

DISCOURSES, COALITIONS, AND DURABLE IDENTITIES: NARRATIVES OF
LAWMAKING AND REGULATION OF CLINICAL TRIALS IN COSTA RICA

By

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A DISSERTATION

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

Anthropology – Doctor of Philosophy

2019

ABSTRACT

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For over four decades, Costa Rica was an increasingly attractive location for clinical research sponsored by foreign governments and multinational pharmaceutical companies. However, in 2010 the Constitutional Court handed down a decision to suspend interventional medical research which resulted in the loss of over 200 jobs and a professional brain drain, as physician-researchers and their teams either left the country or sought new employment. Over the years two opposing advocacy coalitions, whom I call the Statists and the Neoliberal Entrepreneurs, engaged in strategic use of the media to reinforce their policy perspectives and core beliefs about whether and how clinical research should be regulated within Costa Rica.

This dissertation examines these narratives and discusses how this discourse led to the coalescence of two distinct advocacy coalitions with a membership of elite leaders in academia, the public health system, the government, and private research facilities. The decades-long reiteration of these narratives about clinical research and the role of foreign investment led to each coalition developing a cast of characters, explicitly identifying the heroes, the villains, and the victims of these stories. The analysis of these narratives and coalitions extends three areas of anthropological work. Critical medical anthropology addresses the ways a small country confronts globalization through laws and regulations. The anthropology of public policy allows for the exploration of policies and policymakers (both formal and informal) as problem spaces to be examined. Finally, this dissertation illustrates the role of narratives (stories) that are used to

enact and influence change and how the media becomes a vehicle for the transmission of elite discourses.

The central question of this research asks how the lawmaking process impacted the livelihoods and social capital of those in and around the clinical research industry in Costa Rica. Three specific aims have guided my research. To do this, I explore the public debate regarding clinical research in Costa Rica as presented in news articles and opinion pieces. Secondly, I examine the changes in the livelihoods of healthcare and research professionals, support staff, and other stakeholders due to the 2010 Constitutional Court decision to suspend new biomedical research. Finally, I analyze the advocacy coalition strategy of policy narratives used by coalitions for and against clinical research inside the country and the effects these strategies had on identity, both in each's coalition identity and for individuals within each coalition.

This dissertation research utilizes ethnographic methods, narrative analysis and a qualitative use of the Narrative Policy Framework as presented by Gray and Jones (2016) to traces the growth of these two local coalitions and their strategies for changing policy to regulate clinical research in the country. Employing a qualitative approach to the Narrative Policy Framework often used in public policy analysis highlights the ways in which consistent policy narratives shape coalition beliefs, and the durable identities of both the coalitions and the individuals within each coalition. In this dissertation, I have provided evidence of how elites in Costa Rica used the stylistic quality of argumentation through opinion pieces to secure their social position, entrench their perspectives on clinical research in the country as well as to reify Costa Rica's exceptionalism according to each advocacy coalition's definition.

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ACKNOWLEDGEMENTS

Primero, debo agradecer a todas las personas que entrevisté en Costa Rica, eran personas ocupadas que me dieron su tiempo, me invitaron a sus hogares y oficinas, respondiendo mis preguntas con franqueza. Segundo, esta investigación y disertación no serían posibles sin mis amigos de Costa Rica, ellos brindaron su amistad, su apoyo, su visión y su compromiso.

Especialmente, agradezco a mis tres amigas y ayudantes Marcela Molina, Elizabeth Robles y Alejandra Hernández, ellas siguen siendo un extraordinario apoyo. También doy gracias a María José, Monserrat, Fawn, Jeffrey, Isaac, Juan Manuel, Cristián, Sharon, Lucía, Paola, Nerli y mi equipo Dark Side Roller Derby. Todos ellos trabajaron con fuerza y atención. Finalmente, le agradezco a Randolph von Breymann, y a Flory el ama de llaves, ellos crearon un hogar tranquilo y seguro para mí durante mi estadía en San José. ¡Muchas gracias a todos!

My educational journey was decades in the making and I cannot possibly name everyone who supported me in large and small ways, but I thank you. It truly has taken a village to raise this Ph.D. First and foremost, I want to extend my deepest gratitude to Mindy Morgan, who guided me with respect and a deft hand. I simply would not have produced the work you see here without her considerable support. Committee members Adán Quan, Monir Moniruzzaman, and Fred Gifford provided the sails to Dr. Morgan's rudder. I thank them for always being available and supportive during this whole process. I thank Linda Hunt for providing support and guidance in the beginning. Jodie O'Gorman, Chantel Tetreault, Laurie Medina, Libby Bogdan Lovis, Ann Mongoven, Sean Valles, and Tom Tomlinson lent an ear or an idea along the way.

There are so many Michigan State University colleagues I spent endless hours working with, commiserating with, and from whom I sought guidance. Specifically, Linda Gordon, Fayana Richards, Anna Jefferson, Rowenn Kalman, Charlotte Cable, Adrienne Daggett, Karin

Rebnegger, Taz Karim Daniels, Isabel Montemayor, Jessica Yann, Rachel Elbin, Nikki Klarmann and so many more. Terra Waggoner Johnson and Yolanda Brooks were “combat buddies” during a particularly intense time. All of my friends from the Alliance for Graduate Education and Professoriate offered me an opportunity to connect to a larger network of graduate students on campus. I, literally, could not have completed this dissertation without the extraordinary help of Jennifer Shappell in Financial Aid, who always found a way to alleviate my financial pain. I would also like to thank my colleagues from other universities with whom I participated in academic coaching especially Laurie Prange Martin, and Mallory Barnes. Debra Payne, I cannot every begin to repay you for the generosity you showed through the gift of your time, wisdom, and support.

So many people in my life have loved and supported me through this process. Nikki RoseRoyce let me “care” for her house after I returned from fieldwork. Desi and Wessell Anderson fed my stomach and my soul at Gumbo and Jazz and found work for me when I was financially struggling. I thank my aunt, Dale Trafton and my cousin Greg Bleil and his wife Karla for their endless generosity and support. I extend my gratitude to Tracie Prieto and Kim Jones, two people who have seen me at my best and my worst. Their decades long support, kindness, and friendship are so important to me. Lynnette Zahrn King has walked with me for this entire journey from the first day of orientation to this moment of completion. We have studied together, worked together, traveled together, celebrated together, and spent many long hours in coffee shops. You are an inspiration and a role model to me. Finally, this is dedicated to all who raised me: Betty, Allen, and Lois. To Aunt Cathy who has defied all odds.

I received funds at different times during this journey. The Alliance of Graduate Education and Professoriate at Michigan State University provided significant support over the

course of four years. Latin American and Caribbean Studies Research Support, and the Pre-dissertation Award from the Department of Anthropology offset some research costs. I also received significant support through several Office of Study Abroad grants from Michigan State University which helped with expenses for a Study Abroad Program in Costa Rica I attended. Finally, the College of Social Sciences generously supported the final leg of this dissertation. The bulk of my research and fieldwork costs and nearly my entire graduate school experience was covered by student loans.

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KEY TO ABBREVIATIONS

ACF	Advocacy Coalition Framework
ADEVI	<i>Asociación para la Defensa de la Vida</i>
AP	Academic Personnel
Asdecavi	<i>La Asociación Costarricense para la Defensa de la Calidad de la Vida</i>
CAFTA	Central American Free Trade Agreement
CCSS	<i>Caja Costarricense Seguro Social</i> ; often referred to colloquially as “ <i>la Caja</i> ”
CEC	<i>Comités Éticos Científicos</i>
CENDEISSS	<i>Centro Desarrollo Estratégico e Información en Salud y Seguridad Social</i>
CLOBI	<i>Comités Locales de Bioéticas en Investigación</i>
CMA	Critical Medical Anthropology
CONIS	<i>Consejo Nacional de Investigación en Salud</i>
EBAIS	<i>Equipos Básicos de Atención Integral en Salud</i>
FA	<i>Frente Amplio</i>
GAM	<i>Gran Área del Metropolitana</i>
GDP	Gross Domestic Product
GO	Government Officials or Employees
HCP	Health Care Providers
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
IAP	<i>Instituto de Atención Pediátrico</i>
ICE	<i>Instituto Costarricense de Electricidad</i>

ICIC	<i>Instituto Costarricense de Investigaciones Clínicas</i>
ICMRT	International Center for Medical Research and Training
IDEA	The International Development Ethics Association
INCIENSA	<i>Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud</i>
INS	<i>Instituto Nacional de Seguros</i>
IRB	Institutional Review Board
ISI	Import-Substitution-Industrialization
LSU	Louisiana State University
LSU-ICMRT	Louisiana State University-International Center for Medical Research and Training
NIH	United States National Institutes of Health
NPF	Narrative Policy Framework
PAC	<i>Partido Acción Ciudadana</i>
PANI	<i>Patronato Nacional de la Infancia</i>
PASE	<i>Partido Accesibilidad Sin Exclusión</i>
PEG	<i>El Proyecto Epidemiológico Guanacaste</i>
PLN	<i>Partido Liberación Nacional</i>
PRV	Private Research Personnel
PUSC	<i>Partido Unidad Social Cristiana</i>
PRN	<i>Partido Restauración Nacional</i>
SAP	Structural Adjustment Program
SRV	Syncytial Respiratory Virus
TEC	<i>Tecnológico de Costa Rica</i>

UCIMED	<i>Universidad Ciencias Médicas</i>
UCR	<i>Universidad de Costa Rica</i>
UNA	<i>Universidad Nacional</i>
UNED	<i>Universidad Estatal a Distancia</i>
UNESCO	United Nations Educational, Scientific and Cultural Organization
USAID	United States Agency for International Development
USSR	Union of Soviet Socialist Republics

CHAPTER 1: INTRODUCTION

“Moreover, there is a certain urgency to the kind of anthropology that is concerned with power.”—Laura Nader, “Up the Anthropologist—Perspectives Gained from Studying Up”

I had just signed up for a summer study abroad program in Costa Rica through my university in February of 2010, when the professor leading the trip sent me an email with a link to an article entitled, “*Sala IV suspende los estudios clínicos en seres humanos*”¹ (Díaz 2010). I was crushed. I had planned to participate in the summer program so that I could learn about the Costa Rican healthcare system and make contacts and develop collaborations for my future dissertation research on clinical trials conducted in Costa Rica. I had scoured clinicaltrials.gov and discovered that there were upwards of 100 local Costa Rican sites participating in multi-sited clinical trials sponsored by several different multinational pharmaceutical companies. Costa Rica seemed a perfect location for me to explore the ethics of international clinical research. Now, two years into my graduate experience, a significant roadblock caused me to reconsider my original idea. If I could not study clinical research in Costa Rica, then could I study the effects of the suspension of clinical research on the livelihoods of local physician-investigators, their research team members, pharmaceutical company employees, and others who had been directly affected by the suspension?

Fast forward to November of 2013, having just completed my comprehensive exams and defended my proposal, I was ready to pack everything into storage and set my sights on moving to San José, Costa Rica. Again, I saw an article in *La Nación*, one of Costa Rica's most prominent newspapers (Oviedo 2013). The legislature had approved a law, and the president

¹ "The Constitutional Court suspends clinical studies in humans"

signed it. Now that a law was in effect, regulation clinical research in the country could begin again. Clinical research was back on track in Costa Rica. Or was it?

Fully committed to exploring the effects of the suspension on research personnel, I wondered how the new law would affect my dissertation research. I had questions to answer: what happened to them as a result of the suspension; how the suspension had affected patient care if at all; and how the public debate of about clinical research in Costa Rica had affected the suspension and the law project. The requisite institutional approvals were in place, and so I continued with my current plan with the caveat that I would include study participants should I have an opportunity to talk to them while in the country. The twists and turns and drama of the 2010 suspension and the approval of the 2014 law of these two decisions, I would find out, that were just a small peek into the story of clinical research in the country.

As I discovered over two years of fieldwork, I came to see these research professionals as caught between a globalizing neoliberal biomedical economy (the pharmaceutical industry) and a state trying to maintain some control over the flow of commerce into their country. But why clinical research? Why was this particular industry singled out as particularly damaging to Costa Ricans and the Tico way of life?² When Amazon, Intel, IBM, McDonald's, Starbucks, Walmart, eco- and medical tourism, and many other globalizing industries were developing an increasingly powerful presence, why were pharmaceutical companies and U.S. educational and health agencies sanctioned; and at what expense to local citizens?

For nearly two decades, Costa Rica had been an increasingly attractive site for clinical research on vaccines, diabetes, and asthma, among other disease states. In 2010, however, the

² Costa Ricans call themselves Ticos (or Ticas in the feminine) and this nickname is based on the Costa Rican affectation of the diminutization of words with the addition of –tico/--tica such as “chicotico” for little guy.

Constitutional Court brought the whole thing to a halt. As a result, no new protocols were approved for nearly five years. Pharmaceutical companies shifted their sites to Guatemala and Panamá, and Costa Rican physician-investigators lost opportunities for publication and international collaborations. Approximately 200 people, who had worked locally in clinical research lost their jobs. Many of these workers either had to leave the country to find work, return to work in the public health system, or remain unemployed. In 2015, a law was passed by the full legislature to regulate clinical trials once again; however, inconsistencies remain between the law and the regulations passed to enact the legislation. Many people remain skeptical about whether pharmaceutical companies will return or whether lost momentum will ever be regained.

It is true that the randomized clinical trial is probably the most effective way to test the effects of new medications in humans and we have had unprecedented successes in many areas of medicine as a result. It is also true that many human rights atrocities were perpetrated in the name of science, especially on people of color, women, incapacitated adults and children, and people from less developed countries (Howard-Jones 1982). Anyone who has needed institutional review board approval for human subject research in medicine, public health, or the social sciences has had to attend classes and training that remind us of the kinds of abuse and violence that can be inflicted by state and private institutions including health systems and academia. It is with this first-hand knowledge of both the benefits and risks to individuals and society that I entered the field in San José, Costa Rica on January 14, 2014. It is also with this knowledge that I seek to craft a dissertation that challenges my cultural assumptions about science, knowledge, and biomedical markets to best represent the people I interviewed and to produce a critical, yet balanced view of lawmaking and regulation of clinical research in Costa Rica.

In this dissertation, I argue that the narratives, which formed around the role of clinical research within the country, led to the coalescence of two distinct advocacy coalitions. These coalitions used the policy strategy of opinion pieces to engage each other in the ongoing debate regarding the effects of globalizing biomedical economies on Costa Rican bodies. Each coalition sought to influence policymakers. This led to one coalition's efforts to suspend clinical research in the country in 2010, and then four years later, the other coalition's efforts to pass a local law that regulates it. Further, the reiteration of these narratives about clinical research and the role of foreign investment over forty years led to each coalition developing a cast of characters, explicitly identifying the heroes, the villains, and the victims of these stories. This analysis is supported by and extends three areas of anthropological work:

- 1) the use of critical medical anthropology to examine the tensions between globalizing biomedical economies and local state management of foreign investment;
- 2) the anthropology of public policy and the idea of policy and policymakers as problem spaces to be examined from a cultural and critical perspective;
- 3) the role of the narratives (stories) we use to enact and influence change and the role of the media in elite discourse.

In an ever-increasing global biomedical marketplace, this research significantly adds to the knowledge base in the areas of international clinical research and international markets, law-making and policy-making, livelihood studies, and medical anthropology.

The central question of this research asks how the lawmaking process impacted the livelihoods and social capital of those in and around the clinical research industry in Costa Rica. Three specific aims have guided my research. First, to explore the public debate regarding clinical research in Costa Rica as presented in news articles and opinion pieces. Second, to

examine the changes in the livelihoods of healthcare and research professionals, support staff, and other stakeholders due to the 2010 Constitutional Court decision to suspend new biomedical research. Finally, to analyze the advocacy coalition strategy of policy narratives used by coalitions for and against clinical research inside the country and the effects these strategies had on identity, both in each's coalition identity and for individuals within each coalition.

This dissertation is theoretically grounded in critical medical anthropology, itself a theoretical perspective that draws upon other areas of cultural anthropological research to understand the intersections of political economy, health, illness, the body as a contested space, the culture of biomedicine, health systems, and emerging technologies among many other lines of research (Rhodes 1996, Sargent and Johnson 1996, Morsy 1996). For this dissertation, critical medical anthropology (CMA) is best for examining the impact of the globalization of biomedical research on local health systems and the effects on the individuals most affected by these processes and systems. One criticism of CMA is that the main focus of investigation is at the "top" of the power structures. However, Singer and Baer argue that this idea arrests the power of the critical lens on the ground. The benefits of a critical perspective are that this theoretical conceptualization of political economy and power structures considers the "experience and 'agency,' that is individual and group decision making and action" and that these are constructions that can be analyzed carefully (Singer and Baer 2007, 34).

Witeska-Mlynarczyk writes that critical medical anthropology "merges political-economic approaches with culturally sensitive analysis of human behavior grounded in anthropological methods" and it is this approach that most influenced my methodology, analysis, and overall perspective during fieldwork, analysis, and writing (Witeska-Mlynarczyk 2015, 385). It is in this "big-tent" approach that medical anthropology, especially critical medical

anthropology provides the concepts, methods, and “structural models of health and wellbeing in ways that are critically reflective, cross-cultural, people-centered, and transdisciplinary” (Panter-Brick and Eggerman 2018, 1). As such, critical medical anthropologists are concerned with how people acquire disease and seek treatment within the more extensive political-economic process and asymmetrical power structures within and across national borders.

This dissertation research takes, as its starting point, the influence and effects of globalization and neoliberalism in creating a fertile ground for clinical research in Costa Rica in the late-1980s and early 1990s. With the reluctant signing of CAFTA in the early 2000s, more aspects of the local health system were privatized, and a distinct mixed medical system of public care and private care provided patients with multiple options, and physicians with multiple incomes as each crossed and recrossed the porous boundaries between the two (Rayner 2014, Lee 2012, King 2016, Noy 2013).

Globalization, Neoliberalism, and the Costa Rican State

Several decades after the first Latin American experiment in neoliberalism took place in Chile, Latin American countries still struggle with maintaining autonomy while participating in a global marketplace (Paley 2001). Venezuela has cut off all contact to devastating results on its economic, and social well-being, while Cuba has dipped a toe into a socialist-capitalist model, and, as the result of lifted sanctions by the United States, is in the first blush of burgeoning entrepreneurship (Grugel and Riggirozzi 2018, Brotherton 2008). Costa Rica has also struggled with finding an approach to the demands to privatize through the neoliberal policies of the United States and international monetary institutions (Rayner 2014).

Costa Rica is an exception in Latin American in terms of stable democracy, development, and social welfare. It fell under the sway of such ideals when faced with a severe economic crisis

in the early 1980s along with other countries in Central America. International lending agencies attached trade agreements (in this case, the Dominican Republic and Central American Free Trade Agreement known as DR-CAFTA or simply CAFTA) and privatization to structural adjustments (Chasteen 2006, Harris 2008, Harris and Nef 2008, Silva 2001, Marti 1982, Rayner 2014). Begrudgingly and with much citizen protest, Costa Rica accepted the United States as a trading partner, which has resulted in destabilization of the political party system, support for clientism, and intra-municipal conflicts and destabilization due to decentralization (Rayner 2014). These decisions challenged many of the national myths of exceptionalism, the priority for peace, and the wellbeing of the country's citizens when pressured by the US to become a staging ground for their interventions into the war in Nicaragua (Bengoa and Sanchez-Robles 2003, Ryan 2004, Wilson 1994, Marti 1982, Seligson 2001, Honey 1994).

According to Ureña García (2011), by the 1990s, Costa Rica had an influx of “*moles*” (malls) and fast food with the Gap, H & M, Express, Taco Bell, Wendy's, and McDonald's popping up all over the metropolitan area and elsewhere. He argues that “telecommunications were the cornerstone of globalization and a consumer society” (Ureña García 2011, 212). This triple threat of economic crises, trade agreements that opened the globe to Western products and services, and a push to privatize previously government-managed programs that led to the explosive growth of multinational corporations, including pharmaceutical companies and other health markets (De Grauwe and Camerman 2002, Petryna and Kleinman 2006).

As a result, to understand how the Costa Rican Constitutional Court came to suspend clinical research in 2010, one must understand the role that the United States played in shaping the views of globalization in the minds of local elected officials over forty years. It is necessary to consider the context in order to situate this dissertation research properly. The explosive

growth of clinical research in Costa Rica in the 1990s was the direct result of the growing global reach of pharmaceutical companies, whose growth was fostered by the twin processes of globalization and neoliberalism as implemented by international monetary institutions. It is this context presented first, to understand better the analysis of opinion pieces written in the early days of the new millennium.

A Brief Discussion of Globalization, Neoliberalism, and the State

Briefly, a great push was made to modernize poor and developing countries to access their human and natural resources and to stave off communism in the 1950s³. However, models using the Marshall Plan as a template failed to replicate post-World War II European success in these struggling countries. Regardless, new models of development began to change the measurement of progress. Yet, the shining examples of such progress remained the developed countries of the West (Moyo 2009, Ortiz 2006). While the idea of a homogenized world has failed in many respects but has succeeded in others—especially in the global transfer of ideas—the global economic experiment is still being conducted in various locations around the world with variable results (Edelman and Haugerud 2005, Hannerz 1989, Grugel and Ruggirozzi 2018).

Neoliberalism rode in on the heels of the Marshall Plan type of development models, with the goal of reconfiguring Marxist ideas of capitalism, addressing threats of Communism, and supporting developing countries through World Bank and International Monetary Fund loans (Chasteen 2006, Harris 2008, Harris and Nef 2008, Silva 2001, Marx 1978). With the principals of neoliberalism—a free market with minimal to no governmental regulation—it was argued that privatization of social welfare programs and state-run services would lead to better services for

³ Office of the Historian, Department of State, United States of America. Accessed March 17, 2018. (<https://history.state.gov/milestones/1945-1952/marshall-plan>)

citizens without the bureaucratic ennui found in government while simultaneously encouraging citizens to replicate the entrepreneurship ideal through responsibility for themselves and their communities (Harvey 2005, Roseberry 1988, Kingfisher and Maskovsky 2008, Rayner 2014, Noy 2013).

Globalization's Critics

Alan V. Deardorff writes in "What Might Globalisation's Critics Believe?" that we are troubled by what even to call the critics of globalization when he notes that they are "loosely called anti-globalists" (Deardorff 2003, 639). One of the challenges Deardorff faces is that critics of globalization are not against globalization in a general sense. Instead, they are "opposed to globalization in its current form" (Deardorff 2003, 643). He considers and rejects other labels such as "anti-corporate," "globalisation skeptics" and settles on "globalisation critics" as the best option for, while they are critical of globalization, "their criticism is not necessarily unmixed with praise and many of them are quite capable of imagining changes in the global economy that would leave it global" and acceptable to them (Deardorff 2003, 643). The critical takeaway--besides lacking an appropriate label that truly encapsulates who globalization critics are--is that globalization is complex and challenging and often beneficial, even for its critics.

Deardorff notes that critics hold the corporations at fault, not the developing countries themselves, and he claims that critics see the corporations as "the villains" (Deardorff 2003, 641). While the market is held accountable, critics still blame the corporations, seeing the "owners and managers...[as] heartless, greedy, profit-seeking monsters" (Deardorff 2003, 642). Ultimately, Deardorff acknowledges that globalization critics have valid points in some cases (agriculture and textiles) where globalization needs to do more, while other cases such as

intellectual property where there are definitely flaws that corporate power's influence in political spheres seems to aggravate (Deardorff 2003).

John S. Dryzek, in *Deliberative Global Politics*, argues that globalization has resulted in a weakening of the central state such as put forth by Gramsci and Foucault. He posits that through globalization, the discourse of democracy has been decoupled from the state and argues for a "transnational discursive democracy" (Dryzek 2006, 26). Like other critics and challengers of globalization, Dryzek sees corporations as wielding immense power when they can "threaten to take their operations elsewhere if a country tries..." to impose any restrictions upon the corporation (Dryzek 2006, 98). Like Edelman and Haugerud above, Dryzek frames globalization as more than about economics, but also as a global exchange of ideas, media, and culture (Edelman and Haugerud 2005, Dryzek 2006).

Martin Shaw argues in "The Global Transformation of the Social Sciences" that the rise in critique of globalization can be traced to just after 9/11, which "has widely been seen as marking an end to the liberal globalism of the previous decade" and notes that this discursive shift has been instrumental in highlighting "important challenges to the emergent global civil society" (Shaw 2003, 35). Even critics from the left or the right cannot ignore globalism completely. Whereas many who take on globalization do so from an economic perspective, Shaw, like Dryzek, argues that "'global' is more than any one trend...[and]...represents a fundamental integrative tendency in world politics, culture, economy, and society" (Shaw 2003, 36). He sees globalization as having, at its core, a strongly "political infrastructure" that has decentralized states but reformed them into globally linked states that manage geopolitical and economic issues both within and between networks and boundaries. Another aspect of this political core is that there is a growing "global civil society" that aligns around central "agendas

and networks to guide, organize, and legitimize their actions” (Shaw 2003, 36-37). In this way, Shaw aligns with Dryzek’s idea of a global deliberative democracy through this growing and vocal worldwide civil society.

Because of these diffuse and sometimes contradictory discourses for and against globalization, a modern anthropologist is challenged to define her setting in the traditional ways. This leaves her to struggle with reshaping traditional methods of anthropological research to address cultures that exist simultaneously in different locations and whose landscapes, ideas, and organizing principles have been reshaped by Western markets, commodities, and cultural exports (Collier and Ong 2005, Friedman 2006, Gille and Ó Riain 2002). One such arena reshaped is the globalizing of biomedicine, especially the markets of biomedicine or what I call, globalizing biomedical economies.

Corporate Power and Globalizing Biomedical Economies

Corporations have been a part of the economic firmament since the 16th century. For example, in Britain, where they began as the original non-profits, they were under the direct control of the crown and an alternative to corrupt entrepreneurs, small partnerships, and guilds to consolidate resources and protect the group’s best interests (Makwana 2006a). However, as colonial power expanded across the globe, corporations became both representatives of European power and tools for extracting human and non-human resources from far-flung environs. While the US instituted charters to restrict the power of corporations, their power grew just before and just after the Civil War, both politically and economically, and by the late 1800s, corporations had succeeded in lobbying for protections under the 14th amendment of the US Constitution as Corporate Personhood (Makwana 2006a). However, with the introduction of neoliberal

principles in the 1970s, corporations have expanded their reach into nearly every corner of the globe.

The basic tenets of neoliberalism include the idea that private economic markets are the best venue for managing the apportionment and use of labor, materials, and resources (Armada, Muntaner, and Navarro 2001). Further, this ideology disavows governmental regulations of markets with the idea that a free market will ultimately regulate itself to maximal benefit of all. To achieve these ends, a focus on free trade, deregulation of corporations, privatization of nationalized programs such as health and pensions, and economic liberalization have been implemented (Makwana 2006a, Armada, Muntaner, and Navarro 2001). While the stated goal might have been economic prosperity for all countries and people, the reality is that, with the rise of multinational corporations (MNCs), economic and political wealth have been concentrated in the hands of a few, while the majority suffer staggering inequalities that affect health and dignity (Armada, Muntaner, and Navarro 2001, Makwana 2006b). Armada *et al.* note that, while the stated goals of neoliberalism are global equality, the empirical evidence indicates otherwise, “...studies in the United States...show increased inequities resulting from the privatization of health services...worse health outcomes [and] ... barriers to health care access” (Armada, Muntaner, and Navarro 2001, 731). It is in this fertile ground that MNCs have flourished, especially since the global economic crisis of the 1980s (Armada, Muntaner, and Navarro 2001).

Many modern corporations started seeking labor and material resources in developing countries with renewed vigor to reduce expenses and maximize profits. Developing countries lacked the political infrastructure to adequately regulate the business of profit-making, the treatment of workers, or the depletion of local resources. In the 1980s, MNCs were able to use the global economic crisis to further cement their power and influence over local and national

governments and international agencies such as the World Bank, the World Trade Organization, and the International Monetary Fund. Funded by corporations and armed with a neoliberal agenda, these international organizations were poised to cajole countries with loan repayment challenges into privatizing their public welfare systems such as healthcare, pensions, and public utilities. Multinational corporations were ready to assume the management of these enterprises (Makwana 2006a, Armada, Muntaner, and Navarro 2001).

One of the fastest growing global markets is pharmaceutical sales. Its largest markets remain the United States and Western Europe, but, with the fall of communism and increasing awareness of global markets, sales have increased in Eastern Europe, Asia, and Latin America (Petryna 2009, Glickman et al. 2009). As a result, the business of searching for new medications has also expanded. There are more than 350, 000 trial sites globally and the US regulatory agencies are incapable of maintaining proper oversight or monitoring for this expanding market (Petryna 2009).

There are several reasons for this expansion of research into resource-poor countries. In the United States, stringent regulations, slow bureaucratic processes, and the increasingly expensive costs of study drugs and diagnostic tests related to healthcare have made clinical research in the United States cost-prohibitive. Prospective US human subjects, with chronic or terminal diseases such as diabetes, HIV/AIDS, or cancer, have often been treated with multiple medications and enroll in clinical research in a last effort to find a viable treatment. Their disease state and treatment history make their participation as human subjects risky; complicates the results of the study and adds to the expense of conducting the clinical trial. Other countries provide treatment naïve study subjects, less stringent regulatory procedures, and the ancillary

tests and treatments at a much lower cost than in the United States or Europe (Glickman et al. 2009).

Building on the idea of things having a biography or a life cycle (see Kopytoff 1986), Van der Geest *et al.* (1996) consider the lifecycle of pharmaceuticals from bench to market and through the prescribers into the hands of consumers and, ultimately, their efficacy in treating disease. To do so, one must consider the context, the agents, the exchanges and the norms involved at each stage of a medicine's lifecycle. These elements make the pharmaceutical industry a fruitful area of investigation for medical anthropologists as, through globalizing biomedicine, pharmaceuticals transect nearly every point on the globe (Santoro and Gorrie 2005).

For Rajan, biocapital is the overarching concept under which he studies genomics and pharmaceutical in the US and India. He argues that this concept helps to understand the “larger epistemological and political economic terrains...within which they [genomics] were situated” (Rajan 2006, 2). With a new reading of Marx’s political economies and Foucault’s biopolitics, Rajan focuses on “the *globalizing* dimensions of capital and, increasingly, of technoscience” although he is quick to note that comparisons can be asymmetrical and that it is important to the continued study of globalizations to focus on the particular expressions of it within localized contexts (Rajan 2006, 14). As a result, Rajan (2005) addresses the effects of market exchange and the merging of life sciences and capital to provide personalized medicine within India and the United States and argues that these processes have led to the development of a “sovereign consumer subject” triangulating between knowledge constructions of genomics and the market ideals of speculative capitalism (Rajan 2006, 19).

I define globalizing biomedical economies as those industries related to aspects of healthcare that have become global in some aspect. This includes both the legal and illegal organ trade, medical tourism, medical device manufacturing, and pharmaceuticals. Through this concept, I can show how clinical research entered Costa Rica, along with other industries of globalization such as fast food restaurants, outsourced manufacturing and services, and cell phone companies and became normalized in the wake of the structural adjustments of the 1980s.

For example, one of the results of structural adjustments was that Costa Rica began privatizing aspects of many previously nationalized industries and services, one of which was its public health system *La Caja Costarricense de Seguro Social*, the CCSS, or colloquially known as the *Caja*. As in other countries, this resulted in a mixed medicine system of patient care in which physicians who work for the Caja often provided parallel private healthcare services, and, also, maintain private practices (Gifford and Rodriguez 2011, Casas and Vargas 1980, Clark 2002, 2010, Rayner 2014). This ability to work in the private and public health sectors at the same time allowed Costa Rican physicians to recruit their CCSS patients into clinical trials that they were leading in the private practice. This flexibility was a point of contention between the two coalitions that were forming around the roles clinical research and its markets were playing in Costa Rica. For the Statists, these foreign companies were threatening the country's autonomy and the health of their citizens. Further, those working in clinical research and private medical practices were making better livings than those treating patients in the *Caja*. In the next section, I will discuss how intimately entwined biomedicine and the state have been in treating and governing populations.

States and Governmentality

Historically, biomedicine has been closely tied to the needs of the state in maintaining population health through such initiatives as sanitation, managing epidemics, and defining the boundaries of good population and individual health. To understand more about the functioning and treatment of human bodies and to extract the most production, experimentation and the body parts of the gendered, racial, or others who are disenfranchised have been used to further population health. This section will focus on how biopolitical processes render bodies useful to the state and its institutions in the context of globalizing biomedical research.

For Foucault, what distinguished the modern state from sovereign power was the shift from a deduction, of goods, services and even lives of citizens to an encouragement of life and its preservation through various regulations over populations and disciplines over individuals (Lemke 2011, Foucault 1984). Foucault defines this relationship between the health of the individual and the population with the economic and civic needs of the state as biopolitics, and it became the analytical measure of his investigations into the evolution of prisons, universities, hospitals, and clinics. He saw this optimization of power as disciplines which he defines as "an anatomo-politics of the body" (Foucault 1984, 262). As power transitioned from sovereign to the modern nation-state, more focus was placed on citizens' bodies through controls such as discourse, practices, and institutions (Lysaught 2009).

Further, Foucault discusses the "art of governing" in which governments should be seen as governing with a light hand and acknowledged that there is not a single source of governing power, but that it is distributed across multiple venues within the state so that citizens can be "nurtured," culled," or "disciplined" as necessary, whereas Gramsci's approach places the locus of power on the "level of ideas" with an emphasis on "hegemony or domination" (Rose,

O'Malley, and Valverde 2006, 84-85). According to Rose *et al.*, Foucault wants us to shift our focus away from the peak and peer into the valleys, for we must ask who the governed are to understand how the governing of them led to the formation of states (Rose, O'Malley, and Valverde 2006).

James Ferguson and Akhil Gupta (2005) extend these ideas into the analysis of states as objects of ethnographic enquiry. For the authors, the state “represents [itself] as [a] reified [entity] with particular *spatial* properties...of ‘vertical encompassment’” which gives states power over all “other institutions and centers of power” (Ferguson and Gupta 2005, 105-106). The vertical axis of this spatiality speaks to a hierarchical approach through which the state can oversee what is happening at the “grassroots” level (Ferguson and Gupta 2005, 106). Encompassment is the umbrella under which the state encompasses all of the social institutions of civil society (Ferguson and Gupta 2005). The authors argue for an “ethnography of encompassment...that would take as its central problem the understanding of processes through which governmentality (by state and nonstate actors) is both legitimated and undermined” (Ferguson and Gupta 2005, 122-123).

Rayner, in his study on the grassroots protests of CAFTA in Costa Rica, in which another set of coalitions formed for and against the signing of the trade agreement, illustrates how Costa Rican citizens pushed back, not only against their own government, but against the idea of free trade by refusing to take up neoliberalism, thereby ‘asserting the sovereignty of the Costa Rican people over the transnational corporations that profit from their land and labor’ (Rayner 2014, 5). Here, I use these ideas of governmentality and of an ethnography of the state to understand the way in which clinical research in Costa Rica was impacted by state actions and how both state bureaucracies and social institutions were impacted by clinical research.

Social Capital, Elite Discourses, and Narratives

Social Capital

Social capital is the thread that runs through this entire dissertation. Physician access to opportunities to lead biomedical research projects sponsored by multinational pharmaceutical companies; the ability to access newspapers to put forth ideas for and against clinical research; the ability to survive the 2010 suspension of clinical research in the country; the opportunities to influence governmental authorities and agencies; and to shape policy into law were all the result of enormous amounts of social capital. In this section, I illustrate all of the ways in which the idea of social capital has influenced this dissertation research.

This dissertation builds upon the idea of “capitals” that Bourdieu introduced in “Forms of Capital” in which he outlined the three types of capital that he measures: cultural, economic, and social capital (Bourdieu 1986). While the research done for this dissertation could use each form of capital as an effective lens, this research is especially grounded the idea of social capital, which comes to an individual through “social obligations” and can sometimes be transformed into economic capital (Bourdieu 1986, 47). Social capital is accrued through “durable [social] networks of more or less institutionalized relationships...membership in a group [and] provides its members with the backing of the collectivity-owned capital... which entitles them to credit, in the various senses of the word” (Bourdieu 1986, 51). These durable networks are deep and rich in Costa Rica.

Socially, people are connected first by blood, with the family as the center ring of sociality, then by class and occupation (Biesanz, Biesanz, and Biesanz 1999, Mannon 2017). These relationships are consecrated via different institutions of culture or locale and maintained through exchanges such as gifts or favors, and each member of the group holds the responsibility

of maintaining the parameters of the group. According to Portes (2000), social capital is accrued through these relationships, and the advantages that one receives lay with the people on the other end of the social arrangement. Portes applies two meanings to social capital in that he considers both individual social capital and collective social capital (Portes 2000). In a review of social capital, Portes explains its attractiveness as a concept.

One idea is that social capital trades upon this political-economic idea of capital as power and gives equal weight to the types of power (read capital) that are less tangible but no less powerful than money or culture but does require investments in each to increase one's social capital (Portes 1998). He argues that there are three purposes to social capital: “social control,” “family support,” and “benefits through extrafamilial networks” (Portes 1998, 9). What I am offering here is the idea that policy strategies and narratives maintained policy core beliefs and that these strategies, narratives, and beliefs maintained the boundaries of each coalition thereby strengthening professional social networks (Bourdieu 1986, Portes 1998, 2000).

Fukuyama, in “Social Capital and Civil Society” argues that social capital is a cultural component of modern society and that it “cannot be so easily created or shaped by public policy” (Fukuyama 1999, 1). Instead, it is an informal but powerful force toward cooperation in groups and a suspicion of those outside of the group. I offer the opinion pieces and ethnographic information that support this view of in-group solidarity and out-group suspicion. Several informants from the Neoliberal Entrepreneurs labelled a magistrate as a dictator, accusing him of single-handedly orchestrating the 2010 suspension. On the other hand, several Statists felt that two physician-researchers were able to avoid sanctions and put away vast amounts of money due to their powerful family connections to governmental officials. Both of these ideas could be

substantiated through the narratives presented in news articles and opinion pieces in the local newspapers in Costa Rica.

Discourses

In 1956, sociologist C. Wright Mills developed the idea of the “power elite” who are “men whose positions enable them to transcend the ordinary environments of ordinary men and women; they are in positions to make decisions having major consequences” and they are “in command of major hierarchies and organizations of modern societies” including governmental agencies and corporations among others (Mills 1956). These power players control and manipulate the discourse of hegemony and the tools for the production of discourses such as mass communications.

In his book, *Elite Discourse and Racism*, van Dijk provided a comprehensive evaluation of the role of elite discourse in maintaining systemic racism. His evaluation of discourse in corporate, political, academic, and educational spheres as well as the media’s role in maintaining the status quo of racism in the State’s institutions illustrates how elite discourse and elites in general (in this case white elites) maintain hegemony through their control of newspapers, textbooks, corporations, opinions, ideologies, and more (van Dijk 1993). His main argument is that elites play a critical role in perpetuating hegemony through their control of the primary forms of symbolic communication that reproduce the messages of this discourse and notes that the “public actions of the elites are predominantly discursive” and so maintain discursive hegemony through “many types of text and talk that define” their agendas, leaving the non-elites as passive consumers of these messages (van Dijk 1993, 9).

Tuen van Dijk's work on elite discourses formed a foundational platform from which to analyze the narratives of each coalition. Having interviewed doctors, professors, researchers,

judges, legislators, and other high-level government officials, I knew that I needed to understand the role that elites play in carrying specific narratives forward. I also understood that what I was witnessing in printed opinion pieces were vociferous arguments between elites in which the average Costa Rican might not participate. His in-depth work on elite discourses in the maintenance of structural racism proved to be valuable in understanding what I witnessed and read.

In his analysis of the various discourses of the elite, including written and oral texts, van Dijk argues that these texts “are assumed to be monitored (and explained) by underlying *cognitions* of language users...by memory processes and representations such as mental models of specific events, knowledge, attitudes, norms, values, and ideologies” (van Dijk 1993, 13). One of the ways in which the elite control the State narrative is through the media. Van Dijk argues that media discourse is somewhat different than other kinds of elite discourse because elites need the mediating force of the media to further their messages and raise their profile with both the public in general and, specifically, with other elites. Because the media sits at the nexus of many other state institutions, the media wields more power in its active cultural reproduction and how media elites “control...other elites” (van Dijk 1993, 243). For these narratives to have power, elites must use culturally embedded metaphors. Below George Lakoff and Mark Johnson discuss how metaphors inhabit our conceptual system in such a way that the object becomes the metaphor and the metaphor becomes the object.

They argue that our conceptual system under which we function on a daily basis is structured in metaphors and that “language is an important source of evidence for what that system is like” (Lakoff and Johnson 1980, 3). To illustrate this claim, the authors link the idea of arguments to the idea of war, noting all the ways that arguments are metaphorically framed as

wars, and finally how these metaphors of war become the defining features of an argument. This is because humans tend to think in metaphors. Further, the authors suggest that we view ideas as “objects” and words as “containers” and that when we speak or write, we are sending these containers along a “conduit” for the listener to unpack (Lakoff and Johnson 1980, 8). These metaphors, objects, containers, and conduits are highly cultural, and the authors argue that “the most fundamental values in a culture will be coherent with the metaphorical structure of the most fundamental concepts in the culture” and that these values and concepts are deeply embedded in the metaphors we use and the value systems we function under.

Metaphors were especially prominent in the idea of the *maquila*, a Spanish word with no direct English equivalent but is a product of globalization and neoliberalism. The word means sweatshop or factory, but it is the type of factory that is shady and unethical; that pushes product out the door at unholy speeds. This metaphor was used in opinion pieces against clinical research sponsored by foreign drug companies. They imply that Costa Rican trial participants were pushed through trials only for the benefit of local physician-researchers, who were lining their pockets with lucre and the foreign companies, no different than the garment factories pumping out cheap clothing for the rest of the developed world.

Narratives

Charlotte Linde (2008), in her book *Working the Past: Narrative and Institutional Memory*, focuses on the ways that institutional and individual narratives and memories helped an insurance company to both preserve and modify its past and present institutional stories, both past, and present. While her specific focus was on “institution” as an organization, institutions can be much broader, more fluid, and more abstract. For Linde, “institution” can also mean “any social group that has a continued existence over time, whatever its degree of reification or formal

status may be" (Linde 2009, 7). I would argue that those working in the clinical trial industry in Costa Rica and their opponents have been engaged in institutional memory making and narrative using the institutional tools of the media and the legal system for over 40 years. While stakeholders on both sides of the debate used the exact same tools to achieve their ends --the stories they tell--they used the tools to further their own idea of institutional change as it relates to clinical research and in the process reified specific identities. As shown in the narrative analysis in chapter 3, certain word choices and the laden value in these choices led to distinct identities that address broader questions of globalization versus state autonomy and regulation of one aspect of globalizing biomedical economies. For example, a cursory examination headlines for another aspect of globalizing biomedical economies--medical tourism--in which Costa Rica is an industry leader, does not suggest adverse effects on Costa Ricans and their rights nor does the idea of foreigners seeking medical care and treatment from Costa Rican physicians elicit a strong opposition from the elite⁴.

In "Narratives of National Identity: Sexuality, Race, and the Swiss 'Dream of Order,'" Véronique Mottier (1999) discusses how identity is socially constructed via specific narratives that have historical importance. While she is tackling issues beyond the scope of this dissertation, the idea is that "discursive practices" help to construct a national identity that sometimes contradicts formal narratives, in this case on Switzerland as a nation of diversity (Mottier 1999, 2). Further, she argues that these informal narratives influence social policies and the construction of identity (Mottier 1999). Costa Rica, often called the Switzerland of Central America, also has a national identity built as much on myth as on reality. This national identity

⁴ "Sun, sand and root canal: Medical tourism booms in Costa Rica" (Url: <https://reut.rs/2Dt5sGm>) "Why this Texas doctor says Costa Rica's health care system beats the US" (Url: <https://cnb.cx/2DAFPDF>) Both accessed April 20, 2019.

propelled the main arguments for the Statists, often citing the country's support for human rights, dignity, and access to healthcare, in spite of visible cracks in the myth (Seligson 2001, Lee 2012, Campo-Engelstein and Meagher 2011). It is these narratives and constructed identities that gave power to the two policy coalitions and empowered their members to participate in argumentation in national newspapers in the form of opinion pieces. Below, I explore the frameworks that allow me to understand coalition formation, their strategies, and their beliefs.

Policy Frameworks, Strategies, and Beliefs

Anthropological Approaches to Understanding Policy Formation

Okongwu and Mencher (2000), in "The Anthropology of Public Policy: Shifting Terrains," see the connections between globalization and public policy in the ways that globalization affects local and national policies. They also argue for an understanding of how ideology and policy are inextricably linked and that these globalized ideologies have infiltrated the discourse of economics, politics, and the social sphere. It is as though globalization has unleashed multiple tentacles in multiple locations and social institutions and it is the task of policy anthropologist to untangle them, tracing the stories in the process.

Michael Eisenberg agrees with Okongwu and Mencher about the role that anthropology can play in understanding the culture of policies. In his view, the "study of policy is inherently anthropological," and Eisenberg discusses the long history of medical anthropologists interacting with public policy, especially as it relates to health policy (Eisenberg 2011, 97). He argues that "policy is everywhere" and impacts us personally, or in terms of regulating some aspect of social or public good and puts special emphasis on this regulating of the public good. Policy in this realm can be used in three ways: as "distributive policies" which benefit everyone; as "re-distributive" which are taken from one group and given to another; or as "regulatory policies"

which limit the actions of "individuals, groups, and corporate entities" (Eisenberg 2011, 96). These policies are greater than the rules, laws, and regulations that frame them, with various parts of local, state, national, and international governing bodies shaping policy formation and implementation.

Catherine Kingfisher, in her book *A Policy Travelogue: Tracing Welfare Reform in Aotearoa/New Zealand and Canada*, argues that policy-making is a key feature of “[doing] culture” (Kingfisher 2013, 2) and challenges the ideas of early anthropologists and other scholars' view of policy-making beginning at the center and diffusing to the periphery a la a world systems model. This world systems model contrasts with a "methodological nationalism" which centers policy-making and the movement of policy from within the exclusive domain of the nation-state (Kingfisher 2013, 5). Instead, Kingfisher challenges both of these earlier analyses of policy-making by building on the idea of assemblages presented by Collier and Ong (2005), writing that "policymaking is a process of assemblage [and] policy [which] travels across jurisdictions will be less linear and more multidirectional, polyvocal, mess, and ‘irrational’” than the older diffusionist and methodological nationalism models make it seem to be (Kingfisher 2013, 4-5). In her analysis of welfare reform policies developed in New Zealand and adopted by Canada, she challenges us, to consider policy-making, not only as an “artifact and architect of culture” but to consider policy as a mechanism for understanding culture and culture as a mechanism for understanding policy (Kingfisher 2013, 3).

Methodologically, Kingfisher argues that, when analyzing policy, we need to consider both the temporal life of the policy, as well as understand policy-making as a “translational” process which is “messy with blurred boundaries and complexity” and “involves processes of assemblage” which require the anthropologist to “[connect] theoretical frames and practices in

new ways” (Kingfisher 2013, 14). Using translation and assemblage as a methodological approach to analyzing policy allow us to acknowledge the “cut-and-paste processes of piecing together that are involved as policies travel up, down and sideways” (Kingfisher 2013, 15). This approach allows for “rich complexity of ethnographic realities in which participants interact to jointly construct, assert, struggle over, challenge, and modify particular readings of their worlds” and through this process “they invite us to theorize policy production as piecemeal, always in the making, and always about unfolding and shifting struggle” (Kingfisher 2013, 16). In this dissertation, I take up the ideas of assemblage and travel in the life of a policy by tracking the discourse around regulation of clinical research, starting in the late-1970s concerns of ethical abuses and continuing to the passage of the new law in 2014 to regulate clinical research in the country. These ideas allowed me to follow each policy, regulation, audit, project, and law up, down and sideways.

Paul Sabatier and Hank Jenkins-Smith are credited with the development of the “Advocacy Coalition Framework (ACF)” which they use quantitatively to describe how coalitions form, develop their core beliefs, and implement certain strategies in the effort to influence the development of policy (Sabatier and Weible 2007). They sought a framework that would be amenable to addressing the hypothesis that explored “‘wicked’ problems” that affect the policy-making process such as “substantial goal conflicts, important technical disputes, and multiple actors from several levels of government” (Sabatier and Weible 2007, 189). The ACF employs a structure that asks us to identify the “stable parameters” that include such elements as the parameters of the “problem area,” what type of “natural resources” are available, the “socio-cultural values and social structure” and the local “constitutional structure” (Sabatier and Weible 2007, 191). These stable parameters are in a feedback relationship with “external events” which

include changes in the local economy, public opinion, “the systemic governing coalition,” and [p]olicy decisions and impacts from other subsystems” (Sabatier and Weible 2007, 191). Both the parameters and the external events can apply pressure to “consensus for major policy change” and the “constraints and resources of the “[policy] subsystem actors” (Sabatier and Weible 2007, 191). Finally, the meat of the framework can be found in the “policy subsystem” which provides an algorithm for understanding how coalitions form and what frames and reinforces their “policy beliefs” (Sabatier and Weible 2007, 191). Further, the algorithm assists in identifying what kind of resources and the strategies coalitions marshal use to impact the “decisions by governmental authorities” who make the “institutional rules, resource allocations, and appointments” which then leads to policy being generated, ultimately impacting people through the policy’s influence on external events (Sabatier and Weible 2007, 191). Many analysts who use this framework focus on the subsystem, specifically on the formation of advocacy coalitions and their policy beliefs (Sabatier and Weible 2007).

Shanahan *et al.* bring a quantitative analysis of policy narratives to the Advocacy Coalition Framework (ACF), arguing that “[narrative] is not the sole province of interpretative methods, and narrative theory can offer meaningful contributions to ACF research” (Shanahan, Jones, and McBeth 2011, 536). The close analysis of policy narratives allows the explanation of the ways in which narrative is used to “negatively characterize opponents” which becomes a fundamental aspect of “coalition membership” and shapes public opinion (Shanahan, Jones, and McBeth 2011, 545). They call this extension of the ACF the Narrative Policy Framework (NPF).

The authors illustrate how the NPF can be used to quantitatively test hypotheses within the Advocacy Coalition Framework by focusing specifically on the meso-level of the ACF. These concepts include the “belief systems...the glue that bind [coalitions] together [and] policy

learning ... an enduring alteration in thought or behavioral intention [by] the coalition” and are both internal elements of the advocacy coalition subsystem (Shanahan, Jones, and McBeth 2011, 545-546). These elements of the meso-level of the policy subsystem are linked with “public opinion” which is considered an external element and can act as a “constraint...shock ...[or] a resource” for the coalition” and “strategy” which is an influencing mechanism that coalitions use in their interactions with governmental policymaking institutions (Shanahan, Jones, and McBeth 2011, 545-546).

Policy narratives are seen as a powerful force for affecting policy learning, and the authors argue that the "power of a good story is likely to shape subsystem policy learning...regardless of the available scientific information" (Shanahan, Jones, and McBeth 2011, 549). Shanahan *et al.* clarify that these narratives are not the same as public opinion. Whereas public opinion is easily measured in polls, policy narratives are used to create a more subtle and graded perspective. It is here, at the narrative level that we are introduced to the "narrative characters" that add the heroes, victims, and villains for the public to invest in so that their opinions are shifted toward whatever policy the coalition is supporting (Shanahan, Jones, and McBeth 2011, 553). For the Narrative Policy Framework to have the most benefit, researchers need to illustrate how these narratives shape policy outcomes. What I am offering in chapter 5 is an illustration of the policy narratives of the two coalitions I worked with in Costa Rica by using the qualitative approach to the Narrative Policy Framework put forth by Gray and Jones (Gray and Jones 2016).

In the rest of the dissertation, I trace the growth of clinical research inside Costa Rica and examine the tensions and challenges that accompanied that growth. To do so, I provide context for understanding why Costa Rica was such an inviting site for foreign pharmaceutical

companies and brief descriptions of the institutions that played a significant role in assisting or impeding this scientific and economic endeavor. This context is followed by a discussion of the field site, the research design, participant sampling, methodologies, and analytical processes. Chapter 3 examines the narratives the Costa Rican press and elites used to talk about clinical trials, starting in the late-1970s and proceeding through the early-2000s. By focusing on the writing of opinion pieces by stakeholders on opposite sides of the public debate on clinical trials in the country, I illustrate the early formation of two distinct coalitions for and against clinical research at the time. I also discuss the development of the Statist Coalition and the policy beliefs that led to a Statist identity. Chapter 4 focuses on the effects of the 2010 Constitutional Court decision to suspend clinical research in Costa Rica. Specifically, I analyze data from a short survey I conducted with my own research participants that asks about the effects on the livelihoods of the people involved in clinical research. In this chapter, I focus specifically on three areas of social capital affected: prestige, status, and international opportunities, as well as the effects of the suspension on individual agency and survival strategies. Here I introduce the development of the Neoliberal Entrepreneur Coalition and the Neoliberal Entrepreneur identity. Chapter 5 uses Gray and Jones' (2016) qualitative application of the Narrative Policy Framework that employs a storytelling approach to identifying the policy core beliefs of advocacy coalitions. Finally, in the concluding chapter, I summarize the arguments of this dissertation, offer conclusions, and reflect on recommendations for future research.

CHAPTER 2: CLINICAL TRIALS IN COSTA RICA: CONTEXT, SETTING, AND METHODOLOGIES

To understand the history and debate around clinical trials and the process of law-making, one needs to understand the context in which the clinical trials industry flourished from the early 1970s to 2010, when the constitutional court suspended them, and into 2014 when a national law regulating these types of pharmaceutical company sponsored trials going forward. During this research, many of the individuals I interviewed held multiple roles across various state and private institutions, sometimes consecutively and sometimes simultaneously. For example, one participant had been a teacher, a professor at the University of Costa Rica (UCR), a dean at the university, a legislator, and finally, an ambassador. Or, a physician could work in the morning in the public health system (CCSS) and in the afternoon in his or her private practice, sometimes seeing the same patient in both places. The same holds true for lawyers, microbiologists, bioethics experts, and many of the other individuals I interviewed.

Collier and Ong (Collier 2006) and others discuss the challenges of doing ethnographic work in the age of globalization and argue that, traditional approaches of anthropological research can fail to capture the ways that people, institutions, and economies traverse borders and the tensions caused by globalization at the local level (Friedman 2006, Gille and Ó Riain 2002). Collier returns to the issue of globalization and the “global assemblage” approach to thinking about the boundary-shattering anthropological problems (Collier 2006, 400). Global assemblages “are the actual configurations through which global forms of techno-science, economic rationalism, and other expert systems gain significance” and that these assemblages “have a distinctive capacity for decontextualization and recontextualization, abstractability and movement, across diverse social and cultural situations” (Collier 2006, 400). This globalizing

boundary crossing of clinical research—sponsored by corporations in one country, conducted in another, and presented at international conferences and in international journals-- meant that I too had to cross local and global spaces and boundaries to understand the fluid movement of Costa Rican elites and understand how their various roles informed their beliefs, attitudes, and practices as it related to clinical trials inside the country.

In this chapter, I will provide brief historical and descriptive information about Costa Rica and the various social institutions that clinical research has impacted or that clinical research has been impacted by. I will follow with a discussion of the setting for this research, the research design, and data collection methods. An in-depth discussion of the participants in this research will follow, including the criteria by which they were stratified. A discussion of the archival data collection portion of this research focuses on the archives accessed and the vast number of documents given to me by informants. Later, a discussion of the interview process is covered with sample questions from the interview schedule. Finally, the chapter will conclude with a section on data analysis will focus on the methods employed to analyze news articles, opinion pieces, and governmental documents.

Brief History of Costa Rica and Its Institutions

Costa Rica has a national narrative of its history that informs their position in the world today and as one of the longest-running, most stable democracies in Latin America. This national narrative supports an exceptionalism that many Costa Ricans are invested in, even as, they critique their government, their politicians, their health system, and aspects of their society. To understand Costa Rica's evolution into one of the most stable democracies in Latin America, one must start before the Spaniards arrived.

Pre-Columbian indigenous culture consisted of small groups of hunters and gatherers who had access to tropical rainforests and now-extinct animals such as mastodons and giant sloths (Biesanz, Biesanz, and Biesanz 1999, Mitchell and Pentzer 2008, Molina Jiménez and Palmer 2009). However, shortly after the Neolithic revolution, early inhabitants began to engage in horticulturalist practices, gradually domesticating more and more plants and animals. This led to a long and slow introduction of agricultural techniques and the country's location between larger civilizations to the North and South allowed them to absorb important agricultural information. As a result, by 800 C.E., the local farmers became adept at the growing and cultivating of such crops as yucca and corn (Molina Jiménez and Palmer 2009, Mitchell and Pentzer 2008, Biesanz, Biesanz, and Biesanz 1999). The most visible artifacts from these pre-Columbian times are large granite, perfectly round spheres, often transported miles from the original quarry site. Thousands of years later they remain mysterious to scholars as to their purpose, means of transport, and significance (Molina Jiménez and Palmer 2009).

By the time of Spanish contact, Costa Rica was home to several hundred thousand indigenous people in approximately twenty distinct cultural groups. However, Costa Rica did not hold the vast and highly stratified civilizations like the Mayans in Northern Central America/Southern Mexico or the Incas to the South. These small groups engaged in both large agricultural projects and the kind of foraging and hunting that allowed much of the land around them to remain wild. However, when the Spanish conquerors breached the "rich coasts" of what is now Costa Rica, this indigenous, cultural diversity was decimated through diseases, so that, in less than a hundred years, there were only 10,000 original people left from the pre-contact peak of 400,000 (Molina Jiménez and Palmer 2009).

Spanish conquest of the country seemed an afterthought for the Spanish. The terrain, lack of valuable minerals, and small amount of indigenous people (in comparison to the complex societies to the North and South) made Costa Rica virtually useless to the Spanish Crown. Between 1519 and 1525, the Spanish invaded and claimed the bulk of Central America and by 1540 and for the next thirty years, “the political organization of Central America was stabilized” with the center of power located in present-day Guatemala (Molina Jiménez and Palmer 2009, 20). While the Caribbean side of the isthmus remained untamed, the bulk of the Pacific coast side was under Spanish control. In the mid-sixteenth century, Costa Rica was fully integrated into the “colonial economy” providing many crops and local crafts, such as corn, honey, salt, hammocks, blankets, and pottery (Molina Jiménez and Palmer 2009, 29).

In *The Ticos*, Biesanz, Biesanz, and Biesanz note that, during the colonial period, “Costa Rica, the Cinderella of Spanish colonies, was taxed, scolded, ignored, and kept miserably poor” (Biesanz, Biesanz, and Biesanz 1999, 17). Due to its poverty and isolation from the centers of Spanish economic and religious power in the area, the Spanish colonists in the area forged a unique social order that would inform the formation of a democracy after independence (Biesanz, Biesanz, and Biesanz 1999). While these early years of colonization are exalted in the origin story, it fails to account for the decimation of native people and land to accommodate colonial farming practices. It cannot be ignored that the confluence of many unique factors contributed to the unique evolution of Costa Rica as a country in 1821, the year of its independence from Spain and while the nascent country had a rocky start as nearby countries tried to lay claim to the tiny territory (Biesanz, Biesanz, and Biesanz 1999, Molina Jiménez and Palmer 2009). While, within the new republic, the elite of the four main cities of the Central Meseta (Cartago, Heredia, San José, and Alajuela) fought regularly to claim status as the capital, with the conservatives squaring off against the

progressives in coalitions that would mark much of Costa Rica's political process into the 21st century (Biesanz, Biesanz, and Biesanz 1999).

Overview of the Economy, Democracy, and Institutions of Costa Rica

Costa Rican Exceptionalism

The pre-colonial and colonial experience of Costa Rica has, as mentioned above, contributed to particular narratives that are both embraced and challenged by citizens of the country. This “origin story” of how the country came to be has informed the “national political mythology” which we will see informed the debate on clinical research in Costa Rica (Booth 1998, Mannon 2017, Molina Jiménez and Palmer 2009). One narrative highlights Costa Rica's humble agrarian beginnings that illustrate differences from the rest of Central and Latin America and compares the country to Switzerland in its peaceful, egalitarian, and neutral approach to its interactions with its neighbors and on the world stage (Mannon 2017, Molina Jiménez and Palmer 2009).

The main narrative that informs ideas about governance and democracy is “the evolution of the nation's democratic institutions and practices” and Booth, in *Quest for Democracy*, cites Gudmundson in challenging the simple version of this narrative and characterizing this journey as much more complex and challenged (Booth 1998, 29). Post-independence, the exportation of coffee created a new elite class—coffee exporters. These exporters very much depended on small coffee farmers. This dependence set up a patron/peon system which created a sense of egalitarianism (Booth 1998, Mannon 2017, Stone 1989).

In the twentieth century, many children of coffee families entered medicine and law. Stone traces the ancestry of presidents, legislators, and others of the political class to just six Spanish families that arrived with Spanish colonization of the country. He notes that this “class

endogamy” is illustrated in marriages within the class (Stone 1989, 25). This cycling into and out of various political or governmental offices, law, medicine, and academia by the Costa Rican elite is visible today (Biesanz, Biesanz, and Biesanz 1999). For example, a doctor from a prominent family can move from chief of a hospital department to the Minister of Health, to the president of the public health care system, to president or legislator, all the while teaching in the university’s medical school. A lawyer from a prominent family can follow a similar trajectory with stops as a court clerk, magistrate, legislator, president, and maintain a steady career teaching in one of the public or private law schools. All of whom are part of the original economic and political elite (Stone 1989). The only entry into this class is through birth or marriage. Moreover, while the majority of Costa Ricans are *mestizo*, this connection to Spain through family allowed the elites to identify themselves as white and European at heart (Biesanz, Biesanz, and Biesanz 1999, Mannon 2017).

The middle class of Costa Rica might seem like the elite class in the occupations they might find themselves in, such as medicine or law, but their trajectory is confined to treating patients within their class or the classes below them in the case of medicine or into bureaucratic positions within the government for either lawyers or physicians (Stone 1989). According to Stone, the only significant difference between the middle-class and the elites is that the members of the middle-class cannot trace their ancestry back to one of the original six families or that the ties are so weak as not to confer enough social capital to move them into the elite class (Stone 1989). Stone explains that the working class and the poor usually had menial jobs in the government or, if they accessed education, could reach the middle-class through medicine and law. The class structure in Costa Rica, unlike other Latin American countries, maintained an air of egalitarianism that grew out of the neglect of the colony by the Spaniards and with this

egalitarianism, comes an emphasis on the overarching welfare of all citizens of the country (Stone 1989, 26-27).

This stable democracy narrative was embraced shortly after the civil war when the junta of leadership led by Figueres found the narrative helpful in achieving their goals of abolishing the military and using the funds to provide education and the beginning of health care to citizens (Booth 1998). This national myth, while based in fact, fails to adequately characterize the early conflicts around voting and a coup d'état in the early twentieth century (Booth 1998). Booth writes that, "Costa Rica's great myth contends that democracy arose and persists because of high degrees of social equality, equality of land distribution, racial homogeneity, and a tradition of nonviolence" (Booth 1998, 30). This formed from the idea of the "small farmer" who struggled right alongside the remaining indigenous people (Mannon 2017, 27). While some aspects of this myth are true, Costa Rica's evolution into a stable democracy is much "more complex...and paradoxical" than we might believe (Booth 1998, 30).

Palmer and Molina address this national ideal of exceptionalism and how it sanitizes the colonial poverty into "habits of work and sobriety" and "the shared misery [of this time]" into a "'rural democracy'" (Palmer and Molina 2004, 1). The country and its citizens have struggled with racism and xenophobia, and the acceptance of this myth by scholars fails to allow for "the country's relevance for understanding patterns of development in Latin American and elsewhere" (Palmer and Molina 2004, 2). Painting this picture of exception allows a glossing over of some of the more important distinctions that do make the country unique because of the complexity of its evolution into a stable democracy. Nonetheless, many of the values of egalitarianism and the welfare of all citizens supported by the nation's constitution, its

commitment to human rights, and direct access to the public health system and the constitutional court, both of which is discussed in more detail below.

Costa Rica and Its Institutions

Unlike many other Latin American countries, Costa Rica did not suffer the growing pains related to independence from Spain and starting a new democracy and so, early on, the fledgling country selected leaders, like Juan Mora Fernández, an educator, to lead the formation of the new government, constitution, and original laws. While there were some violent dictators and an early period of instability, after the civil war in 1948, the country abolished the military, and it has remained a stable democracy since (Booth 1998).

The country has seven provinces, which divided into eighty-one counties. Each county is divided into districts with local control through municipal councils which manage the licensing for gambling and alcohol, waste management, road maintenance. One could describe the government of the country as “‘semi-presidential and semi-parliamentarian,’ an ideal framework for compromise, lacking an active center of decision-making” (Biesanz, Biesanz, and Biesanz 1999, 65). This structure developed after the civil war in 1948 when a junta under José Figueres wanted to keep each of the three branches of government from retaining too much control over elections or the presidency coming under the sway of another dictator (Biesanz, Biesanz, and Biesanz 1999, Mitchell and Pentzer 2008).

As a liberal representative democracy, Costa Rica has three branches of government with the president and legislators elected for four-year terms and must sit out at least one term before being reelected to office. The legislature appoints judges to eight-year terms which automatically renew unless the legislature intervenes (Biesanz, Biesanz, and Biesanz 1999, Chamberlain 2007, Wilson 1998). The *Asamblea Legislativa* (Legislative Assembly) holds the most power of the

three, but some argue that the Constitutional Court, one of four chambers to the Supreme Court, has gained more power since its inception in 1989 (Biesanz, Biesanz, and Biesanz 1999, Wilson 1998). Much of the bureaucratic work of the government falls to the many autonomous agencies that manage the day-to-day functions of the country's electrical utility (the Costa Rican Institute of Electricity or ICE) as well as the Costa Rican Social Security Fund (CCSS), among several hundred more (Biesanz, Biesanz, and Biesanz 1999, Mitchell and Pentzer 2008).

The Costa Rican Constitution

Shortly after independence, Costa Rica began the process of developing a new democracy. Turning to Europe for examples, the country modeled its civil law system on Napoleonic Civil Law creating its first constitution in 1825 (Barker 1991, Ordóñez, Sayle, and DeGennaro 2009). It was after the civil war in 1949 that it became the guiding document for the democracy and while reforms have occurred in the years since, the basic structure and ideals have remained the same (Barker 1991, Booth 1998, Molina Jiménez and Palmer 2009, Ordóñez, Sayle, and DeGennaro 2009). It is in the constitution that the limits of each branch of government are delineated and the abolition of a standing army which led to an emphasis on "civil government" by removing the army as the main "institution ...[that] undermined democracy" (Booth 1998, 57). Further, the leaders of the country inculcated an emphasis on individual rights, both personal and political, that have been enhanced over the years by reliance on human rights declarations of the United Nations.

The constitution protects citizens (and foreigners) from slavery, restricted travel, their right to privacy, right of association, to peaceably assemble, right to petition any branch of the government or state official, freedom of speech, and a right to life and dignity⁵ (Booth 1998).

⁵ Constitución Política de la República de Costa Rica (The Political Constitution of the Republic of Costa Rica)

While the constitution claims Catholicism as the state religion, it allows a freedom of religion. Clergy and non-specialists are not allowed to engage in political activities in which they infuse religious tenets or ideology (Booth 1998). Further, the Costa Rican constitution places great weight on “‘unrenounceable’ rights and protections” including: the protection, by the state, of the family, mothers, and children, equality in marriage (until 2018, this was only in relation to heterosexual marriages), equal rights of non-married parents as custodians of their children and other protections related to wages, work, labor unions, and more (Booth 1998, 58). Because of the emphasis on human rights, the country has received high praise from international bodies and the leaders of other countries.

The Supreme Court

The Supreme Court of twenty-four judges and consists of four chambers: the criminal court chamber, two chambers that address civil and merchant cases, and the constitutional court, established in 1989 (Wilson 1998, Biesanz, Biesanz, and Biesanz 1999, Booth 1998, Molina Jiménez and Palmer 2009). The Fourth Chamber (Sala IV) sees all cases of unconstitutionality brought before them by individuals or groups. There are two mechanisms in place: the *recurso de amparo* and the *acción de inconstitucionalidad*. *Amparos* are submitted by anyone, written on anything, and presented anytime (Wilson 1998, 2004). The constitutional court has been accused of political maneuvering and taking an activist role in the adjudication of some cases and, as we shall see, played an essential role in the conduct of clinical research in Costa Rica (Wilson 1998, 2004).

La Asamblea Legislativa (the Legislative Assembly) and Political Parties

Until the Constitutional Court was formed in 1989 (Wilson 1998), the Costa Rican legislature, *la Asamblea Legislativa*, held the most power of the three branches of government

(Biesanz, Biesanz, and Biesanz 1999, Booth 1998). There are fifty-seven seats in the legislature, which are filled at the same time that the presidency is voted upon (Booth 1998). Representatives (*diputados* in Spanish) serve for four years at a time and cannot hold office consecutively. Each delegate represents their party and a sector of their province's population. Delegates are "not elected but *selected*" by their party because citizens vote for the party to represent them and not the individual (Biesanz, Biesanz, and Biesanz 1999, 67, Colburn and Cruz 2018, Mitchell and Pentzer 2008).

The legislature's prime duty is to enact, change, and repeal laws, as well as, manage taxation. Further, it is the check against the president's budget, protecting against overspending and begin impeachment proceedings against "high officials" and "overrides an executive veto" (Booth 1998, 59-60). They also can intervene in licensing issues and appoint certain officials and, working with the president, create, staff, and fund autonomous institutions" as needed or appropriate (Mitchell and Pentzer 2008, 205). The assembly maintains five regularly meeting committees and can convene ad hoc committees as necessary (Booth 1998). A standing committee was formed, for example, to gather information regarding medical research involving human subjects and use this information to formulate a law that would regulate clinical research in the country.

For a long time after the formation of the new government in 1948, the country had, for all intents and purposes, a two-party system because the *Partido Liberación Nacional* (National Liberation Party or PLN), and *Partido Unidad Social Cristiana* (Social Cristian Unity Party or PUSC) represented the center-left and the center-right respectively. Often, Costa Ricans would change parties and alternate their votes for president between the two parties. National elections have an almost festival air about them with people lining the streets and waving the flag of their

party while cars festooned with party flags continuously honk as they proceed down the major boulevards (Booth 1998, Biesanz, Biesanz, and Biesanz 1999, Colburn and Cruz 2018).

Costa Rican citizens are aware of the corruption that infuses the political process, and freely participate themselves when they need favors, however, in 2004, a corruption scandal shook the small country and permanently damaged the two parties' control on politics and offices in the country (Colburn and Cruz 2018, Biesanz, Biesanz, and Biesanz 1999). The scandal involved three former presidents and involved kickbacks from foreign companies. Two were from PUSC, and one was a member of PLN. From 2002 to 2017, the two parties continued to split the presidency alternating PUSC's Abel Pacheco, PLN's Oscar Arias and, the first female president, Laura Chinchilla. However, by the end of Chinchilla's term, new parties were throwing their hats into the presidential ring leading to Luis Guillermo Solís, from *Partido Acción Ciudadana* (Citizens' Action Party, or PAC), being elected in 2014. His tenure in office was mired in a corruption scandal involving favoritism for a Chinese cement company (Colburn and Cruz 2018).

Today, the Legislative Assembly has representatives from eight different parties, and nine representatives are independent, though lean more one direction or another. PLN holds seventeen seats and PUSC holds nine. The party of Solís, PAC holds ten seats, while the rest of the seats are divided up between very conservative independents or parties such as the *Partido Restauración Nacional* (The National Restoration Party, or PRN) or leftist parties such as *Frente Amplio* (Broad Front, or FA), while some of the parties splintered off the two major parties. Historically, there have been a total of thirty-seven parties that came into existence at different times during Costa Rica's long history with democracy.⁶

⁶ <http://www.asamblea.go.cr/ca/SitePages/Inicio.aspx> (Accessed November 10, 2018).

Public and Private Health Systems in Costa Rica

Since the abolition of a standing army in 1948, education, sanitation, and health care funding came from the old defense source (Sáenz et al. 2011). For Costa Ricans, access to health care is viewed as a right, although this right is not explicit in the constitution, but has been enacted through constitutional resolutions, which “[guarantees] the right to the protection of health within the human rights doctrine” (Saénz del Rocío, Bermúdez, and Acosta 2010, 4). The first article of the “General Law of Health”, passed in 1973 states, “The health of the population is a public good supervised by the State.”⁷ The CCSS, built as a “solidarity model,” did not emphasize profits when charging fees for service and was not meant to generate profits but was meant to support the health, unemployment, retirement, and disability insurances (Chamberlain 2007, 103). This focus on non-defense related institutions has led to remarkable statistics in education, public health, and the overall health Costa Rican citizens. At the start of the 21st century, Costa Rican life expectancy is on par with more developed countries at nearly 80 years for women and about 75 years for men (Molina Jiménez and Palmer 2009, Mitchell and Pentzer 2008).

Nearly all Costa Rican citizens receive care under the public health care system called, *la Caja Costarricense de Seguro Social* (CCSS or *la Caja*) originated in 1942 for laborers in the coffee and banana fields, and since has grown to cover all fully employed Costa Ricans (Biesanz, Biesanz, and Biesanz 1999, Mitchell and Pentzer 2008, Sáenz et al. 2011). The system is a tripartite system in which the government pays a third of the premium, the employer pays a third, and the employee pays a third. The CCSS provides services for the ill, the elderly, the disabled, the very poor, children, and pregnant women (Biesanz, Biesanz, and Biesanz 1999, Saénz del

⁷ “*Ley General de Salud*,” www.cendeisss.sa.cr/etica/biblioa.html (accessed November 11, 2018)

Rocío, Bermúdez, and Acosta 2010, Noy 2013). Further, the CCSS has an executive board which can pass regulations which are “mandatory and universal” (Biesanz, Biesanz, and Biesanz 1999, 152).

Overhauls in the 1970s, the 1980s, 1990s created EBAIS⁸, small “health teams” that primarily serve rural areas, national hospitals in the capital of San José and funded privatizing certain services within the CCSS (Morgan 1989, Mitchell and Pentzer 2008). The 1990s also saw a robust growth of the private health care system and well as more Costa Ricans using *medicina mixta* (mixed medicine) which combines access to public care while also being treated at a private practice or hospital, often by the same doctor. With the ascendance of the private health system, Costa Rica has become a medical tourism destination due to the high-quality care and generally lower cost of care (Biesanz, Biesanz, and Biesanz 1999, Mitchell and Pentzer 2008, Sáenz et al. 2011).

While some form of private care has been a constant in Costa Rica’s approach to health since the mid-19th century forward to the formation of the Costa Rican Social Security Fund (CCSS), the idea of *medicina mixta* became more prominent after the civil war and with the CCSS reforms of the 1970s (Clark 2010). Even in the 1800s, the idea of cutting-edge medicine channeled through physicians and public health experts trained in Europe and the United States indicates a consistent tension between “international connections” and “the consolidations of the nation-state (Palmer 2003, 4). These young physicians were often stationed in far-flung areas of the country or filled the role of company physician, especially at the United Fruit Company, and private care co-existed with the growing public health system throughout the 1940s (Palmer 2003, King 2016).

⁸ EBAIS stands for *Equipos Básicos de Atención Integral en Salud*

For much of the 20th century, the Ministry of Health oversaw all aspects of health provision through the Caja. A restructuring in the 1990s gave the Ministry of Health supervisory and regulatory oversight for such things as drug pricing and approval; environmental issues; health promotion; and more. The CCSS focuses primarily on the “purchasing and provision of healthcare” although, in the early part of the 21st century, an effort was made to give control over budgets and purchases to individual hospitals and clinics. As a result, the CCSS executive board wields extreme power that rivals that of the legislators. Legally, this executive board can develop and pass regulations that must be enacted by all parts of the system inside the country. While health indices remain high, so do the costs associated with a growing elderly population and the types of chronic health issues that increase spending over the long term (Saénz del Rocío, Bermúdez, and Acosta 2010, Mitchell and Pentzer 2008, Biesanz, Biesanz, and Biesanz 1999, Rosero-Bixby 2004).

There are twenty-three public hospitals within Costa Rica, approximately 150 CCSS clinics, and almost 670 health team centers. The CCSS system of services covers the geography of the country as well as the needs of citizens. The first tier of service consists of small health teams and other small health clinics that provide vital preventative and primary care services, especially in rural areas far from the capital. The second tier covers emergencies, specialized medicine, and general surgical procedures. This tier provides large clinics, secondary hospitals, and larger provincial hospitals. The final tier, almost exclusively located in the metropolitan area of San José, is where the national hospitals and women’s, children, rehabilitation, and psychiatric hospitals are located (Rosero-Bixby 2004, Saénz del Rocío, Bermúdez, and Acosta 2010).

Critiques of the public health system include the long wait times for non-essential surgeries, generic medication, corruption, and the lack of specialists for such things as eye

surgery, which are farmed out via contract to Colombia, where patients are sent for the procedure by the CCSS. Further, many employers, now only hire workers part-time so that they do not have to contribute to the CCSS for their workers' health care. Finally, since the Ministry of Health, as discussed above, is now more a governing body, there are schisms between the health policy generated by the Ministry and application as done by the CCSS. Because of these issues, many people divide their health care into services that are cheaper or free or adequate through the CCSS and health care that is specialized, immediate, and cutting-edge through the private health system (Saénz del Rocío, Bermúdez, and Acosta 2010, Noy 2013, Biesanz, Biesanz, and Biesanz 1999, King 2016).

King (2016, 15) notes that the “ideologies and practices of public and private health care mix in emergent and complex ways.” By the early 1990s, a small percentage of Costa Ricans were seeking insurance through the National Institute of Insurance (INS), which has been in existence since 1924 and was intended to be a “method of wealth distribution for Costa Rican nationals” (Chamberlain 2007, 117). This provides extra support for individuals for services provided through the *Caja* and provides insurance coverage for cars, agriculture, and property (Saénz del Rocío, Bermúdez, and Acosta 2010, Noy 2013). As well, many aspects of health care are privatized including laboratories for blood work and other health tests, ambulance services, radiology, often through cooperatives. Scholars attribute the push to privatize to the role of international monetary institutions, such as the World Bank, which applied pressure during loan renegotiations to allow a neoliberal model of health care commodification (Lisulo 2003, Homedes and Ugalde 2005, King 2016, Lee 2012). Moreover, while patients enjoy this freedom of movement between the public and private healthcare systems in Costa Rica, so to do the

physicians, often working in the *Caja* in the morning and their private practice in the afternoon (Lee 2012, King 2016).

A robust medical tourism industry currently exists in Costa Rica and is the bread-and-butter for the bulk of nearly a dozen private hospitals, with *Clinica Bíblica* in downtown San José and founded in 1929 the oldest and the *Centro Médico San Rafael*, accommodating tourists in the Northwestern province of Guanacaste, the most recently opened (2011).⁹ These private hospitals supplemented with a multitude of private practices, some expansive and modern-looking while others are small, neighborhood clinics (King 2016, Lee 2012). Many of the physician and allied health care participants of this research frequently shifted between the public hospital or laboratory and their private practices.

Public and Private Medical Education

From 1888 to 1940, Costa Rica did not have a public university, until the University of Costa Rica (UCR) was founded in San Pedro, a district to the East of downtown San José. For thirty years, it was the only university for the entire country (Biesanz, Biesanz, and Biesanz 1999, Molina Jiménez and Palmer 2009, Mitchell and Pentzer 2008). In the seventies, the country saw three more public universities open: The National University (UNA), located in Heredia; the Technological Institute (TEC), located in Cartago and four other sites around the country; the University for Distance Learning (UNED), also with several campuses; and several private campuses for technology, trades, and medicine. Public universities in Costa Rica are considered superior to private universities, including private medical schools (Mitchell and Pentzer 2008).

⁹ <http://costarica-connection.com/costa-rica-private-hospitals/>

The Legislative Assembly passed a resolution in 1953 that led to the creation of the medical school at the University of Costa Rica.¹⁰ It is considered the premier medical school in the country (Mitchell and Pentzer 2008). The school has a residency program at the *Caja's* hospitals that “function as university hospitals” (Programa Estado de la Nación 2017, 254). Until UCR’s medical school opened, physicians were trained in the United States or Europe and returned home to practice, relying on regular clinical case meetings to remain updated on medical issues in the country and health news from other countries (Palmer 2003).

An early formation of a medical association attempted to lay the foundations for a school of medicine, as well as the University of Santo Tomás, which also attempted to form a medical school until closure in 1888 (Palmer 2003). Palmer argues that the lack of a medical school inside the country, when medical schools were opening all over Latin America in the late nineteenth century, served to keep Costa Rican physicians on the cutting-edge of international medicine due to the welcome they provided to European physicians who brought new medications, procedures, and tools to the country (Palmer 2003).

Press and Media in Costa Rica

Costa Ricans were addressing the role of the press within the country as early as 1835 and added an article to the constitution to protect the freedom of the press (Rockwell and Janus 2003). Article 29 is short and condensed into one sentence. The article states, “Everyone may communicate their thoughts by words or in writing and publish them without prior censorship; but they will be responsible for the abuses committed in the exercise of this right, in the cases and the mode that the law establishes.”¹¹ In many cases, the press has been free to print anything

¹⁰ Information regarding the medical school sourced from the school’s website:
<http://www.emedic.ucr.ac.cr/index.php/home/historia>

¹¹ Constitution of the Republic of Costa Rica 1949 (rev. 2011): Constitute,
https://www.constituteproject.org/constitution/Costa_Rica_2011?lang=en (accessed February 10, 2019)

it chooses, yet there have been tensions between the press and the government over time.¹²

Costa Rica does not have a state-owned newspaper, although it does have two state-owned television stations, a radio station, and a state-owned publishing arm called *Editorial Costa Rica*, which publishes histories of the country, as well as fiction and the results of studies on various topics. (González Dobles 1981).

One role that newspapers and other media sources have in the country is to reify the national identity, although most of this reification is being done by media that is privately owned and has consolidated many newspapers and magazines under one heading. For example, *La Nación*, the largest daily newspaper, is just one investment in media by *Grupo Nación*. The publishing group also publishes the leading business newspaper *El Financiero* and a tabloid, *La Teja* (the Tile), which publishes more outrageous stories. The investment group also publishes six magazines that include *Sabores*, a cooking magazine; *Perfil*, a magazine about local celebrities, arts and culture; and several others. Recently, it has launched internet platforms for event ticketing, digital printing, and a job search site.¹³

The country supports four daily newspapers: *Al Día*, *Diario Extra*, *La Nación*, and *La República*. *La Prensa Libre* is the oldest continually running newspaper in the country and is an evening paper. *El Financiero*, owned by *Grupo Nación* is weekly, as are two English language newspapers geared toward the large ex-pat community in the country (The Tico Times and the Costa Rica Star). The newspaper of the University of Costa Rica, *Semanario Universidad* is circulated every Wednesday. There is one publicly owned television station, *Trece* (13) and two private ones (*Teletica* and *Repretel*). However, cable services provide programming from the

¹² Freedom House: Costa Rica <https://freedomhouse.org/report/freedom-press/2015/costa-rica> (Accessed September 9, 2018).

¹³ From *Grupo Nación* Products page: <https://www.nacion.com/gnfactory/especiales/gruponacion/productos.html> (Accessed February 23, 2019).

U.S. (dubbed and undubbed), as well as shows from other parts of Latin American, especially the soap operas called *telenovelas*. Radio is the primary way in which rural Costa Ricans get their news, and the country owns two radio stations, *Reloj* and *Radio Nacional*. Two other private radio stations focus on news and talk and one radio station that plays jazz.¹⁴

In this section, I presented a brief history of Costa Rica and the different institutions involved in or affected by the public debate regarding the conduct of human subject biomedical studies, such as sponsored by foreign pharmaceutical companies. This description of the setting of this research also provides a foundation for understanding how the elite of medicine, law, government, academia, and the public and private health care realms move through these realms, either consecutively or contemporaneously. In the next section, I will present a setting description that is pertinent to my research design, methodologies employed, and data analysis techniques.

Research Setting

The map of the country in Figure 2.1 helps to orient the reader to the metropolitan area where research was conducted. This area is known as the *Gran Área del Metropolitana* (GAM) of San José and includes San José which is the capital of Costa Rica (in San José Province) and the following cities: Heredia (Heredia Province), Alajuela (Alajuela Province), and Cartago (Cartago Province) (Figure 2.2). This ethnographic research was conducted within the Greater Metropolitan Area because this is where the national public hospitals and the largest private hospitals are. Also, all of the managing body and administrative offices of the *Caja Costarricense de Segura Social* (CCSS) are in downtown San José as well as the Ministry of Health. The

¹⁴ BBC Costa Rica Profile, Media: <https://www.bbc.com/news/world-latin-america-19414705> (Accessed November 8, 2018).

offices and courts of the different chambers of the Supreme Court and the legislature are in San José too.

Most public universities and several private medical schools, such as *Universidad Ciencias Médicas* (UCIMED) are within the metropolitan area. Until the suspension of clinical research in 2010 closed some organizations, the offices of several private research organizations, are or were located within or near San José, including *Instituto Costarricense de Investigaciones Clínicas* (ICIC) and *Instituto de Atención Pediátrica* (IAP). The Latin American home office for many pharmaceutical companies such as Pfizer, Merck, and GlaxoSmithKline are here. Except for the *Proyecto Epidemiológico de Guanacaste* (a large Human Papilloma Virus study located in the Northwestern corner of the country), the bulk of interventional medical studies using human subjects were conducted within the metropolitan area, either within the CCSS, in private research centers, private medical schools, or within private medical practices.



FIGURE 2.1: POLITICAL MAP OF COSTA RICA.¹⁵

¹⁵ http://www.worldmapsonline.com/academia/academia_costa_rica_political_map.htm
Used in accordance with Section 107, Fair Use, of the Copyright Law, Title 17 of the United States Code.

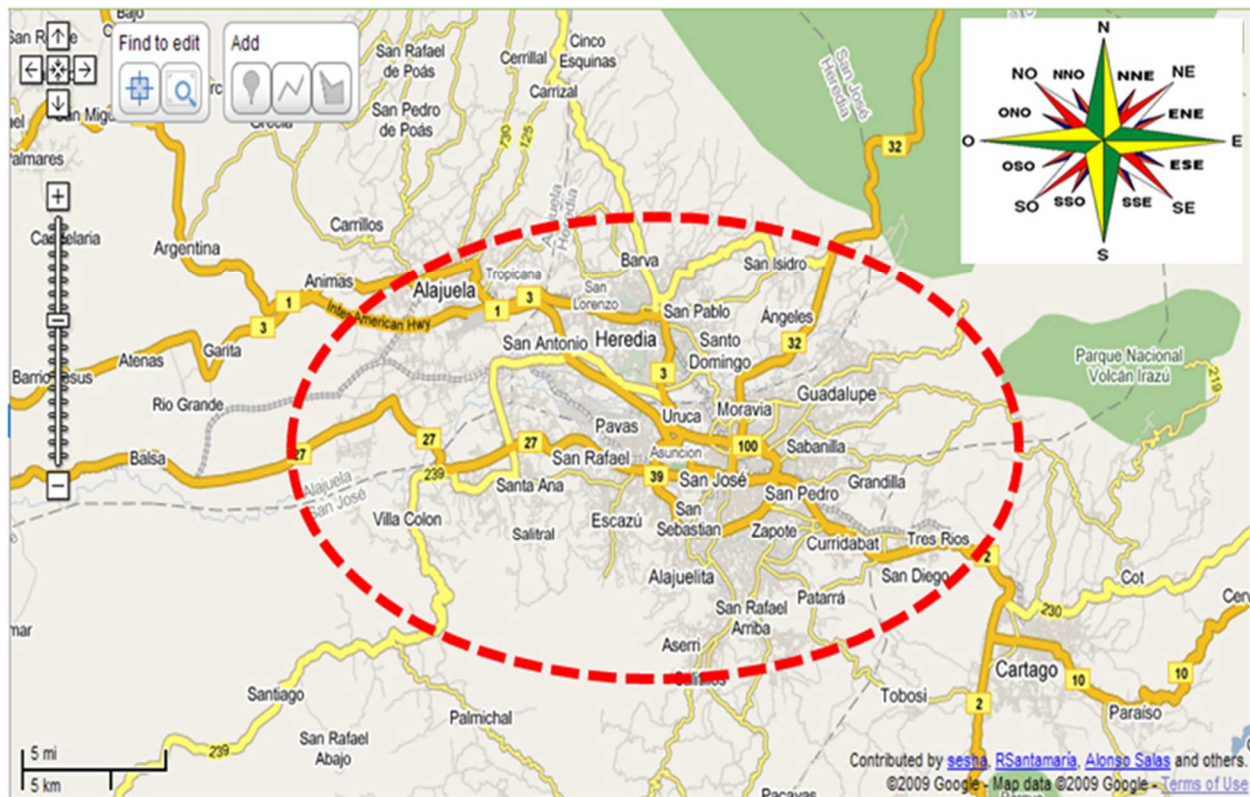


FIGURE 2.2: MAP OF THE GRAN ÁREA DEL METROPOLITANA.¹⁶

Research Design and Data Collection Methods

Research Questions

The overall question asks how the lawmaking process impacted the livelihoods and social capital of those in and around the clinical research industry. Three specific aims have guided my research. First, to explore the public debate regarding clinical research in Costa Rica as presented in news articles and opinion pieces (Op-eds). Second, to examine the changes in the livelihoods of health care/ research professionals, support staff, and other stakeholders because of the 2010 Constitutional Court decision to suspend new biomedical research. Finally, to analyze the

¹⁶ http://www.lhscr.com/index.php?atencion_domicilio/area_de_cobertura
Used in accordance with Section 107, Fair Use, of the Copyright Law, Title 17 of the United States Code.

advocacy coalition strategy of policy narratives used by coalitions for and against clinical research inside the country and the effects these strategies had on identity, both in the coalition and for individuals within the coalitions.

Michigan State University's Institutional Review Board (IRB #: 10-545) approved this research. All interview instruments were translated into or written in Spanish, including the research proposal, approval letters, consent forms, the interview guide, and survey instruments. While many of the participants are bilingual, most of the interviews were conducted in Spanish, although sometimes participants wanted to speak English or code switched from Spanish to English for parts of the interview.

Research Design

This research is a qualitative exploratory research design, which rests on a theoretical foundation of critical-interpretive medical anthropology, in which research into medicine, disease, treatment, and care are placed into a contextual frame of global capitalism and the lived experiences of individuals are explored in an effort to understand how institutions and larger processes affect an individual's experiences. Since pharmaceutical companies and their research into new medications have been globalized for the last three or four decades, this critical-interpretive perspective provides a strong theoretical framework for understanding the challenges of regulating clinical research sponsored by multinational pharmaceutical companies and other foreign entities inside Costa Rica and how these challenges have affected local stakeholders.

This design, data collection and analysis then contribute results that add to the body of theoretical work in the areas of globalization, capitalism, medicine, clinical research, and policy-making (Johnson 2015). Data was collected through fieldwork in the *Grande Área*

Metropolitano (GAM) of San José, Costa Rica. This researcher was in the field from January 2014 through March 2016.

The design of this research benefits from interdisciplinary approaches to interrogating the research question and aims. Throughout fieldwork, the techniques and skills specific to cultural anthropology were applied including participant observation, semi-structured interviews, field notes, a short survey, and archival research. Sociocultural linguistic narrative analysis provided frameworks for analyzing the public debate as found in print media with a focus on the news genre of editorials and opinion pieces. For analysis of the policy-making process, I employed to research and models from public policy analysis. Specifically, I applied the Narrative Policy Framework using a qualitative approach to examine how advocacy coalitions formed; what policy strategies each coalition used to influence policy-makers; and how coalition narratives reinforced specific identities of various stakeholders who were either for or against clinical research in Costa Rica. . Finally, I used semi-structured interviews, field notes, and short surveys, all standard tools of cultural anthropology (Gray and Jones 2016).

The research design included three phases, which, while listed here as distinct, often overlapped as informants shared news articles and government documents from their private files or suggested libraries or archives where more information could be found. The first phase involved the collection of archival materials such as print news media and government documents. This work served several purposes. First, to develop context and background knowledge of the growth of clinical research and the key stakeholders involved in its growth or inhibition and how the subsequent suspension affected class status and social capital of health care professionals and other stakeholders in Costa Rica. Second, the work with print media assisted in developing themes and questions for the interview guide; to generate a list of potential

informants; and finally, to provide another source of data with which to triangulate information from informants.

Phase two of fieldwork focused on question and survey development, recruitment plan development, pilot testing and semi-structured interviews with informants, which addressed all three aims as thematic sections of the interview guide as well as informants' recollections of the growth of clinical research. Initial interview participants were convenience sampled from friends and colleagues. Face to face, cold call approaches were used for early interviews, in which we walked into different departments on the campus of the University of Costa Rica. This generated several interviews, from which we could generate more referrals through snowball sampling (Babbie 2013).

Participants

Fifty-seven participants volunteered for the study. The inclusion criteria included direct involvement with the debate about and subsequent suspension of clinical research within Costa Rica. I stratified the participants across four categories which included academic researchers or bioethicists; government functionaries, elected and appointed officials, judges, private attorneys, and government ministry or agency employees; physicians, management, employees of the public health system (CCSS) and those who returned to work in the *Caja* after losing employment in clinical research. Finally, we sought out physicians with private practices, researchers, or research team personnel, currently or previously employed in clinical research to interview.

There were some challenges in stratifying across these four categories of participants, in part because many participants occupy more than one stratum. For example, a physician can practice medicine in the CCSS while maintaining a private practice at the same time.

Alternatively, someone could own a private laboratory but work for one of the public health system laboratories as well. Finally, due to the suspension, many people who had worked exclusively in private research returned to the public health system, an alternative career (one they had training in before entering the research field), or academia. Therefore, the categories indicate both their primary source of employment and where they were interviewed, i.e., in an academic, government, public health system, or private research or private practice setting. If they were retired or unable to find work, I stratified them according to where they had worked at the time of the 2010 clinical trials suspension. This resulted in fifty-seven participants stratified as such: twelve academics (AP) from two public universities; seventeen participants from the governmental, political, and legal sphere (GO); eleven participants from the public health care system and associated agencies (HCP); and seventeen participants from the private research, university, or practice sphere (PRV) (see Figure 2.3).

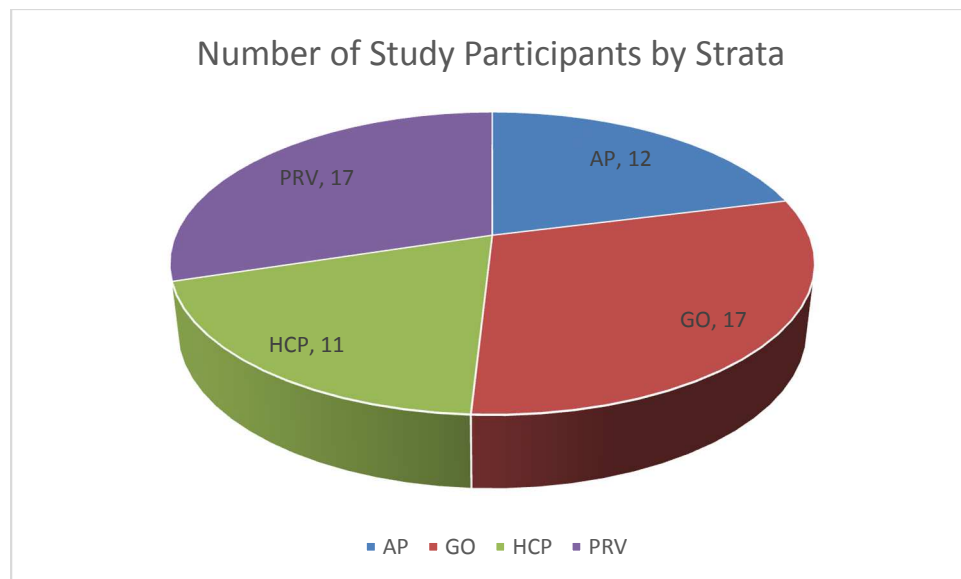


FIGURE 2.3: RESEARCH PARTICIPANTS BY STRATA.

I interviewed twenty-eight men almost evenly distributed across the four categories and twenty-nine women with the bulk of the women located in the private research (PRV) and the governmental arena (GO) (See Figures 2.4 and 2.5).

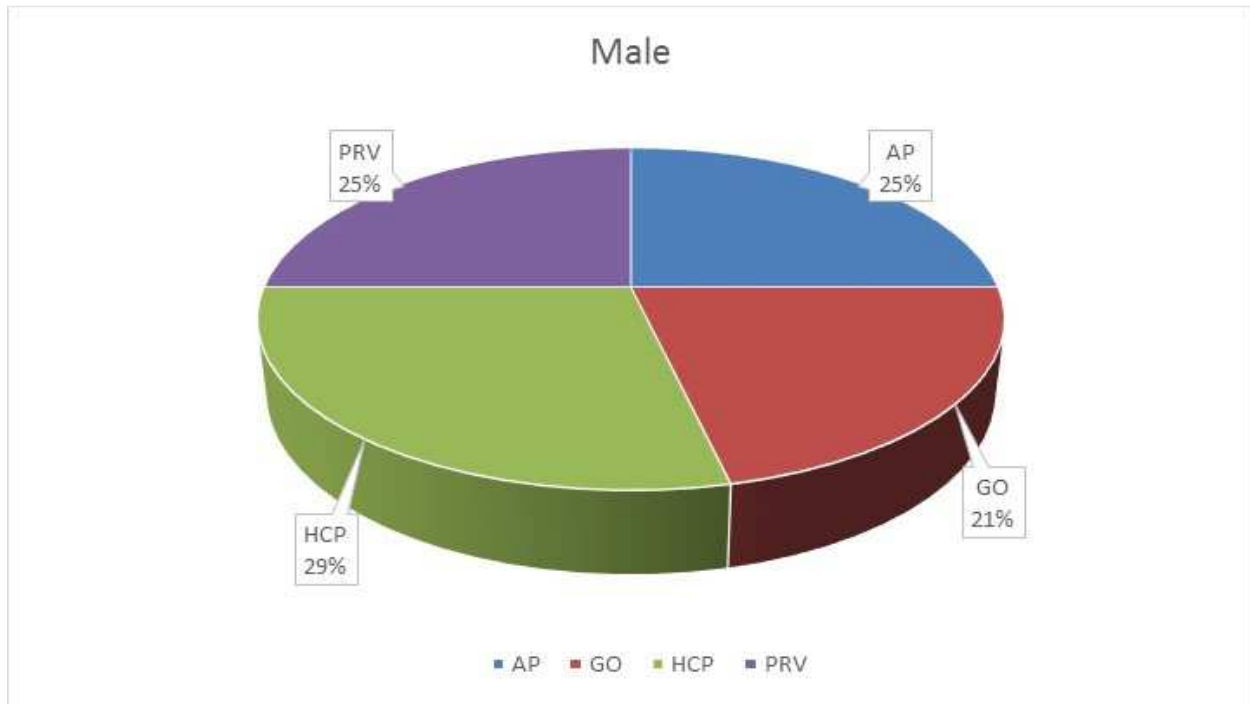


FIGURE 2.4: PERCENTAGE OF MALE INFORMANTS BY CATEGORY.

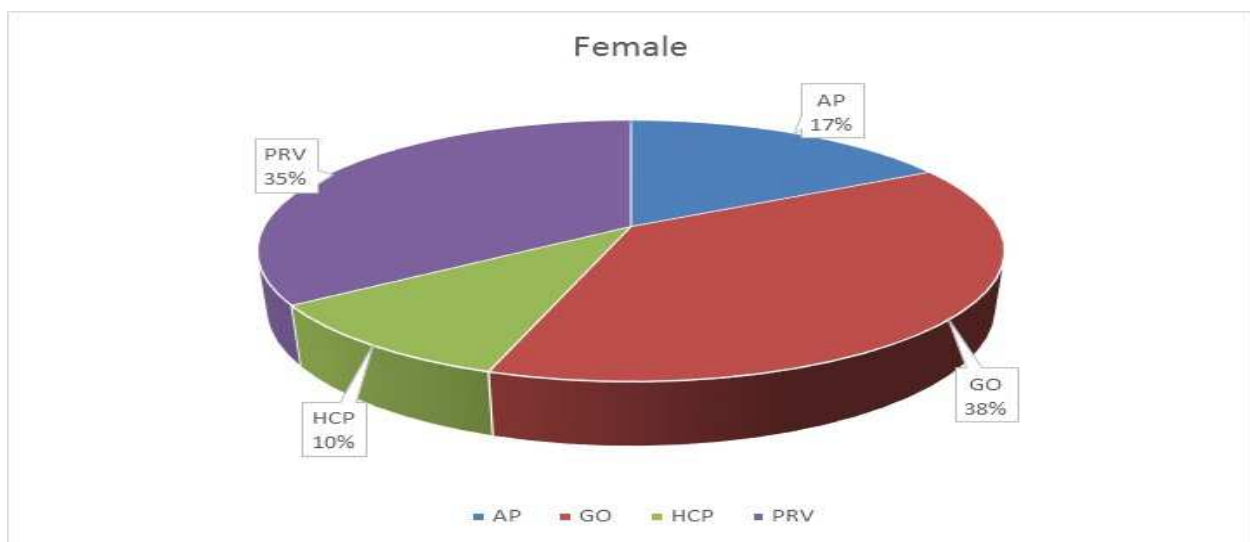


FIGURE 2.5: PERCENTAGE OF FEMALE INFORMANTS BY CATEGORY.

The ages of the participants ranged from the late-twenties to over sixty-five years of age. The largest age group was the over sixty-five with twelve participants in this age range, followed by the 36-40 age range with eight participants, and the 56-60 age group with eight participants (See Figure 2.6).

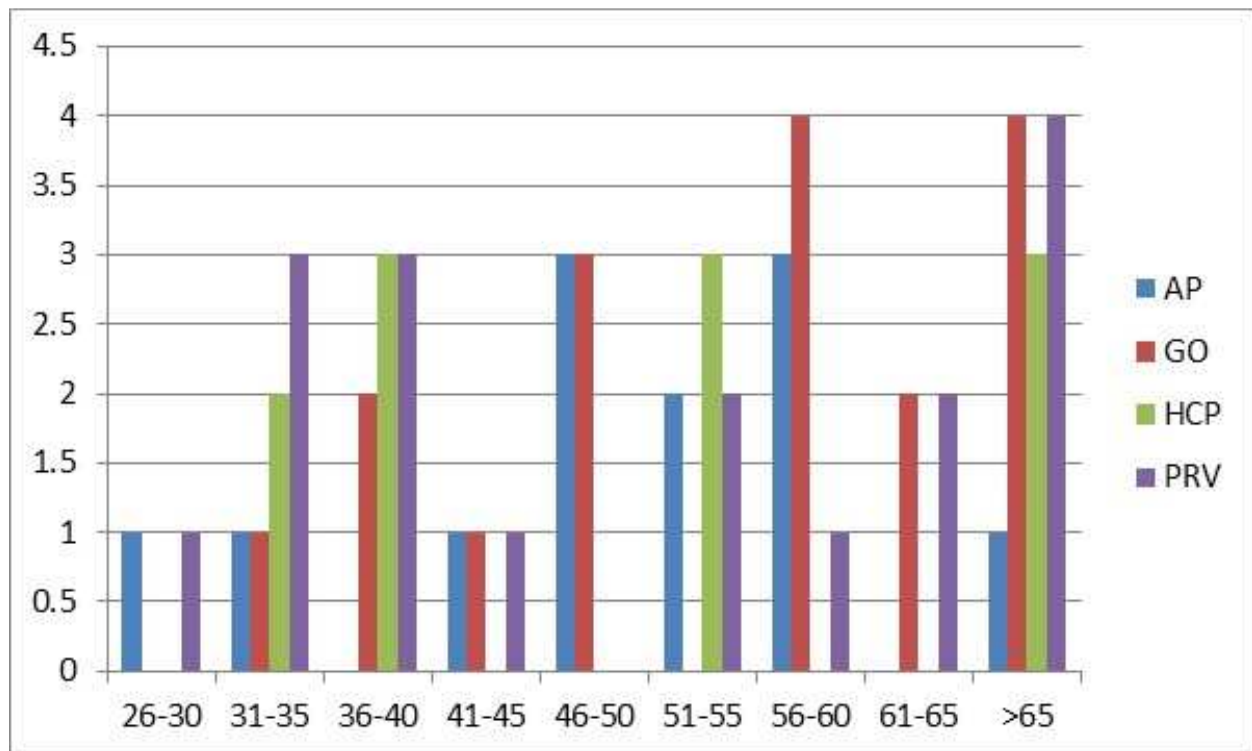


FIGURE 2.6: AGE OF INFORMANTS BY CATEGORY.

I gave all informants the opportunity to remain anonymous or to give consent to use their names in this work. Some I interviewed have been publicly active with opinion pieces in the local newspapers, journal articles, or cited in government documents. While the majority (35) of fifty-seven respondents agreed to the use of their names within this dissertation, twenty-two requested anonymity. Because many of the participants who participated this dissertation research are from the similar backgrounds and class status, and were directly involved in some aspect of the debate on clinical research, the usual methods for maintaining the anonymity of participants by using a pseudonym and changing ethnographic details were not going to provide

enough protection for those who wished anonymity. Therefore, I have chosen to use names in the instances in which I am citing publicly available articles, news stories, or government documents, and anonymity for participants in the ethnographic narrative derived from the interviews, except in very rare cases. Therefore, to differentiate between comments made by participants during our interviews and those quotes culled from publicly available information, I have placed in italics, any quotes drawn from transcripts of our interviews.

Data Collection

Sampling Methods for Interviews. Due to the specific scope of my research question and aims, I created an “*a priori* framework” using results from a pilot study conducted in 2010 (Johnson 1990: 40). This involved using previous employment within the clinical research arena as the starting point for understanding how the lawmaking process impact people’s livelihoods in and around the clinical research industry. I used key informants to assist in the development of the semi-structured interview question schedule and contacts I met through my previous research in a pilot study in 2010.

However, to only consider the experiences of those employed in clinical trials before the suspension would fail to capture the whole story of clinical research within the country. Therefore, I needed to include key stakeholders in other fields such as academia, the government, and the public health system (Guest 2015). I also wanted to make sure that I included viewpoints from informants who were against the way clinical trials were regulated in the country before the suspension. Therefore, I used a non-probabilistic, purposive sampling method combined with respondent-driven, or snowball sampling (i.e., referrals) (Babbie 2013, Guest 2015). As a result, I actively sought out specific informants for their perspective on the research topic, and then engaged in snowball sampling during interviews to generate more and a

more generalized list of informants. Each respondent was asked to refer at least five more individuals to interviews.

A limitation to the sampling was the lack of currently employed pharmaceutical company respondents. Although there are regional offices for at least three pharmaceutical companies located in San José, company policy restricted employees from talking about their work to those outside of the company. Every attempt to seek respondents from this arena failed. While non-probabilistic sampling does involve some potential pitfalls concerning statistical analysis, the exploratory nature and narrowed topic of this research project made this method of sampling the most useful in addressing both research question and the three specific aims listed above (Guest 2015, Babbie 2013).

Collection of Print Media and Governmental Documents. I sought to understand two issues through archival research. The first task is to determine how the growth of and regulation of clinical trials in Costa Rica and the subsequent 2010 ban affected class status and social capital of health professionals and other stakeholders. Second, how the suspension of clinical research within the country changed the relationship that Costa Rican health professionals and key stakeholders had to the international medical and science community, I gathered both news articles and government documents to investigate the growth of clinical research within the country and the accompanying legislative, judicial, and regulatory documents. Themes from the articles included: the pros and cons of clinical research in general and specifically in Costa Rica, bioethical concerns, primarily as related to a few specific studies that happened in the early 1990s, conflicts of interest, governmental oversight, and advancement of science and the role of pharmaceutical company-sponsored research.

I collected two types of texts: local news stories about clinical trials and national records and legal documents. The news stories included: news articles, opinion pieces, editorials, *campos pagados* (a type of paid article), local academic journal articles, and press releases that related to clinical trials, the 2010 suspension of clinical research on human subjects, the effects of the ban, and the subsequent law projects. I used keywords in Spanish that had equivalence to “clinical trial” (*ensayo* or *estudio clínico*) “clinical research (*investigación clínica*),” “biomedical research” (*investigación biomédica* or *médica*), “medical tests” (*pruebas médicas*) and “research with human subjects” (*investigaciones con seres humanos*) and significant event dates (e.g. the 2010 suspension) to focus my search of newspapers, journals and government records based on knowledge gained through my preliminary research in 2010. These searches returned a total of one hundred and seven items: eight journal articles, four books or government documents, three dissertations or theses, and ninety-two newspaper articles from eight different periodicals. Out of the ninety-two articles I sourced, four were not directly related to clinical trials, so eighty-eight news articles across the eight different periodicals were included in the databank spanning nearly twenty years (1995-2014). In addition, two participants each gave me a set of the same news articles from the mid-1970s about an ethical abuse in a study about vaccines for children.

I downloaded thirty-eight articles directly from each newspaper’s website as were available. I made hard copies for five articles from the weekly, *Seminario Universidad*, the newspaper of the University of Costa Rica. For the rest of the articles, I had to go to the National Library in downtown San José and request the original print article from the reference librarian. I was only able to make hard copies of articles from 2009 to 2014 due to the delicate nature of the articles. Therefore, research assistants and I wrote summaries of each article from 1995 forward to 2009. In the summaries, we noted names mentioned in the articles for possible

interviews and as the basis of a social network analysis component to the study, any agencies mentioned and the meaning their acronyms, and any important dates and legal documents mentioned. These news articles, official government documents, and dates coupled with ethnographic narrative have allowed me to construct a timeline reflecting the growth of clinical trials and the parallel policies, laws, and regulations in Costa Rica. Later, as more of the periodicals uploaded their archives to the internet, I was able to access digital versions of most of the articles for which we had only had summaries.

Further, several participants provided us with news articles and other documents that they had collected, such as members of the Costa Rican Association of Research in Human Health, formed after 2010. Membership included physician-investigators, study coordinators and other members of research teams, bioethics specialists, and other stakeholders. We had an opportunity to view many of the emails that passed between members as one of the officers of the group forwarded emails with links to article that also included commentary on the ongoing events. We also were able to email the entire association for recruitment into our study. In the end, we interviewed twenty-one members of the association, either through contact via the listserv or through other referral sources.

This archival work proved to be very valuable during the interviews. For example, a specific audit that the CCSS conducted in 2000 that led to ethical questions was mentioned several times by informants. It also helped me to determine some of the key stakeholders in the debate around clinical research in the country by the frequency with which these individuals were mentioned in news articles. As a result, I was able to focus my recruitment on making sure I included these individuals where possible. At least eight of my informants were people whose names I had culled from articles.

Participant Observation. I attended two weeklong training sessions sponsored by the *Centro de Desarrollo Estratégico e Información en Salud y Seguridad Social* (CENDEISS), an agency within the *Caja* that focuses on organizational and employee development and training. I also attended two conferences. One focused on international development ethics (The International Development Ethics Association (IDEA) Conference, 2014) and another (the 4th Ibero-American Conference on Health Law) that focused on health law and included a panel on clinical research and human dignity with two presenters who discussed the current situation (in 2014) in Costa Rica regarding clinical research. Finally, I attended a round table at the medical school at the University of Costa Rica to which I was invited.

Semi-structured Interviews. I conducted fifty-seven semi-structured interviews with academic professionals, governmental professionals, CCSS health care professionals, and private physicians, laboratory owners, and research professionals. Interviews were done in Spanish, although some informants spoke in English to me either during the entire interview or off and on during the interview. Interviews were between thirty minutes to ninety minutes. Although, one interview was three hours long and another was six hours throughout two days and included three informants.

All interviews were tape-recorded, with both written and verbal consent. In all but four interviews, my lead research assistant accompanied me to the interviews, took field notes, helped to clarify responses, conducted two interviews solo, and managed the section of the interview on social networks and referrals to potential respondents. I did two interviews alone and two more with other research assistants. Finally, in one particularly challenging and extended interview with three informants, both my primary research assistant and a backup research assistant joined to take field notes, each one of us focusing on one of the three informants.

Interview Schedule. Two pilot interviews were done to test the questions generated from the pilot study and archival research. While semi-structured interviewing lacks the rich detail of participant observation or the classic ethnographic techniques of unstructured interviews, interviewing elites required flexibility and creativity on my part as participant observation was rarely an option available, and I did not want to take too much of my participant's time (Gusterson 1997, Ortner 2003, Nader 1972, Fife 2005). Interviews were held at a location of the participant's convenience and included restaurants, offices, and their homes. One interview was conducted in a public area of my boarding house while another participant was interviewed via Skype as the person was in another country.

The first section of the interview focused on demographic statistics such as age and gender, but also included such items as educational background from secondary school forward; any degrees conferred, and any professional certifications the participant had acquired. As well, in this section, I asked for a brief oral history of the participant's previous employment and involvement in international and local professional and civic organizations.

The second section focused on each participant's experience in clinical trials. I wanted to get a sense of everyone's role in clinical research in Costa Rica, be it as a part of a research team, as a governmental official or employee involved in law-making or regulation, or as an academic with bioethics expertise. This question was deliberately a broad and open-ended question to gather as much detail, personal experience, perceptions, and attitudes as possible. For many of the participants, this question alone took up the bulk of the interview.

The second and third questions in section two focused on what individuals thought were the best aspects of clinical research and what were the worst aspects of clinical research. While, in the fourth question, I wanted to find out how participants viewed the role of the press in the

evolution of clinical research in Costa Rica, the subsequent suspension, and the process of developing a law to regulate research. The final question of this section asked if the participant him- or herself lost employment or if they knew of anyone who had lost his or her job because of the suspension. This question also provided a segue into the third section on livelihoods.

Section three consisted of two open-ended questions. The first asked about how working in the field of clinical research affected their lives before the suspension. The last question of the section asked how the new law for regulating clinical research has affected their lives, either professionally, socially, in academia or other spheres of influence. Between the two open-ended questions was a short, twelve statement survey.

These twelve statements asked whether the interviewee lost or gained (or not applicable): employment; income; prestige, status in social circles; real estate; grants or funds; patients; the ability to work in the *Caja* and/or his or her private office; international opportunities; publication opportunities; academic opportunities; and whether the participant needed more educational training because of the suspension. This short survey coupled with specific questions on schooling and previous and current employment were used to create a database with which to investigate how the 2010 suspension affected the livelihoods of people working in or around clinical research. Interviewees were also encouraged to either write comments or comment on their answers for the benefit of the audio recording.

Section four examined how health care professionals, previously employed in clinical research, seek to fulfill their obligation for providing health care and their perceptions of the limitations or resources available to do so while navigating both the public and private systems and globalizing biomedical economies. It was structured in such a way that the same question was asked three times: “According to your experience or the experience of others, tell me about

clinical trials patient care within the public and/or private health care systems before the suspension in 2010”, “after the suspension”, and “as the result of the new law”. This section proved to be challenging to do in part due to the long and slightly complicated sentence structure in Spanish. With insight from my research assistant, I added a short preamble to the section that focused more on what the questions were trying to get at, which was if informants felt that clinical research and then the policy changes that ensued enhanced, inhibited, or had no effect on patient care.

The final section investigated people’s social networks and, coupled with data from the demographics section (which schools the participants had attended, previous employment, and professional organizations), sought to illustrate the close social networks in which people involved in engaging and critiquing clinical research circulate. The section also asked for referrals to others who might participate in this study from the interviewees and so, my research assistant managed the bulk of this section.

We gave each of our participants a “*red social*” (social network) form, which consisted of a list of names collected from print media, many of whom were well known leaders in the country and categories of relationships including: family, social, professional, economic, educational, governmental, and finally, any other connection not already listed. We, then, questioned participants about how people they knew from the social network form might have offered support for them during the suspension when and if they lost their job or any other opportunities listed in the livelihood survey.

Data Analysis

Phase three involved compiling and analyzing the data by generating themes, engaging in narrative analysis of archival materials and modifying livelihoods and narrative policy

frameworks to better understand the public debate about clinical research in Costa Rica that spanned forty years. Below, I will explain each step of the analysis process.

Ethnographic materials

During the fieldwork period, fieldnotes were formalized and reviewed. During and after the fieldwork period interviews were transcribed by native Spanish speakers, primarily, but not exclusively Costa Rican Spanish speakers. Data were analyzed both through hand-coding, and the MAXQDA Software (VERBI 1989-2018). Coding was both deductive and inductive.

Deductive coding was shaped by interview schedule themes, while inductive coding was shaped by close readings of transcripts, archival print media, and government documents to draw out themes not captured by interview schedule keywords (Ryan and Bernard 2003). Demographic information and survey data were entered into Excel spreadsheets, converted to graphical representations of the data, and analyzed for patterns by interview group (academics, government personnel, public health system employees, and private research professionals) (Gravlee 2011, Bernard 1988).

I did all translations for both the ethnographic quotes and the print media and governmental document quotes used in the dissertation. I used a variety of Spanish-English dictionaries and two dictionaries specifically for Costa Rica words. Finally, when these methods failed me, I reached out to my research assistants for help.

Document Analysis

Archival sources were analyzed both on their merit, as source materials for specific events, and to confirm themes generated by ethnographic data. Two types of archival materials were used: print media archives and government document archives. Only primary sources were used in the analysis. Due to the sheer volume of articles, editorials, and opinion pieces, I focused

primarily on opinion pieces with few exceptions including the few articles and *campos pagados* (paid space) that included patient voices. Selected opinion pieces underwent a close reading and coding by keyword using MAXQDA. Further, quantitative analysis options within the software allowed for developing distributions of specific keywords between the two coalitions and graphical representations of these distributions were analyzed for patterns (Ryan and Bernard 2003, VERBI 1989-2018, Gravlee 2011). I did all translations using dictionaries and occasionally checking my translation against my research assistant's translations.

Another technique derived from policy analysis includes the Narrative Policy Framework which included deductive methodology through applying the pre-determined codes of “setting, plots, characters, and policy solutions” to opinion pieces and the discourse of a single legislative plenary session (Gray and Jones 2016: 202). Inductive coding developed themes around the idea of harms engaged in by the “villains” within a coalition’s narrative and well as conscious use of policy strategies to manipulate the media or government officials for the benefit of a coalition (Gray and Jones 2016: 204).

A Note on Anonymity

In writing up the results of my research, I have chosen to make all the people I interviewed anonymous which includes sharing very little detail regarding their specific roles or the places that they worked. I do this for a particular reason. Nearly half of my respondents chose to remain anonymous for this dissertation. Because I am working with an elite and specific population that has moved through different arenas related to clinical research in Costa Rica, even the use of names, positions, and locations of those who are comfortable with the use of their names, risks that those who prefer anonymity will be identifiable by proximity. As a result, I only use names, locations, and positions when using publicly accessible materials such as

websites or news articles as is the case when discussing the opinion pieces in chapter three or the debates on the floor of the Legislative Assembly. There are a few very specific instances in which I used the names and details of someone I interviewed. Each of those individuals gave consent. As anthropologists, we have a responsibility to minimize risk for our informants and, while some would argue that those in positions of power in society lose the right to anonymity, an outsider can never accurately predict the risks even for the elite within another country (Bernard and Gravlee 2015, Morse 1991).

CHAPTER 3: HOW COSTA RICANS DISCUSSED CLINICAL TRIALS: MEDIA DISCOURSE AS POLICY STRATEGIES

The banner headline read, “CHILDREN GIVEN A DANGEROUS VACCINE” (Excelsior 1976a). It was 1976, and a scandal was erupting around the work of the Louisiana State University collaboration with the Costa Rican Ministry of Health. Together they created a center for research called the “International Center for Medical Research and Training” which would come to be known as LSU-ICMRT or ICMRT and a study on the Syncytial Respiratory Virus (SRV), was at the center of the controversy. When asked about this early scandal, one informant from the research coalition responded that, yes, there were improprieties related to SRV study and its informed consent that were at the heart of the blazing headlines. However, he noted that leftist politicians would continue to use “*this situation to demonize*” clinical trials and “*to strengthen their discourse*” against clinical research and international collaborations over the next four decades. If Costa Rica were to have a Tuskegee syphilis or a Willowbrook State School hepatitis level scandal, then the studies that were run out of ICMRT would be made to fit the bill by detractors and they would use the press strategically again and again to amplify their concerns. Researchers and other stakeholders on the benefits of clinical research would themselves engage in the similar strategies to counter messages that they felt “demonized” clinical research.

In Costa Rica the earliest record of clinical trials in the country dates to the early 1960s (Trejos Willis 1986, Ugalde A and Homedes 2014, Householder et al. 2019). However, Steven Palmer (Palmer 2003) notes, in his book on the growth of biomedicine in Costa Rica, that, by the end of the nineteenth century, Costa Rican physicians were engaging in vaccination against smallpox using both vaccines cultured from local cattle herds and a vaccine from Germany.

Palmer writes that, “The report [of using vaccines to guard against smallpox] suggests that a spirit of technical innovation and improvement was alive among Costa Rican practitioners” more than 100 years before the ICMRT scandal (Palmer 2003, 51). All this progressive scientific innovation seemed to fade away as outrage dominated the press for several months in 1976.

This chapter traces the early discourse frameworks regarding clinical research in the country through the events and ramifications of the ICMRT scandal as presented in legal documents, press articles, correspondence, and ethnography. Further, a deeper dive into the use of opinion pieces in local newspapers in 2002 will illustrate how the debate regarding clinical research in the country began to harden into policy beliefs that shaped the formation of two distinct coalitions for and against clinical research at the time.

To understand how these two coalitions formed, I will illustrate the early use of competing narratives in the ICMRT scandal through a close reading of articles on the issue from the late 1970s, then I will present the results of a content analysis on sixty-three opinion pieces from seven different print media sources. I will follow the content analysis with an in-depth exploration of use of two words in print media (*experimento* and *estudios*) as policy strategies by using data from a series of 2002 opinion pieces written by members of each coalition in dialogue with each other. These two words became a shorthand for determining which side of the debate on clinical research in the country as each coalition member who wrote an opinion piece used these words to clearly position themselves and their coalitions in the public eye and with each other. Finally, I will discuss how the policy narratives of coalition of the Statists, can lead to the formation of durable identities of coalition members (Neoliberal Entrepreneur member identity will be discussed in a later chapter).

Elite Discourse and Policy Narratives

Elite Discourse, Policymaking, and the Role of the Media in Coalitions

Tuen A. van Dijk (van Dijk 1993) writes about the role of elite discourse in corporate, political, academic, and educational spheres as well as the media's role in maintaining the status quo in the state's institutions. He illustrates how elite discourse and elites in general maintain hegemony through their control of newspapers, textbooks, corporations, opinions, ideologies, and more. Van Dijk claims that elites, due to their position in society, can be resistant to change or unaware of their own roles in perpetuating hegemony because it threatens their "normative self-concept" (van Dijk 1993, 9). In his analysis of the various discourses of the elite, including written and oral texts, van Dijk argues that these texts "are assumed to be monitored (and explained) by underlying *cognitions* of language users...by memory processes and representations such as mental models of specific events, knowledge, attitudes, norms, values, and ideologies" (van Dijk 1993, 13). One of the ways in which the elite control the state narrative is through the media.

Van Dijk argues that media discourse is somewhat different than other kinds of elite discourse, because elites need the mediating force of the media to further their messages and raise their profile with both the public in general and, specifically, with other elites. Because the media sits at the nexus of many other state institutions, it wields more power in its active cultural reproduction and how media elites "control...other elites" (van Dijk 1993, 243). Other elites often rely on the media to further their own goals in politics or business.

Media also provides an avenue for reifying or rebelling against ideologies or world views. Charlotte Linde [2008] notes that institutions can be "any social group that has a continued existence over time, whatever its degree of reification or formal status may be" [7]. I

argue that those working in the clinical trial industry in Costa Rica and their opponents have been engaged in institutional memory-making and narrative using the institutional tools of the media and the legal system for more than 40 years. While stakeholders on both sides of the debate used the exact same tools to achieve their ends, such as the narratives, or the "stories" they tell [Linde 2008:4], they also used these tools to further their own idea of institutional stability or change as it relates to clinical research in Costa Rica and, in the process, reified specific identities.

Policy Coalitions and Policy Narratives

As discussed earlier, Sabatier and Jenkin-Smith developed the Advocacy Coalition Framework (ACF) as a model for evaluating the elements of coalition formation, the strategies (especially their use of media) they employ to make policy change, and how each coalition's policy core beliefs are shaped by an aggregation of each member's own values and beliefs (Sabatier and Weible 2007). The ethnographic work of examining these core beliefs and the media strategies used can be found at the meso-level elements in the policy subsystem as illustrated in the framework.

Sabatier and Weible identify what they call the "policy iron triangle" of stakeholders in policy stasis or change (Sabatier and Weible 2007, 192). These stakeholders include interest group leaders, legislators, and agency officials. Each of these stakeholders have beliefs that define the parameters of their discourse and action on a policy. The authors frame these beliefs as a "belief system hierarchy" (Sabatier and Weible 2007, 194). At the base are "deep core beliefs" that form because of socialization and are very resistant to change. Policy core beliefs are also difficult to change, engage coalition members across a subsystem, and are the embedded in the member infrastructure of a coalition. By identifying the different policy core beliefs at

work, one can start to frame the outlines of the coalitions involved in a policy dispute and even policy differences within an individual coalition (Sabatier and Weible 2007).

Policy core policy preferences have three characteristics: they span the entire policy subsystem; they are very significant; and “have been a major source of cleavage for some time” (Sabatier and Weible 2007, 195). These policy core policy preferences bind coalitions together and can transition into the final level of the beliefs hierarchy, which is secondary beliefs. Secondary beliefs are more malleable to change and limited in scope and focused more on specific aspects of a certain policy. As result, they are more easily modified by the addition of new information or stakeholders. Researchers have analyzed policy belief systems from both a qualitative and quantitative perspective. These different levels of beliefs give shape to the advocacy coalitions. Sabatier and Weible write that the framework

Predicts that stakeholder beliefs and behaviors are embedded within informal networks and that policymaking is structured, in part, by the networks among important policy participants [often those in their policy iron triangle]. The [framework] assumes that policy participants strive to translate components of their belief systems into actual policy before their opponents can do the same (Sabatier and Weible 2007).

To integrate these beliefs into policy, it is necessary for stakeholders to build alliances, develop similar strategies, and access common resources. Later, I will focus on the development and vocalization of core and policy beliefs through public debate in news media which evolved out of the 1976 ICMRT scandal and how the different coalition narratives became more strategic with their narratives by 2002 when we analyze a series of opinion pieces.

Analyzing Policy Narratives and Media Strategies

Alexa Robertson (Robertson 2017) explains the role of narrative in storytelling and print as entertainment and lessons and highlights their role in developing a sense of community. She writes that “[i]t is through stories we tell and are told that we make sense of society; it is through

narratives that our situation in the political and cultural landscape, and that of everyone else, is reinforced” (Robertson 2017, 122). According to her, we also can observe how “...identities and actions come into being through [the] stories” (Robertson 2017, 123). By studying media narratives through opinion pieces written by coalition members, that we can observe elite power dynamics at play.

Maria José González Rodríguez writes that “language as a social practice [is] construed by, and at the same time [is] construing...the social” (González 2007, 49). We can see this in the use of opinion pieces as policy strategy. Costa Rican elites are constructing identities (and sometimes employment) around their public positions as expressed through op-eds. This strategy strengthens the policy beliefs each coalition holds by further binding each coalition member to the coalition as a social group and as a policy force (Sabatier and Weible 2007).

Robertson suggests that, as interpreters of narratives, we need to focus on more than just the “events” of a narrative, but also the “story as told by the author” which exposes “the power of a narrative” by “discerning and documenting the techniques used by the teller...to show how their words should be understood” (Robertson 2017). For example, I analyze word choice to illustrate how one coalition highlights historical research abuses, which leads the reader to attach violence, abuse, and experimentation to clinical research. As interpreters of the narratives used in Costa Rican newspapers by different stakeholders, we focus on more than just the events of the narrative and instead focus on the story the author is conveying which exposes the impact of the narrative through the choices employed by each author to inscribe the boundaries of their individual and coalition positions.

Op-eds as a Genre

Newspapers and other news media often straddle the delicate balance of "fact and values" as a large social and cultural institution (Kowalchuk and McLaughlin 2009, 702). While news articles written by staff or freelance journalists carry an oft-challenged expectation of objectivity in asking who, what, where, when, why (and how) of newswriting, opinion pieces (op-eds) always contain the specific point of view of the author writing it. As Kowalchuk and McLaughlin note, even the "spatial separation of 'fact' and 'opinion' in the very layout of the newspaper reflected the new ideology of professional journalism..." (Kowalchuk and McLaughlin 2009, 702). In Costa Rica, opinion pieces around clinical trials were often written by members elite groups including doctors, lawyers, academics, elected officials, and government agency and the public health system staff and management (Buozis and Creech 2018).

Opinion pieces as a genre of journalism, therefore serve to "shape public opinion and elite policy" (Kowalchuk and McLaughlin 2009, 697). In the press, these pieces bring the public's attention to a policy issue that elite coalitions are wrestling with, both with each other, and with the values, ideals, and interests attached to the issue from both sides. The op-ed discourse surrounding clinical research and its regulation in the country carried on in fits and starts for nearly fifty years while the country's governmental, health, legal, and academic elite tried to develop policy, law, and regulation that built upon the international standards in use since World War II and reconcile these standards with the country's constitution, values, and national and individual best interests. Studies of media discourses are a solid form of linguistic and journalistic research; however, Belmonte argues that editorial and opinion media are a

“Cinderella” genre, with the research on opinion pieces even more scarce than on editorials (Belmonte 2007).

Op-eds are also displays of power, as the structure of the language itself can indicate the writer’s social standing as well as who the writer is engaging in dialogue (Belmonte 2007, González 2007). As a policy strategy, opinion pieces serve to flex core beliefs around a policy or issue, announcing these beliefs to the public and to opposing coalitions. As each coalition deploys this strategy again and again, policy core beliefs start to form and, with each reiteration, establishes the distinct boundaries of each coalition (Sabatier and Weible 2007).

A Smoking Gun: LSU-ICMRT Syncytial Respiratory Virus (SRV) Vaccine Study

Costa Rica has become in the last few years, not only the “guinea pigs” of large transnational pharmaceutical companies, but as a “no man’s land” where they produce medications and pesticides that are prohibited in the United States and Europe. —Isidro Sánchez¹⁷

The SRV study was conducted through the International Center for Medical Research and Training (ICMRT) formed through a contract established between Louisiana State University (LSU) and the Ministry of Health in 1962 with funding support from the United States National Institutes of Health (NIH) for four years, and, thereafter, from the pharmaceutical company, Merck, Sharp and Dohme, thereafter. This center engaged in vaccine research in Costa Rica, including influenza vaccines (in which 20,000 Costa Rican students were vaccinated with a vaccine of suspect quality), measles vaccines, and the SRV vaccine, some of which were past their viability date (Elizondo Camacho and Mora Luna 2000, Brenes Valverde 2013). The SRV study enrolled several children from a daycare center in the San José area.

¹⁷ “Medicinas que no curan, envenenan” por Isidro Sánchez (artículo publicado por Ramírez y Alfaro, 1980, pp. 130-134 (*In Ética y Salud: Un Enfoque Ético para Trabajadores de la Salud*)).

In 1976, this research unit and the subsequent vaccine studies were guided by such international regulations such as the “Nuremberg Code (1947),” the “Helsinki Declaration (1964)” (Howard-Jones 1982). These guidelines became the ethical foundations for engaging in clinical research (Emanuel 2003) in the US and abroad. The Tuskegee Syphilis Study had been running for nearly three decades, but its ethical improprieties had yet to be uncovered when ICMRT opened. And so, it was in the context of such malfeasance in the United States that the LSU-ICMRT vaccine trials were developed¹⁸.

By analyzing some of the first articles related to clinical research in Costa Rica, it is possible to understand how two distinct policy narratives would lead to both the 2010 suspension of clinical trials in the country and the challenges faced over the four years, post-suspension, that it to enact a local law to regulate clinical trials in Costa Rica. Two informants each gave me some articles from 1976 that addressed the ICMRT scandal. Each of these interviewees were active members of the two opposing coalitions and both saw these articles as important to share with me. I argue that the narratives in these articles were the progenitor narratives for developing policy core beliefs for each coalition. These narratives did not change much over time and served to further entrench each coalition’s policy core beliefs around clinical research in the country throughout the next several decades (Sabatier and Weible 2007). The analysis of

¹⁸ The Nuremberg Code was written due to the results war crimes trials in Nuremberg, Germany, post-WWII, in which it was determined that experiments had been done on concentration camp internees. The main premise of the code was the idea of participant informed consent for any type of human subject research. The Tuskegee Syphilis Study (1932-1972) was a natural history study conducted by the U.S. Public Health Service to trace the effects of untreated syphilis in 400 African-American men. Unethically, none of the men were told that they were participating in a study and were also not informed of their infection. Even after a successful treatment had been discovered, the men were never informed that a treatment was available. A journalist exposed the study and its irregularities in 1971 and the study was closed a year later. This study, along with the Willowbrook State School for the Retarded in which mentally disabled children were infected with hepatitis then treated with gamma globulin to test efficacy. It was Tuskegee and Willowbrook that led to the development of the Belmont Report which provided the structure of respect for persons (through informed consent), justice, and beneficence (Guerrini 2003, Fisher 2007).

three of the 1976 articles will illustrate how some of the early elements of the coalition narratives developed.

Scandal Erupts

In 1976, it was discovered that informed consent for participation in the SRV vaccine study had not been sought from the parents of some children from a local day-care, violating many international guidelines for clinical research (Ugalde A and Homedes 2014, Elizondo Camacho and Mora Luna 2000, Householder et al. 2019). For the funders of the center (NIH and LSU; later multinational pharmaceutical companies), Costa Rica proved to be an exemplar location for clinical research for keeping costs down and no legal framework to pursue unethical conduct (Ugalde A and Homedes 2014, Householder et al. 2019). By 1974, Merck Sharp and Dohme, a foreign pharmaceutical company, became the main financier for ICMRT and the center was busy enrolling subjects for several vaccine studies including influenza measles, and the syncytial respiratory virus. More than 34,000 individuals, 20,000 of which were children, were enrolled in the various studies that were conducted on discontinued (in the US and Europe) vaccines (Ugalde A and Homedes 2014, Householder et al. 2019).

Shortly after the malfeasance was discovered, the National Children's Trust (PANI),¹⁹ concerned physicians, and other professionals took legal action against the center, however the directors of ICMRT were never charged because there were no laws that had the power to hold them to criminal charges (Brenes Valverde 2013). A special commission was formed by the Legislative Assembly to address the violations related to the SRV study. While an Executive Order was passed in 1975 to create an Institutional Scientific Committee to oversee and consult with the Ministry of Health regarding clinical research, it was not until 1976 that the Legislative

¹⁹ *Patronato Nacional de la Infancia*

Assembly attempted to pass the first law to regulate clinical research within the country.

However, the law was vetoed by the Executive Branch, claiming the General Health Law²⁰ was sufficient for regulation of clinical research in Costa Rica (Elizondo Camacho and Mora Luna 2000).

In an article with a banner headline that reads, “CHILDREN GIVEN A DANGEROUS VACCINE,” the article laid out the facts: ICMRT had vaccinated the children of domestic workers who were in childcare at the “*Casa del niño-hogar-escuela*” without consent from parents or guardians. The article claims that the vaccine is “considered dangerous” and that “the children suffered high temperatures, swelling in the throat, and symptoms that resembled...the mumps” because of the injection (Excelsior 1976a). The article reiterates the lack of permission before a paragraph that states, “The only person that gives a positive outlook to these activities... is the doctor in charge of the children’s health” and notes that the parents of the affected children have organized and will be presenting their complaints to a tribunal. The parents are requesting compensation for damages from the vaccination (Excelsior 1976a).

A specific perspective is conveyed initially by the headline—that vaccines are dangerous— and then carried throughout the article with words such as “*experimental* (to experiment)” and “*como laboratorio* (like a laboratory)” (Excelsior 1976a). This narrative was contrary to the historical use of vaccines by the country in the treatment of smallpox and the commitment of the public health system (CCSS) to provide for the care of its citizens through the public health system (Palmer 2003).

The final paragraph quotes the parents of the children enrolled in the study and reads, “‘Never will we permit our children to be used in [this] type of work [like clinical trials]’”

²⁰ *Ley General de Salud*

(Excelsior 1976a). That outsiders to our ideas could proceed in this manner is reprehensible and worthy of punishment’, said the complainants” (Excelsior 1976a). Here, in this first article on the scandal, a critique of clinical research within the country developing. Already, there is a sense of “outsiders” coming to use Costa Rican bodies, especially vulnerable infants’ and children’s bodies, to the benefit of other countries and pharmaceutical companies. For this nascent coalition, we have already established who the victims are (children and their unsuspecting parents) and that foreign researchers and companies are the villains.

The following day, November 9th, *La Nación*, had this headline, “They will accuse the center that vaccinated children without permission; Weinstok [Minister of Health at the time] prohibits [the center] from continuing to operate; director admitted his fault” (La Nación 1976). The article opens with news of a sanction against ICMRT, saying that “The Minister of Health, Dr. Herman Weinstok, decided to completely cancel all of the permits, current and pending, for the International Center for Medical Research and Training of the University of Louisiana [sic] for having violated the regulation regarding human experimentation for the second time in less than a year” (La Nación 1976).

The article notes, in the second paragraph, that the “entity [ICMRT] passed over the basic provisions of the regulations for research and experimentation in human beings, which is consulting the parents, guardians, or those in charge of the minors when they were given some vaccine or substance for research” (La Nación 1976). In these first two paragraphs narratives are beginning to form. There is the introduction of a foreign entity, ICMRT which is linked to the United States through its relationship with a university in Louisiana (Louisiana State University). Research and experimentation are now linked together, so that, over time, research comes to represent experimentation for the coalition against clinical research in the country. And, by using

the phrase “some vaccine or substance” without the permission of the parents or guardians, the author (not credited in the article) has created a shroud of mystery around the center, the vaccines, and whatever else may be going on inside this center in the hands of foreigners. Later news articles will inform us that many of the vaccines and “substances” have been discontinued in the U.S. or Europe, further inculcating the public to this horror happening to nearly 20,000 Costa Rican children (La Nación 1976).

In this article, the progenitors of the Statist coalition policy narratives are taking shape. There are victims, villains, and heroes. The villains encroach from the outside and insinuate themselves into Costa Rican society. Heroes are guarding the gates. They are learned men holding positions of power in the Ministry of Health, the university, the hospitals. The narrative is clear: young children, unbeknownst to their parents, who did not give consent, are subjected to experimentation with unpatented vaccines and other substances at the hands of foreign researchers who failed to abide by local regulations. Yet other voices with a different narrative will soon be heard.

For example, in an article from November 18, 1976, a voice in favor of keeping ICMRT open is heard. It is in *Excelsior* and consists of portions of a letter sent to the periodical by Mr. Omar Francisco Jaén calling for the Minister of Health to revoke the decision to close ICMRT (Excelsior 1976b). His argument was that a prestigious international organization, already honored in Costa Rica should not be shut down based on the mistakes of junior personnel. He argued that all the great men of science and discovery had suffered the fear and disbelief of the governments and societies of their times. He is particularly critical of the Leftist leaders in Costa Rica, when he says (as quoted by the newspaper), “The irresponsible critique...has existed in the world against all of that which is science and scientists, they have ceased to have any reason, due

to the carelessness and attitudes that have sometimes seemed to be people without judgment" (Excelsior 1976b). He continues, "But an error by junior personnel does not give us a motive to pursue eminent researchers as if they were a group of cannibals" (Excelsior 1976b). Here, Mr. Jaén constructs science, scientists, and, specifically, researchers as the victims of irresponsible critique.

He continues by naming scientists and explorers who were doubted by state and religious leaders in their time including Archimedes, Galileo, Hercules, Gay Lussac, and Christopher Columbus. He chastises Costa Rican leaders when he argues, "It should not be strange, ...that today there are many enemies of ICMRT, especially because they seemed to have made the mistake of having the help of a North American university when for some leftist leaders [in Costa Rica], only in the USSR is there science and only in the socialist countries you have to receive help" (Excelsior 1976b). In a subsection of the article with a bolded heading of "*Anterior a Pasteur* (Before Pasteur)," Jaén is quoted as writing about the "curious fact" that Costa Rica enacted a law for vaccinations nearly 50 years before Pasteur tested his rabies vaccine in humans. This law "ordered the establishment of four laboratories ... to make a vaccine against small pox," all located in what is now called the Greater Metropolitan Area of San José (Excelsior 1976b).

According to the article, Jaén further comments that the law charges that these four laboratories should engage in scientific knowledge exchange and receive city funds and materials to realize the goal of creating vaccines. Finally, the law declared that parents were responsible for making sure that their children were vaccinated at all the appropriate ages (Excelsior 1976b). The article (1976b) summarizes with these words from Jaén

It is curious...that today, 135 years after our great-great grandfathers created vaccines in Costa Rica with complete success, we do not have a single laboratory

that manufactures vaccines and we [instead] must import [them]...But, what is the most interesting is that a giant scandal has been made for an inoffensive vaccine without importance that was given without parental permission, when for so long before this, the law obligated parents to vaccinate their children.

We are beginning to see above that the elements of a contrasting narrative are developing, which will evolve into a coalition narrative for those engaged in research. This narrative focuses on the benefits of science and discovery and pits uninformed leaders against the rational men of science. He argues that all great men of science from Ancient Greece to today have been persecuted in their time.

In comparison to other articles about ICMRT, this article is measured and uses historical evidence drawn from ancient Greece and Europe (Excelsior 1976b). This is important, because many physicians and other learned members of the elite class were schooled in Europe in the 19th and early 20th century (Palmer 2003). As well, Jaén—through the editors of the newspaper—reminded citizens that Costa Rica has a long tradition of efforts and interests toward vaccinations, presaging even the father of modern vaccines, Louis Pasteur (Excelsior 1976b).

Ten years later: a recap according to Dr. Alfonso Trejos Willis

An article posted on the University of Costa Rica's website gives a short biography of Dr. Trejos²¹. He was a representative for the Health Area of the University Council from 1973-1977 and his background and training were in Microbiology. In Costa Rica, this allows one to work in a hospital laboratory or one of the many privately-owned laboratories that dot the cities and towns in the country. The biography acknowledges that under Clodomiro Picado²², Dr. Trejos engaged in successful research and teaching at the university. His research focused on the aging

²¹ <http://www.cu.ucr.ac.cr/cu/historia/miembro-anterior/Accion/show/ExMiembro/alfonso-trejos-willis.html> (Accessed March 26, 2018)

²² Clodomiro Picado trained as a serologist under Louis Pasteur and became famous for his work on antivenom (Palmer 2003).

process, for which he produced many publications. Dr. Trejos became a vocal opponent to the methods used in clinical trials in Costa Rica and had several protégés who continued his work after his death through opposition to clinical trials in the country. Ten years after the ICMRT scandal, Dr. Trejos provides a summary of the events and discusses what has and has not changed in the intervening decade.

Dr. Trejos's article, entitled "Ten years later: The unethical procedures of the LSU-ICMRT" recaps the history of LSU-ICMRT within the country and the types of research the institute conducted there. However, this is not just a summary as his language includes the use of phrases like "little by little" ICMRT added studies that were like "artisanal craftsmen following, like recipes, the protocols" created by pharmaceutical companies, which here, Trejos calls "*casas comerciales* (commercial houses)" thereby setting the stage for another angle to the argument against clinical research inside the country (Trejos Willis 1986). He frames this activity of research for pharmaceutical companies as "scientifically and ethically spurious" and notes that by 1972, nearly 80% of the research was funded by Merck, Sharp and Dohme, Inc. (Trejos Willis 1986). This reminds those reading the article, published in the University of Costa Rica's weekly newspaper, *Semanario Universidad*, that questionable and unethical research was sponsored by a major pharmaceutical company, already a villain in the coalition narratives.

To define the victims of this unethical research, Trejos discusses the type and number of vaccine trials conducted between 1968-1969 and notes that 1% of the Costa Rican population—all children—had been enrolled in these studies. In that same time period, "34, 000 Costa Ricans" were part of studies that tested two forms of an influenza vaccine and in 1975, children were enrolled into a study for testing a vaccine that was not designated for testing in children which the director of ICMRT, Dr. Villarejos (who, Trejos notes, is Bolivian and another

foreigner) claimed were “vaccinated in error” (Trejos Willis 1986). Trejos points out that these influenza vaccines had previously been tested in other countries “larger and more advanced than ours” and that, in those countries, the number of participants per population were 35.5 for one million, while in Costa Rica, the ratio of participants to population was 17,000 for million (Trejos Willis 1986). Readers could conclude that massive experimentation was happening in the country.

According to Trejos, a special governmental commission had been convened in the late 70s to present recommendations for changes in the laws and regulations to ensure such improprieties would not occur again. Another commission was later convened that reformed the pertinent articles of the General Health Law. But, according to the author, the “legal transgressions and the ethical lapses of the personnel of LSU-ICMRT did not stop there” (Trejos Willis 1986). He itemizes these transgressions in the following paragraph:

it is known, through documents collected from the hearings of the Special Commission of the Legislative Assembly, that LSU-ICMRT studied vaccines in children of a young age without authorization of their parents; used a vaccine against measles that was unsuccessful as of seven years ago; that a vaccine against the syncytial respiratory virus was tested for the first time in Costa Rica in June, 1974 in young children and only was used for a second time in a small group of children...in Philadelphia by Dr. Weibel in April 1976 (Trejos Willis 1986).

Trejos sums all of this up by acknowledging that these lapses occurred a decade ago and yet states that “LSU-ICMRT continues among us for a dedicated time” and, while smaller, “[it is] surviving; trying to establish relationships with national entities and scientists and now trying to convert into a commercial serology laboratory for [HIV/AIDS] (Trejos Willis 1986).” Here, Trejos conveys a narrative of a continuing battle. The enemy remains in their midst: foreign researchers, foreign companies, and foreign substances.

A single question follows this paragraph. It asks, “When are Costa Ricans going to recover our dignity” (Trejos Willis 1986)? This question, probably more than any other comment on ICMRT, captures best the arguments of the Statists—those who have taken on the health and well-being of Costa Ricans regarding all things that can threaten the sanctity of life. To do so, Dr. Trejos announces within the article the formation of “*La Asociación Costarricense para la Defensa de la Calidad de la Vida* (The Costa Rican Association for the Defense of Quality of Life) or *Asdecavi* (Trejos Willis 1986). This is an official coalition with an official agenda:

...and we note that many were concerned about consumer advocacy and our sovereignty, we can expect that the answer to the previous question will not be long awaited. We have the votes for [this] (Trejos Willis 1986).

Asdecavi is noted as one of the signature legacies of Dr. Trejos in a profile in the university newspaper in 2004, several years after his death. In this article, the mission of *Asdecavi* is to defend “the citizen before the unscrupulous industries and merchants” (Hilje Q. 2004). This association also spawned a journal entitled “*Ciencia y Pueblo* (Science and People)” (Hilje Q. 2004). *Asdecavi* was a precursor to the Costa Rican Association on Bioethics which evolved into another association *ADEVI* or the Association for the Defense of Life, found on the website, “*Vida Humana Internacional*,” which appears to be a missionary group focusing on “life in the Hispanic world”.²³ The *ADEVI* website no longer works and a now-defunct blog.²⁴

In summary, the LSU-ICMRT scandal served as a crucible from which was forged the steely determination of those who have taken on the literal meaning of the Costa Rican Constitution. The constitution states that “human life is inviolable” and to preserve Costa Rican lives against corrupt national and international industries and businesses (Brenes Valverde 2013).

²³ <http://www.vidahumana.org/organizaciones-afiliadas/item/63-costa-rica>

²⁴ <http://adecostarica.blogspot.com/>

As an example of this determination to protect Costa Ricans, a member of the Statist coalition and an informant wrote in an email

When a society privileges these externalities [riches, prestige, power, etc.] on the moral and ethical values that justify the activity, it is corruption that appears, and in the approved [2014] law, [there is still] a privileged scheme of profit and enrichment upon the defense of the person and his dignity.

At the same time, physicians and others who had been trained in the United States and Europe—and exposed to clinical research there—were eager to bring new medical and scientific technology into the country. As a member of the Neoliberalist Entrepreneur coalition and an informant told me

The final product was an important harm to the development of clinical research in the country. In fact, in a biased way, the history of these investigations was used as one of the basic arguments, to justify the prohibition of the investigation in Costa Rica, promulgated by the ruling of the Constitutional Court ... and we sank in 4 years of "medieval obscurity" [after the 2010 suspension of clinical research in the country].

As seen in these two quotes, policy narratives have durability. For the Statist, there is still a threat from outside (externalities) and that corners will be cut in the name of economic benefits will continue—even with a law—to usurp the dignity of Costa Ricans who participate in clinical research. While the Neoliberal Entrepreneur narrative carries into the present that biased opposition attacks on clinical research threatened advancement of scientific knowledge, to the point that Costa Rica regressed to the Dark Ages for four years.

In the next section, selected opinion pieces from Spring 2002 are analyzed. In each op-ed, the writer is addressing someone from the other coalition directly. They will illustrate both the argumentative nature of the op-eds and how the narratives from 1976

continue to bolster each coalition's narrative while challenging the policy narratives of the other coalition.

Clinical Research in the *Caja* and the Country: Spring 2002

As González discussed above, opinion pieces serve several goals. They can draw new adherents to one's position. They can be deployed strategically to achieve gains in policymaking. They can point to the position and power of the author by what they say and do not say in the piece (González 2007). Op-eds can perform work for each coalition when used in a dialogic manner, by defining the boundaries of one's own coalition or introducing a new position or issue to the group and the public. They can also publicly exalt or shame an individual for an act or an idea (González 2007). In this section, several opinion pieces from Spring and Summer 2002 will be qualitatively analyzed for policy narratives, tone, and policy strategies (van Dijk 1993).

The opinion pieces discussed below addressed a December 2001 internal audit conducted by the Board of Directors of the *Caja Costarricense de Seguro Social* (CCSS) and investigated the role that the *Centro de Desarrollo Estratégico e Información en Salud y Seguridad Social* (CENDEISS) plays in training medical personnel (Ávalos 2002). Ángela Ávalos, a reporter for *La Nación*, notes that CENDEISS was lacking direction, failing to adequately fill medical specialty vacancies in various departments and hospitals. Neither the Executive President of the *Caja* nor the Executive Director of CENDEISS were prepared to discuss the report, even three months after its completion. But how do we get from a personnel and strategic planning issue to clinical research? One of CENDEISS's goals, besides developing and training staff and medical professionals, is the promotion of educational, biomedical, and social research (Ávalos 2002). It is about this report that some of the opinion authors structure their arguments.

Media Strategies and Coalition Narratives

Statist Coalition Narratives: Cambronero poses questions

A content analysis was done with thirteen years (from 2001 to 2014) of opinion pieces collected and archived for this study. In those opinion pieces, the word *experimento* and its derivatives were used eighteen times by authors connected to the Statist coalition, while the word *experimento* was only used six times by the Neoliberal Entrepreneurs and only in response to a Statist group member's op-ed. The use of the word *experimento* was often coupled with other words, as exemplified by Rep. Cambronero's op-ed title below, with words to like guinea pig, factory (*maquila*), and risk (*riesgo*). Already, the title easily identifies Cambronero's stance toward clinical research by using *conejillos de Indias*, which translates as guinea pig. Secondly, he refers to clinical studies as *experimentos* (experiments) which have a history in the articles on the ICMRT studies of the late-1970s. Cambronero's op-ed represents the main themes of Statist narratives: the connections between profits and science; the weak oversight that current guidelines and regulations provide; the abuse of Costa Rican citizens and; the invasion of foreign pharmaceutical companies, coming to do here, what they cannot do in the United States or Europe.

Rep. Juven Cambronero Castro, a legislator for the National Liberalist Party (PLN), uses a series of rhetorical questions in this op-ed, published on March 2, 2002. The piece is entitled "*Conejillos de Indias: Experimentos con los fármacos*" (Cambronero 2002). He presents a blistering critique of clinical research in Costa Rica by opening with the question, "Would you allow your son to be part of a pharmaceutical experiment?" He follows with a scenario in which you might allow your son to participate if recommended by the doctor treating your son. The next question asks,

And if they said to you that that doctor receives considerable monetary gratification for each child recruited for the experiment? Perhaps in that case you consider it necessary to hear the opinion of the hospital authorities where your son or daughter receives care before making the decision. But, what would pass if they told you that no one in the hospital is interested in monitoring those trials or, worse still, that the named functionaries who look after their rights (members of the Bioethics Committee) also have economic interests in this matter...(Cambronero 2002)?

He ends this section with ellipses, which are called “*puntos suspensivos*” in Spanish, and is part of a group of arbitrary marks such as commas and asterisks that informs the reader of some irony, hesitation, or parody (Alvarado 2006). These ellipses create a type of suspense for the reader. The reader is left to wonder: what *does* happen if the doctor enrolls my child into a clinical trial? After the physician has received the money for recruiting him, will he ignore him going forward? Cambronero leaves the question hanging so that readers will try to sit with that question and ponder over what might be beyond the ellipses (Cambronero 2002)²⁵.

Beyond the attention-grabbing title that uses “guinea pig” to describe people—children—enrolled in a study, Cambronero [2002a] uses the phrase *conejillo de Indias* just once more in the last sentence of the article when he writes, “Would you let your child be a guinea pig in a pharmaceutical experiment²⁶? Coupled with the series of rhetorical questions that frame a parent’s decision-making process about the care of her son, Cambronero implies that neither physicians nor the ethics board have the will to stop experimentation in the CCSS (Cambronero 2002). He continues this scenario by asking, “what if, as well, they tell you that it is proven that the CCSS authorities do not exercise control over that which the subscribed law and international

²⁵ Pero ¿qué pasaría si le dijeran que nadie en el hospital se interesa provigilar esas investigaciones o, peor aún, que los funcionarios nombrados para velar por sus derechos (miembros del Comité de Bioética) también tienen intereses económicos en el asunto?...

²⁶ ¿dejaría que su hijo fuera el conejillo de Indias en un experimento farmacéutico?

conventions obligate them to do,” leaving parents to wonder if the country’s beloved public health system is too fragile, too overrun by greed to care for their children (Cambroner 2002).

These questions are followed by a paragraph that begins as “Other questions” (Cambroner 2002). These other questions are a series of questions asking the prospective reader if the reader is aware that U.S. and European pharmaceutical companies find it easier to “test” a medication or treatment” in Costa Rica than in the United States or Europe where people do not “lend themselves easily to clinical research” and that there are not any studies being done in private clinics (implying that all clinical trials are done in the *Caja*²⁷). Also, he argues that the benefits of a new medication will not go to “neither your child nor the country” and that any new medication “must be purchased from the companies that produce them in the same circumstances as other medications” (Cambroner 2002). Finally, just before closing the piece, he lists a series of government agencies that have denounced clinical research in the CCSS including: the General Comptroller of the Republic, the Ombudsman's Office, the Internal Auditing Unit of the CCSS, the Investigative Commission of the Legislative Assembly, directors of CCSS hospitals and clinics, the *Washington Post*²⁸, and other Costa Rican press. He ends with this ominous question: “Would you let your child be a guinea pig in a pharmaceutical experiment”? (Cambroner Castro 2002a). The full weight of multiple state institutions is being used in this op-ed to urge the public to denounce clinical trials inside the country. He has, in his own

²⁷ According to an exhaustive list compiled by one informant and shared with me, from late 2000 to year-end of 2002, most studies were, in fact, conducted in private research facilities, clinics/private practices, or in private hospitals such as *Hospital CIMA* and *Hospital Bíblica* [HCP 101].

²⁸The reference to the *Washington Post* references an article from December 21, 2000 by Karen DeYoung and Deborah Nelson entitled, “Firms find Costa Rica ‘Special’ Place for Trials; Government Struggles to Keep Up with Drug Testing” [DeYoung and Nelson 2000]. In this article, the authors describe the overwhelming amount of clinical research going on within the country, swamping the Ministry of Health’s efforts to inspect the research and that the ease with which pharmaceutical companies can open new studies makes Costa Rica “special” (DeYoung and Nelson 2000). This article was regularly cited by those who strongly pushed for more national regulation of clinical research.

narrative, reaffirmed a Statist perspective that sees current clinical research in the same light as historic abuses in the realm of medical research. He sees the *Caja*'s inaction and is asking the parents of children who might be vulnerable because of this inaction to shoulder the burden of protecting their children from such unscrupulous physicians who would use their children to line their own pockets.

Neoliberal Entrepreneur Coalition Narratives: Responding to Cambronero

Dr. Adriano Arguedas Mohs, Director of Research and Dr. Guillermo Rodríguez Gómez, President of the private research center, *Instituto Costarricense de Investigaciones Clínicas* (ICIC), respond to Cambronero in an opinion piece published on March 14, 2002, entitled “*Investigación Clínica: El Diputado Juven Cambronero cuestiona sin conocimiento*” (Arguedas and Rodríguez 2002). They claim that Cambronero is engaging in a campaign of disinformation about clinical research as evidenced by his comments on twelve days earlier (Arguedas and Rodríguez 2002). In fact, the subtitle of their response is quite direct: “Representative Juven Cambronero Castro questions without any knowledge” (Arguedas and Rodríguez 2002). Here, they engage in that public argumentation discussed earlier in this chapter. Arguedas and Rodríguez call Cambronero out by his name. They are physicians who have a private research facility, who are standing up to a legislator, elite to elite as Cambronero and the physicians engage in a battle to shape the local narrative on clinical research in the country at this moment in time (Belmonte 2007).

In the article, the physician-investigators challenge each one of Rep. Cambronero's claims. They open by noting the damage the representative does to the reputations of medical professionals and to the values of “hundreds of parents whose children participate in research

projects”²⁹ (Arguedas and Rodríguez 2002). They address Cambronero’s claim that most of the research is conducted in the *Caja*, noting that the bulk of clinical research (at that time) is done in private research centers such as their own and that both patients and the country receive benefits in terms of access to new treatments. The CCSS receives payments for services such as laboratory results and x-rays that are carried out in the research facilities; “the CCSS does not disburse one cent,” they argue (Arguedas and Rodríguez 2002). This narrative highlights the benefits to patients and the country and frames critics as ignorant and misinformed regarding the benefits of clinical research.

The tenor of this opinion piece is as direct, using declarative sentences instead of questions, and statistics to rebut the representative’s rhetorical questions. Study volunteers are referred to as patients and participants, never as guinea pigs or human subjects, essentially elevating the participant from his or her role as a victim to the whims of greedy researchers to partners in a mutually beneficial journey to add to medical knowledge (Arguedas and Rodríguez 2002, Cambronero 2002). Tenor can be used to win others to one’s position and solidify relationships between coalition members. The author of an opinion piece assumes the mantle of expert, as presented here (González 2007). Here, Arguedas and Rodríguez seek to present facts and only use value-laden words to target Cambronero or his claims. For example, the authors call the Representative’s claim of financial conflicts of interest for members of the ethics committee “slandorous”³⁰ and argue that Cambronero is ignorant of the progress made by the CCSS in regulating clinical research within the public health care system [Arguedas and Rodríguez 2002]. They end the piece with a lament, noting that Cambronero “has declined on

²⁹ “*La posición del diputado lesiona la integridad profesional de los médicos costarricenses y atenta contra los valores morales de cientos de padres de familia, cuyos hijos participan en proyectos de investigación.*”

³⁰ *calumniosa*

three occasions our invitations to visit ICIC”³¹, suggesting that Cambronero is resistant to change, learning, or meeting the researchers in compromise (Arguedas and Rodríguez 2002).

Cambronero Responds

A week later, Rep. Cambronero’s responds directly to Dr. Arguedas and Dr. Rodríguez. His piece is entitled, “*Investigación clínica: Las normas éticas se deben aplicar siempre*”³². Rep. Cambronero writes that he “did not invent the complaints” that have arisen regarding clinical research in the country. He states that he “understands the topic” as an elected official and that “he bases his claims on reports and information from the *Caja*, the Comptroller General and the Ombudsman Office” (Cambronero Castro 2002). He is clear, that he is not “demonizing” clinical research and, in fact, acknowledges its importance in the search for disease cures and adds a personal touch when he says, “I, as a diabetic, enjoy the benefits of the medicines” but that issues arise when “procedures and international and national standards are not followed” (Cambronero Castro 2002). He argues that

The *clinical trials* [emphasis and English in the original] that are conducted in the country, in practice, turn out to be “research factories”. These studies utilize patients to test medications, vaccines, or therapeutic products for foreign pharmaceutical companies, precisely to experiment as there is insufficient scientific evidence of benefits and harms (Cambronero Castro 2002).³³

Here, Cambronero uses the word *maquila*. *Maquila* is an interesting word to analyze. It does not have a direct English translation, but connotes a factory or sweatshop in Costa Rica, when used in the context of pharmaceutical company sponsored clinical research in the country. The word was also used in the public disputes by different coalitions in Costa Rica before the Central

³¹ “*También, es muy lamentable que haya declinado en tres ocasiones nuestras invitaciones para visitar el ICIC.*”

³² Clinical research: Ethical standards should always apply

³³ Los *clinical trials* que se realizan en el país en la práctica resultan ser “maquila de investigación”. Estas investigaciones utilizan pacientes para probar medicamentos, vacunas o terapias producidas por compañías farmacéuticas extranjeras, precisamente para experimentar pues no hay evidencia científica suficiente de beneficios y perjuicios.

American Free Trade Agreement (CAFTA) was signed by Costa Rica in 2009 and is usually used regarding the garment industry (Rayner 2014). Another important element of the word *maquila* is the embedded uses of specifically cultural bound words, which are used to persuade the reader and express deeply held beliefs regarding a policy issue (Belmonte 2007, Sabatier and Weible 2007). In the sixty-six opinion pieces from 2001 to 2014 analyzed for this dissertation research, *maquila* was used in four opinion pieces, three of which are written by Statist coalition members and one written by a Neoliberal Entrepreneur Coalition member. Its use was first introduced in the series of 2002 opinion pieces of which Cambronero's op-ed is an example.

Later in the op-ed, Cambronero argues that the "correct direction" is for CCSS to use existing standards and to propose the appropriate legislation "for the protection of Costa Ricans;" "another important step" is for the Costa Rican Medical Association review the Helsinki Declaration and tasks the president of the association to make sure that all "gates are closed" for engaging in "business with clinical research in the world" (Cambronero Castro 2002). He also seeks to distance himself from the idea that he is demonizing research by emphasizes the value of research for health knowledge explicitly when he states that he has benefited personally as a diabetic from the generation of scientific knowledge. However, he cannot resist hitting the coalition's narratives high points: greedy pharmaceutical companies victimizing patients in *maquilas* for health benefits to citizens from other countries. Cambronero joins other Statists in calling for a local law to regulate clinical research in the country.

By tracking such words as *experimento* and *maquila*, I was able to trace a dialogue that traversed fifty years of clinical trials within the country. These examples from 2002, coupled with news narratives from the 1976 LSU-ICMRT scandal illustrate the techniques and tenor that opinion writers used to develop their perspective and ultimately their coalition identities. The

above exchange between Cambroner and Doctors Arguedas and Rodríguez illustrate this solidifying of narrative and resulting reification of coalition identity. The Statists are here to protect the country's citizens and institutions from the greed and overreach of global corporations and their local agents (i.e. physician-researchers). Neoliberal Entrepreneurs, trained both in Costa Rica and the United States or Europe, see themselves as pioneers, embracing of change, welcoming 21st century medications and treatments. There is little common ground between the two coalitions, which will prove to have the deepest, direct affect on the livelihoods and social capital of people employed in clinical research. As the Statists began to insist more aggressively on a local law to regulate clinical research, another legislator, José Miguel Corrales Bolaños uses the tool an *acción de inconstitucionalidad* (action of unconstitutionality) to protest the unconstitutionality of a 2003 Executive Order to regulate clinical research. The next section explores this action.

Acción de Inconstitucionalidad: The Gauntlet Thrown

According to Barker, actions of unconstitutionality shifted with the formation of the Constitutional Court in Costa Rica (Barker 1991). Prior to 1989, the entire Supreme Court, with a two-thirds majority, could rule on the constitutionality of “dispositions of the Legislative Power and decrees of the Executive Power” but in 1989, gave this power to a “specialized Chamber of the Supreme Court [*Sala IV*]” which would, under “absolute majority,” rule on issues of unconstitutionality related to the “legal norms” of the country (Barker 1991, 378). Barker notes this change from two-thirds majority of the entire Supreme Court, to the absolute majority of the seven-member Constitutional Court, made it much easier to determine certain laws, decrees, and “norms of whatever nature” unconstitutional [Barker 1991: 379]. This action gave tremendous power to the new chamber.

José Miguel Corrales Bolaños played a key role in the development of the new constitutional court by putting forth the original idea, modeled upon the Guatemalan and Peruvian constitutional courts, as a legislator in the early-nineties (Peza [Piza] 1993). This would provide an interesting backdrop to the debates on clinical research in Costa Rica, as Rep. Corrales would also initiate the action of unconstitutionality against the executive order that formed the national council (CONIS) to oversee clinical research within the country.

An attorney I interviewed explained, in detail and with examples of the laws and regulations that were used to render *Decreto No. 31078-S* unconstitutional. First, within the “Law of Constitutional Jurisdiction,” Article 75, found under “Questions of Constitutionality, Chapter I: The Action of Unconstitutionality,” states

To interpose the action of unconstitutionality it is necessary that there exists a matter pending resolution before the tribunals, including *habeas corpus* or *amparo*, or in the procedure which exhausts the administrative channel, in which such unconstitutionality is invoked as a reasonable means of protecting the right or interest that is considered injured.

The previous case pending resolution will not be necessary when, due to the nature of the matter, there is no individual and direct injury, or it is the defense of diffuse interests, or that concern the community as a whole.³⁴

The attorney also referenced the “General Law of Public Administration” from 1978 citing a subsection from the “First Book of the Legal Status, General Principles, Chapter 1, Article 19, Clauses 1 and 2 which addresses executive decrees:

1. The legal status of constitutional rights will be reserved to the law, without prejudice to the corresponding executive regulations.
2. Autonomous regulations on this matter are forbidden.³⁵

Wilson notes that the Constitutional Court signaled almost immediately upon creation that “all laws and decrees would have to pass a constitutionality test” which hindered the law-making role

³⁴ *Ley de la Jurisdicción Constitucional* 1989

³⁵ *Ley General de la Administración Pública* 1978: 5

of the Legislative Assembly (Wilson 2004, 52). Since 1989, however, such tools as constitutional consultations, *recursos de amparo*, and actions of constitutionality have been used by political savvy individuals and groups, both governmental and civic, to challenge the constitutionality of various laws, decrees, executive orders, and norms with which they disagree or had previously been passed by majority.

Rep. Corrales, who served in the legislature three times, filed his action of unconstitutionality on May 7, 2003 during his last term as a legislator.³⁶ While I cannot locate the original action, according to a timeline supplied by an informant, Corrales argued “against the decrees and regulations that regulated [clinical research] alleging that this was a matter of law and was not able to be regulated by decree” and included in his action both the executive order forming CONIS and a regulation passed by the executive board of the *Caja* (Castillo Nieto 2003).

Globalization and Neoliberalization from a Statist’s Perspective

Mary Clark defines statism as the “initiative of state leadership and highly capable technocracies insulated from societal interference” (Clark 1997, 71). However, she notes that countries in Central America and elsewhere in Latin American took a different route that involved creating global networks that drew upon the expertise of “foreign-aid officials, state technocrats, and private businesses” to enhance and build economic policies that embraced global markets (Clark 1997, 71).

The challenge, as Clark outlines it, is that the shift, in the 1980s from an “import-substituting-industrialization [ISI],” which was the economic model for much of Latin America

³⁶ Ticopedia (https://ticopedia.fandom.com/wiki/Jos%C3%A9_Miguel_Corrales_Bola%C3%Blos). Accessed May 8, 2017.

after World War II, to the newer, "export-led growth" methods, led to local resistance, especially by those who gained much from the earlier ISI approach. These politicians and other stakeholders resisted the new economic approach. Those who embraced the new model, as Clark claims, are not strong enough as a local coalition to aggressively push for these outward-focused changes.

To build these transnational coalitions, the setting must be conducive to initiating and sustaining such relationships. Usually, a more developed country, like the United States, steps in to make "recipient countries healthy enough to participate in the world economy" at a time when the government of the developing country is struggling to maintain existing infrastructure as well as difficulties with paying back international bank loans (Clark 1997, 74). Clark notes that "technocrats and businesspersons make good coalition partners for external development agencies because they are experts at the domestic political game, have access to policy-makers, and provide a cover for outsiders and local officials who want to avoid accusations of foreign intervention" and those involved in the most successful arrangements have common goals and ideals toward local economic progress (Clark 1997, 74-75).

Clark calls this the "transnational coalition model" and notes that it has characteristics that model "social coalition[s] in which external actors become players within the domestic political arena and to which the members bring various power resources" such as "foreign aid, weight in the economy, public prestige, and important contacts in public and private sectors" (Clark 1997, 75). However, Clark acknowledges that transnational models have advantages that domestic coalitions do not, especially when the transnational coalitions are extra-governmental.

When Itzigsohn discusses Costa Rica's adoption of an export-based economic system, he talks about the character of the Costa Rican state which "is based on consensus among elites and

cooptation of the opposition" (Itzigsohn 1994, 57). Following the usual tenets of a liberalized market, Costa Rica's state intervention in the 1980s focused only on easing the process for private sector growth. Growth continued through the PLN (National Liberation Party) and the PUSC (Social Christian Unity Party). The surplus GDP was used to instigate some social programs related to food and housing (Itzigsohn 1994). As also discussed in Clark, the state worked closely with extra-governmental entities like USAID to develop new exports (Clark 1997, Itzigsohn 1994). Itzigsohn claims that Costa Rica's caution in the structural adjustment process is "the result of the character of the Costa Rican political system build under the PLN" and notes that social programs were not constrain by the export-oriented approach, even during earlier economic crises. He says that this is, in part, because of the way that democracy happens in the country through active protest and opposition which is mediated by the national desire to reach consensus (Itzigsohn 1994).

While there was growth in non-traditional exports, Costa Ricans still suffered hardships from the recent economic crises which were visible in wages, employments and the per capita GDP, which had not rebounded to 1970s levels yet. Additionally, there were challenges to the state's social welfare system by different groups who were not recovering under the adjustment. These groups wanted the return of pre-SAP social policies. Meanwhile, the international banks and agencies were also applying pressure to decrease the deficit, decrease state involvement in the economy, and "switch from universalist to focalized social policies" (Itzigsohn 1994, 63). This resulted in a constrained budget for the CCSS and education, the two biggest social programs in the country.

Another state system also deteriorated. This was the enforcement of regulations, such as addressing the underpayment of wages and social security payments by employers. Itzigsohn

notes that there were deleterious effects from structural adjustment, but many of the social policies remain intact with the state responding to public pressure through the application of policies that did not follow procedure (Itzigsohn 1994).

In a working paper, van Liemt seeks to define the qualities and ideals that inform anti-globalist identities. He notes, in the introduction, some overarching ideas that illustrate the diversity of anti-globalists. In part, this diversity is the result of "ill-defined" ideas of globalization (van Liemt 2004, 1). As a result, there are those who are simply critical of the whole concept of globalization and see the process as benefiting "corporate globalists" and foresee the ruin of the environment, the development of smaller countries, and tenuous global markets that can cause massive damage in a downturn. It is important to note that anti-globalists seek a "globalization 'with a human face'" and are not fundamentally against globalization (van Liemt 2004, 4).

Some anti-globalists mainly focus on trade issues and the damages or benefits to global markets in terms of fair trade or exportation. Some consider the role that international trade and monetary agencies play on the world stage and the effects of their policies on local governments and economies. Finally, others focus on the increasing global economic power of multinational corporations and the lack of protection of human rights, the environment, and consumer issues. An over-arching theme for anti-globalists is the seemingly short-term objectives of global businesses and entities, driven by profits, trade, and beholden to shareholders. To them these short-term goals supersede the needs of workers, the environment, health and safety, and poverty. Often these very goals inflict the damages for which anti-globalists have the most concern (van Liemt 2004).

In a section entitled, "Who are the anti-globalists," van Liemt identifies some common perspectives amongst anti-globalists. First, many anti-globalists are focused on the effects of globalization on the legitimate interests of individuals through the power being wielded by large global corporations and reinforced by the policies of the international trade and monetary organizations. They see themselves as fighting for those lacking such power--either the nation or the citizens within the nation--and actively fight for these values over the long time periods through methods that inform the public to the damages of globalization, through policy influence, and strategic use of the media. They often meticulously build their cases by pouring over documents and policies and act as facilitators between policy-makers and those they see as not able to access them. Through technology and media, they "mobilize opposition and try to change [policies]" (van Liemt 2004, 3).

According to van Liemt, recurring themes for anti-globalists included "alienation, accountability, democracy, and transparency" (van Liemt 2004, 8). He discusses three types of anti-globalist ideology and critique. The first critique focuses on the "socio-economic *system*" as the main driver of globalization, while others focus on "the *ideology* of the system" related to consumerism and economic issues, and the last perspective focuses on the "*symptoms* of the working of the socio-economic system rather than the system itself" (van Liemt 2004, 6). As an example, Costa Rican Statists were concerned with the drivers of globalization, especially as exemplified in the power of multinational pharmaceutical corporations, as well as the ideology of globalization that preferences profit and the market over the needs of individuals, especially, the needs of trial participants. As a result, they focused on the human rights of dignity, right to life, and access to healthcare as well as the process of lawmaking and the judiciary. They believed that large transnational corporations need to be closely watched and that sanctions are to be put

in place to address ethical and medical violations. It was not the science of clinical research that they took issue with, rather, it was the market aspect that angered them. Kanishka Jayasuriya challenges the developmental model of the state and argues that the "conceptual framework of state capacity" needs to be "replaced with a conceptualisation of states and their associated strategic capacities as products of social and political relationships both inside and outside the state," which will put the focus on "state transformation" instead of a dichotomous perspective of the developed states drawing from underdeveloped states (Jayasuriya 2005, 382).

Jayasuriya addresses the shifts in the perspectives of "statists and neoclassical economists" after the 1997 economic crisis in Asia. While the economists charged state interference in the economic process, the statists charged the economists with a claim that "financial liberalisation" had derailed the "policy capacities" of the state. Jayasuriya argues that the ideal of the "strong state" envisioned by statists is an illusion and fails to adequately consider the "process of state transformation" that are heavily influenced by economic and political globalization (Jayasuriya 2005, 382).

Hewison agrees with others that anti-globalists are not necessarily against globalism, they are against how it is functioning now as a "corporate globalisation" (Hewison 2001, 3). He argues that anti-globalists tend to work from a national stance, placing the culture, markets, and governmental norms of the nation before that of the globalizers. Many anti-globalists focus on import substitution industrialization to strengthen the national position. There are some who do not reject industrialization outright, but still see the state as having an important role in controlling the pace and growth of foreign investment, trade, and international agreements. The problem with globalization for many is that it opens the door to "[entrenched] privilege and power" leading to an increase of exploitation of the country and its citizens (Hewison 2001, 4).

Finally, anti-globalists can form grassroots organizations and coalitions to strike at the global power structures. As an example, Rayner studies the evolution of the coalition of “NO” and the coalition of “Sí” in his research on the debates surrounding the signing of CAFTA in the early 2000s. Rayner's focus is to "show how the autonomous exercise of political agency within a broader collectivity imagined as an 'awakened' people created the possibility for a renewal and reinvigoration of the democratic imaginary" (Rayner 2014, 151). Rayner (2014) describes how farmers formed the coalition of "NO" against the coalition of "SI" led by a politician and other political elites. During the fight over CAFTA, the coalition of No, presented as a leaderless group that stood out as different from the usual voices of protest, like unions, and certainly from the coalition of Sí, which represented the voices of Costa Rica's leadership. The No coalition was leaderless and their actions against the elites powerfully shaped new political identities (Rayner 2014).

Unlike the fight over CAFTA discussed in Rayner's research, the coalitions that formed regarding clinical trials in Costa Rica were elites against elites, the powerful against the powerful and, in fact, while participants in clinical research were regularly held up as victims of either a backward government attempting to block progress or victimized by voracious, local agents of foreign entities seeking wealth through participants and stripping them of their rights in the process, the reality is, participants were rarely asked or offered a platform to weigh in on the debate. They did not, for the most part, form the membership of either coalition, nor did they take to the streets to protest or support clinical research in the country.

Statist Identity

The Constitutionalist

Judge Fernando Cruz was sixty-six at the time of our interview. He was a magistrate on the Constitutional Court, known as *Sala IV*, at the time. He studied law and political science at the University of Costa Rica and received a bachelor's degree in each field. He has a doctorate from the University Complutense of Madrid. He worked for more than forty years as a judicial officer in the public prosecutor's office and then was the chief public prosecutor for Costa Rica for two years in the 1980s. He held judgeships in the criminal courts. He was elected to the constitutional court in 2004 for an eight-year term. Throughout his career, he also taught law at two public universities in the country.

While Judge Cruz's career in law has been long and distinguished, it has not been without controversy. At the end of his term in *Sala IV*, more than two-thirds of the legislators voted to block his reappointment to the court, leading to a fierce debate about term limits and the constitutional court's power, especially over some very sensitive cases that were before the court. In the end, he was reinstated for another term.³⁷ As of this writing, he is the president of the Supreme Court, elected in 2018.³⁸

Judge Cruz has written on the topic of clinical research and human dignity (Cruz 2010). As a guest columnist for the Democratic Tribune, Judge Cruz lays out the Constitutional Court's reasoning for ruling that clinical research must be regulated through a law and not a regulation or executive order as it "defines the limits of the Administration" and that the executive branch of

³⁷ Font, Alberto and David Boddiger. "Judge scandal tests Tico democracy" The Tico Times. November 23, 2012. <http://www.ticotimes.net/2012/11/23/judge-scandal-tests-tico-democracy>. (Accessed July 3, 2017).

³⁸ . Pj.poder-judicial.go.cr/index.php/prensa/393-fernando-cruz-presidente-2018 (Accessed 4/1/2019).

government does not have the power to regulate something, such as clinical research, that affects basic human rights (Cruz 2010).

In our interview, he elaborated on his views, highlighting the ethical challenges of doctors acting as paid recruiters of their own patients into studies. His concern is the effects of commerce on those enrolled in research and how profits for external companies and their intermediaries can overshadow the rights of patients. He says, *“I do believe that there is an incompatibility between economic interests and the protection of those who submit to these trials.”* He agrees with me when I ask him if his issue is with the connection between the market and science. He feels that there is a built-in incompatibility between profits and science and that this incompatibility cannot be reconciled. Judge Cruz was also a leading voice against CAFTA in the early 2000s.³⁹ Judge Cruz is a fighter for the rights of the disempowered. He uses the law to protect the constitutional rights of the citizens of Costa Rica and to limit the powers of the other branches of the government. He is vehemently against global companies and local researchers making profits from participants and sees no benefits to patients or the country as a site of research.

The Academic

Jorge Granados Zúñiga was 51 years old at the time of our interview. He is a professor of biochemistry, research methods and teaches a course in bioethics for graduate students. His training is in biology and biochemistry and he has a master's degree in bioethics. Dr. Granados' previous employment included working in two hospitals and the University of Costa Rica with animals in the laboratory. Previously, he was a professor of research at the university and, at the

³⁹ Font, Alberto and David Boddiger.

same time was involved in clinical research as a study coordinator on phase three and four studies of medications.

At the moment, of our interview, he was the Director of Graduate Study in Biomedical Sciences, an office of the medical school at the University of Costa Rica (UCR). He was also studying philosophy. He sat on a scientific ethics committee (CEC) for the Ministry of Health and is a member of the bioethics committee of the Costa Rican medical association. In the past, he held seats on the CEC and an ethics committee for animal use in laboratories for UCR.

When asked what the best thing about clinical research was, Dr. Granados said, *“The good thing is to help improve the quality of life of people, that is, improve health and allow people to develop better as human beings.”* When asked what the worst part of clinical research is, Dr. Granados said *“that the worst thing is the abuse and the injustices that are committed with people who suffer unfair treatment, right; they do not receive adequate treatment and only a few people benefit from these investigations: Companies or individuals. That is the worst thing that can happen!”* Here, Granados stands at a crossroad. He has his own experiences in clinical research, he has done laboratory research, taught bioethics, sat on ethics committees, and written on the topic of clinical research, and still has misgivings about the process of clinical research as it has unfolded in Costa Rica. In one journal article, he addresses the issues of profit for companies before the “well-being and health of the community in general” when he discusses the rollout of a H1N1 influenza vaccine in the midst of the 2009 pandemic (Granados Zúñiga 2012, para. 11). In another article, Dr. Granados is speaking to benefits of human subject research in the country. In the discussion section, he argues that the recent clinical trials he is reviewing do not meet the UNESCO standards of putting the “needs of countries” above those of “transnational research activities” (Granados Zúñiga 2012 , 7). Later he argues that clinical

research, as pharmaceutical company sponsored research has been done in Costa Rica, has an “inadequate relationship between risk/benefit” and that “offering as benefit the medical and laboratory analysis is wrong and misleading” as this is a regular part of drug studies (Granados Zúñiga 2012 , 8). Dr. Granados is a Statist who “sees the human face” as van Liemt discusses above (van Liemt 2004). It is not that he is against globalization per se, rather he is concerned that globalization as it relates to clinical research is not serving Costa Ricans as much as it is serving the multinational pharmaceutical corporations.

The Physician

Dr. Hernán Collado, cited earlier in the chapter, is a retired surgeon, trained in México. His career spanned four decades. Primarily, he worked in gynecology at the Hospital San Juan del Dios, but at different points in time, he also worked in other locations, sometimes going from one to the other all in the course of one day⁴⁰.

In a magazine profile⁴¹, Dr. Collado professes a long interest and ethical concern for patient-doctor relationships and emphasized these issues in his role as a professor of medicine. His concern for medical ethics led him to study bioethics through the philosophy department at the University of Costa Rica (UCR) and to receive a master’s in bioethics from the University of Murcia in Spain. He has taught classes at UCR and at the Association of Physicians and Surgeons, Costa Rica’s equivalent to the American Medical Association.

Dr. Collado is also a member of the Costa Rican Association on Bioethics and added his name to a 2012 opinion piece entitled, “Freedom of experimentation and human rights” (Zamora Zamora et al. 2012). In this article, the authors acknowledge the benefits of medical research,

⁴⁰ “*Medicina, Vida y Salud*” *Setiembre 2007*

http://portal.medicos.cr/documents/20183/20923/med_30_setiembre3.pdf/581de227-ee79-45e1-89f7-56e16ffcf1be (Accessed April 2, 2019)

⁴¹ *Ibid.*

while acknowledging the historical abuses that have also occurred. Some of those abuses have happened in Costa Rica, including placebo-controlled studies in asthma, depression, and chronic obstructive pulmonary disease when standard of care treatments already existed leaving patients “deprived of the usual treatment, were exposed to possible damage to their health and quality of life,” and, the authors argue, this requires a law based on bioethical principles that puts the rights of the patients first (Zamora Zamora et al. 2012, para. 5-6).

In this article, Collado and his colleagues focus on the human rights violations that they attribute to outside forces, specifically multinational pharmaceutical companies that exist outside of the country’s jurisdiction. They also note that the international bioethical guidelines that exist for clinical research do not have sanctions in place for researchers who violate the guidelines (Zamora Zamora et al. 2012). This is the type of statistician who sees himself as fighting for the rights of citizens disempowered by global corporations.

The Ministry Official

María Elena López received her degree in medicine from the University of Costa Rica with a specialty in pediatric medicine and a master’s in public health from the University of Antioquia in Medellín, Colombia. At the time of our interview, Dr. López was sixty-eight years old. She had just retired from her position as Minister of Health, which she had held from May 2014 to February 2015, when she resigned. Much of her career she has focused on public health issues. She was a practicing physician for only a short while before transitioning to an emphasis on public health. Over several years, she held directorships for the Child Health Unit, Department of Community Health, the Department of Child and Adolescent Health, and Director of Health Services, all of which are departments of the Ministry of Health. She also was the Director for the Center for Strategic Development for Health and Social Security Research which

is a part of the Costa Rican Social Security Fund (CCSS). She taught bioethics at the National University (in Heredia) and was an invited professor at the University of Costa Rica. And did epidemiological research at the Costa Rican Institute of Research and Teaching in Nutrition and Health (INCIENSA). She was also one of the founding members of the Costa Rican Association on Bioethics (Ávalos 2003).

When asked about what she feels is the best things about clinical research, Dr. López said that *“this would be like trying, knowing what we are doing [in relation to] the health problems that the country has.”* When she was asked about what she thought were the worst aspects of clinical research, Dr. López says that

Well, this ... I think that research that was done before, very epidemiological, trying to investigate the causes and health problems of the, of, of some population groups [then] we passed in the eighties and nineties [to] a maquila investigation, I mean [as] designed and this was becoming routine in the services, it was no longer to know the problems of our country if it was not for testing drugs and interventions X and this had already been designed, they were investigations that were already mounted and sometimes do not respond to needs of the people, of our country. That created a very large market, very important.

Dr. López takes a stance seen in news articles and opinion pieces, tying clinical research to this idea of factories that are designed to provide information on drugs already on the market and failing to address the needs of Costa Ricans. This theme is the main theme of the Statists, which has its progenitor in themes from the articles written in the mid-seventies that have been discussed previously⁴². Such Statists as Dr. López view increasing global corporate power as dangerous and threatening the sovereignty of the country and the health of its citizens as they are used in the factory of research.

⁴² See “The Smoking Gun” section of this chapter.

Each Statist presented here represents the values, ideals, and commitments held by those who fought against the growth of clinical trials in Costa Rica. The Statist coalition formally organized itself much earlier than the Neoliberal Entrepreneurs did by forming the Costa Rican Association on Bioethics as early as 2003. Their issues are clear: they oppose the mixing of science with profits; they are against the role that pharmaceutical companies play in sponsoring research in the country; they believe that the benefits of human subject research should confer to the study participant above profits or benefits to other countries. They see themselves as protecting citizens from perceived avarice on the part of local researchers, saving them from the factories of research that experiment on guinea pig patients.

Conclusion

In this chapter, I explored elite narratives and policy core beliefs of Statists and Neoliberal Entrepreneurs by examining word choice and tenor, as well as illustrating how, over the course of a decade and a half, each coalition's narratives reified core beliefs and entrenching the identities of individuals in each coalition. The press played an important role by providing a stage upon which coalitions could argue about the risks and benefits of ongoing clinical trials within the country.

As the coalitions came to use the pages of the opinion section to hash out their differences, Statists became more insistent that a law be passed by the legislature to regulate research in the country. José Miguel Bolaños tipped the scale from talk to act when he filed an action of unconstitutionality in the Constitutional Court in 2003. It would take seven years for the court to finalize a decision, but in the next chapter we will see the effects of that decision on the lives of people employed in clinical research in Costa Rica.

Finally, brief sketches of four individuals from the Statist Coalition were presented, relying on transcripts, published materials, biographies, each example illustrated how individuals in the Statist coalition took on the core beliefs and the identity of the coalition.

In the next chapter, I will discuss the effects of the 2010 Constitutional Court decision to suspend clinical research in Costa Rica on research employees, academics, government employees and officials, and public health system physicians and employees. I will examine three aspects of livelihood loss: social capital, agency, and survival strategies. Finally, I will present the specific characteristics and core beliefs of the individuals who formed the Neoliberal Entrepreneur coalition.

CHAPTER 4: SUSPENSION: NARRATIVES OF LOSS AND FOUND IDENTITIES

“I think that the new law...was the product of a war, of a war of ... 1549 days. During these 1549 days, the flag of the institute was at half-mast. We were mourning research, because they killed [clinical] research in Costa Rica.”

This is how a local, well-respected researcher described the 2010 suspension of clinical trials by the Costa Rican Constitutional Court that made Costa Rica the only country in the world to suspend clinical trials within its borders. For clinical researchers, their teams, and local employees of multinational pharmaceutical companies, this felt like a war, a murder of scientific advancement within the country.

For those who worked in clinical research in the country, the injuries included a loss of physical and/or economic capital such as the loss of employment, of income, grants and funding, patients and, in rare instances, a loss of real property. An informant put the job losses at nearly two hundred⁴³. But per records maintained by the leader of one private research facility, beyond the two hundred employees who lost their jobs, another two hundred potential employees were not hired because of the prohibition. This researcher tells me later in the interview:

[I had to lay off] sixty people. Six zero. That's why I started a new company [here] and [did research outside of the country], and we took some of the Costa Ricans and brought them [there], and some of them moved to work for the new company [here] and the others--I couldn't keep them.

Yet, there are other losses to livelihood that are not as easy to document such as changes in professional prestige, social status, and loss of international opportunities that can often be as debilitating as the actual loss of income. For many working in clinical research made them feel

⁴³ Private communications.

as though they were on the cutting edge of medical advancements and gave them opportunities to participate in international collaborations or conferences.

In this chapter, I will discuss the 2010 Constitutional Court decision to suspend clinical research in Costa Rica. Next, I will examine post-suspension effects on the prestige, status, and international opportunities available to informants after the suspension using the idea of two social capitals put forth by Portes (Portes 2000). Drawing on Amartya Sen's idea of agency as an ability to choose, I will examine post-suspension agency, as measured by publishing opportunities, academic opportunities, and the need for more (or different) education or retraining (Sen 1999).

In the next section, entitled "Survival Strategies and Neoliberal Flexibilities," I examine how the need to *survive* in the middle-class leads to strategies that allow those affected by the suspension to maintain their position and social standing. Finally, extending Freeman's work on neoliberal flexibility and entrepreneurial selves, I will define the qualities of my informants who make up the coalition of Neoliberal Entrepreneurs (Freeman 2014).

***Sala IV* Decision to Suspend Human Subject Research**

José Miguel Corrales, who served in the legislature three times, filed his action of unconstitutionality on May 7, 2003 during his last term as a legislator.⁴⁴ While I cannot locate the original action, according to a timeline supplied by an informant, Corrales argued "against the decrees and regulations that regulated [clinical research] alleging that this was a matter of law and was not able to be regulated by decree" and included in his action both the executive order forming the National Council on Health Research (CONIS)⁴⁵ and a regulation passed by

⁴⁴ Ticopedia (https://ticopedia.fandom.com/wiki/Jos%C3%A9_Miguel_Corrales_Bola%C3%B1os). Accessed May 8, 2017

⁴⁵ *Consejo Nacional de Investigación en Salud*

the executive board of the *Caja*⁴⁶ to regulate clinical research in the public health system (Castillo Nieto 2003).

Seven years later, in May 2010, the Constitutional Court's decision was published in *La Gaceta*, the official publication of the government. In the decision, the court granted the annulment that Rep. Corrales requested of the executive order and the CCSS regulation from 2003 as well as another CCSS regulation from 2005 by citing provisions in Articles 89 and 91 of the Constitutional Jurisdiction Law. This suspension would only affect new research going forward. Studies approved before the suspension would be allowed to continue until their planned end date, however any new biomedical research that was to begin after the published court decision was to "remain totally suspended until the law required is put into effect."⁴⁷ The court also clarified that its duty lay with issues of unconstitutionality and not with law-making and is "a matter reserved for the legislature."⁴⁸

Immediately after the decision a period of chaos ensued. There was a lot of confusion on whether epidemiological and observational research projects were also suspended. For example, one interviewee, an epidemiologist, tells me,

Actually, there were like 8-10 months ...10 months in fact when Sala IV came out and said that 'you cannot work with the regulations'...for example, in the Caja the day after the [court decision] the CLOBIs [Local Bioethics Committees, located inside each CCSS Hospital] were closed; maybe not physically closed but nothing could be delivered. That was a very radical thing in that sense, right? More or less the decision of the Constitutional Court said, what were the investigations or if it was all of the research that were under that prohibition that went more or less ... 10 months where I was there in a very watered-down question.

⁴⁶ *Caja Costarricense de Seguro Social* (CCSS)

⁴⁷ 2010 EXPEDIENTE: 03-005236-0007-CO. In VOTO: 2010-006524. Sala Constitucional, ed. Costa Rica: *La Gaceta* # 96.

⁴⁸ *Ibid.*

Even after the new law was passed, there continued to be confusion. She tells me that the law is “*typing it by the type of study design and putting it all in one box...[it] becomes very cumbersome for some research because they all have to comply with the requirements regardless of the risk, I think that... [it is not] the kind of risk in what is in the law and regulation.*”

Shortly after the court’s decision, in confusion over which research could continue and which had been banned, the effects were being felt, in terms of people’s income, employment and in intangibles like prestige, status, and opportunities. According to a magistrate involved in the decision, it was important for the Constitutional Court to protect “fundamental rights” and to place limits on executive power, arguing that the court those fundamental rights can only be maintained through laws, not regulations (Cruz 2010).

Livelihoods Survey

Included in each of the interviews I conducted was a short survey meant to gather data on what each participant gained and lost in relation to their livelihoods because of the 2010 suspension. For the purposes of the survey I created, I am using Bebbington's research on rural livelihoods in the Andes (Bebbington 1999). He developed a model that considers the livelihoods of rural individuals from the perspective of five "capital assets" (Bebbington 1999: 2021). Whereas other models focus heavily on natural assets such as land, access to water, and livestock, Bebbington asks us to broaden the concept of resources beyond the natural and consider a broader range of assets that include labor and markets, as well as income and products. The assets that Bebbington includes are produced assets, human assets, natural assets, social assets, and cultural assets (Bebbington 1999).

The short survey presented a series of twelve statements that focused on various changes to livelihoods such as: employment, income, real property, prestige, status, publications,

international collaborations, and more. Each statement has an option to circle “lost,” “gained,” or “not applicable” except for the last statement regarding retraining, in which the circled options are “some” or “none”. Each respondent was told that he or she could either write comments in the space below each statement or say the comment for the audio recording ⁴⁹. Below, I discuss certain results of this survey that focus on the idea of individual and collective social capital, agency, and survival strategies to overcome the effects of the suspension (Portes 2000).

Social Capital

Alejandro Portes argues, in “The Two Meanings of Social Capital” that the idea of social capital suffers from some confusion regarding its real meaning and is often overused as a result. He identifies two types of social capital. One is individual capital which one can achieve through building relationships and a collective social capital which he calls “civicness” (Portes 2000, 4). I argue that clinical research personnel in Costa Rica were engaging in both types of social capital. Individually they increased their social capital via employment in the field of clinical research and all the prestige and status attained as a result. The network of principal investigators, study coordinators, ethics committee members, and other key stakeholders in the government, public health care system, and academic institutions that came together to form the Costa Rican Association for Research in Human Health⁵⁰ contributed to the civicness of collective social capital by becoming an organized coalition in which members actively participated in shaping policy through opinion pieces, participating in legislative roundtables, and lobbying legislators regarding law project 17.777. Below, I will discuss the results of the survey questions that address social capital. This section is part of a group of three statements

⁴⁹ Due to the fluid movement between the public and private health systems and into and out of academia and government employment by many of my informants, I asked each informant to participate in the survey, even if the person had not had direct experience with clinical research.

⁵⁰ *La Asociación Costarricense de Investigación en Salud Humana*

(prestige, status, and opportunities for international collaboration) that investigate a loss or gain of social capital because of the suspension. These are some of the more intangible effects on the livelihoods of those employed in clinical research or invested, as stakeholders, in the outcome of the suspension on the livelihoods of those who worked in private research.

Prestige: I (lost/gained/not applicable) prestige in my professional life as a result of the ban.

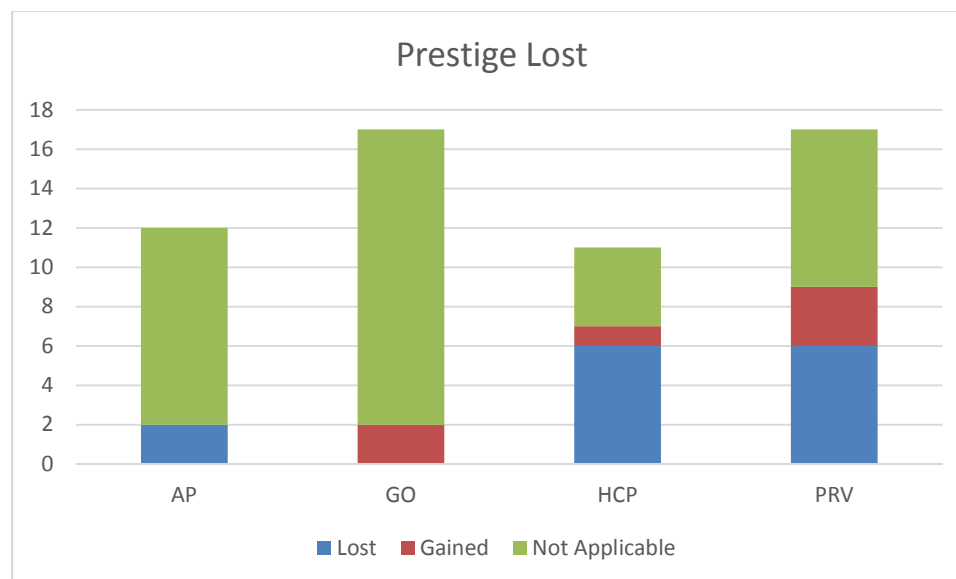


FIGURE 4.1: I (LOST/GAINED/NOT APPLICABLE) PRESTIGE IN MY PROFESSIONAL LIFE AS A RESULT OF THE BAN.

Of the fifty-seven people I interviewed, a total of fourteen people stated that they had lost prestige. We see in the graph above (Figure 4.1) that two out of twelve academics, six out of eleven individuals in the CCSS, and six of the seventeen respondents from the private research arena made this claim. However, two of the seventeen people in governmental roles interviewed, one person at the CCSS, and three people in private research stated that they had gained prestige because of the suspension.

Academic Personnel (AP). For example, of the two academics who indicated that he or she felt a loss of prestige, one, a researcher at one of the local universities, noted that she had lost

opportunities to participate in different international projects in 2010 due to the suspension. While the types of research conducted in her group were observational or epidemiological, there was a period immediately after the court decision when it was unclear which type of human subject research was to be suspended: observational, epidemiological, *and* interventional (clinical trials) or just interventional. This created confusion that led to her research group turning down international opportunities leading to a loss of prestige within those groups. As she explained to me, participation and publication, while not a tangible loss like wages or employment, is a loss nonetheless and for academics can significantly affect one's prestige and ultimately their livelihood.

Government Officials or Employees (GO). Most of the respondents positioned in the government felt that the suspension had no effect on their prestige. However, two people felt they had gained prestige. One rose to leadership in the National Council on Health Research (CONIS) while another gained prestige through recognition by various commissions for his work on the law project.

Public Health Providers (HCP). Of those who either worked in the public health sector during the prohibition or transitioned back to the CCSS because of the prohibition, one felt he had gained prestige because of the suspension of clinical trials, while six felt they had lost prestige, and four claimed no effects to prestige. Of the six who felt they lost prestige because of the suspension, one public health system physician, a young woman trained both in Costa Rica and the United States, felt that she had lost the ability to conduct clinical research within the country, as she returned from the U.S. training post-suspension. Therefore, she could not publish on important work in periodicals or journals. While another physician had worked in the public health system in general medicine and now practiced gynecological medicine. As a resident, he

did research in gynecology, and as an assistant he did some basic research and works now with a pharmaceutical company outside of Costa Rica.

One public health care informant is an older physician, whose entire career as a physician was spent working inside the *Caja*. He also taught at both a public university and one of the private universities while maintaining a private practice. At the time of our interview, he was retired from practicing medicine, but he remained a professor emeritus at one of the public universities and is studying bioethics. He felt that he gained prestige through his writings in newspapers and journals on the topic of clinical research.

Three of the six health care professionals who felt that they lost prestige because of the suspension had previously worked in private research centers. One physician, a prominent researcher prior to the suspension, laughs as he says, “*Without a doubt I lost prestige in my professional life...they don’t invite me to anything anymore.*” Another who continued to work in clinical research post-suspension on on-going clinical trials until 2013, notes that, yes, he lost prestige in his professional life. However, now, in his new role in a public health system hospital, he is learning a lot in this new specialty

Private Research Personnel (PRV). Of the six participants who work or have worked in private research, one who was a well-respected researcher, noted, “*Yes, I lost prestige professionally, especially, most of all, at the international level. People could not understand how come... a country like this prohibited that [clinical trials].*” On the other hand, one participant, a woman, who had worked as a study coordinator prior to the suspension, became very active in the Costa Rican Association for Research in Human Health which lobbied to have a voice in the creation of the new law. She stated, “*Lost prestige? I wouldn’t say I lost prestige but gained it as a result of the role I played in the Association!*”

Status: I (lost/gained/Not Applicable) status in my social circles (non-professional) as a result of the ban.

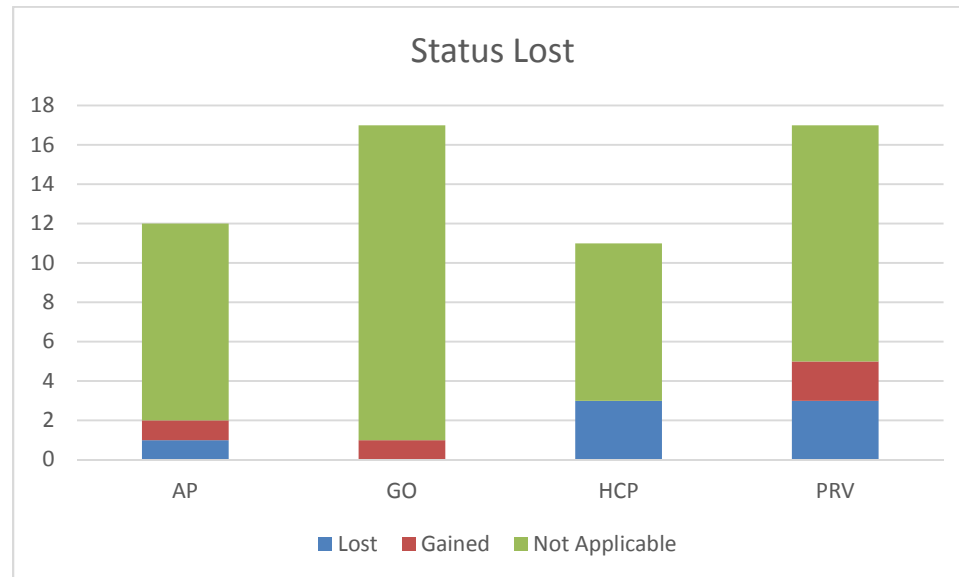


FIGURE 4.2: I (LOST/GAINED/NOT APPLICABLE) STATUS IN MY SOCIAL CIRCLES (NON-PROFESSIONAL) AS A RESULT OF THE BAN.

Of the fifty-seven interviewees, we see in Figure 4.2, that a total of seven informants felt that they had lost status in social circles. According to the strata, one academic, three interviewees in the CCSS, and three respondents from the private research arena claimed that they had lost status in their social circles in their non-professional circles because of the 2010 suspension. However, one academic, one person in a governmental role, and two people in private research stated that they had gained status because of the suspension.

Academics (AP). An academic researcher, who felt a loss of status, not in social circles, but professionally, notes in the interview:

These questions of 'Status' ...are intangibles but if one feels the measure of studies is in the number of publications and one is cannot work then he or she is not able to publish. Then after, one says 'There is [a loss of status] if one cannot publish'. This implies a certain 'Status', as well, a certain prestige, both local and internationally.

Government Officials or Employees (GO). While no governmental respondents felt that they had lost social status because of the suspension, one participant felt he had gained social status because of the law, because he became the Chair of CONIS, the National Council on Health Research after the new law was enacted in 2014.

Public Health Providers (HCP). Three participants who work in the public health system responded to the statement as having lost social status; one commented that the lost ability to publish affected her social status, while another physician said that, *“Yes, I think so, clearly I lost status because I was...it was a field that was a little more exclusive, clinical research, an area that...medically, was feeding me, because nowhere else—nowhere—[in] another area of medicine, [do] I get that knowledge, that information first hand.”* No one working in the public health system felt he or she had gained social status because of the suspension.

Private Research Personnel (PRV). Three people in the private research field felt that he or she had lost status. A prominent researcher said, in relation to losing social status, *“Yes! Clearly, I lost status because people associate me with research, then in the moment when they prohibited research, everyone said ‘Ah! Surely that was because he was doing something bad’.”* However, two respondents commented that they had gained status in their social circles because of the suspension. One interviewee, an owner of a laboratory wrote that he gained status, *“Like ‘status’ in the sense of participating in the struggle to recover research with the approval of the law and the regulation.”* Another person interviewed also acknowledged the increase in social status because of her participation in the development of the new law.

International opportunities: I (lost/gained/Not Applicable) international opportunities as a result of the ban.

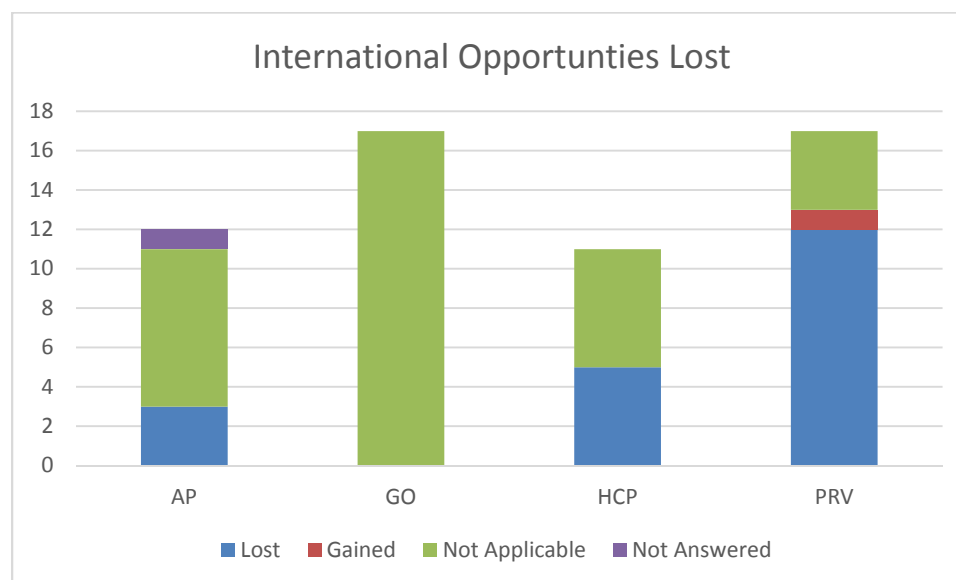


FIGURE 4.3: I (LOST/GAINED/NOT APPLICABLE) INTERNATIONAL OPPORTUNITIES AS A RESULT OF THE BAN.

With this statement, I wanted to understand the effects of the suspension on international opportunities to collaborate. As noted in Figure 4.3, those hardest hit had been working in private research institutions—often collaborating with multinational pharmaceutical companies, governmental organizations (like the NIH) or private research centers in the United States. Overall, a total of twenty respondents felt that they had lost international opportunities. Of the twenty, three academics, five CCSS providers, and twelve private research personnel claimed a loss of international opportunities because of the suspension. One individual in private research felt that she gained some international opportunities. Government personnel considered the statement not applicable to them.

Academics (AP). Of the twelve informants I interviewed in the academic setting, three believed that they had lost international opportunities because of the suspension. While the University of Costa Rica does not engage directly in interventional clinical research (i.e. new drug research),

many in fields such as biology, microbiology, pharmacology, and even odontology, do engage in observational, epidemiological, and genetic studies, while others specialize in bioethics.

For example, one informant said:

For example, in this period--we are speaking of 2010—we lost a pair of windows [of opportunity] at the international level because of this situation [the suspension] because of how we did not have clarity of what the issue was [regarding what type of research was affected] nor who there was to do it.

However, another informant, a genetic researcher, noted that the university did not lose international opportunities, but that there was “*international concern*” about the suspension, while a pharmacist and educator said that he lost, “*the opportunity to offer services, not only within the country, but also not with any businesses or institutions outside of the country.*”

Public Health Providers (HCP). Of the eleven individuals in the public health system I interviewed, five noted that they had lost international opportunities. Two had been physician-investigators who had been working in private research at the time of the suspension and felt the loss of international opportunities. For example, a physician and former investigator presented me with an example when he said

I was beginning to collaborate with the World Health Organization on a pneumonia project—to create a diagnostic and treatment guide of pneumonia for countries that are less developed, and I went to the first meeting last year and this year I had to say that I couldn’t continue because clinical research was not able to be done here in the Caja.

Another physician speculated, “*Clearly, I lost [opportunities], I can’t imagine which ones, but I am sure that they were very good opportunities.*” Even though the loss was something unknown, because of the suspension, the physician felt he had suffered a loss of what could have been if he been able to continue as an investigator.

Private Research Personnel (PRV). A total of twelve individuals in the private research arena felt that they had lost international opportunities because of the suspension of clinical research in

the country. For example, one researcher noted wryly, “*International opportunities? Without a doubt I lost them. That was the greatest loss.*” Some respondents, such as a young pharmacist, were just starting to develop opportunities to participate in international conferences and publications. This pharmacist noted that she had just started to publish in small national publications, and said that other research team members, who had been working for the principal investigator longer, had presented at conferences and publish at the international level. She saw the opportunity to take a similar trajectory lost when the suspension happened and said, “*so then, I believe that I lost it [the opportunity] because, eventually, I would have done it.*” However, one study coordinator at a private research center felt she had gained an international opportunity because she left the country to find work. She says:

A few years later [after the suspension], imagine, then, when Pfizer closed its operations here, I said, ‘Yes I believe that it would be better for me to leave’, right? Because here everything is closing, little by little, everyone was closing their clinical [research] operations, and there were very few studies that remained—only those that had many more years left. [They were] very large studies, but outside of that, nothing new was starting, besides the frustration is terrible, right—because you see everything you are losing.

She elaborates:

Here, yes, in fact, I—in that moment—received two offers, that were very interesting. One was in New York and another was in Africa. I lived in the United States for two years after studying physical therapy, doing an internship for postoperative treatment of the back, shoulder, and knee. I chose Africa precisely for the specific characteristics...that they have. So, that was how I gained very much on a personal level.

Post-Suspension Agency

Social or human agency is a concept that draws from both philosophy and anthropology. For philosophers, such as Amartya Sen, agency is the ability to choose and, in that choice, attain the goals and achievements one envisions for himself. However, individual agency is constrained by the context in which one finds herself. There are political, social, economic situations which

can impede or enhance one's individual agency. Sen states that "[t]here is a deep complementarity between individual agency and social arrangements," and that we must acknowledge both individual agency and the relationships we have that extend or inhibit our agency (Sen 1999: xii).

For anthropologists, agency, especially neoliberal agency, functions as a socially constructed and mediated self-perspective that allows one to view oneself as a "business" in that one's labor and body have value to others and can be marketed as such (Gershon 2011, 539). Keane (2003), in his genealogy of agency in interpretive anthropology traces it from the anthropology of the particular *à la* Abu-Lughod to the self-aware individual who can contemplate his or her place within the larger processes swirling around her.

Carla Freeman in her article addressing class and labor in Barbados, frames agency in a context more closely related to flexibility. More specifically, she discusses the ways in which Barbadian women have used the neoliberal moment to become entrepreneurs and to resist the outmoded ideas of respectability—seen as those individual aspects tied to colonialism, bureaucracy, the Church, and the middle and upper classes—versus reputation, which had previously been the cache of the working class who had limited access to respectability. In the cases Freeman presents, women from both the middle and working class have used a "neoliberal flexibility" along with a "reputational flexibility" to create opportunities for themselves where none existed (Freeman 2007, 252).

For Costa Rican physician-investigators and their teams, their consciousness of their own agency *and* their place in the larger processes of the state and the world were made clear on the day that the Constitutional Court suspended clinical trials. For some, a high level of social capital and agency allowed them to remain in clinical research, but only if they left the country.

For others, they could choose to return to previous occupations—again by leveraging social capital and individual agency. Others re-entered the public sphere in health care or in government which are two regularly traveled routes for the educated elite. Still others could not recover from the loss of employment and retired or continued to look for new employment. Therefore, in the series of statements below, I wanted to understand what kind of choices, opportunities, and freedom of movement (agency) those informants in clinical research had and whether additional effort and education was required to make this pivot to new occupations and livelihoods. I identified four survey questions that best represented agency. These included publishing opportunities; academic opportunities; ability to retrain for new employment; and the ability to work within the *Caja* and (or) the private healthcare sphere.

Publishing Opportunities: I (lost/gained/Not Applicable) publishing opportunities as a result of the ban.

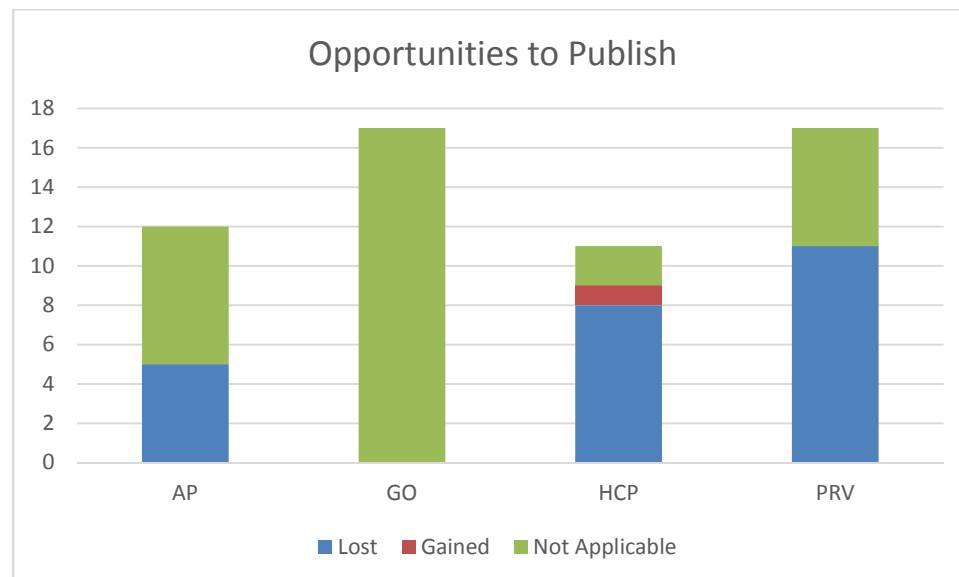


FIGURE 4.4: I (LOST/GAINED/NOT APPLICABLE) PUBLISHING OPPORTUNITIES AS A RESULT OF THE BAN.

This question is the first survey question that focuses on agency lost to the suspension. As stated above, agency is exhibited in the ability to make choices that achieve the goals one sets for

him-or herself. For researchers of all stripes publishing is an important source of recognition of one's research abilities and this recognition leads to more opportunities to engage in research and research collaborations, both locally and abroad. Publishing in journals also raised the country's profile in biomedical knowledge production. For example, the Guanacaste Epidemiological Project (PEG)⁵¹ is one of the largest natural history studies of the human papilloma virus in the world and located in Costa Rica (Kelly 2010). One local lead investigator on this study became the most published scientist in Costa Rica (Monge-Nájera and Ho 2019). It was just one of many studies of which Costa Rican research teams were a part that have contributed to the knowledge base for various disease states.

A total of twenty-four informants of the fifty-seven people interviewed felt that they had lost opportunities to publish (Figure 4.4). One person saw a gain in publishing opportunities. There were no changes for government officials or employees.

Academics (AP). Of the twelve academics I interviewed, five stated that they had lost opportunities to publish. One interviewee aptly described the endless cycle of research and publishing when she said she lost opportunities to publish

because one, as I say... perhaps if one person had many projects or other activities, then, let's say, if there were delays [because of the suspension] and there are no publications...without them [the publications] you cannot look for new funds.

While another informant implied that he also could not close the circle that academics need to close through publishing when he said, *"I lost [the ability to publish]. I wanted to do experimental research ..., but I couldn't do so partly because of the ban [of clinical research]."*

⁵¹ *El Proyecto Epidemiológico Guanacaste (PEG)*

On the other hand, another academic who works for the medical school noted that there was no change to his ability to publish because, as he notes, “*I was able to publish in other fields.*”

Public Health Providers (HCP). Of the eleven people I interviewed within the *Caja*, eight noted that they felt they had lost the ability to publish. One physician, who was opposed to the way clinical research had been done in the country, felt that he had gained publishing opportunities through regular opinion pieces regarding clinical trials in newspapers.

Private Research Personnel (PRV). Of the seventeen informants working in private research facilities, eleven felt that they had lost opportunities to publish and contribute to scientific knowledge. One informant captured this feeling well:

...you say that everything is missing, or in medicine, every day there is something new and we were losing publications and participating in all that world of knowledge. Every day something was lost, and it was four years, that’s where I started looking for work outside [of the country].

Academic Opportunities: I (lost/gained/Not Applicable) academic opportunities as a result of the ban.

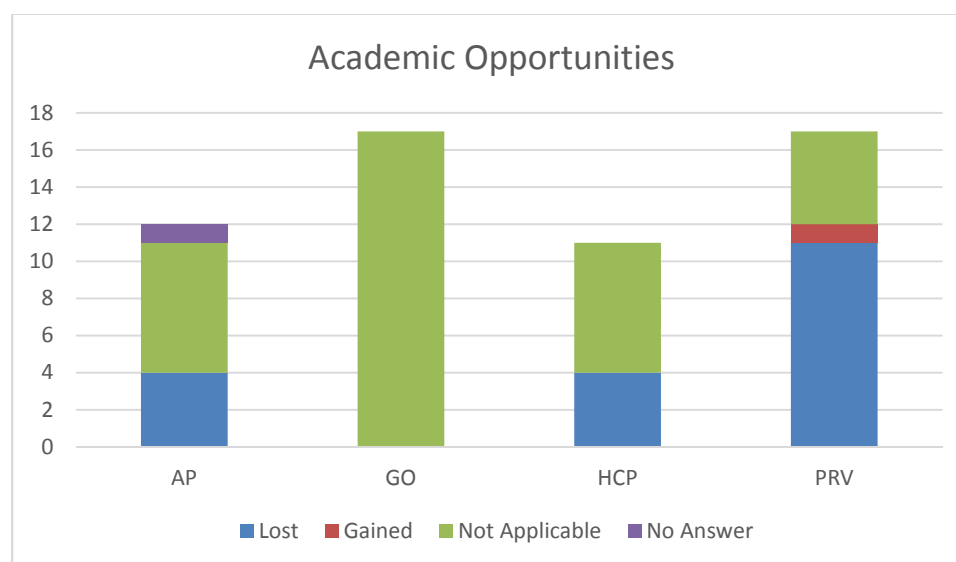


FIGURE 4.5: I (LOST/GAINED/NOT APPLICABLE) ACADEMIC OPPORTUNITIES AS A RESULT OF THE BAN.

A total of nineteen respondents felt that they had lost academic opportunities (Figure 4.5). It is not surprising that some (four) academics would feel the effects of the suspension in their ability to access academic opportunities, yet, what was interesting is that eleven people working in private research, including some at a private medical school with a research arm, felt that they had lost academic opportunities. Four people working in the public health system also felt that they had lost academic opportunities as well. A gain of academic opportunities was noted by only one person. The government informants all felt they had no change in their academic opportunities.

Academics (AP). Out of the twelve academics I interviewed, four felt that they had lost academic opportunities because of the suspension of clinical trials within Costa Rica. For example, the dean of the medical school, who selected not applicable to academic changes for himself, spoke for the school overall when he said

It strengthens the arguments of our professors, to be able to carry out research, including inside the country and in the various establishments of the country's medical systems, the Caja, or the National Insurance Institute.

One professor noted that the clinical trials ban affected funding for internships and another academic follows up from his comment regarding publishing by saying, “*I lost. [I was] unable to publish the above [study results], the university was affected,*” and claimed that he lost academic opportunities because of the restrictions the suspension placed on graduate work in the various professional health and medical schools.

Public Health Providers (HCP). The four public health system providers simply circled that they had lost academic opportunities with no other comment.

Private Research Personnel (PRV). Of the eleven individuals working in private research who felt that they had lost academics opportunities, some noted that they no longer had money to pay

for further education, while others noted that the educational programs in clinical research they were developing folded after the 2010 suspension.

Education/Training: I needed (more/none/Not Applicable) educational (re)training as a result of the ban.

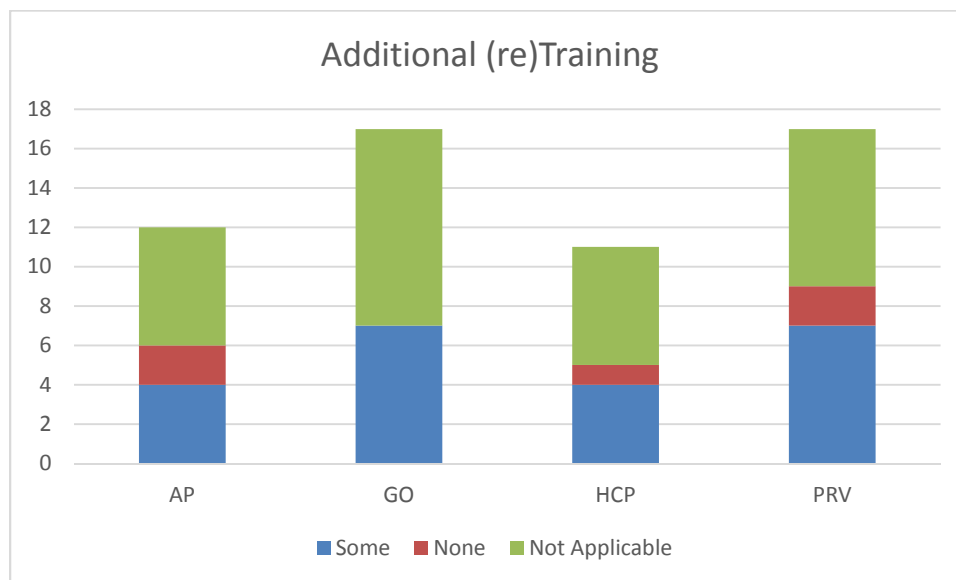


FIGURE 4.6: I NEEDED (MORE/NONE/NOT APPLICABLE) EDUCATIONAL (RE)TRAINING AS A RESULT OF THE BAN.

In this statement, I wanted to understand what my informants had to do to seek other work. Did they need to train in an entirely new field? Did they have to retrain for work they had done before entering the private research industry? Did they need to educate themselves so that they could take a more active role in the various law projects unfolding in the legislature? Did they need extra training to understand and comply with the new law? A total of twenty-two individuals felt that they needed more training to recover from the suspension (Figure 4.6).

Academics (AP). Four out of eleven academics said that they needed more training mainly to conform to the new law. One academic-researcher noted that she needed more training to “conform to the new law” to continue working on future projects. Yet, a pharmacy professor

noted that a person needed more training so that he or she could “*know the scope [of the suspension] and of what [this] consisted [to avoid] incurring legal violations,*” during the suspension.

Government Officials or Employees (GO). Of all the survey statements, the need for extra training (to adjust to the new law) was the single question in which government employees and elected or appointed officials marked as needing more training. Seven of the seventeen governmental employees or officials interviewed noted that they needed additional training in such themes and areas as bioethics and good clinical practice, normally reserved for physicians or research teams. While others needed training to better understand the new law and prepare for registering researchers. One ex-Minister of Health noted that she needed more training in pharmacovigilance for her new position in the ministry.

The one of the chiefs of staff to a legislator told me that she needed to do a lot of reading and asking questions of experts to understand research with human subjects, since this was an area far removed from the usual work she did. She often had to seek out experts outside of the government to learn and understand more about the field of clinical research. She noted that she participated in meetings with stakeholders from pharmaceutical companies, health law and bioethics experts, former and current (at the time) ministers of health, physician-researchers, and others to craft a draft of the new law.

Interestingly, a former legislator marked “not applicable” for this statement, but commented, “*How difficult is this question, no? Because as a result of the prohibition, I entered a process of debate, then yes, I got that part [education], but it seems that [this statement] is no because it is a question of occupation, so not applicable to me.*”

Public Health Providers (HCP). Of the eleven *Caja* respondents, four selected the answer for more training, one respiratory therapist wrote that he needed training as a project manager, another, an administrator in the main office of the *Caja*, wrote “yes” but did not elaborate. Another, a physician, initially thought that, no, he had not needed more training, but then said, *“I’m going to [answer] some, because for what I do now, [the work] is very specific.”*

Private Research Personnel (PRV)Seven of those working in private research noted a need for additional training. One respondent needed to update her training in nutrition so that she could begin to “think like a nutritionist” again, taking courses in vegetarian diets and diabetes as well as to *“dust off and update what is current in nutrition, methods, and everything.”* While an administrator in a private research organization, upon reading the question aloud, said

Yes, clearly yes for the law, it is to say, as the law was published. Yes, we created a course in good clinical practice and I was a speaker as well ... they made a presentation of the changes that [had changed] according to the law, that are governing now and the truth, if I have read the law 40 times that is the truth, to be very clear of what we are doing.

Another participant needed some training to move from one area of research into storage and distribution of medications, which was an entirely different area of work for her. On the other hand, one interviewee noted that, because of the suspension, she took courses in bioethics so that she could be more active in the efforts of the Costa Rican Association for Human Health Research.

Ability to Work: I (lost/gained/not applicable) the ability to work with the *Caja* and/or my private practice as a result of the ban.

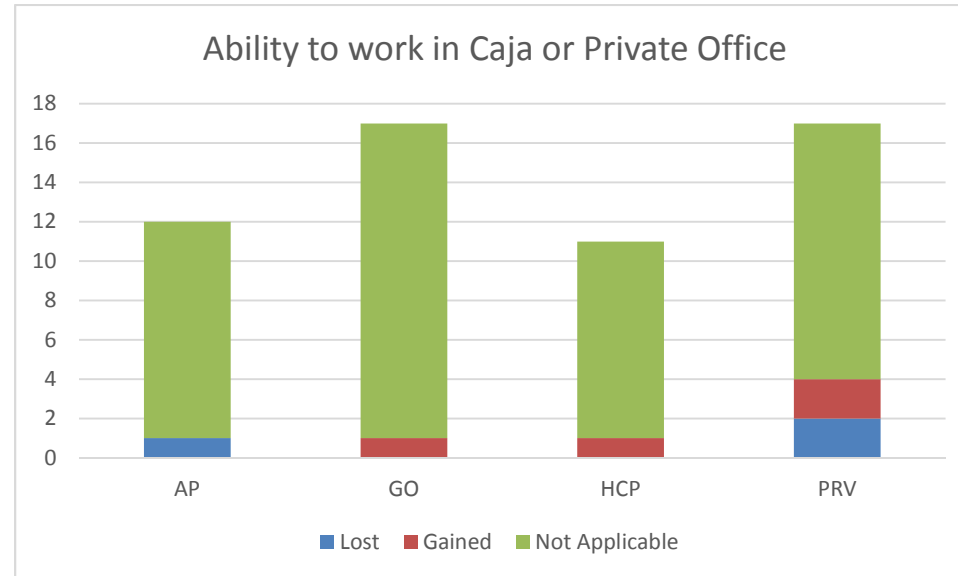


FIGURE 4.7: I (LOST/GAINED/NOT APPLICABLE) THE ABILITY TO WORK WITH THE *CAJA* AND/OR IN PRIVATE PRACTICE AS A RESULT OF THE BAN.

In Costa Rica, physicians often maintain a private practice in conjunction with her care of patients within the *Caja*. Many times, the public health system patients will see the doctor in his private practice for certain procedures or tests for which there are waiting lists inside the *Caja* (King 2016). I was curious about how the suspension of clinical trials in the country affected a health care professional's ability to move between the two health systems. With this question, I had hoped to explore this idea. Once I entered the field, however, I found that this freedom of movement was less affected by the suspension of clinical trials in 2010 than I had originally thought. A total of three people felt they had lost the freedom to move between the public and private health systems, while four felt they had gained a greater freedom (Figure 4.7). This statement, more than others, illustrates the fluidity of working in both public and private practice, often at the same time, and shows the challenges some faced to reenter the CCSS.

One academic said that he lost attendees to his bioethics courses which he conducts within the public health system. As it relates to working with the *Caja*, another academic, who had marked "not applicable" commented that

I feel that here, because of the structure of the university, yes, there was a period in 2010 (during the suspension) where one was not able to, above all, do research that they had been doing in conjunction with the Caja, right, because, the Caja did not have a bioethics committee to look over the research protocols.

One physician had been employed by the *Caja* for ten years prior to entering the clinical research field. She then held roles as a study coordinator and administrator in private research from the early 2000s up until the suspension in 2010 and said that her intent was to return to practicing medicine after working in clinical research. She says, "*I worked for six months as a specialist and I didn't feel comfortable, then I decided that still it [practicing medicine] wasn't for me.*"

For those who set aside medical practices for administration roles in clinical research, this added another layer of challenge in finding employment again. For example, another former study coordinator, trained as a general physician told me, *“For a generalist, Costa Rica has a big problem, because, just last year alone, 15,000 generalists were without work”* therefore, after working as a study coordinator, she was unable to return to work as a general physician. Her reasons were twofold: she had not practiced medicine for quite a while and needed, as she joked *“eight million courses”* to recertify to work in the Caja because she had *“lost her skills as a physician.”*

On the other hand, four respondents noted that they had gained the ability to work in the Caja or in a private practice. A physician, who had maintained both a private practice, a practice in the public health system, and a research practice noted that

Now I see more patients than before, but there [private practice] there is no affect. Actually, it never affected the private office. I have always carried out the rhythm that I want. I gained the ability to work in the Caja because I returned to the Caja, in fact.

And another physician said that

Actually, I never have worked with the Caja, I mean, I worked a few months, but I didn't enjoy working for the Caja. It never had been my goal, because the Caja is not an institution that has the necessary tools for you to be able to perform, if you give good care to your patient.

Laughing, he said, *“Now I get unionized”* as he circled “not applicable.” A study coordinator, who had been a nutritionist before working in clinical research, returned to a private practice in nutritional consultation and as a result feels that she gained the ability to work in private practice.

Survival Strategies and Neoliberal Flexibilities

What did my informants do to recover when their social capital, agency, and employment were threatened? Who did they rely on? Did their entrepreneurial identity carry them to the next chapter of life? At what cost? In this section, I draw from the work of Dennis Gilbert in his study of the middle-class in México and their “survival strategies” during the economic crisis that hit México in the mid-1990s (Gilbert 2007, ix) as well as the work of Carla Freeman and her ideas of “neoliberal flexibility” (Freeman 2007, 252).

Gilbert notes that middle-classness is difficult to pin down and there is a long history of social scientists from Marx and Weber to Freeman, and Gilbert himself attempting to define and provide the boundaries for the middle class. He draws on the work of Marx and Weber to build his definition, using some assumptions to bound class. His specific focus is on households rather than individuals and beyond the scope of this dissertation, yet he defines the middle class as *“families headed by individuals with non-routine, non-manual occupations, living on incomes comfortably above the popular average but below the peak of the national pyramid”* (Gilbert 2007, 12, italics in the original). Gilbert’s informants, though never asked directly what class they believed themselves to be in, defined middle-class as “the character of the work and the standard of living” (Gilbert 2007, 14). One key argument Gilbert makes is that the middle-class, unlike what he calls the “popular class,” seeks to preserve their standard of living. They are not just trying to survive but trying to continue to thrive. In his book, Gilbert categorizes the various survival strategies used as: budgeting through reallocating spending and seeking other income sources; capital as defined by Bourdieu; and “transubstantiation” or the ability to convert various forms of capital into other capitals (Gilbert 2007, 46).

In “The ‘reputation’ of neoliberalism,” Freeman illustrates how the larger ideals of neoliberalism can be strategically used to allow a working-class Barbadian woman to reject the strict cultural precepts that lead to respectability and use the strategies of reputation-building by to create a new neoliberal identity and seek a higher tier on the economic ladder. They use these new reputations to reach toward respectability. Freeman seeks to "recuperate the framework as an evocative heuristic for analyzing the Barbadian 'particulars' of neoliberal 'sameness' and more generally, for engaging in the dialectics of economic and cultural spheres in the contemporary context" (Freeman 2007, 254). For her and for her informants there is a constant negotiation between the global and local as well as between respectability and reputation, especially for women who are stepping away from the hegemonic gender frameworks that confine women to respectability but expect them to preserve their reputation. It is this tension between respectability and reputation that she explores in the article.

Throughout the fieldwork for this dissertation, there were examples of the entrepreneurial spirit of physician-researchers and their teams as they adopted identities shaped by the neoliberal opportunities brought to Costa Rica via the globalization of clinical research. Here, I use neoliberal flexibility to show how this flexibility became a survival strategy after the Constitutional Court suspended clinical research in 2010. Much like the people Gilbert interviews in México, the people I interviewed relied on multiple forms of capital to maintain their economic and social positions. They sought out new employment, returned to previous employment, or shifted efforts to move from part-time to full time. Some in clinical research, using their prestige and international connections, left the country to continue working in the same field in other countries in Latin America, the United States, Africa, and China. However, just like Gilbert’s sources, many chose to remain in Costa Rica.

However, the majority of the people negatively affected by the suspension stayed in Costa Rica and leveraged their previous training, professional networks, and their diversification in employment to maintain themselves while the legislature worked in fits and starts to create a new law and regulation to manage clinical trials in the country. Of the fifty-seven people I interviewed, only one was not employed and still seeking work at the time of our interview. She blamed her lack of employment on her age and her medical training as a generalist. As can be seen by the chart below (Figure 4.8), 51% of my informants hold more than one job currently, with only 42% working at one job. Figure 4.9 illustrates that those who currently work in clinical research or government jobs are most likely to only hold one job, while those in academia are most likely to hold two or more jobs.

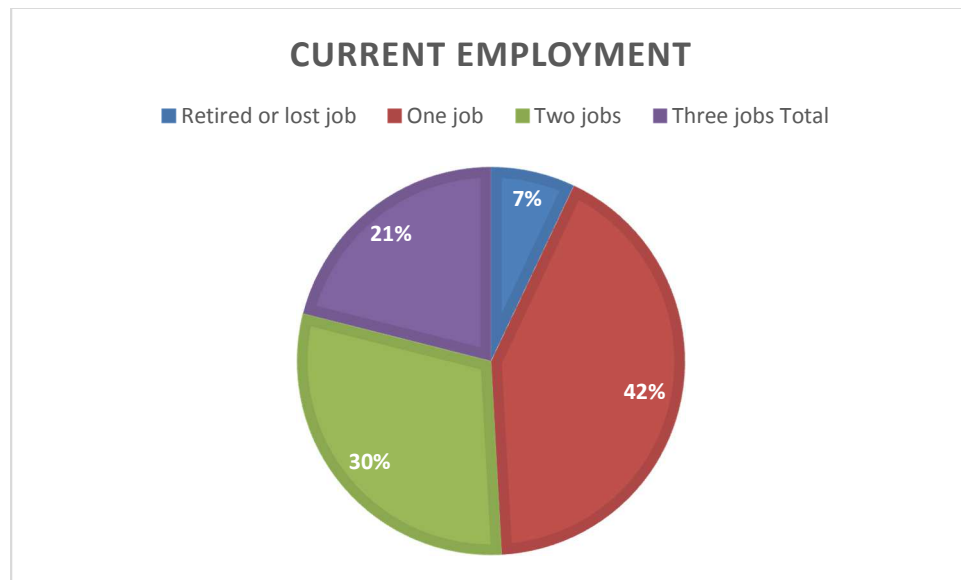


FIGURE 4.8: CURRENT EMPLOYMENT STATISTICS.

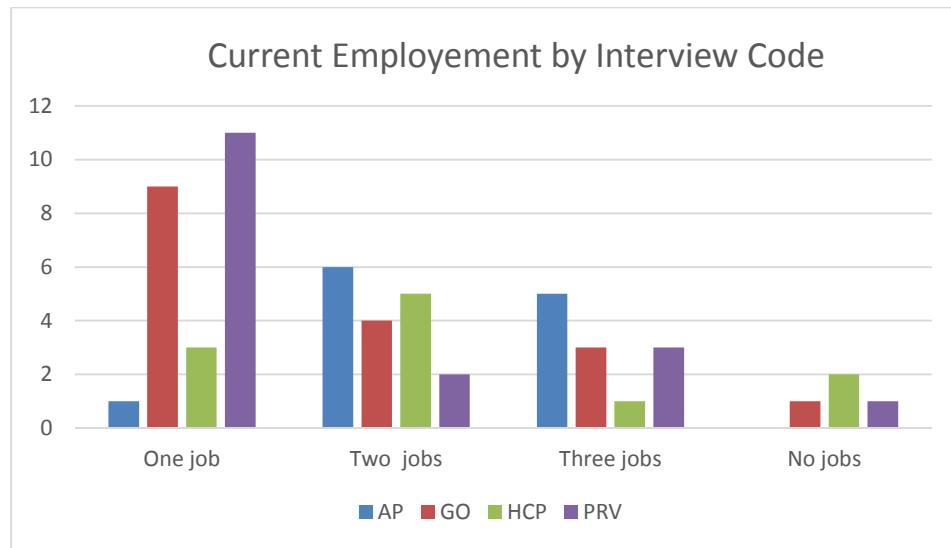


FIGURE 4.9: CURRENT EMPLOYMENT BY INTERVIEW CODE.

Above, I explored the effects of the Constitutional Court’s 2010 decision to suspend clinical research in the county. Specifically, I focused on the ban’s effects on the social capital, agency, and survival strategies for those interviewees who were affected by the suspension.

Next, I will explore the ideas of neoliberal and entrepreneurial identities as it pertains to those working in clinical research in Costa Rica prior to the 2010 suspension as World Bank and International Monetary Fund structural adjustment programs allowed a strong private health care system to grow alongside of the public one (Ryan 2004). An outgrowth of the private system were opportunities for local physicians to participate, as investigators, study coordinators, and administrators, in multi-sited clinical trials sponsored by multinational pharmaceutical companies and U.S. governmental and academic institutions. . Below, I will present four examples of neoliberal and entrepreneurial identities. These four cases are examples of aspects or traits of neoliberal and entrepreneurial identities and include “flexibility,” “entrepreneurship,” “autonomy,” and identity as discussed by Freeman in *Entrepreneurial Selves* (Freeman 2014, 15-17, 49).

Neoliberal Entrepreneur Identity

Here, I am working with concepts of neoliberal identity and flexibility and drawing on what Carla Freeman calls, the “entrepreneurial self” as an extension of Foucault’s technologies of self (Freeman 2007, 2014, Gershon 2011). Gershon identifies a key element of the neoliberal identity as the “self that is a flexible bundle of skills that reflexively manages oneself as though the self was a business” (Gershon 2011, 537). These skills are extensive and shaped both by globalization and the local political and economic context as well as by the business in which one works. Freeman also acknowledges this flexibility in her extensive fieldwork in Barbados, where she witnessed and documented the ups and downs of “the project of neoliberal self-making and the changing cultural economy” (Freeman 2012, 87). She argues that there is a “neoliberal mandate for flexibility in all realms of life—the capacity to constantly retool, retrain, and respond to the shifting tides of the global marketplace” are the new definition of middle-classness (Freeman 2012, 85).

In *Entrepreneurial Selves*, Freeman extends this self-making project to the idea of entrepreneurship and argues that an entrepreneur is more than a creator of enterprises, but, in the process, creates “the self as entrepreneurial project inextricable from the enterprise and market sphere” (Freeman 2014, 2-3). In Costa Rica, structural adjustments allowed physician-investigators and other members of their research teams to embrace these ideas of neoliberal and entrepreneurial self-making. However, they did so in tension with the state which ultimately brought the abrupt halt to the clinical research industry with the 2010 suspension of clinical research within the country.

One can see these global-local tensions building in a late 80s piece by Álvaro Quesada, called “A Dictionary of Costa Rican Patriotism,” in which he critiques the influx of neoliberal

ideas into Costa Rica in the form of a dictionary of terms which have undergone, according to him, a “redefinition” of Costa Rican ideology because of free market ideals (Quesada 2004, 225). He is particularly harsh when defining “Democracy” which he states is a “[g]overnment of the entrepreneurs, by the entrepreneurs, for the entrepreneurs,” tersely defining every technocratic government that sprang out of the structural adjustment programs in the 1980s and 1990s (Quesada 2004, 226). He defines “Entrepreneur” in equally scathing terms, saying, he is the “Democratic archetype of Man. Said of all those capable of selling their soul, their country, or their people, with the noble goal of protecting or incrementing their properties or their business” (Quesada 2004, 226). In the space between neoliberal self-making and the sharp-tongued critiques of statist such as Quesada, we find our clinical researchers and their team members below.

Flexibility

Dr. Abdelnour is a young-looking fifty-three-year-old pediatric physician and, currently, head of the teaching unit of the National Children's Hospital in San José, Costa Rica, where he supervises interns and residents. His training in medicine started at a private medical school in Costa Rica and from there he went on to receive a specialty training in pediatrics at the University of Costa Rica and a doctorate in clinical immunology at the University of Gothenburg, Sweden. After training, he spent, as he said in the interview, *"practically my whole professional life, in the Caja as a general practitioner, a pediatrician, and an immunologist."* Because he wanted to be more involved in clinical trials, he worked for two years for a pharmaceutical company to develop medications and vaccines; returned to the public hospital again for a short while, and then worked for six years at the Institute for Pediatric Care, a private research facility in Costa Rica.

Dr. Abdelnour told me that he feels that clinical trials are very beneficial and feels that he has a unique perspective having worked for both a pharmaceutical company and for a research institute as a principal investigator and sub-investigator. When I asked him about the work he did in clinical research and that work's effect on his life, he told me:

I combined the part of being a doctor with the part of research. I believe that there was no negative affect, I enjoyed doing this, not just seeing patients but also research that allowed me to go to medical conferences to present new, novel information; to make connections with other research centers and researchers; to be an opinion leader.

Still, he did not just consider the benefits he personally received as an investigator. Yes, he had recognition as an opinion leader and it was a good living economically, but he also saw the work they were doing in Costa Rica as elevating the country itself.

In this one example of many, we see how flexibility allows an individual to move between different tasks and different worlds. And for Dr. Abdelnour, this was one of the benefits he mentioned more than once. By having one foot in patient care and another foot in research, he could focus his time and energy on the tasks he most enjoyed in each arena. He enjoyed flexibility in his work and personal goals because of clinical research in the country. After he left the pharmaceutical company he could balance his patient load at the *Caja* and the participants in the clinical trials he ran. He tells me later in the interview that he has always worked in the rhythm that he wanted.

Entrepreneurship

Dr. Rodríguez is short, older man with silver hair and an easy smile. He has been working in clinical research for more than two decades. Some people I talked to during my fieldwork consider him to be the father of clinical research in Costa Rica. He founded the Costa

Rican Institute for Clinical Research (ICIC)⁵² in 1992, which is billed as a "Site Management Organization." According to the institute's website, he was trained in internal medicine at the University of Costa Rica and critical medicine in Texas. He has also taught at both medical schools and prior to opening his research institute, he was the Chief of Intensive Care and the Department of Respiratory Therapy at the Hospital México in San José. He is also credited with developing the country-wide 911 system. Besides ICIC, Dr. Rodríguez founded the Network of Clinical Research in Latin America and the Costa Rican Institute of Oncology in 2010. He is the author of many scientific articles and textbooks. ICIC provides support for investigators, clinical research organizations, pharmaceutical companies, universities and other stakeholders in clinical research. The company also conducts research and runs a commercial Institutional Review Board. The company is an "exporter of knowledge" and was made a zona franca, or free trade zone under this category.

Dr. Rodríguez was on the forefront of a burgeoning industry within Costa Rica, and, as the country increasingly became a desired clinical research location by pharmaceutical companies, he built businesses that would help facilitate the process of doing research there. Archived news articles discuss a period when ICIC also worked with the *Caja* to do clinical research inside public hospitals. This lasted until 2000 when the *Caja* broke a contract with ICIC, deciding that the provision of health care and not clinical research was their mandate (Rodríguez 2000, Solis R. 1996). During the suspension, Dr. Rodríguez branched out with work in Panamá, India, and China.⁵³ Here we see almost archetypal elements of entrepreneurship as

⁵² *Instituto Costarricense de Investigaciones Clínicas* (http://cec-icic.com/el_instituto.php Accessed on March 24, 2019)

⁵³ *Ibid.*

Dr. Rodríguez followed the market where it would lead and built businesses and an identity along the way.

Autonomy

Dr. Ramírez has a private practice at a large clinic specializing in endocrinology. He received his medical training in endocrinology at the University of Costa Rica and did his specialty training in Texas. He worked as a principal investigator for a decade up until the suspension, managing several phase three and four studies, including an important international diabetes study. At the time of our interview, he was actively involved in two studies and a professor at the university. When asked about the role clinical research played in the care of his patients, Dr. Ramírez stated that his patients loved participating in the studies. He tells us that, for one international study, he was the best recruiter of all the sites. He says, *"I had an excellent research team--the best coordinators. The patients were happy. We earned well; we paid well; we treated the patients well."* Dr. Ramírez is an excellent example of autonomy. In a country where many medical students, after receiving their degree, are required to provide several years of patient care in the *Caja* as repayment for their schooling, Dr. Ramírez has always maintained a private practice. He remains unburdened by responsibilities to the state public health system to this day.

Identity

Ms. Martínez was forty years old at the time of our interview and is trained as a nutritionist at the University of Costa Rica. She received recent education in diabetes to assist her in her current role as a nutritionist, both at a clinic and in her private practice. She is also a study coordinator on two studies: one that was approved before the 2010 suspension and another that was one of the first studies approved after the passing of the 2014 law regulating research in

the country. Ms. Martínez was also the secretary of the Costa Rican Association for Research in Human Health, a coalition of researchers and their research teams that formed after the suspension. The association played an important role in lobbying the legislature on the formation of the new law.

Ms. Martínez worked in clinical research as a study coordinator from 2000 until the suspension in 2010. As a study coordinator, she says she oversaw all the logistics of the study, including the administrative and regulatory work. She worked closely with the participants of their studies, some of which ran several years. While she enjoyed her role as a study coordinator, she often lent her skills as a nutritionist, especially in diabetes studies and said that the good things about clinical research fall into three categories for her: benefits to the patient; social benefits, and professional benefits.

Professionally, she felt she was doing "*beautiful work*" that was "*very important*," but, she said, "*Had I known that [the suspension] would happen, I would have continued as a nutritionist and by 2010, I would have had a huge private practice.*" Still, even after the suspension, Ms. Martínez played an important role in the previously mentioned association where she learned a great deal about the way government works. When she found herself rubbing elbows with politicians, judges, and other important people she said that she "*developed, a little bit, a character or determination to fight for that which one believes is just.*"

Ms. Martínez took pride in her identity as a study coordinator and in the work she did in that position. However, because of the suspension, she found herself conflicted about having put a decade into work that could end so suddenly. The efforts she put into the Costa Rican Association for Research in Human Health helped her discover a whole new part of her identity as a political activist.

Conclusion

In this chapter, I wanted to answer the question of what happened to those working in and around the clinical research industry when the 2010 suspension was enacted by the Constitutional Court. While those most affected were in the clinical research industry, even those who conducted observational research or laboratory research faced a period of ambiguity immediately after the suspension. One observation I noted while doing fieldwork is that there is a fluidity that exists in and between different spheres of employment in Costa Rica. Many who lost employment or income in clinical research easily returned to the *Caja* or found work in academia, or the government. Physician-investigators could increase the patient numbers in their private practices and study coordinators who had originally trained as nutritionists quickly found work in that field again. The strategy of flexibility exhibited by my informants allowed them to consider all options for recovering from the initial shock of the suspension. From the survey, income, prestige, publishing, academic opportunities, and international opportunities were what my informants felt they lost the most.

Almost immediately upon the court's decision, a new coalition was formed—the Costa Rican Association for Health Research that rallied those most affected by the suspension. Through their strategies of writing opinion pieces in local newspapers and seeking to shape the nature of the new law, they imbued this coalition with their neoliberal entrepreneurship. In the next chapter, I will investigate the law-making process and its effects in the lives of those involved. For one researcher, the day the new law was passed was the end of a war:

And on the day, the law was passed, my two sons raised the flag again, during a meeting here with two hundred investigators—the day the law was passed. So...eh... this new law, what it did was ... far from hurting us...it favored us a lot because it made us the only country, besides Chile, in all of Latin America, that has a law for [clinical] research. Only Chile and Costa Rica have a law."

CHAPTER 5: COSTA RICAN COALITIONS: STRATEGIES, SETTINGS, CHARACTERS, AND THE MORAL OF THE STORY

As discussed in earlier chapters, a colonial experience of isolation from direct Spanish rule, little intervention from other countries, and an emphasis on providing social goods have allowed Costa Rica to develop an especially vigorous democratic process that can be both frustratingly slow and inclusive (Garro 2010, Rayner 2014). The Legislative Assembly responsibility is “to enact, reform, interpret, and abolish” policies and laws (Departamento de Relaciones Públicas 2016, 9). The legislature also fills critical roles in the judicial system including magistrates in the Supreme Court (Departamento de Relaciones Públicas 2016).

The legislature also needs to work closely with the Constitutional Court to ensure the constitutionality of each law or regulation passed. To pass a bill into law, a “court consultation” is conducted by the constitutional chamber and has resulted in the Constitutional Court significantly impacting policy-making in the country, because this need to review the constitutionality of each law, which minority political parties have used to redistribute political control within the legislature away from the two majority parties (*Partido Liberación Nacional* and *Partido Unidad Social Cristiana*) (Wilson 2004). As a result, limits to “policy-making autonomy” include such prescience from the representatives as to anticipate “potential court [rulings]” before the bill is even brought to the floor or sent for consultation and put any modifications of existing law into consultation with the court (Wilson 2004, 57).

The Constitutional Court has affected policy-making by allowing direct communication of citizens with the court through *recursos de amparos* and *acciones de las inconstitucionalidades* especially in the ability of disenfranchised groups to directly access the court through the two tools listed above (Wilson and Rodríguez Cordero 2006). While the court

created a more level field for constitutional complaints, *recursos de amparos* and *acciones de las inconstitucionalidades* also were taken up by elites as we have seen with the 2010 suspension of clinical research and as in the use of the tools by minority political parties as discussed above (Wilson and Rodríguez Cordero 2006). Therefore, to understand the policy-making process in Costa Rica, one needs to view Costa Rican democracy as an ongoing experiment in governing.

Costa Ricans see the constitution as a living document that can be challenged by citizens on every level of society through the Constitutional Court and legal mechanisms such as *habeas corpus*, writs of *amparo*, and actions of unconstitutionality (Wilson 2004). This tension plays out in the Constitutional Court, within the halls of the legislature, and on the opinion pages of the country's newspapers. As a result, there is real tension and drama in developing policy and laws.

This chapter will highlight how the Neoliberal Entrepreneurs and the Statists coalitions continued to use the nation's newspapers and the halls of the legislative assembly to redirect policy advocacy toward the development of a new law to regulate biomedical research within the country. A brief description of the Narrative Policy Framework, a qualitative framework used to analyze coalition narratives in opinion pieces and legislative records will be followed by an examination of the setting and cast of characters in each coalition and how their coalition identity drove their influence and input into the law-making process. Finally, the plot and the moral of the story will be discussed, illustrating each coalition's core beliefs informed a nearly five-decade narrative on clinical research inside the country that resulted in damages to individuals and the country.

Tracking the Law through a Narrative Policy Framework

As mentioned earlier, the Narrative Policy Framework, has its genesis in Paul Sabatier's work with other authors in the 1980s and 90s, in which he sought to address the "wicked problems" that factor into policy analysis when dealing with "goal conflicts, important technical

disputes, and multiple actors from several levels of government” and the importance of these coalitions in the policy-making process in what he called the “Advocacy Coalition Framework” (ACF) (Sabatier and Weible 2007, 189). Important in this dissertation research analysis is his structuring the analysis of policy coalitions in a macro-, meso-, and micro-level framework and his concept of “policy core beliefs” which drive coalitions’ strategies for lobbying their positions to governmental officials (Sabatier and Weible 2007, 191 & 195, Czapiewski 2013).

Shanahan, Jones, and McBeth (2011) focus on an aspect often neglected by those using the advocacy coalition framework, noting that few policy researchers focused on policy narratives because narratives were seen as less quantifiable. The authors seek to apply the same hypothesis-testing used in Sabatier’s model to a “Narrative Policy Framework” (NPF) by “[providing] testable hypotheses...for the accurate assessment of the influence of policy narratives on public opinion, policy change, and policy outcomes” with certain “narrative elements and strategies as ... variables” (Shanahan, Jones, and McBeth 2011, 535). Just as the Advocacy Policy Framework quantified the elements of policy change via variables and testing, so too does the Narrative Policy Framework.

It is the work of Gray and Jones (2016, 194) that transitions the NPF into a qualitative analysis tool. They argue that this method allows for small sample sizes and other study elements which preclude quantitative approaches. They focus on such qualitative concepts of “induction, grounded theory, and thick description” and “expanding its [NPF] ability to speak to normative policy concerns” which fall neatly into the linguistic anthropology tradition of critical discourse analysis to examine “(group) relations of *power*, *dominance* and *inequality*” within various types of discourse (van Dijk 1995, 18, Gray and Jones 2016, 194). It is this idea of tracing elite power

that informs the analysis of opinion pieces and legislative plenary session transcripts published after the 2010 suspension that focus on the process of law-making.

The Gray and Jones Narrative Policy Framework focuses on the dramaturgical elements of setting, plot, heroes, villains, and victims arguing that each coalition builds this dramatic narrative to bolster their position in influencing policy changes. While the ultimate goal of a law to regulate clinical research was shared by both the Neoliberal Entrepreneurs and the Statists, the narratives regarding the law and the strategies to assist or obstruct the policy-making process were distinctly different.

TABLE 5.1: NPF CONCEPTS (GRAY AND JONES 2016, 196).

Concept	Definition
<i>Policy narratives</i>	Consist of four core elements—settings, characters, plots, and morals of the story (policy solutions).
Policy narrative element: <i>The Setting</i>	Consists of “legal and constitutional parameters, geography, economic conditions, and other factors regularly deemed relevant by policy actors involved or associated with a public policy” (McBeth et al., 2014: 228).
Policy narrative element: <i>Characters</i>	Three categories of characters: “victims that are harmed by the problem, villains that intentionally or unintentionally cause the harm and heroes that provide or promise relief from the harm” (McBeth et al., 2014: 228).
Policy narrative element: <i>Moral of the Story</i>	The policy solution promoted by a policy narrative.
Policy narrative element: <i>The Plot</i>	Plots link policy narrative elements by establishing relationships between characters, their policy settings, and the moral of the story (McBeth et al., 2014).

The Setting

According to Gray and Jones (2016), the setting is the regulatory context in which the policy debate emerges and is pursued. This setting can be a physical location, such as on the floor of the Legislative Assembly, or a “discursive space” such as the op-ed section of a

newspaper. It can also be an “ideational ...space in which regulation takes place” (Gray and Jones 2016, 203).

Clinical research in Costa Rica began under the spread of neoliberalism in the early 1970s, from the flawed experiment in Chile under Pinochet and the successful embedding of neoliberalism into the capitalist systems of the US and England under Reagan and Thatcher (Paley 2001, Jones 2012). It was shortly after this that pharmaceutical companies began to reach actively beyond the United States for new research sites and new participants with much of the thrust at the time related to AIDS research in hard-hit areas in Africa and elsewhere (Petryna 2005, Petryna and Kleinman 2006). Finally, the effects of neoliberalism in Costa Rica culminated with the signing of the Central American Free Trade Agreement (CAFTA), which was preceded by divisive protests pitting individuals who embraced free trade against those who saw neoliberalism encroachment as a challenge to the social welfare order of Costa Rica (Rayner 2014). It was against this backdrop that Costa Rica began wrestling with how to regulate clinical trials within the country.

The initial regulatory mechanisms for clinical research rested primarily on international research guidelines developed in the years after World War II. Almost five decades of regulations were built into existing health law or the constitution to regulate clinical research with human subjects. During the peak activity of clinical research from the early 1990s and through to the 2010 suspension, international clinical research and Good Clinical Practice guidelines provided the framework for conducting clinical research in Costa Rica (Gifford and Rodriguez 2011). Still, while there was cursory mention of “experimentation” in animals or a prohibition on the import and sale of experimental medications, there were no specific local regulations or laws, which already concerned some local leaders in health, academia, and the

government⁵⁴ (See “Smoking Gun” in Chapter 4). Many more attempts were made to regulate clinical research inside the country, including a regulation directed toward research within the CCSS hospitals and clinics, and executive order, both signed into effect in 2003 (Castillo Nieto 2004). Also, several bills for law projects were presented, starting in 2000 with the final Bill 17.777 passed by the legislature in 2014.

For example, regarding the debate on the ethics of clinical research before the 2010 *Sala IV* decision, for the members of the two coalitions, the setting was very much indicative of each coalition member’s knowledge of governmental regulation, medicine, medical research, and bioethics. It also included their strategic decisions to use the media, especially opinion pieces to add to each coalition’s membership while trying to build public and political support for continuing (Neoliberal Entrepreneurs) or suspending clinical research (Statists) or, after 2010, developing a law to regulate this type of research in the country.

It was in this setting that two distinct coalitions began to form around the idea and conduct of clinical trials within the country. As early as the mid-70s, some research improprieties came to light (see chapter 4) and by the time of the 2010 suspension, the divisions and discourses regarding clinical research had hardened into very consist narratives as often played out through opinion pieces and news articles in the local newspapers. It was in this post-suspension context that concerted effort to develop a local policy for clinical research began in earnest. Each coalition had its ideas of what needed to be addressed, how it needed to be addressed, and by whom clinical research would be regulated.

⁵⁴ Article 25 of the General Law of Health of Costa Rica (1999) states “No person may be subject to experimentation for the application of drugs or techniques without being duly informed of the experimental condition of these, the risks that they run and without their prior consent, or that of the person legally called to give it if it corresponds or was prevented from doing so.”

The Characters: Villains, Victims, and Heroes

Every good narrative has characters—protagonists and antagonists—who move the plot forward. As seen in chapter four, as early as the 1970s both coalitions in the debate regarding clinical research were clearly articulating who they thought were the villains, victims, and heroes of their respective points of view. By 2010, each coalition has now redrawn the lines to account for the suspension and while, we see many of the same stakeholders in each coalition, the discourse shifted to focus more specifically on the creation of a new law, which both sides conceded was needed. Moreover, so, while the coalition membership changed little, and some characters remain in their designated positions, the focus of the debates were now on the quality of the law, the impediments to passing the law, and what the country and individuals lost due to delays in passing the law.

For nearly fifty years, the debate that raged around clinical research had focused primarily on the risks and benefits to enrolled participant/patients in clinical trials. The debate shifted considerably when the Statists successfully enlisted the Constitutional Court in suspending clinical research within the country. Now, both coalitions had their sights set on a law, but who could help craft that law; how the law would protect participants and regulate ethics committees and investigators; what sanctions, restrictions, and monitoring mechanisms to put in place; and how to regulate multinational pharmaceutical corporation sponsorship of medical research within the country needed to be hammered out. Since 2000, ten law projects (“*expedientes*”) had been presented to the legislative assembly and only one, *Expediente 17.777*, was finally passed into law as *Ley 9234*.

Each coalition can and will often have competing ideas of harm, plot, and cause. The NPF discusses four types of harms committed by villains: mechanical, accidental, inadvertent,

and intentional harm. Gray and Jones (2016) note that mechanical harm is a function of state systems and institutions working as designed but creating harm in the process such as the Constitutional Court's decision to suspend clinical trials which led to the loss of employment for nearly 200 local employees of clinical research teams. Accidental harm is the result of "random (surprising) acts," while inadvertent harm results from certain actions that were not meant to cause harm, but ultimately did (Gray and Jones 2016, 206). Finally, there is intentional harm when "nefarious actors actively seek to do damage" (Gray and Jones 2016, 206). One could argue that the decision by the Constitutional Court to suspend clinical research was a deliberate act to do damage. Several members of the Neoliberal Coalition I interviewed, suggested that one magistrate was bent on shutting clinical research down and many, privately, painted him as a villain.

Villains

The NPF identifies three types of villains. The "unaware villain" engages in inadvertent harm and both coalitions actively believe that stakeholders are genuine in their interests and goals, while "uncaring villains" and "evil villains" can do either mechanical or intentional harm, by either protecting their own best interests at the expense of others or actively trying to cause harm to those in the opposing coalition (Gray and Jones 2016).

TABLE 5.2: VILLAINS (MODIFIED FROM GRAY AND JONES, 2016.).

Neoliberal Entrepreneurs	Statists
<ul style="list-style-type: none"> • <i>Diputados</i> and politicians in general • Administrators in government and the CCSS • The Constitutional Court (<i>Sala IV</i>) • People who were obstructing or demonizing clinical research (usually in the media) • Specific <i>Diputados</i> and <i>Diputadas</i> and judges • Unethical researchers • Academics against clinical research 	<ul style="list-style-type: none"> • Specific individuals involved in research and/or perceived to have conflicts of interest (especially economically) • Specific individuals with legal or medical backgrounds who are working with Neoliberal Entrepreneurs • Transnational pharmaceutical companies, foreign and local contract research organizations (CROs), Foreign government and pharmaceutical sponsors of local research • Public health institutions in general, CCSS specifically • Specific academics and private universities • Testing labs • The press • The Commission on Social Issues (Legislative committee)

Neoliberal Entrepreneurs

As seen in Figure 5.2, Neoliberal Entrepreneurs viewed certain elected officials and politicians in general, especially the Constitutional Court, were the villains. At least three informants from the Neoliberal Entrepreneur coalition referred to one magistrate as a “*dictator*” who, according to them, single-handedly coaxed other magistrates to hand down the decision to suspend clinical trials in the country. The original action of unconstitutionality brought to *Sala IV* by a legislator from the National Liberation Party (PLN) and the eventual decision construed as mechanical harm and intentional harm according to coalition members. The mechanical harm was in the use of an action of unconstitutionality to strike down Executive Order 31078-S.

For Neoliberal Entrepreneurs, however, it was the machinations of certain magistrates that led to the suspension and the numerous motions by certain legislators that tabled Bill 17.777 for several years that seemed like acts of intentional harm. According to informants in coalition A, the efforts to develop a law were likened to a war that lasted 1549 days, in part because of all the motions that slowed the process. Those involved in the suspension and the obstructed process of the bill through the legislature were often mentioned by name as consciously seeking to damage certain individuals involved in research.

For example, a few participants I interviewed said that, from their perspective, Representative Venegas initially agreed with Bill 17.777, but at what seemed like the last minute, she put forth motion after motion that delayed the passage of the bill. The chief of staff for a representative from the National Liberation Party (PLN) commented that a current bill “*for people with disabilities...[took] one debate and two [Constitutional Court] consultations to pass*” while “*[Bill 17.777] took six months...and eighteen Constitutional Court consultations*” to pass. The consequences of which included “*the flight of talent [out of the country] and research*

institute[s] closing.” She closes with, a “*skilled and educated workforce—talent—was lost.*”

Other villains included administrators in the government and the public health system, unethical researchers, who gave ammunition to the Statist coalition through their behavior, those demonizing clinical research in the press, and specific academics, especially those who participated in the Costa Rican Bioethics Association.

Statists

The Statists were clear about who their villains were as seen in Figure 5.2. They included multinational pharmaceutical companies and local researchers who worked with them, whom, they argued, had economic benefits, as a foremost priority, over the rights and safety of participants. For example, in an open letter to the legislature published in *El País*, Carlos Zamora Zamora, he listed members of the Neoliberal Entrepreneur coalition. He claimed that they had conflicts of interest and “notoriously” were invited before the Commission on Social Issues (a committee inside the legislature) to “express their point of view” which Zamora argued were influenced by their relationships with multinational pharmaceutical companies (Zamora Zamora 2012).

The list includes eleven names, including the founders of the two leading private research centers and their employees, a member of the ethics committee of a private medical school involved in clinical research, three attorneys from a law firm that represented the local research companies in contract issues, and two independent physician-investigators. Further, in the same open letter, Zamora listed two physician-researchers and one lawyer from the firm working with investigators as “expert reviewers of the text of the law” (Zamora Zamora 2012). For the Statist coalition, these individuals were “evil villains” intentionally doing the dirty work of international pharmaceutical companies, so that they could maintain the economic benefits of working with

and for them. For example, in one interview, we were asked to stop taping while an informant went into detail to explain why a renowned researcher had such powerful connections that the government could look away for years in the face of what this coalition believed to be on-going abuses. While the Neoliberal Entrepreneurs named a few individuals as having an intentional motive for harm, the Statists saw nearly everyone working in clinical research as doing the bidding of globalized pharmaceutical companies, reflecting an on-going discourse of the threat to Costa Rica's autonomy because of the effects of globalization that peaked with the fight over CAFTA in the early 2000s (Rayner 2014).

One of the strategies we have seen used most effectively has been the use by each coalition of newspaper opinion pieces to push each coalition's narrative. Members of the coalitions had no fear in calling out specific individuals in these pieces. There were some dichotomies between the two coalitions, such as the Neoliberal Entrepreneurs painting those obstructing the passage of the law as villains and the Statists painting those involved in research and their supporters as villains, especially through focusing on the economic benefits for investigators. However, there were some specific "enemies" for each coalition.

As in examples in previous chapters, the public can observe this elite debate regarding clinical research through news articles and opinion pieces. Such a dialogue ensued in the summer and fall of 2011 between Dr. Elías Jiménez Fonseca, a physician, past director of the national children's hospital, and president of the Costa Rican Association of Human Health Research and Rep. María Eugenia Venegas, member of the Citizen Action Party (PAC) and a former educator.

In the summer of 2011, Rep. Venegas became the lightning rod for obstruction of the law when she joined with other legislators from the Accessibility without Exclusion Party (PASE),

and the Broad Front Party (FA) in objecting to ten aspects of the law project that they felt catered to commercial interests over the rights of participants and citizens. Xinia Espinoza, a member of the National Liberation Party (PLN), which sponsored the bill, noted that she was stunned by Venegas's objections, quoted as saying that "She [Venegas] worked a lot with this project. She should be consistent and not announce that she is going to block it [the bill] by blocking it" (Sin Autor 2011). Several informants remained puzzled by Venegas's opposition to the bill when interviewed for this dissertation research. One informant, Venegas's chief of staff at the time, said her primary concern was to uphold the mission of the *Caja* to provide care for the country's citizens and not turn into "*a center for biomedical research.*"

In response to Rep. Venegas's objections, Doctor Jiménez wrote a short opinion piece entitled "Announced Obstruction" about the obstacles raised by Venegas that needed to be cleared to pass law project 17.777 (Jiménez Fonseca 2011b). In the piece, he addresses the issues Rep. Venegas raised for stalling the passage of the law. He contradicts her objections regarding the legislative commission on social issues. Jiménez lists each of the ten complaints she had which revolved around such issues as conflicts of interest and independence from outside influence in the National Council of Health Research (CONIS) and institutional review boards, called *Comités Ético-científicos* (CECs). As well, Jiménez counters, the Ministry of Health does not interfere in the activities of either the University of Costa Rica or the CCSS, allowing them to function autonomously, as always. Each objection raised by Venegas is challenged and corrected according to Jiménez's view, reflecting the views of Neoliberals, while outlining the views of the Statists. Using the human rights rhetoric of the Statists, Jiménez (2011b) writes,

The absence of this law undermines the right of patients to enjoy scientific advances, especially when no alternative medication exists, and against the right of researchers to [conduct] research and to contribute with scientific development, a right guarded by our constitution, international treaties, and the General Health Law [of Costa Rica].

In this short op-ed, Jiménez addresses the obstacles that he and his coalition feels are holding up the passage of this law through the language that he believes the opposing coalition will understand: the rights of participants to access cutting-edge medications and the rights of local researchers to pursue medical knowledge.

Eight days later, Rep. Venegas replies in *La Nación* with a pointed and direct letter to Dr. Jiménez in “That which Don Elías does not say.” She elaborates on the reasons for her objections and ending the piece by stating that “[my] responsible attitude is uncomfortable for a small group of businessmen who profit from experimentation in human beings, from opening the doors of the CCSS [to research] through questionable agreements” (Venegas 2011). In this claim, Venegas also charges Jiménez with the task of coming to her office to speak about the issue and to stop using the press to accuse her without cause.

Just two days later, in the same newspaper, Dr. Jiménez responds, with “Quality medical care: a moral obligation.” He takes a different tack and frames clinical trials, especially trials of bioequivalence, as important for the safety and efficacy of generics, and as one of the three foci of quality health care along with “medical care that is available and humane [and] ongoing medical education at the university level” (Jiménez Fonseca 2011a). He urges the speedy passage of the law and notes that “clinical research within the public health and academic institutions can be done at reduced cost by local, trained professionals” (Jiménez Fonseca 2011b). While Jiménez does not mention Rep. Venegas by name, he subtly suggests that any impediment in quickly passing the law will put patients (the victims of the delays) at risk,

especially as it relates to generic medications which are the type of medication used most often in the *Caja*.

In this short exchange of opinion pieces, each writer codified their coalition's position. Neoliberal Entrepreneurs presented their villains as obstacles to the passage of the law and enemies to medical and scientific progress as well as impeding patients' rights to access advanced medical treatment and care. Dr. Jiménez also portrays researchers as local producers of medical knowledge that benefits both the country and the investigators economically and as a global leader in clinical research.

Statists also see patients and research participants as victims but frame them as victims to outside forces, primarily multinational pharmaceutical companies. These companies are assisted by local "businessmen" who get rich off the backs of patients whose rights to "dignity" and "wellbeing" must be protected from these foreign interests and local investigators by elected officials and other stakeholders charged with protecting them (Venegas 2011).

Victims

We can see from Figure 5.3 above, that both coalitions list common victims, however, what is interesting is that there is a divide in how clinical trials participants, the country, and health care, are perceived and what they are losing. It is important to note that both coalitions saw their work as paternalistically protecting citizens from the opposing coalition's interference or damages.

TABLE 5.3: VICTIMS (MODIFIED FROM GRAY AND JONES, 2016.).

Neoliberal Entrepreneurs	Statists
<ul style="list-style-type: none"> • Participants and patients who can no longer access research • The country, the local economy, the CCSS and quality of care in general • Citizens of Costa Rica in general • Professionals working in clinical research (physician/investigators and their teams, pharma employees, private medical university research staff) • Citizens without access to cutting edge care (via research) • Medical and scientific knowledge and knowledge production • Founders of two private research facilities (ICIC and IAP). 	<ul style="list-style-type: none"> • Costa Rican citizens and children in general • The poor, uneducated, and the vulnerable (specific mention: the physically and mentally disabled) • Humans who are treated like objects/subjects of experimentation • Citizens used in the <i>maquilas</i> of clinical research • Patients in general, the sick, and the very sick adults and children specifically

Neoliberal Entrepreneurs.

For Neoliberal Entrepreneurs, the people who suffered the most were participants in clinical research and, ultimately, Costa Rican patients who were not going to have access to cutting edge medicine (Figure 5.3). For example, one anecdote mentioned by a few informants was of a cancer-stricken woman who had no viable treatment options remaining and no clinical trials to join due to the suspension. She pled her case to the Constitutional Court for access to experimental medications and, after much deliberation, the court granted her request. Unfortunately, it was too late because the woman had died.

Eduardo Brilla was an active member of the Neoliberal Entrepreneur coalition, both in print and in the Association for Human Health Research. He is an emeritus dean of the Microbiology Department at the University of Costa Rica and proprietor of a laboratory that provided laboratory services for numerous clinical studies until the suspension. On July 7, 2011, Brilla (2011) countered, in an opinion piece, a frequent argument used by the opposing coalition that Costa Ricans were at the mercy of foreign pharmaceutical companies with little benefits to either patients or the population's health.

Dr. Brilla itemized some benefits to patients and the country, especially regarding stomach cancer, which in Costa Rica is an ongoing problem with unclear origins. As of 2014, it was the 7th leading cause of death in the country, and Costa Rica was ranked 14th in the world for stomach cancer deaths⁵⁵. Brilla directly challenged the opposing coalition's argument that more was being taken from the country compared to what was given to it. He writes that a Costa Rican gastric specialist "was established in Costa Rica as the principal investigator of a multicentered international study of stomach cancer, whose treatment was based on tumor

⁵⁵ <http://www.worldlifeexpectancy.com/costa-rica-stomach-cancer>

genetic patterns [which oriented] the treatment according to the genetic characteristics of the tumor” (Brilla S. 2011). In this case, he argued, clinical research was providing some benefits to both participants and the country.

Statists

Statists saw participants in research, the very sick, and, mainly, children as prey to foreign entities who were using the country as a factory for research and economic gain (Figure 5.3). Rafaela Sierra is a biologist and epidemiologist who works in the Program on Cancer Research at the University of Costa Rica and was a member of the Costa Rican Association of Bioethics, which aligned with the Statists. Sierra’s op-ed can be construed as a direct message from the association. She wrote an opinion piece, entitled “Who protects the rabbits?⁵⁶” found in *La Nación* on November 24, 2011, just months after Dr. Brilla’s piece in the same newspaper (Sierra 2011). Sierra sets the villains as pharmaceutical companies fleeing strict regulation in the U.S. and Europe which “obligates [the companies] to seek other populations” and “in that search, these companies have found some countries that are like ‘paradises for clinical experimentation’ for their lack of effective regulation” (Sierra 2011). Costa Rica, she argued, is that paradise due to its superior public health system which provides care for a majority of Costa Ricans. She hints at the idea of citizens being used by pharma as “*conejos*” when she writes, that “[the infrastructure] along with the lack of a law, favors experimentation in Costa Ricans” (Sierra 2011). This article touches on the consistent coalition message over decades: that foreign companies want to engage unsuspecting Costa Ricans, especially children, for experimentation with complete disregard of their human rights.

⁵⁶ by which she means guinea pigs or in Spanish *conejillos de indias*

Heroes

TABLE 5.4: HEROES (MODIFIED FROM GRAY AND JONES, 2016.).

Neoliberal Entrepreneurs	Statists
<ul style="list-style-type: none"> • Clinical research professionals in general • Founders of local research organizations and their organizations • The Costa Rican Association of Research in Human Health • <i>Instituto de Clodomiro Picado de la Universidad de Costa Rica</i> • Commission on Social Issues (Legislative committee) • A policy roundtable convened by the Commission • The President and the Executive Power in general • Specific <i>Diputados</i> and <i>Diputadas</i> • Government agencies such as the <i>Defensoría de los Habitantes</i> and the Ministry of Health 	<ul style="list-style-type: none"> • Specific individuals who assisted in the suspension or obstructing the passage of law project 17.777 • Specific individuals who provided academic, political, and coalition support • <i>Sala IV</i> • <i>La Asamblea Legislativa</i> • Citizen associations aligned with the coalition, specifically the Costa Rican Association of Bioethics • <i>La Caja</i> • <i>El Consejo de la Universidad de Costa Rica</i> • Costa Rican citizens who participate in clinical trials • Stakeholders who support strict laws on clinical research

Neoliberal Entrepreneurs

In Figure 5.4, Neoliberal Entrepreneurs claim that the heroes in this struggle were local physician-researchers who brought training in clinical research back from the United States and Europe. For example, several informants credited the founder of the Costa Rican Institute of Clinical Research (ICIC), Dr. Guillermo Rodríguez Gómez, as single-handedly introducing modern clinical research to the country. Many felt they, themselves, had become heroes as pioneers of clinical research within the country.

For example, one study coordinator, who was forced to look for other work after the suspension, became very active in the Costa Rican Association of Research in Human Health. She became an officer of the association and regularly worked with elected officials on law project 17.777. She told us that they “*fought face to face with an unreasonable political position*

[that of the Statists].” According to her, her coalition and the opinion pieces they wrote were fighting against retrograde ideas of clinical research based on historical events such as Nazi experiments. She and others we interviewed, noted that the opposition “*demonized*⁵⁷” clinical research in the press, in governmental audits, and the legislature.

Those active in the Costa Rican Association of Research in Human Health, a local association of physician-investigators, study coordinators, bioethics specialists, and other stakeholders came together just days after the decision to suspend clinical research. They considered the association and its membership to be a driving force in tracking the legislative process and the visibility of the debate in the press. Many of the opinion pieces published by those in this coalition were written by officers in the organization at various points over the four years between the suspension and the passed law.

The association was an opportunity for many who had lost or were losing their jobs and concerned about the future of clinical research to focus their frustration and develop strategies for input into the creation of the law as well as keep the “rational” voice of clinical research in the public eye. As the law project made its way through special committees and round tables and plenary after plenary, members of the coalition and the association would address the process in the legislative halls and opinion pieces in the newspaper. For example, just a year after the suspension, Adriano Arguedas, a pediatrician and founder of the Institute of Pediatric Care, a private pediatric research facility, wrote an opinion piece that had, as a subheading, “No one in their right mind doubts the necessity of effective medications for children” (Arguedas 2011). In the piece, he focuses on the benefits to Costa Rican children of various types of research as well as the dedication of local researchers in studying new medications and treatments for health

⁵⁷ In Spanish, the word “to demonize” is *satanizar*.

issues that are needed by the country's children. These researchers are presented as heroes who, along with the country itself, are facing "a grand challenge" (Arguedas 2011).

The coalition also identified certain elected officials as allies in the effort to pass the law. They often praised those officials, especially those who participated in the legislature's Commission on Social Issues and who convened a roundtable with stakeholders from both coalitions to educate legislators, although some informants felt that the members of the Neoliberal Entrepreneur coalition had more input into crafting the law. They referred to the law as Pfizer's law. The Neoliberal Entrepreneurs also found support in some of the government agencies. At various times, this included the Minister of Health and the national Ombudsman.

Statists

Many of the Statists identified the entire Constitutional Court, especially Judge Fernando Cruz, as a hero for taking a stand against the pharmaceutical industry and local physician-investigators (Figure 5.4). They also found support in the Legislative Assembly, especially members of the Citizens Action Party (PAC) and Broad Front Party (FA). Both before and after the 2010 suspension, members from both parties put forth different law projects, including the 2002 Bill No. 14.636 sponsored by José Merino del Rio and José María Villalta, both of the Broad Front (FA) party and another bill (No. 17.693) sponsored by the entire Citizen Action Party (PAC) in 2010, shortly after the suspension.

As discussed above, Representative Venegas became a hero to the cause, and vilified by the Neoliberal Entrepreneurs, for her numerous motions for amendments and issues related to Bill # 17.777. For example, in a plenary session of the Legislative Assembly on the 6th of March 2013⁵⁸, Dip. Venegas defends herself to her colleagues, noting that she has come in good faith to

⁵⁸ *Acta de la Sesión Plenaria N. 44, La Asamblea Legislativa*

each debate and is not impeding the progress of the bill. She says to the other representatives, that “your ghosts that you see are only yours that you see.” She casts herself as a hero, reminding the others in the session that she too has benefited from research, having brought her medications to the plenary. However, Rep. María Eugenia Venegas, in our interview, felt a great responsibility to review each detail of Bill No.17.777 and fight to take time to digest and understand all of the aspects of the law.

Other heroes to the Statists include Alfonso Trejos Willis, a microbiologist who was one of the first to call attention to the ICMRT studies⁵⁹ and under whom, many bioethics specialists trained, especially at the University of Costa Rica (UCR). At various times over the several decades that the debate swirled around clinical research, there were Statists in the Ministry of Health, CENDEISS⁶⁰, and in leadership at UCR. They also viewed research participants as heroes for enrolling in clinical trials when they might not receive any benefit from them. She, like many academics, bioethicists, and physicians not directly involved in clinical research, was advocating for stringent laws on clinical research, while the Neoliberal Entrepreneurs were advocating for including legal parameters that reflected the international norms and guidelines which already provided a structure for clinical research.

The Plot

According to Gray and Jones (2016), the plot consists of the motivations of the perceived villains as defined by the opposing coalition; how the heroes of each coalition address those motivations; and then links these motivations and actions to a policy solution or the “moral of the story” (Gray and Jones 2016, 196). It is here in the plot of the policy story that we seek to

⁵⁹ See Chapter Four: Discourses of Clinical Research in Costa Rica

⁶⁰ *Centro de Desarrollo Estratégico e Información en Salud y Seguridad Social* (The Center for Strategic Development and Information on Health and Social Security)

understand the types of harms villains in which might have engaged. As delineated by in the Narrative Policy Framework, there are four types of harms: “mechanical,” “accidental,” “inadvertent,” and “intentional”(Gray and Jones 2016, 206). The policy setting is the political, regulatory, ideological, discourse, or physical space in which the policies are being challenged or created (Gray and Jones 2016).

Neoliberal Entrepreneurs

According to informant interviews, opinion pieces, and legislative plenary sessions, the plot of the “story” for this coalition puts Costa Rica in the vanguard of clinical research before 2010. The medical and scientific knowledge generated addressed health issues that many Costa Ricans suffered from and increased the quality of patient care. Because of clinical research, jobs were created, and foreign investment from pharmaceutical companies both helped individuals and the country to benefit economically.

The stakeholders in this coalition argued that international guidelines and local regulations and councils (such as Executive Order 31078-S and The National Council on Health Research⁶¹) were enough for protecting participants from harm. However, as the result of efforts by individuals from the Statist coalition, the *Sala IV* 2010 decision to suspend clinical research in the country and the resultant inaction on the part of the legislature led to a brain drain as talented physicians and other health professionals left the country to continue work. Those that stayed often had to take on two or more jobs to compensate for what they lost, while others were unable to find employment at all. They argued that health care suffered as a result and some patients died due to lack of access to cutting edge medications during the suspension. Many informants felt that Costa Rica had been returned to a “*dark age*” by those who would demonize research as

⁶¹ *Consejo Nacional de Investigación en Salud* (CONIS)

an abusive and unethical factory putting Costa Rican bodies and rights at risk. For the Neoliberal Entrepreneurs, the clear villains were the elected officials, academics, bioethics specialists, and government administrators who amplified decades-old problems and framed investigators as getting rich off the backs of innocent children, the gravely ill, and citizens in general.

Statists

Those coalition members who participated in interviews for this study or wrote opinion pieces saw clinical research as a threat to the right to dignity, life, and health of all Costa Ricans. They viewed multinational pharmaceutical companies as using Costa Rica as a *maquila* for clinical research by taking advantage of its people and its health infrastructure, purely for economic gain and local investigators as doing the bidding of these nefarious companies who preyed upon small countries with good health infrastructure. It is this economic gain that pitted this coalition's members against local researchers, and, as they viewed it, the researchers were putting money over the protection of participants, which these statists viewed as inherently unethical.

Their argument, and ultimate action of unconstitutionality framed all local orders, regulations, and international guidelines as insufficient to protect the rights of participants and cite abuses from the 1970s and within the CCSS in the 1990s as justifications for the suspension. The Statists saw a need for a judicial authority or legislative process to step in to protect the health, rights, and dignity of participants and patients and to sanction and penalize those who would abuse those rights through clinical research and used the newly formed Constitutional Court to impose such authority on clinical research.

Many saw the role of elected representatives to be the voice of vulnerable and voiceless Costa Ricans and so deemed the legislature the best governmental body to address the issue. The

coalition came to believe, during the law-making process, that the Neoliberal Entrepreneurs were manipulating the process by inserting themselves into the roundtables and commission meetings to shape the new law in their favor, which the Statists felt were direct conflicts of interest. As a result, Statist legislators used motions and other legislative techniques to slow the approval process until the ambiguities, and the lack of severe sanctions could be addressed and refined. One such ambiguity stemmed from the role CONIS would play in the local regulation of clinical trials and its independence from the influence of pharmaceutical companies or local research organizations. Some Statist members felt vilified by the Neoliberal Entrepreneurs, especially in the press.

The Moral of the Story (Policy Solution)

After nearly 50 years of vociferous debate and entrenched views, Law 9234 was passed and signed by President Chinchilla in the winter of 2013. An accompanying regulation, Executive Order 39061-S was passed July 2015. The Statists feel that the law will benefit pharmaceutical companies more than they would like. On the other hand, Neoliberal Entrepreneurs are finding incongruencies between the law and the regulation, most notably, a differing number of members on local ethics review boards (from seven members in the law to fourteen members in the regulation). Still, everyone agrees for the most part that, “at least we have a law now.”

Conclusion

By the time of the 2010 suspension, distinct coalitions formed on opposing sides of the issue of clinical research inside Costa Rica. The well-practiced narratives and strategies they used developed over forty years of flexing in the news and the legislative hall as many law projects had been presented, but none passed. Through Narrative Policy Framework, I was able

to deconstruct these narratives and identify the values, strategies, characters, plots, and policy solutions for each coalition. These methods and conclusions are valuable for understanding how coalitions form, what holds them together, and how they maintain their policy core beliefs.

CHAPTER 6: CONCLUSION

In 2010, a decision was made by the Constitutional Court of Costa Rica to suspend clinical research inside the country until a local law could be crafted to regulate the process. It took four years for that law to pass. In the meantime, nearly two hundred people lost their jobs and medical research ground to a standstill. How did the Constitutional Court come to this conclusion that clearly had real life effects on locals working in clinical research? What was the motivation for the decision? And what would or could change going forward?

This dissertation sought to answer these questions by tracing public narratives on clinical research over the course of forty years and illustrates how this discourse became a strategy used by loosely-formed groups that, over decades, became entrenched and official coalitions that lobbied government officials and institutions for influence over clinical research in the country. One side wanted to save the country from foreign influence in the form of multinational pharmaceutical companies, while the other group saw themselves as a vanguard of the medical future, elevating and engaging Costa Rica on the world stage. Much of the drama played out in local newspapers. By tracing this debate among elites through their use of opinion pieces, I was able to trace the formation of policy coalitions and their policy beliefs, ultimately leading to durable identities of both the coalitions and individual members. This enabled me to examine how each coalition's policy narratives influenced key events in the evolution of clinical research in the country and the struggle to regulate it.

This dissertation research employed ethnographic interviews with key stakeholders in and around clinical research and coupled these interviews with narrative analysis of newspaper opinion pieces. Further, using a qualitative approach to the Narrative Policy Framework Model as put forth by Gray and Jones (2016) and often used in public policy analysis highlights the

ways in which consistent policy narratives shape coalition beliefs, and the durable identities of both the coalitions and the individuals within each coalition. These coalitions had a profound impact on local researchers, regulations, policies, and lawmaking. This illustrates how Costa Rica struggled to control the flow of globalized biomedical economies into the country and find its place in an increasingly interconnected world.

Statists and Neoliberal Entrepreneurs

The idea of advocacy coalition identities comes from Sabatier and Weible (2007) and the integration of policy beliefs with members own beliefs and values. These beliefs become deep core beliefs and are very resistant to change. This resistance to change also informs the coalition's overall belief structure, influencing policy strategies. There is an iterative aspect to the mixing and melding of these individual and coalition beliefs, reinforcing the values and membership among individuals in a coalition.

One of the strategies of coalitions is to develop a policy narrative that reflects the coalition's core beliefs. Using op-eds in local newspapers, Statists and Neoliberal Entrepreneurs engaged in storytelling to define the victims, villains, and heroes in the long narrative arc of clinical research in Costa Rica. By repeating these narratives again and again over such a long period, each coalition became more committed to opposing the other coalition; less likely to listen to divergent viewpoints; and more resistant to new information (Shanahan, Jones, and McBeth 2011). The result, in this dissertation research, were durable identities so divergent and entrenched as to be immediately recognizable by even an outsider like me.

The Statists perceived the Neoliberal Entrepreneurs as handmaidens to foreign interests and commerce. The Neoliberal Entrepreneurs saw the Statists as hindering medical progress and the opportunities for Costa Rica of international recognition and economic opportunities for the

country at large and for citizens in terms of employment opportunities. Each coalition took a paternalistic approach to the country's citizens. The Statists sought to protect hapless research participants from foreign research factories on local soil and the greedy physician-researchers who lined their pockets with money for every volunteer through that factory door. Neoliberal Entrepreneurs, on the other hand, viewed themselves as the couriers of cutting-edge medical science, new technologies, and new drugs. They were bringing new hope for old diseases in the form of vaccines, treatments, and diagnostics.

This dissertation examines the effects of each coalition's policy work on the lived experience of Costa Rican who worked in clinical research and the strategies they employed to survive the clinical research suspension while the debate over a new law raged for four years. I argue that tracing the narratives and discourse strategies around a particular issue can illuminate the early formation of advocacy coalitions and track the formation of coalition identities. This work has broader application in understanding the ways that countries peripheral to the West negotiate globalization and neoliberalism through resisting or embracing the process.

Elite Discourses, the Role of Opinion Pieces in Elite Discourse, and Narrative Policy Frameworks

Elite Discourse and Narrative Analysis of Opinion Pieces

Thurlow and Jaworski (2017) argue that it is important to reinvigorate class studies by looking at the top of the power structures and seek to understand the methods that elites use to define and confirm the boundaries of the class. One of these methods is to examine the discourses in play, because "language and communication are so central to the production and circulation of class ideologies" (Thurlow and Jaworski 2017, 246). By centering these discourses, we can better understand the process of power consolidation so important in maintaining class inequality. The authors draw on Bourdieu (1991) when they discuss the

“constant processes of classification, evaluation, and legitimation” that happen regularly through various discursive activities including the media (Thurlow and Jaworski 2017, 246).

In *Elite Discourse and Racism*, Van Dijk (1993) devotes an entire chapter on the role the media plays in elite discourse. He argues that the elites need the media as a mediator to forward their messages and to raise their profiles with the public in general and, more importantly, with other elites. He notes that the media is not passive in this activity but an active force of cultural reproduction by actively and centrally shaping “the social cognitions” of those who consume these media sources (van Dijk 1993, 242). In Costa Rican opinion pieces regarding clinical research, the media was used almost entirely to engage other elites, with the language used and the comments made, generally, above the cognition of the general public.

While the media holds considerable power, it is made more powerful by its position at the center of many other elite institutions and discourses, allowing those in the media to exert control over others in positions of power and influence who cannot pursue their goals in politics or business without the support of the media by reproducing power (van Dijk 1993). In a later chapter van Dijk discusses newspaper editorials and notes that they replicate an argumentative writing structure for the purposes of shoring up the elite perspective through the reproduction and legitimation of social cognitions and models (van Dijk 1993).

In considering some methodologies with which to analyze texts and discourses, Boréus, and Bergström (2017) discuss two that influenced this dissertation research. First, they discuss the analysis of argumentation and focus on the structure of an argument suggesting that there is value at looking at how different camps might argue for or against something and they also consider the techniques that are used to make such a case. Such techniques include appealing to emotion to create a sense of interpersonal communication. The second approach is through

narrative analysis in which the researcher draws out the stories from historical events to deduce the “ideological power and ‘common-sense’ understandings of the way the world works” (Boréus and Bergström 2017, 7). As a result, the characters and other elements are examined as well as what is said.

Robertson (2017) digs deeper into narrative analysis as a methodology. It is important to consider narratives as legitimate discourses for analysis, because it is not just the stories we tell, but the stories that we live and share socially that are also narratives and they shape our perceptions and behaviors. We also need to determine what constitutes narratives when considering them academically and also popularly. Robertson also considers the different ways to analyze narratives. Finally, what do we gain or lose by using narrative analysis to understand texts and discourse (Robertson 2017)? When studying narratives, we must consider the two stories that exist in parallel with each other. The first story is the description of events, while the second story is the author’s own story, inserted implicitly into the first story. One benefit of narrative analysis is that we start to understand how narrative can illuminate how we develop and maintain identity. Studying narratives also allows one to trace and understand power differentials (Robertson 2017). Costa Rican opinion pieces on clinical trials were a natural fit for narrative analysis because they were a description of events and the very act of writing an opinion piece forces us to consider the author’s story and life experiences.

Newspapers and other news media often straddle the delicate balance of “fact and values” as a large social and cultural institution (Kowalchuk and McLaughlin 2009, 702). While news articles written by staff or freelance journalists carry an oft-challenged expectation of objectivity, opinion pieces always are written from the author’s point of view and these types of print articles mold the public’s thoughts on the topic or policy being presented (Buoziš and Creech 2018,

Kowalchuk and McLaughlin 2009). Buozis and Creech (2018) argue that news and journalism “as a site of textual practice, reveals broader social relations and cultural meanings” and so, analyzing news texts is a way in which one can discern these social relations and cultural meanings (Buozis and Creech 2018, 2). Further, the various types of articles and genres available in a newspaper “offer a schema” for examination of social forces (Buozis and Creech 2018, 2). As discussed above, there is an explicit intent at objectivity, whereas by studying the different types of texts, or genres of news, one can understand “certain cultural logics, market pressures, and professional values” of the authors or of the newspaper itself (Buozis and Creech 2018, 8).

Op-Eds are a unique type of news genre. Originally meant to be a counterpoint to an Editorial, which expressed the views and stance of the newspaper owners, the op-ed was literally ““opposite the Editorial Page”” in a newspaper and were to serve as an “arena to provoke new ideas and discussion on public policies” (Coppock, Ekins, and Kirby 2018, 60). In some respects, the op-ed continues to serve as that arena, however, unlike the original intent of news editors for opinion pieces to provide the general public contrasting views on different issues of import at the time, today’s opinion pieces are written by elites for elites to address issues of most concern to elites (Coppock, Ekins, and Kirby 2018). According to Sommer and Maycroft (2008), op-eds build “support for an idea, improves access and relationships with policy makers, and expands and enriches the author’s reputation” (Sommer and Maycroft 2008, 586). In Costa Rica, this was evidenced by an opinion piece author addressing his or her op-ed directly to a lawmaker or other government official.

In this dissertation, I have provided evidence of how elites in Costa Rica used the stylistic quality of argumentation through opinion pieces to secure their social position, entrench their perspectives on clinical research in the country as well as to reify Costa Rica’s exceptionalism

according to each advocacy coalition's definition. For the Statists, they did this through their discourse on the dangers of foreign influence, the greed of local physician-researchers, and the role of the Costa Rican study participant as hapless victim to this influence and greed.

Neoliberal Entrepreneurs, on the other hand, signaled exceptionalism by a discourse that elevated the country as going toe-to-toe with more developed countries in terms of scientific knowledge productions, bringing highly technical jobs to the country and thereby boosting the local economy. Their discourse in relation to study participants focused around the benefits of access to new medications, cutting-edge techniques, and higher quality care.

Narrative Policy Frameworks

Okongwu and Mencher (2000) suggest that an anthropological analysis of public policy has value in understanding the effects of public policy on the lived experiences of those most deeply affected by policies. They especially acknowledge the power of structural adjustments and multinational corporations in influencing local policies and the value that ethnographic methods bring to processes and bureaucracies that can lose sight of the ramifications of laws and policies on such diverse issues as homelessness, migration, globalization, agriculture, and the environment (Okongwu and Mencher 2000). Most policy analysis frameworks are based on models developed in the United States and Europe, however Catherine Kingfisher suggests that policies can have a "life" that transcends national boundaries, resulting in new ways to analyze policies that take into account how they are changed by local and global pressures (Kingfisher 2013). She acknowledges that anthropologists have used their research methods and cultural insights often outside of the field of anthropology when called upon as expert witnesses or used their skills to document the experiences of patients and staff in hospitals, welfare offices, and at sites of immigration (Kingfisher 2013).

Critical medical anthropology (CMA) has a long history of critiquing those in power, the institutions they run, and the effects of these power differentials and inequalities on the individual's health (Panter-Brick and Eggerman 2018). The field takes an eclectic approach to research that allows for various methodological approaches toward answering questions that span the focus on the individual to the focus on macro-processes related to such issues as health policy, health outcomes, biotechnology, globalization, and clinical research (Panter-Brick and Eggerman 2018). The field does not shy away from interdisciplinary approaches or hew rigidly to hallowed methodologies. Eisenberg (2011) argues that, since mid-twentieth century, such noted American anthropologists as Boas, Mead, and Benedict challenged U.S. and foreign policies. He argues that medical anthropology is a natural fit for policy studies with its emphasis on social processes, inequalities, biomedicine, and the increasingly globalized and marketized biomedical economies around pharmaceuticals, medical tourism, and the organ trade, just to name a few (Eisenberg 2011). Therefore, the study of policy coalitions, their narratives, and law-making around clinical research falls squarely into the critical medical anthropological realm.

Narrative Policy Frameworks (NPF) grew out of the work of Paul Sabatier and Christopher M. Weible (2007) that established tools to empirically track the processes of policy formation and identify, both the governmental stakeholders and the special interests that exist outside of government, but influence policy in profound way. Shanahan, Jones, and McBeth (2011) drilled down into an area of policy-making that seldom garnered attention due to the challenges of quantification, that of narratives. They sought to understand what a policy narrative is and what their influence was in advocacy policy groups. What they found is that policy narratives have profound impacts on policy development, alteration, and outcomes. This allows

the NPF framework to be used to “document policy change or status quo” and to use the NPF as a schema or model that is inherently multidisciplinary in the ability to analyze how “policy narratives shape policy output through influence on coalition membership and public opinion” (Shanahan, Jones, and McBeth 2011, 545). Gray and Jones (2016) take the narrative policy framework from the realm of quantitative analysis and applied a qualitative approach relying on iterative analysis and thick description. The benefits of this framework in critical medical anthropological research and, specifically, in the fieldwork for this dissertation is the systematic dramaturgical approach to defining the setting, plot, characters, and moral of the story. By 2014, when I started my fieldwork, the narratives related to clinical research and its regulation in Costa Rica were well-established, making Gray and Jones’ qualitative approach to the narrative policy framework the most advantageous approach to studying discourses that had been in play for over forty years.

Limitations, Contributions and Future Research

Limitations

This study is based on data collected from 57 interviews, 273 newspaper articles, including 66 opinion pieces, hundreds of thousands of pages of government documents, including law projects, decrees, internal audits of the Costa Rican Fund for Health and Social Security (CCSS), and legal writings. There were five opportunities for participant observations in order to understand lawmaking and regulation of clinical trials in Costa Rica. The sample size for the qualitative interviewing is large enough and diverse enough to accurately capture the attitudes and perceptions of stakeholders on opposite sides of the debate on clinical research in the country. However, hundreds of people were employed in clinical research over four decades, and lack of access and time constraints limited the total number of interviews conducted. I

believe that the archival research and use of opinion pieces more than adequately captured the views of many of those I was unable to interview.

This research project was intentionally purposive as I sought to understand a long-standing problem that spanned decades, with numerous actors involved, and large archives of documents and articles, and significant effects on certain individuals employed in clinical research prior to the 2010 suspension. I did not interview anyone who was not, in some way, connected to the topic of clinical research in Costa Rica. Also, I confined my search for interview participants to the greater metropolitan area of San José, Costa Rica, which has the potential to limit access to anyone who was involved in research in other parts of the country, such as those researchers involved in a human papilloma virus study in the Northwest of the country. Therefore, I cannot claim that this research is representative of the whole of the country.

Law 9234, the “The Regulatory Law for Biomedical Research⁶²” was approved by the Legislative Assembly early 2014, shortly before I arrived in Costa Rica. As such, many stakeholders were still trying to understand how to recommence clinical research again as outlined in the new law. It would take nearly a year and a half for Decree 39061-S, the “Regulation for the Regulatory Law for Biomedical Research⁶³” to be approved. There were many inconsistencies between the law and the regulation, as pointed out by interviewees during fieldwork, that added to the delay in restarting research there. As a result, I was unable to do participant observation of a research team in action. Secondly, while I interviewed individual members of ethics review boards, I was unable to conduct participant observation in the meetings themselves. Finally, some populations for interviewing were unavailable to me.

⁶² *La Gaceta Número 79—viernes 25 de abril del 2014*. Accessed April 2014.
(https://www.imprentanacional.go.cr/pub/2015/04/24/COMP_24_04_2015.pdf)

⁶³ *La Gaceta Número 138—viernes 17 de julio del 2015* Accessed July 2015.
(https://www.imprentanacional.go.cr/pub/2015/07/17/COMP_17_07_2015.pdf)

Though I tried, I was unsuccessful in getting interviews from any local employees of pharmaceutical companies. I was also unable to interview participants who had been or were currently enrolled in clinical trials.

Contributions

This dissertation research contributes to the theoretical body of work in critical medical anthropological by examining how elites in a middle-income country address globalizing biomedical economy and the influx of foreign ideas and investments into the country. Further, this research bridges two arenas of health research: a) that of the lived experiences of those engaged in health systems and their policies; and b) the role of advocacy coalitions in the production of elite narratives that impact public policy. Through close analysis of op-ed narratives in local newspapers, I was able to trace the development of durable identities as expressed in the policy core beliefs of each coalition. By identifying key words and phrases in use by each coalition, I was able to develop models of coalition identities, which I labeled the Statists coalition and the Neoliberal Entrepreneurs coalition.

By qualitatively examining the narratives of each coalition in opinion pieces through Gray and Jones' Narrative Policy Framework, I was also able to understand how each coalition created its own story of clinical research in the country and to use these stories strategically to influence the development of laws, regulations, and court decisions. Finally, this research contributes to the work done by other cultural anthropologists who find value and import in studying the elite as they work to maintain the hegemonic ideologies that benefit them while affecting those more disenfranchised than them (Nader 1972, Gusterson 1997, Marcus 1995, Mosse 2006, Stich and Colyar 2015, Panter-Brick and Eggerman 2018, Eisenberg 2011).

Future Recommendations

Cultural anthropology has a long tradition of studying the effects of globalization, neoliberalism, and state policies on the disenfranchised, the poor, and the Other. This research emphasizes the importance of studying, not only how policy is made, but how elites engage in discourse and strategies that shape the laws which impact their citizens and their relationships in the rest of the world. Laura Nader emphasized the importance of studying up decades ago, but old habits die hard (Nader 1972). In a world where a small number of individuals control the bulk of global capital, it is time to shift our focus to the top of the pyramid and begin to understand the belief systems, motivations, desires, and attitudes of those holding positions of power locally and globally. This research provides a look into these ideas and processes by illustrating how elites in Costa Rica struggled with the impact of globalization – specifically, around clinical research—and created mechanisms that controlled the flow of globalized biomedical economies into the country. As a result, this dissertation research has implications for the anthropological study of public policy. For example, the frameworks and methodologies used to determine the narratives used by each coalition in the debate of clinical research in Costa Rica could also be applied in the current debate on “Medicare for All” which has become part of the narrative for the 2020 US presidential elections⁶⁴. This research also has implications for conceptualizing of issues related to globalizing biomedical economies and how states manage the influx of foreign investment and patients seeking better health care at cheaper prices.

⁶⁴ Katz, Josh, Kevin Quealy, and Margot Sanger-Katz. 2019. Would 'Medicare for All' Save Billions or Cost Billions. The New York Times, April 10, 2019. Accessed April 10, 2019. (<https://www.nytimes.com/interactive/2019/04/10/upshot/medicare-for-all-bernie-sanders-cost-estimates.html>)

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