The Helms-Burton Act is comprised of four titles that introduce both punitive and prescriptive measures. In two main provisions, the Act systematized previous sanctions placed on Cuba and expanded the extraterritorial aspects of the embargo. The first, Title I, accomplished the former of these objectives. Any *national* company caught trading with Cuba would be subject to legal action, financial sanctions, and its leadership could even face prison time (Hoffmann, 1998; "Cuban Liberty…", 1996).

Title III of the Helms-Burton Act is the provision that legalizes sanctions on international subsidiary companies and discourages all foreign entities from trading with Cuba. What renders this provision legal are the $6 billion dollars in property claims that the US holds against the island. The logic is essentially that if companies affiliated with the US conduct trade with Cuba, they are potentially "trafficking in" the property that Cuba confiscated from the US (Sweig, 2009). By laying these neocolonial property claims on Cuba, the US sought to prevent foreign companies from capitalizing on a market that they had shut themselves out of. For foreign companies, the Act exacerbated the uncertainty of investing in Cuba. Title III soon came under international scrutiny due to its extraterritorial reach and caused disputes between the US and members of the European Union, Mexico, Canada, Brazil, Argentina and others (Hoffman, 1998; Roy, 2000:58, 92-95).

Some nations reacted by putting forth legislation that would nullify Title III. Among these were the UK who had already passed a Protection of Trading Act in 1980, Canada that passed an act to amend the Foreign Extraterritorial Measures Act (FEMA) to include a provision whereby the attorney general would have permission to block attempts by foreign claimants under Helms-Burton to enforce judgments in Canada, and Mexico who passed a Protection of Commerce law that penalized anyone who while in Mexican territory obeyed another country's laws aimed at reducing Mexican trade or foreign investment in a third country (Roy, 2000:58, 92-95). Within the US, senators and other officials warned about the Act's blatant interference in market activity and its undeniable violations of trade agreements like GATT and NAFTA (Roy, 2000:58).

Nonetheless, internal pushback and the legal action taken up by foreign states to oppose the US' extraterritorial measures had minimal impact on preserving their companies' ties with Cuba. Helms-Burton and Torricelli had successfully isolated the island from as much trade as possible. Initially, the effects were devastating; but the shock served to kick into action the import substitution industrialization (ISI) that Cuba had been postponing—or unsuccessfully attempting—both within and outside of biotechnology. Essentially these policies shook Cuba out of its comfortable dependence on the US and Soviet subsidies. Furthermore, Cuba's distance from US-European dominated markets allowed for the country's socialized vision for biotechnology to burgeon without the encroachment international capital.

Effects of the Embargo, Western Hegemony, and York Medical Canada

This section explores some of the concrete consequences that the embargo had for Cuba and how it shaped much of the emerging market terrains that Cuba was beginning to explore in the 1990s. By the beginning of this decade, Cuba was becoming eager to unfurl its marketing potential. It had developed the first and only meningitis B vaccine in the world, which joined several other locally developed vaccines (such as the hepatitis B, tetanus, and polio vaccines) that served as inexpensive alternatives to US-patented products, had developed reagents useful for different types of diagnostic tests, and had several other products in various stages of development (Reed & Galindo, 2007:5-7).

It was critical that Cuba already had an arsenal of biotech products that were ready for sale because when Torricelli and Helms-Burton came into effect, the industry faced major challenges. Concepcion Campa Huergo, director of the Finlay Institute,

explained in a 2004 article that the industry had to scrimp and scrounge to get its hands on the machinery it needed. “Labs are filled with gear from Europe, Japan, and Brazil. The occasional device from the US has traveled the ‘long way around’—through so many middlemen (and markups) that it may well have circled the globe” (Starr, 2004). The embargo greatly augmented the price of raw materials for Cuba and it also diminished the industry’s access to critical products.

Access to scientific materials such as gels and solvents—necessary for the most basic biotech processes—was jeopardized. And because of the relatively small number of biotechnology supplier countries, Cuba struggled to either smuggle in, or pirate their own versions of these items. For example, 75% of the world’s supply of insulin comes from neighboring Puerto Rico, but as a US territory, the island was barred from selling the multi-purpose hormone to Cuba (Reid-Henry, 2010:124). If even 10% of US-patented molecules or parts were present in a multinational product, that company could face severe retribution if it sold the product to Cuba. One Swedish corporation was prevented from selling a sophisticated piece of equipment because it contained just one filter patented under US law (Reid-Henry, 2010:124). Cuba was also barred from dealing in US dollars, making its financial transactions all the more convoluted. In 2004 the U.S. Federal Reserve fined UBS, Switzerland's largest bank, $100 million for illegally dealing in dollars with Cuba (Frank, 2009). Helms-Burton and Torricelli functioned on an intellectual front as well. The US Treasury deemed the publishing of scientific articles by Cuban authors, and even co-authoring with US scientists, to be an infringement of the embargo. However, major publications such as Nature and Science defied this convention.

Two situations were developing simultaneously. On the one hand, Cuba was transitioning from an economy of self-reliance to an export economy. It had developed an industry articulate enough to no longer rely on US pharmaceutical imports and was now able to meet its national medical needs and produce a marketable surplus of biotech products. On the other hand, the US embargo began to restrict the flow of necessary materials to Cuba, thus hindering its production process. The embargo upholds this function even today, which still leads to supply shortages in the medical and biotechnology sectors. However, the embargo's protectionist effects begin to surface as the industry continued to expand and seek out development ventures with foreign companies. The embargo helped steer Cuban biotech into smaller, less lucrative, trade ventures with less-established companies where directors sought to find solutions to the challenges posed by Cuba's unique nationalized model instead of subjecting it to their own regulations. While both Cuba and the US pharmaceutical industry sought to engage in trade with each other, the embargo blocked these attempts consistently.

In 1995, one of the US's largest pharmaceutical companies, Merck, purchased biological samples of Cuba's hepatitis B vaccine for testing at their US labs. The company's executives were caught bringing the samples in from Havana and were subsequently charged $127,000 in sanctions. The highest fine for this offense is up to $250,000 and 10 years in prison (Reid-Henry, 2010:124). While Merck tried to import the vaccine clandestinely, other US companies who sought to do so lawfully faced insurmountable hurdles under Helms-Burton and Torricelli. In order to bring in samples for testing, companies had to prove a "compelling national interest" to the US Office of Foreign Assets Control (OFAC). But access was denied time and time again. Under the

Clinton administration, pharmaceutical corporation GlaxoSmithKlein, was able to receive clearance to license Cuba's meningitis B vaccine, but the drug was never brought to market (Randal, 2004:1741). Under the Bush administration, other such deals were even less successful. CancerVax, a California-based biotech company, sought to license three of Cuba's cancer drugs in 2004 and while they were eventually granted permission from the OFAC, the deal fell through. This was in part caused by allegations from the Bush administration that Cuba was using its biotech facilities to develop biological weapons. The government's claims were never retracted and further damaged relations, outraging three of the scientists who developed the cancer vaccines, Tania Crombet Ramos and two of her colleagues (Randal, 2004:1740).

As these examples show, the US pharmaceutical industry was knowledgeable about Cuba's scientific capabilities and eagerly sought to establish trade ventures with the Cuban industry. More surprisingly perhaps, Cuba was responsive to these attempts and open to the possibility of out-licensing its valuable compounds to them. But this readiness to engage in trade ventures, especially with larger US pharmaceutical corporations, could have been disastrous for the Cuban industry.

An important aspect of Cuban biotechnology that contributed to its sought-after status was that the industry dealt in products. While hundreds of other actors within global biotechnology were focused on speculative investments, services and other platforms, Cuba was concerned with the concretization of medical research to medical products. As Agustín Lage Dávila remarked, "biotech is about manufacturing things. Most biotech in the world still can't do this" (Reid-Henry, 2010:109).

As a result of the US trade embargo, and specifically Helms-Burton and Torricelli, a non-US affiliated Canadian company approached the CIM about a joint-development venture. After several negotiations the small company successfully gained the rights to in-license Cuba's cancer drugs (Reid-Henry, 2010:110-11). Because York Medical was free of the extraterritorial reach of the embargo that caused legal entanglements for multinational corporations, it was among a small pool of companies able to lobby Cuba for this kind of contract.

York Medical was founded on the problem of cancer. While the company did not conduct its own scientific research, it dealt in cancer therapeutic products through ventures with biotech labs. The Canadian company's main purpose is to take promising compounds through various stages of downstream development: clinical trials, obtaining regulatory approval for their sale in the markets to which the company has rights, partnering with relevant companies, and so on (YM Biosciences Annual Report, 2004:12). If the all the necessary tests are passed, then York Medical tries to out-license the drug to a larger pharmaceutical company for production and marketing (Reid-Henry, 2010:106-111).

The company's CEO, David Allan, saw in 1981 that Cuba was conducting promising cancer research and believed the industry was in need of better management. He became committed to a close involvement with the CIM and to reconciling Cuba's ontological differences with the demands of certain international markets. Several risks were involved—the clinical testing could prove ineffective, the technology itself could fail, patents were not assured—these risks were customary. But they were compounded by the uncertainty of working alongside CIMAB, the CIM's marketing wing. The

CIMAB was deeply unprepared to market Cuba's products in a different regulatory environment; advertising was wholly alien to it (Reid-Henry, 2010:106-111). York Medical, as a product of the capitalist private market system that Cuba wished to break into, was quite comfortable in this realm. This was the essence of their joint venture: YM negotiated the difficult waters of marketing while the CIM focused on research and production. The relationship between York Medical and the CIM was established in a way that differentiated it from the bigger and more enterprising ventures of US pharmaceutical companies with developing countries, like India for example. For one, the collaboration was small scale. Only a handful of cancer drugs became the focus of relations. But before delving into a discussion of the intricacies of Cuba's relationship with York Medical, it is important to gain insights into the kinds of developments taking place contemporaneously in other biotech hubs outside of Cuba.

The relationship between Cuba and the small Canadian company contrasts larger trends that Kaushik Sunder Rajan identifies in his 2012 article wherein developing countries like India become sites for resource extraction and outsourcing. India's once-vibrant generics industry has been largely effaced and replaced with the infrastructure to provide a cheap supply of patients for clinical trials for multinational pharmaceutical corporations. This phenomenon is one of the axes of a pervasive trend towards greater and more complex forms of extraction from biotech industries in developing countries. Due to the embargo, Cuba has developed a rich biotech industry while escaping the uneven nature of agreements and joint ventures with more powerful multinational pharmaceutical companies. However, the economic pressures on the governments of developing countries to engage in deals with multinational pharmaceuticals is ever-

present and can lead governments to expose both their nascent industries and their populations to exploitation at the hands of big capital. Some of the ramifications of this are the propagation of neocolonial wealth transfers from the global South to the global North and the prospect of imminent harm to the populations of developing countries. India's position within the global biotech economy creates a relevant foil to the Cuban context because like Cuba, India is an important actor in biotechnology in the global South. The two countries are similar in several aspects except for Cuba's current exclusion from unregulated exposure to certain biotechnology markets and the companies in those markets (Sunder Rajan, 2012).

Sunder Rajan describes that the worldwide expansion of biocapital and the homogenization of health logics dictated by mostly by the US and Europe created the pressure for India to de-construct its production-based biotech industry and replace it with a service-based one (2012:330-335). Several issues were at play in this transition. The most powerful perhaps was India's decision to sign on to patent-respecting regulations—regulations that Cuba is also a signatory of. Indian biotechnology was founded on the back of a number of companies whose viability depended on ignoring patents. These companies invented valuable reverse-engineering techniques for the production of generic drugs, which are beneficial both to the Indian people (because they are an inexpensive local alternative to foreign-patented drugs) and beneficial to organizations like Médecins Sans Frontières (MSF) who procures 25% of its essential medicines, and 80% of its anti-retrovirals for worldwide distribution from India (Sunder Rajan, 2012:335). Under new IP regimes, however, Indian generics companies became unlawful. Therefore not only do multinational pharmaceutical companies diminish the

medical self-sufficiency of single industries like India's, but also the networks of accessibility dependent upon these countries' production of accessible medicine. Essentially, US-based pharmaceutical corporations, represented in this relationship simply as 'big capital,' seek to establish and maintain a global monopoly on their products by eliminating competitor industries that threaten to provide alternatives at lower prices.

This development—the end of Indian generics—benefitted the interests of multinational pharmaceutical companies twofold. Not only were foreign products to take precedent in the local Indian market, but foreign companies were now also in a position to buy-out Indian generics companies which were an attractive acquisition for use in post-patent cliff scenarios in the west (Sunder Rajan, 2012:334). Following the dismantling of India's generics industry, the liberalization of local biotechnology took the form of privatized surrogacy. An enormous registry was formed for Indians to enlist as participants in clinical trials for international companies. The country quickly became a global hub for clinical trials--but the therapeutics emerging therefrom were sold on markets that most Indians are financially excluded from (Sunder Rajan, 2012:332).

By way of exposure to aggressively for-profit markets, through deals and partnerships with foreign multinational companies, Indian uprooted its self-sufficient generics industry and placed its population in a crisis situation. While a very specific set of circumstances led to these conditions in India, Sunder Rajan analyzes these events as transient and globally applicable. The international pharmaceutical industry is constantly expanding and searching for new sites to extract raw materials, sell its products, or in India's case, derive cheap labor. Sunder Rajan argues that the very fusion of value and

biotechnology creates the need for the perpetuation of crises (2012:338-341). The destabilization of biotechnology industries in the global South only differs in the degree to which this is carried out in each country, but the pressures for these dynamics to develop are integral to the very system of North-South industry relations.

The disenfranchising reforms that India's biotechnology industry underwent demonstrate the effect that these partnerships can have when the agency of the developing industry is disregarded. Unlike India, Cuba is shielded from much of the speculative meddling that multinational corporations do in developing countries. Furthermore, the Cuban government is far more dedicated to the protection of its socialized generics industry than India's government was to its own. Nonetheless Cuba's commitment not to turn the country into a production site for foreign companies does not guarantee the industry total protection from the destabilizing forces of international markets. With greater exposure to global trade comes greater risk of succumbing to destabilizing forces of capital.

In general, as Cuba became an important producer of affordable drugs, vaccines, and medical equipment, it also began engaging in more trade, and receiving attention as a potential drug-development partner. However, the State Council demonstrated an off-and-on eagerness to accept investment opportunities. Until the 2000s, Cuba's trade deals had been relegated in large part to bartering and there seemed to be a unanimous consensus—both in the State Council and among scientists—that the industry should begin to focus on securing greater financial investments from sales and development contracts (Reid-Henry, 2010:115-143). This was not an easy task for a country facing economic and logistical hurdles like those imposed by the embargo. And despite the

overall trend in favor of the marketization of biotech, the State Council often hindered scientists' efforts to strike up these deals. Between 1997 and 1999 however, the Canadian company York Medical (today YM Biosciences) landed its major partnership with Cuba—one that endures for nearly two decades.

In the CIM-YMB deal both parties set stipulations. CIM director Agustín Lage Dávila was elected to YMB's board of directors—a move signifying the closeness of their ties and a transparent environment. The deal revolved around the production and marketing of a handful of Cuba's cancer drugs which, despite being in early stages of development, exhibited exceedingly promising results (Reid-Henry, 2010:109-12).

YMB couldn't offer as great of an investment nor the scale of development that most multinational corporations could but perhaps its small size afforded Cuba greater involvement in the downstream development of its products than the country would have otherwise had. YMB invested an initial $7.5 million and a subsequent $10.1 million in the Cuban industry over the next five years. These sums were only to cover the overhead costs of development--YMB was to contribute further returns in the form of royalties once the molecules were out-licensed or the final products brought to market (Reid-Henry, 2010:106-9).

YMB aided Cuba in other significant ways too. The Canadian company secured access to clinical trials outside of Cuba and more generally, it raised the CIM's profile internationally. In 2001, the merger's lead product TheraCIM hR3 was approved for phase II clinical trials in Canada and would eventually become Nimotuzumab, one of Cuba's most promising cancer drugs against the growth of head and neck tumors. When California-based CancerVax sought to purchase the rights to test these cancer drugs in the

US in 2004, the company would have had to out-license the products from YMB-CIMAB instead of directly dealing with the CIM (Reid-Henry, 2010:106-10).

In a significant capacity, YM Biosciences served to protect Cuba's products and also to advance and legitimize them for sale in western markets. Perhaps most remarkable about YMB and Cuba's partnership was the attention devoted to working around each other's different perspectives. It was a serious challenge for YMB to create ways to "commercialize" and "legitimize" Cuba's image. Exemplary of this was the idea of representing Cuba to potential investors as a single company—"Cuba SA" (Reid-Henry, 2010:111).

The jagged edges of Cuba's national approach to biotechnology didn't quite allow it to fit into western processes of marketization. This triggered further debate within the industry about Cuba's place in the global biotech market. Pressures to reform the industry came from a myriad of voices both from within the industry and from without. Vice minister of public health, Abelardo Márquez, called for a strengthening of marketization and for the adoption of "modern" management techniques within the biomedical centers (Reid-Henry, 2010:109). Here, "modern" and "professional" were codewords for conformity to Western, and consequently global, industry and market standards—but Cuba had already been making steps in that direction. The country had been following the World Health Organization's protocols for ethical clinical trials for years and the State Council had finally been convinced of the necessity of implementing national and international patents (Torres Yribar, 1983). YMB took the country a giant leap further by guiding the CIM through the different phases of drug development. The intricacies and idiosyncrasies of Western biotech began to reveal themselves to Cuban scientists who

would have been both unprepared and perceived as illegitimate had they attempted to sell their products directly to pharmaceutical companies. In Cuba the lack of distinction between research and production within its centers made it difficult to adapt to and to navigate the convoluted systems of upstream and downstream biotech development in the West.

YMB's status as a small developer in the pharmaceutical world allowed it to enter into a trade relationship with Cuba as its equal. YMB was in a position where it had to bargain with Cuba, it could not offer glamorous investment proposals, it could only offer its management services (Reid-Henry, 2010:111). As a result, both parties found themselves grappling with the clash of cultures that framed Cuba's debut into the marketing world but they did so in a way that never sought to alter the foundational aspects of the Cuban model. Through their small and concrete venture, Cuba's biotechnology industry got its feet wet in the processes of marketization.

For these reasons the CIM's collaboration with YM Biosciences would become the country's blueprint for future trade deals. Within the first two years of the Cuban-Canadian merger, Lage Dávila inaugurated Cuban offices in the Beijing-based Biotech Pharmaceutical Ltd. Corporation, product of a joint venture between the CIM and China's Life Center. The same year, UK based protein-engineering company Biovation announced a license agreement with the CIM that granted Biovation a nonexclusive worldwide license to the CIM's antibody engineering technologies (Reid-Henry, 2010:143). And so, Cuba entered into a new era of international cooperation and participation in global markets.

Intellectual Property Regimes, TRIPS, and "Regulatory Overstretch"

The rise of international regulations had a significant impact on biotechnology industries across the world and Cuba was no exception. Starting in the mid 1990s, regulatory bodies emerged seeking to dictate the right and wrong ways of producing and trading biotechnology. This marked a turning point after which, nations could no longer conduct themselves according to their own stipulations without international repercussions. Those seeking to standardize protocols were largely driven by personal interest when they proposed patents laws for the commodification of knowledge and inventions. Eventually international negotiations led to the creation of regulations rooted in Western conceptions of property and ownership.

These regulations are represented by different pieces of legislation but the most powerful was the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Throughout the 1990s a series of international negotiations brought TRIPS to a head. The treaty's legislative authority was ample, and its cohesive set of rules for international trade incorporated a rigid understanding of intellectual property rights (Weissman, 1996). TRIPS represented the global shift towards the privatization of knowledge that would create a new and disparate climate among biotechnology industries of developed and developing countries.

While the embargo restricted Cuba's exposure to western markets and limited the country's selection of trading partners, the overlap of TRIPS and the embargo influenced Cuban biotechnology in more complex ways—some of which allowed it to adjust itself to market changes in exceptionally beneficial ways. (Ways that allowed it to maintain its alternative character). Before delving into a discussion of Cuba's positioning within the

emerging knowledge economy (created by IP law) and describing TRIPS' effect on Cuban formulations of intellectual property, it is necessary to grapple with how these developments came about in the first place.

In the 1980s and 1990s, a sort of legislative world war within the global biotech industry reached its boiling point. Delegates from North American and European countries spearheaded negotiations on the necessity of codifying intellectual property rules into law. They wanted new enforcement mechanisms to slash the amount of copied and counterfeited products coming from the global South (Gorlin, 1999). The US insisted that intellectual property protection be included in the deliberations taking place at the Uruguay Round General Agreement on Tariffs and Trade (GATT), which began in 1986 and finally concluded in 1994 (Weissman, 1996:9). The negotiations were taken up during a series of conferences held by two international regulatory committees. Developing countries strongly favored the World Intellectual Property Organization (WIPO) negotiations over the GATT negotiations. This was because developing nations had greater, or at least equal, leverage in WIPO negotiations and less leverage in the GATT rounds (Weissman, 1996:15). In the end, GATT undertook the debate on TRIPS and those present put forth their modifications and suggestions for the treaty.

Cuba was one of 12 countries that was most active in tabling alternatives to TRIPS during the negotiations. It argued the position that industrialized nations had benefitted from a lack of IP laws when they were growing their biotech industries and that it was only fair to allow developing nations to do the same (Reid-Henry, 2010:119). While not discarding the argument that IP laws might incentivize innovation, Cuba argued in favor of keeping certain biotech products and information open to the public. Cuba and other

developing countries essentially advocated for protection of the public domain holding that patents actually act as barriers to innovation (Hayden, 2010:85-88; Weissman, 1996). Despite pervasive criticisms of TRIPS, the international agreement came into force in January of 1995. Its passing constituting a landmark achievement for countries at the forefront of biotechnology—who now had legal grounds on which to assert their economic and scientific hegemony over emerging industries. As legal scholar Rosemary Coombe argued, TRIPS promotes "a bargain between the developed and underdeveloped countries that offers better terms of trade to the latter if they acknowledge the interests of Western capital as being their own" (1996:1357-1366).

One of the conditions that TRIPS imposes on its signatories is an adoption of US-style patent laws. This rule mandates that the lifespan for patents be 20 years long (Weissman, 1996:4). Scholar Cori Hayden remarks on the monopolistic, and indeed imperialistic, deployment of patents and their effect in Latin America. Her research traces emerging economies for copies and generics that TRIPS-style regulations have induced in Argentina. Primarily she describes how patent law has essentially criminalized the production of generics leading the US to impose sanctions on countries that allow for the production of accessible and local medicine (Hayden, 2008). The argentine government reacted to TRIPS by instating legal protections for the country's local *copista* industry in response to national unrest (Hayden, 2010:96). While a wave of dissent swept across developing nations in defiance of TRIPS, some nations embraced the treaty more than others. Cuba, surprisingly, reacted to the passing of TRIPS with greater amenability than its counterparts. Despite the country's failure to secure fairer conditions during the

tabling of TRIPS, Cuba loosened its confrontational position once the agreement asserted itself globally.

On April 15, 1995 the Cuban government signed the TRIPS agreement and five days later it joined the World Trade Organization. Rosa Simeón and Blanca Tormo, who worked within the Ministry of Science and Technology and the CIMAB respectively, held that these were steps in the country's overall progression toward attaining more business development deals and Western alliances (Jiménez, 2011; Reid-Henry, 2010:121-2). However, Cuba's unique situation both within (as a TRIPS signatory) and outside of global regulatory terrains (marginalized by the embargo), positioned it in a sort of legal limbo where the country was able to maintain its allegiance to its partners in the developing world and uphold its alternative model for biotechnology—all while still attempting to insert itself into lucrative markets.

A director at ONIITEM, Cuba's national patents office put it this way: "Our system now has the best of both worlds" (Reid-Henry, 2010:128). Cuba continued to sell its open-sourced technology to countries that did not respect US patents—a grave offense under TRIPS. Cuba had codified its patent law in the early 1980s but post-TRIPS it began to normalize the practice of registering tens, and eventually hundreds of patents in countries around the world. The way Cuba structured its patent law was fundamentally different from other TRIPS nations, though. In the same style as the rest of the country's regulatory code, Cuban patent law fell in line with the state's socialist expectations for biotechnology. By means of promoting the idea of the state's *paternidad* (or paternity) over biotech inventions, the government asserted itself as the ultimate owner of the industry's products (Reid-Henry, 2010:120; Torres Yribar, 1983). According to Decree

Law no. 68, the individual or group who author an invention, have the right to be remunerated according to the invention's economic importance. Beyond this, the individual inventors must defer to their institute, and so too must the institutes ultimately defer rights to work the patent the state. The state has final authority to use, exploit, and commercialize the invention (Reid-Henry, 2010:120; Torres Yribar, 1983). This formulation of IP rights is entirely dissimilar from that found in US and European systems, whose objective is just as much about protecting the inventors from competitors, as it is about protecting them from the state. Cuba's extreme socialization of patents is a critical part of what makes their biotechnology alternative from these countries.

It was by signing on to TRIPS that Cuba gained proximity to spheres of influence replete with lucrative opportunities for development deals—but did so without undergoing extreme TRIPS-mandated changes. Changes that warrant the implementation of conditions that favor free capital over Cuba's socialized model. Legal scholar Robert Weissman explains that this was not possible for other developing countries that were TRIPS signatories (1996). Cuba found itself in an unprecedented and exceptionally advantageous position, which Simon Reid-Henry argues was only possible because TRIPS and the embargo sought to regulate the same space. He argues, "the overlapping of these two logics of power results in a case of 'regulatory overstretch' in which the dialectical relationship between the two logics collapses" (2010:127). He extrapolates:

> The relevant issue here is sovereignty […] By seeking to override Cuban sovereignty through its extraterritorial clauses, what the embargo actually achieves is to inscribe Cuba's particular form of property rights more strongly into Cuban territorial space. The embargo thus sustains Cuba's alternative intellectual property system by virtue of 'blockading' it from the influx of capital that is supposed to be the principle mechanism of TRIPS' own brand of 'disciplinary neoliberalism. (Reid-Henry, 2010:125-6)

While TRIPS aims to submit global biotechnology industries to neoliberal reforms—in exchange for the prospect of greater capitalization on their products and services—in Cuba's case this condition was impossible. The Cuban market could not be altered because it could not be accessed. The embargo was immutable and posed a query too complex to work through. Thus, Cuba became excluded from pressures to reform its socialist model into an investment-economy for foreign contenders.

Conclusion

Cuba's pharmaceutical autonomy was largely motivated by the embargo because it forced Cuba to invent its own versions of US vaccines and medicines to cover the healthcare needs of its population. It also incentivized the country to continue innovating. Perhaps today the industry is developed enough that it no longer requires this incentive but certainly in its formative years, the Helms-Burton and Torricelli Acts provided a critical impetus for research and development. With regard to the rise of international regulations during the 1990s which fostered intellectual property regimes, the embargo in part afforded Cuba the ability to implement socialized patent law without obvious external objections. While still permitted to be part of TRIPS, "regulatory overstretch" allowed Cuba to take on several development ventures (with Canada, China, the UK and others) without conflict and without having to compromise its self-sufficiency, its socialized IP law, or its trading practices with non-patent respecting countries. For the most part the embargo held Cuba to its promise of orienting biotechnology R&D towards the health needs of the Cuban population, and to proliferating its doctrine of medical internationalism.

Chapter Three: Prognosis for the Industry's Future Directions

In the last twenty years there has been a loosening of the two conditions that I argue are necessary for maintaining Cuba's alternative model for biotechnology. Internally, the state has loosened its monopoly on national industries and externally, President Obama has overturned several embargo restrictions. This short chapter seeks to provide some insight into how these changes could possibly impact Cuba's biotechnology industry in the long run. Specifically, I address the economic changes brought about by Raúl Castro's administration since 2006, and the extent to which the implementation of mixed-market policies has reformed the country's objectives for biotechnology. Following this, I examine a watershed moment in Cuban-US biotech history: the establishment of a trade-venture between the CIM and Roswell Park Cancer Institute in Buffalo, New York in 2016. Finally, I address voices from within the US' for-profit pharmaceutical industry who speculate openly to each other about the viability of selling their products in Cuban markets and seeding manufacturing jobs to Cuba. These perspectives serve to inform what the future involvement of US pharmaceutical companies in Cuba might look like, and how their presence could potentially alter Cuba's alternative model for biotechnology.

Raúl's Mixed-Market Policies and Obama's Loosening of Embargo Regulations

To assess the future of Cuban biotechnology it is necessary to address some key political and economic changes that have occurred in recent years. The first significant change was Raul Castro's ascent to the presidency in 2006. The younger Castro's administration ushered in a new era characterized principally by economic liberalization. Declines in the price of valuable exports (such as nickel), combined with rising costs of basic imports (such as food and clothing), left Cubans unable to meet their needs (Pérez, 2009:118). The new administration was adamant about reversing these trends by minimizing the country's reliance on basic imports, and maximizing the growth of its export commodities. Most significantly, it vowed to do so by liberalizing its markets and by implementing trade policies that were favorable to foreign investors ("Sixth Congress…", 2011). These changes constituted a paradigm shift for the revolutionary government that had previously been unwaveringly protectionist in its economic strategy, excluding its dependence on Soviet subsidies and its current support from Venezuela (Chase, 2011). By describing the shift in Cuba's socio-economic landscape I seek to shed light on how these new circumstances might generate new expectations for Cuban biotechnology.

In 2011, the government adopted a landmark resolution that set in motion a wide range of economic reforms. The cohesive set of regulations was crafted by the 6th Congress of the Communist Party, through a process involving over 600,000 proposals for deletions, additions, and modifications that were put forth by Cuban citizens through public debates in 2010 (Birch, 2015:173-4; Laverty, 2011:23-5). Agricultural reform was the first change to be implemented when idle state-owned land was relinquished to the full-ownership of farmers and collectives to increase food production. Other notable

developments included the decentralization of state control to reverse inefficient management over industries, the eventual phasing out of the dual-currency system and plans to discontinue the country's outdated ration-card system in favor of more cost-effective welfare programs also became a national priority ("Sixth Congress...", 2011). In an attempt to bring Cuba's economic practices up to speed with the globalized economy, the State Council allowed lucrative private markets to emerge and go largely unchecked. Tourism and the private housing industry became the first sites of unregulated capital flow. While these markets have created more private sector jobs, they are also responsible for growing levels of wealth inequality among Cubans (Archibold, 2015).

In rejection of Fidel's earlier branding of entrepreneurs as "parasites", Raúl described the need for self-employment as an "active element in facilitating the construction of socialism in Cuba" (Laverty, 2011:27). In 2011 he announced the elimination of one million costly and inefficient state-sector jobs in favor of reallocating national funds to more productive enterprises. As of 2014, 500,000 of these positions were successfully eliminated ("Sixth Congress...", 2011; Bowie, 2014). Also representative of the new era of liberalization is the ability for companies to set prices according to international standards—and more generally to gain autonomy from the state. Thus the government is not only shrinking federal branches but also relinquishing decision-making authority to business heads in certain sectors (Laverty, 2011).

The party's reforms radically transformed Cuba's economy, and by extension, the nation's attitude towards capital and productivity (Bowie, 2014). In terms of biotechnology, the government does not seem willing to deregulate the industry in favor of privatization. While this may change in coming decades, as of present Raúl reinforces

the Party's position that the state is the sole owner of Cuba's industries ("Sixth Congress...", 2011). But while the government may not intend to privatize biotechnology, it is certainly keen on capitalizing on the sale of its products—a process that if overemphasized can nonetheless subvert the industry's socialized functions in favor of the demands of foreign capital. As one Cuban biotechnology official remarked, the industry's emphasis on cancer research is driven in part because it pays better (Reid-Henry, 2010:115). In general, developing treatments for chronic diseases will give Cuba greater access to foreign markets. As the third greatest source of national revenues, biotechnology is likely to experience greater pressure to produce saleable goods and services in the new economic era (Brotherton, 2011).

In the US, the amendment of embargo regulations has the potential to advance the neoliberalization of Cuban biotechnology. In 2014, Obama approved a set of reforms to create limited but precise avenues for capital exchange with Cuba. While still condemning the Cuban government, the reforms seek to nurture "Cuba's nascent private sector" by providing goods and liquidity to entrepreneurs, facilitating higher remittances, and providing US credit to certain entities ("Fact Sheet…", 2014). These regulations center on streamlining market transactions that primarily benefit Cubans in the private sector, as well as US banks, companies, and tourists. Although limited in scope, Obama's reforms hint at a rapprochement of the US and Cuba's market sectors. And at the very least they blur the lines of permissible trade. The arrival of companies like Netflix, JetBlue, and AirBnB could be a precursor to the introduction of Merck, Pfizer, and a slew of pharmaceutical sister companies (Vasel, 2015). In the final section of this chapter I

address some of the interests that US pharmaceutical companies have in Cuba, and the potential effects that trade with these entities could have on the Cuban industry.

Finally, it is important to acknowledge that Cuban biotechnology is in a peculiar position being both a form of healthcare and a source of national revenue. While current president Raúl Castro's reforms and the easing of embargo regulations can make biotechnology more profitable for Cuba, these recent measures also have the potential to weaken certain socialized aspects of the industry. If financial investments in biotechnology research and development are no longer governed by Cuba's national health needs and instead become dictated by US markets then the core of what determines Cuban biotechnology's alternative character will have been dismantled.

CimaVax

The arrival of CimaVax to the US in 2016 marked a milestone both for the CIM and CimaVax's recipient, Roswell Park Cancer Institute. As the first pharmaceutical trade-venture between the two countries since the embargo, the outcomes of the CimaVax deal will set the parameters for future collaborations between Cuba and the US in the biotech sector. Both the media and Roswell Park publicized the vaccine's arrival and eventual approval for clinical trials in the US (Zhang, 2016; Lee, 2015). But what is missing from the discussion, at least publicly however, are the details about how CimaVax will be produced and marketed in the US once it is FDA-approved. What most concerns us here is the degree of Cuba's involvement in maintaining the affordability of CimaVax (for US patients) once the vaccine is under the control of a US pharmaceutical company.

As I have argued throughout this thesis, an essential factor that sets Cuba's model apart from that of the West is its guarantee of affordability—for both Cubans and non-Cubans alike. What is likely to occur—if the CimaVax deal is anything like Cuba's previous trade ventures—is that the CIM will receive a fixed dollar sum from the company purchasing rights to distribute it and a percentage of the royalties over a certain period of time (Reid-Henry, 2010:142-48). So unless the CIM is insistent about safeguarding CimaVax from inordinate price increases in their contract with the purchaser, the $1 dollar a shot lung cancer vaccine could potentially cost the US population much more (Zhang, 2016).

What the CimaVax case brings to light is that if Cuba can no longer ensure the affordability of its products outside of its borders, the nation's alternative biotechnology model runs a risk of disintegration. Previously the industry has sold its drugs and medical supplies to governments intending to provide affordable care to their populations, with some exceptions (Feinsilver, 1992:92-97). But should Cuba's practice of medical internationalism—which until now has only been applied to mostly lower income nations—also apply to other populations? Certainly wealth disparities in the US, compounded by regressive healthcare policies, impede the affordability of cancer care for hundreds of thousands diagnosed each year. Should the products of Cuban biotechnology not be available to these patients ("Cancer Statistics", n.d.)? These are questions that the industry will have to grapple with as it redefines itself in the new era.

Speculation from the US Pharmaceutical Industry

Anticipation and caution pervade the discussion on investing in Cuba for US pharmaceuticals and related companies. There is a distinct sense of eagerness to establish relationships with the Cubans from executives who are knowledgeable about the country's biotechnology capacities. However, this enthusiasm is tempered by a fear that the Cuban government will place limits on their transactions. By paying close attention to the specialized niche of magazine and journal articles written by and for those within (or tangentially related to) the pharmaceutical industry, we can see certain speculative trends emerging.

Two areas of interest stand out in the conversation about Cuba's biotechnology industry. The first is Cuba's potential as a site for outsourcing drug-manufacturing jobs and the second is the country's potential as an untapped marketplace for US companies to sell their products (McDonald, 2014). Not dissimilarly to the situation in India—where multinational corporations facilitated the development of an industry organized around cheap and expedient clinical trials—in Cuba companies are serious about the prospect of "setting up shop" for cheaper R&D opportunities (McDonald, 2014). Essentially, drug makers and contract manufacturers wish to enlist Cuban scientists for the manufacturing of their products, which would then be sold back on the US market and potentially on the Cuban market as well.

The indifferent attitudes demonstrated by many pharmaceutical spokespersons when musing in print about their financial prospects in Cuba, reflects a profound disregard for, and misunderstanding of, the Cuban biotechnology industry. A predominant opinion in these forums is that trade with the island nation must be averted until Cuba relaxes its policy and accommodates greater incursions of foreign capital. One

industry representative stated, “I might wait for the first McDonald’s to open in Havana before investing too heavily there” (McDonald, 2014). Other industry voices expressed outrage at the high percentage of the state’s equity in joint venture deals, and at the nationalization of profits (Davidson, 2008; Rathbone, 2016). These attitudes reflect a profound disregard for Cuba’s intent to maintain a socialized biotechnology industry and demonstrate the unapologetically extractive intent of the US industry. Because it seems as though US pharmaceutical companies are only interested in bilateral trade that benefits the companies involved, even to the detriment of the Cuban population, the Cuban government will have to exercise extra caution so as to not diminish the Cuban people’s status as shareholders in the biotechnology industry.

Nevertheless, some in the pharmaceutical industry seem to sympathize with the Cuban model and recognize its motivations for trade more precisely. One company spokesperson recognized that it probably is not “the biggest cheque that persuades the Cubans. They are looking for sustainable growth; short-term, medium-term and particularly long-term solutions” (Rathbone, 2015). Others in the industry seem to want to preserve the socialized qualities of Cuba’s model for biotechnology, such as the affordability of its products. Several representatives are hopeful that multinationals will retain Cuba’s reduced drug prices (Rubenfire, 2016).

In conclusion, it is too early to say with outright certainty what character future trade endeavors between Cuba and the US pharmaceutical industry will assume or what repercussions this exchange will have on the country’s alternative model for biotechnology. Certainly the two markets that US companies are seeking to invest in—job seeding and drug export to Cuba—could also benefit Cubans and the national

economy, if executed with care. Nevertheless, as of the present moment, it appears as though the marketization of Cuban biotechnology is moving at a slow and cautious pace and that the companies most willing to compromise and accept the conditions set by Cuba's socialized model will be the first to secure business deals.

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Biography

Originally from Athens, Ohio, Alejandra Marks graduated *magna cum laude* from Ohio University in 2014 with a Bachelor of Arts in Political Science and a minor in French. In 2015, Alejandra began the M.A. program at Tulane University's Stone Center for Latin American Studies. In winter of 2015 she was awarded a departmental research grant, with which she conducted field research in a Mapuche community in Temuco, Chile. In 2016, Alejandra was awarded a summer research grant from the Tulane-Xavier MHIRT program, funded by the National Institutes of Health, to conduct public health research in collaboration with a Cuban professor in Havana. Alejandra will continue her research on public health disparities in Latin America through a Ph.D. program at Tulane University.